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Global advances in the diagnosis, management, and treatment of low back pain

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Global advances in the diagnosis, management, and treatment of low back pain

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Editorial: Global advances in the diagnosis, management, and treatment of low back pain

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Editorial on the Research Topic
Global advances in the diagnosis, management, and treatment of low back pain

Introduction

Low back pain (LBP) is a global health and quality of life concern, affecting millions of individuals and posing significant challenges to healthcare systems worldwide. This Research Topic, Global Advances in the Diagnosis, Management, and Treatment of Low Back Pain, includes a collection of studies addressing this prevalent condition's multifaceted nature. The Topic reviews various aspects of LBP, from diagnosis and treatment to its impact on specific populations and healthcare systems, highlighting innovative approaches and emerging trends across various healthcare levels. The articles include current reviews of epidemiology, diagnosis, treatment modalities, occupational health, patient perspectives, and healthcare system approaches to diagnosing and managing LBP. We aim to explore various diagnostic approaches, therapeutic interventions, and strategies for effectively managing LBP symptoms.

Low back pain (LBP) remains a significant global health concern, affecting up to 84% of people in their lifetime and leading to substantial disability and socioeconomic burden (Ferdinandov). Low back pain affects populations traditionally not considered at risk for LBP. There is a high prevalence of musculoskeletal pain, including LBP, among university students, with electronic device use and lack of exercise as key contributing factors (Kandasamy et al.). Almansour et al. reported a high prevalence of LBP (62.56%) among secondary school teachers in Saudi Arabia, with age, female gender, and increased workload reported as significant predictors. Hu et al. found that sleeping <6.55 h per day was associated with a higher risk of LBP in adults over 50. The study by Ding et al. on emerging manufacturing workers in Beijing, China, further emphasizes the occupational aspect of LBP, reporting the highest prevalence in the neck (15.0%), followed by the lower back (12.5%) and shoulders (11.2%). Other occupations targeted for prevention are highlighted by Hakiranuye et al., who examined the prevalence of LBP among medical trainees and the implications for choosing future medical careers. Zhang et al. reviewed factors affecting functional disability, including lower educational background and posture. These findings highlight the significant impact of LBP on occupational health and career choices, emphasizing the need for workplace interventions and ergonomic considerations.

The diagnosis of LBP is difficult due to the multi-factorial etiology and varying presentation. Improving diagnostic accuracy for LBP remains a critical area of research. Ferdinandov et al. provide a narrative review of common differential diagnoses of LBP in contemporary medical practice, emphasizing the importance of a comprehensive diagnostic approach that considers intrinsic spinal, systemic, and referred pain sources. Morimoto et al. conducted a scoping review on gait analysis using digital biomarkers, including smart shoes, in lumbar spinal canal stenosis, highlighting the potential of wearable technology in LBP diagnosis. These studies emphasize the complexity of LBP diagnosis and the potential for innovative technologies to enhance diagnostic accuracy. The use of digital biomarkers and wearable technology provides for a more precise and objective assessment of LBP (Morimoto et al.).

Effective alternative treatment options for the management of LBP are reviewed. Ferdinandov conducted a systematic review on focused extracorporeal shockwave therapy (ESWT) for LBP treatment. Li W. et al. proposed a protocol for a systematic review and meta-analysis of the efficacy of silver needle therapy for treating LBP. Li X. et al. performed a meta-analysis on the clinical efficacy of acupuncture therapy combined with core muscle exercises in treating chronic non-specific LBP demonstrating favorable outcomes compared to single-core muscle training. These studies highlight the diverse treatment options for LBP and the ongoing efforts to evaluate their efficacy.

Advancements in surgical and anesthetic approaches are also included in this Topic. Mao-jiang et al. evaluated the efficacy and safety of CT-guided joint cavity release for postpartum sacroiliac joint pain management. Boykov et al. investigated thoracic spinal anesthesia with intrathecal sedation for lower back surgery, presenting a potential alternative to general anesthesia. Yankov et al. assessed multidetector CT Hounsfield unit measurements to predict efficacy and complications in percutaneous vertebroplasty for osteoporotic vertebral compression fractures. These studies demonstrate ongoing innovations in surgical and anesthetic techniques for LBP management, offering potential alternatives to traditional approaches and improving patient outcomes.

Liew and Darlow used network analysis to explore the complexity of commonly held attitudes and beliefs about LBP. Attitudes and beliefs affect not only diagnosis but also treatment and outcomes in a cross-sectional study. Mathieu et al. evaluated the appropriateness of specialized care referrals for LBP. There are a significant number of inappropriate referrals to neurosurgeons. Unnecessary surgical referrals increase costs and reduce patient and physician satisfaction. These studies underscore the importance of addressing patient beliefs and optimizing healthcare referral systems in LBP management. The high rate of inappropriate referrals highlights the need for improved triage and referral processes in primary care.

The Research Topic includes innovative approaches demonstrating the ongoing efforts to develop new strategies for LBP management and incorporating technology and coordinated care models to improve patient outcomes. García-López et al. present a pilot randomized controlled trial protocol for using virtual reality to improve low back and pelvic pain during pregnancy. Ramond-Roquin et al. proposed a protocol for coordinated care to reduce the risk of prolonged disability among patients with subacute or recurrent acute LBP in primary care.

Conclusion

This Topic highlights the multifaceted nature of LBP research, encompassing epidemiology, diagnosis, treatment modalities, occupational health, patient perspectives, and healthcare system approaches. The studies provide information to improve the understanding and management of LBP. Future research should focus on implementing evidence-based strategies to improve patient outcomes and reduce the global burden of LBP. Particular attention should be given to:

1. Developing and validating innovative diagnostic tools, including digital biomarkers and wearable technology.
2. Evaluating the long-term efficacy of emerging treatment modalities such as ESWT and silver needle therapy.
3. Implementing and assessing the effectiveness of coordinated care models in primary care settings.
4. Addressing occupational factors and developing targeted interventions for high-risk professions.
5. Improving referral processes and triage systems to ensure appropriate utilization of specialized care.

By addressing these areas, we can work toward more effective, personalized, and efficient management of LBP, ultimately improving the quality of life for millions of individuals.

Author contributions

EM: Conceptualization, Data curation, Formal analysis, Methodology, Writing – original draft, Writing – review & editing. PT: Methodology, Writing – original draft, Writing – review & editing. VD: Conceptualization, Data curation, Writing – review & editing, Formal analysis, Investigation, Writing – original draft.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Generative AI statement

The author(s) declare that Gen AI was used in the creation of this manuscript. AI was used to review the grammar of the manuscript after writing.

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Effectiveness of coordinated care to reduce the risk of prolonged disability among patients suffering from subacute or recurrent acute low back pain in primary care: protocol of the CO.LOMB cluster-randomized, controlled study

Aline Ramond-Roquin[1,2,3]*, Cyril Bègue[1,2], Jonathan Vizzini[1,2], Sidonie Chhor[4], Tiphanie Bouchez[5], Elsa Parot-Schinkel[6], Anthéa Loiez[1,7], Audrey Petit[2], Maria Ghali[1], Matthieu Peurois[1,2] and Céline Bouton[2,8]

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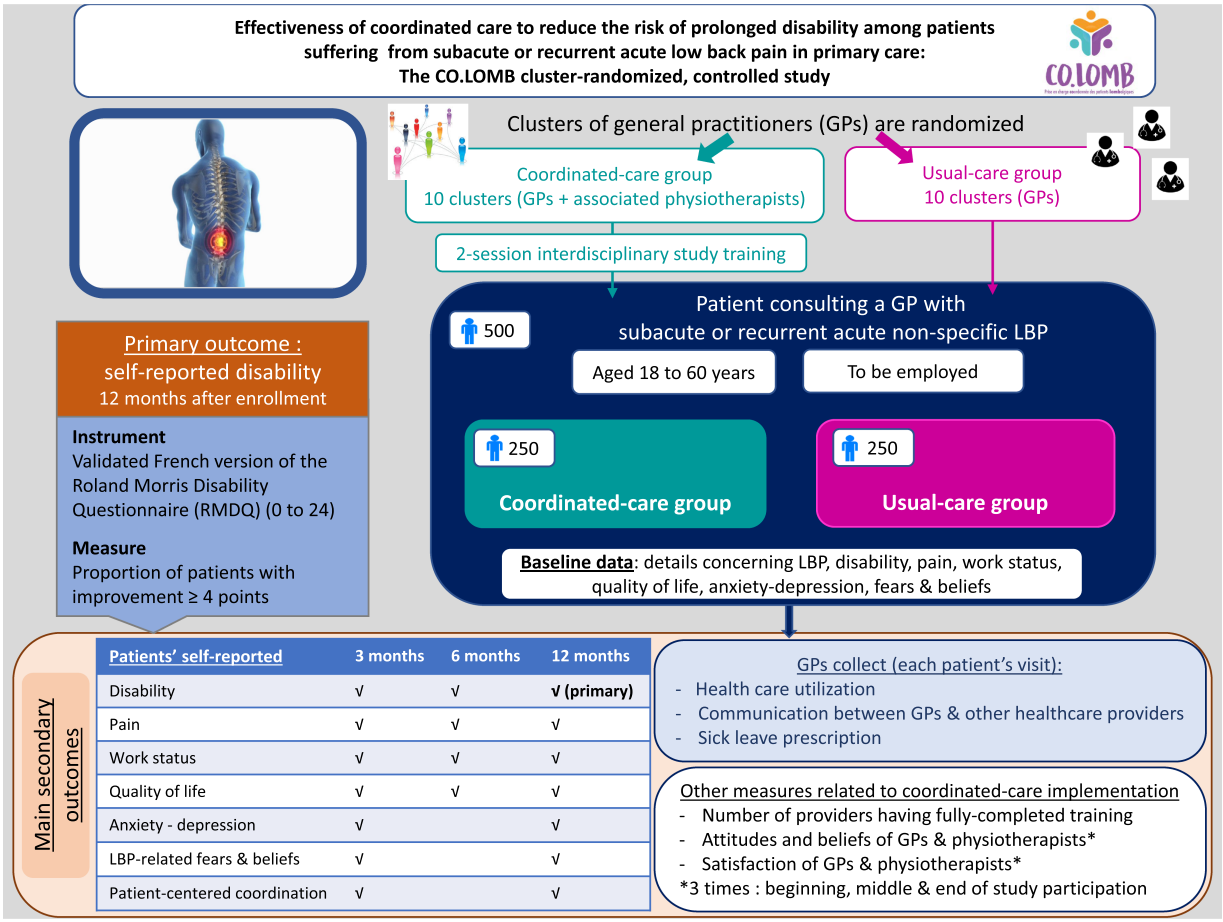
Background: Low back pain (LBP) is a common musculoskeletal condition and, globally, a leading cause of years lived with disability. It leads to reduced social participation, impaired quality of life, and direct and indirect costs due to work incapacity. A coordinated approach focusing on psychosocial risk factors, active reeducation, and the early use of tools to maintain employment, may be effective for improving prognosis of patients with LBP. Primary care professionals and multidisciplinary teams, who see patients in the early stages of LBP may be in the best position to implement such a coordinated approach. We designed this study to assess a coordinated multi-faceted strategy in primary care for patients with subacute or recurrent acute LBP.

Methods: The CO.LOMB study was designed as a multicentric, cluster-randomized, controlled study. Patients aged 18–60 years, with subacute or recurrent acute LBP are eligible. Patients also need to be employed (but can be on sick leave) with access to occupational health services. The clusters of GPs will be randomized (1:1) to either the Coordinated-care group or the Usual-care group. Patients will be assigned the group allocated to their GP. The healthcare professionals (GPs and associated physiotherapists) allocated to the Coordinated-care group will perform a 2-session study training. The following interventions are planned in the Coordinated-care group: exploration and management of psychosocial factors, active reeducation with a physiotherapist, the implementing of tools to maintain employment, and a reinforced cooperation between primary healthcare professionals. The primary objective is to assess the benefit of coordinated primary



GRAPHICAL ABSTRACT

care to reduce disability in LBP patients at 12 months after enrollment: measure using the validated French version of the Roland Morris Disability Questionnaire. Secondary objectives include the evaluation of pain, work status, and quality of life at various time points. The study plans to enroll 500 patients in 20 GP clusters. Patients will be followed up for 12months.

Discussion: This study will evaluate the benefit of a coordinated multi-faceted strategy in primary care for patients with LBP. Notably whether this approach will alleviate the associated disability, attenuate pain, and promote the maintenance or return to work.

Clinical Trial Registration: NCT04826757.

KEYWORDS

low back pain, subacute, acute, primary care, general practitioner, physiotherapist, coordinated care

Background

Low back pain (LBP) is a common musculoskeletal condition. Worldwide, in 2019, 568.4 million suffered from LBP, with an estimated age-standardized point prevalence of 6972.5 per 100,000 people (7.0%) (1). In Western Europe, the estimated age-standardized point prevalence was 9445.4 per 100,000 people (9.4%) (1). Even more concerning, globally in 2017, LBP was the leading cause of years lived with disability (2).

LBP can be classified according to its duration: acute (pain lasting less than 4 weeks), subacute (pain lasting between 4 and 12 weeks), and chronic (when pain has been present for more than 12 weeks).

For most people, LBP improves noticeably during the first 4–6 weeks (3). After this period, LBP improves at a slower rate. At 1 year, many patients still experience low to moderate levels of pain and disability (3). Chronic or recurrent LBP is characterized by functional disability but is also accompanied by psychosocial problems, including anxiety, depression, reduced social participation, eroded family relationships, impaired quality of life, and either temporary or extended work incapacity (4–6). There are direct healthcare costs associated with LBP treatment (4, 5, 7, 8), but also, substantial indirect costs, particularly those related to prolonged work incapacity.

The traditional biomechanical approach of prescribing rest and pain medication are often ineffective (9). The biopsychosocial model for LBP emphasizes the importance of psychosocial risk factors, including psychological, psychiatric, occupational, and social factors. These factors significantly impact LBP and increase the risk for chronic LBP (10). This LBP model suggests that optimal management may be a coordinated multi-faceted strategy targeting different types of risk factors and involving various healthcare professionals.

Most patients with LBP consult general practitioners (GPs) and physiotherapists. Indeed, a French study found that 77% of patients with LBP consulted GPs and 30% underwent physiotherapy (11). Furthermore, occupational healthcare professionals in coordination with GPs play a key role in maintaining employment in these patients (12). In France, all employed workers as well as some self-employed workers have access to an occupational physician (OP) or an occupational nurse, depending on the location of their company. Comprehensive and coordinated care are critical components of primary care, with GPs playing a central role.

In this study we aim to assess the benefit of a coordinated multi-faceted primary care strategy for reducing disability, compared to usual care, in patients, aged between 18 and 60 years, with subacute or recurrent acute LBP.

Method/design

Study design

The CO.LOMB study was designed as a multicentric, cluster-randomized, controlled study. The clusters corresponded to at least 4 GPs practicing in the same geographic area (most often within the same multidisciplinary team). The clusters of GPs identified are located in 4 geographic regions: each attached to a University Department of General Practice (Angers, Nantes, Rennes, and Nice). The clusters will be randomized to either coordinated primary healthcare (the Coordinated-care group) or usual care (the Usual-care group).

Study population

All patients, presenting with LBP at the practices of GPs participating in the study, will be considered for study participation. The eligibility criteria for the study are as follows:

Inclusion criteria

Patients need to meet the following criteria to participate in the study:

1. Patients aged between 18 and 60 years old.
2. Patients consulting a GP with LBP, defined as a pain situated between the 12th rib and the gluteal cleft. The LBP must be either:
   - Subacute LBP, defined as back pain lasting between 4 and 12 weeks and preceded by at least 30 days without back pain.
   - Acute recurrent LBP, defined as back pain lasting for less than 4 weeks and preceded by at least 30 days without back pain. The patients must have consulted a healthcare provider for LBP within the previous 12 months.
3. Patients must be employed (but can be on temporary sick leave) at enrollment.
4. Patients must have access to occupational health services (working for a company that either has its own OP or a company using shared occupational health services).
5. Patients must provide signed consent to participate in the study.
6. Patients must be registered with a social security scheme.

Non-inclusion criteria

Patients meeting any of the following criteria will not be eligible for the study:

1. Patients with a specific LBP, including LBP due to fractures, infections, osteoporosis, inflammatory diseases, or tumors (with confirmed diagnosis or highly suspected, resulting in specific and/or urgent treatment).
2. Patients with LBP with pain irradiating below the knee.
3. Patients for whom active reeducation is contraindicated.
4. Patients performing follow-up for their LBP with a GP not participating in the study.
5. Patients performing reeducation with a physiotherapist not participating in the study and who are unwilling to change physiotherapist (Interventional group only).
6. Patients planning to leave the study territory within the 12 months following study enrollment.
7. Patient planning to retire within the 12 months following study enrollment.
8. Pregnant, breastfeeding, or parturient women.
9. Patients undergoing psychiatric care under duress.
10. Patients admitted into a social or healthcare center for a reason other than for research.
11. Patients unable to read and write in French.
12. Persons deprived of their liberty by judicial or administrative decision.
13. Adult patients under legal protection measure (guardianship).
14. Persons unable to provide consent.

Randomization

GPs will be cluster randomized for the study. The clusters of GPs will be randomized, in a 1:1 ratio, to either the Coordinated-care or the Usual-care group. The randomization will be stratified by the geographical region related to the University Department of General Practice (Angers, Nantes, Rennes, and Nice). The study plans to enroll 20 GP clusters distributed as follows: 10 clusters for the Department of General Medicine attached to Angers (5:5), 4 for each of those attached to Nantes (2:2) and Rennes (2:2), and 2 for that attached to

Nice (1:1). The randomization of the clusters for the Department of General Medicine attached to Angers (10 clusters) will also be stratified by the time of study initiation, since the synchronous initiation of the clusters in Angers is not feasible. The randomization will be performed by the Biostatistical Department of the University Hospital Center ("CHU") at Angers. All patients followed up in the same cluster will be allocated the same group as their GP.

Interventions

Prior to the study, all healthcare professionals (GPs and associated physiotherapists) in the clusters allocated to the Coordinated-care group will undergo a 2-session training for the study interventions. The training sessions will be performed within each of the 10 clusters. Each training will be comprised of two sessions separated by a 2-to-4-week time interval. The first 90-min training session will focus on three blocks: the factors that may influence the evolution and treatment of LBP, the French recommendations that promote active LBP management with therapeutic education (13), and the tools available for maintaining employment in patients with LBP. This first session will be performed autonomously by GPs and physiotherapists, guided by a video. The professionals will be asked to produce a written summary of their exchanges on each block. During the 2–4-week interval between the training sessions, the GPs and physiotherapists will be invited to complete auto-observation questionnaires concerning any patients with LBP that consult them. The second session will consist of a three-and-half-hour in-person training, at each cluster's location, by the clinical training team: made up of the same doctor and physiotherapist. In addition, the clinical training team will systematically invite a local OP to this second session. The session will combine formal presentations related to each interventional component (psychosocial factors in LBP, active exercise reeducation program for patients with LBP, and the tools to maintain employment). The training session will also include several periods of time for the health care professionals to exchange their clinical experiences, and to propose ways to evolve their practices to incorporate the elements associated with the study intervention. During the session there will be a final sequence focusing on interprofessional collaboration, during which the healthcare professionals will decide on the modalities for collaboration to be implemented in the study.

The aim of the training will be for the healthcare professional to appropriate the concepts, tools, and interventions applied during the study. During the training, healthcare professionals will also discuss various aspects of healthcare including care providers, resources offered in the region, as well as potential barriers to collaboration, and how to overcome these barriers.

Healthcare professionals in clusters allocated Usual-care received no study-specific clinical training.

The primary care interventional components in the Coordinated-care group will be as follows:

- Exploration and management of psychosocial factors

Healthcare professionals (GPs and physiotherapists) will be asked to explore, during their consultations, various psychosocial factors, including individual psychological, psychiatric, cognitive-behavioral, family factors (usually named as "yellow flags"), socio-economic factors (usually named as "blue flags"), and socio-occupational factors (usually named as "black flags"). The factors impacting the transition from acute to chronic LBP and the appropriate clinical care will be discussed in detail during the training (4, 10, 14, 15). Furthermore, eligible patients, allocated to the Coordinated-care group will be systematic given the French social security brochure, "I suffer from LBP: what is it and what should I do?" (translated from the French: "Je souffre de lombalgie: de quoi s'agit-il et que faire?") by their GP (16). The brochure will help to educate the patient concerning the evolution of LBP and to eliminate false beliefs.

During the study, the GP will continue to follow the patients according to the patients' individual needs and preferences, as assessed by the patients and their GP. The general recommendation will be to perform regular follow-up visits (for example weekly or every 2 weeks, at least during the early phase of medical care, and especially in the case of sick leave) until LBP-related complaints have been resolved. No specific frequency for the consultations will be imposed by the protocol since the overmedicalization of LBP is known to promote the development of chronic LBP (17). In particular, the duration of disability is known to increase with the number of healthcare consultations, with referrals to specialists, and performing early diagnostic imagery (18).

- Active exercise reeducation program

Patients in the Coordinated-care group will have access to individual reeducation by a physiotherapist trained for the study. The reeducation will be composed of an intensive exercise rehabilitation program. The program comprises of up to 15 sessions of 1 h, 2–3 times per week and included therapeutic education. This approach is commonly recommended for treating LBP (19), but not frequently implemented (due to limited availability of physiotherapists and/or costs for patients). In clinical trials evaluating the efficacy of these programs, these programs usually last between 8 and 31 h. Depending on the physiotherapist's assessments during the program and the patient's needs and preferences, the program can be stopped before the 15th session or can be extended with maintenance therapy sessions.

- Use of tools to maintain employment

GPs and physiotherapists in the Coordinated-care group will be trained during the study to use the tools to maintain employment and will be encouraged to implement these tools early during LBP management to prevent prolonged incapacity at work, extended sick leave or even job loss.

GPs and physiotherapists will be asked to systematically inquire about the occupational situation of their patients throughout the study to better appreciate the evolution of the patient's situation and to adapt the clinical strategy.

The following recommendations and tools, for maintaining employment will be proposed:

✓ GPs and physiotherapists will be requested to systematically refer their patients to either their OP or an occupational nurse (depending on the healthcare organization and the resources available) within 15 days after enrollment.

✓GPs and physiotherapists will be asked to encourage their patients to return to work as early as possible, considering their clinical and occupational situation. Also, health professionals should favor short periods of sick leave, of 1–2 weeks (particularly during the early stages of LBP), instead of long periods. Also, patients will be systematically proposed an appointment with their GP before returning to work.

✓GPs and physiotherapists will be requested to use the tools to help maintain employment available in France in all relevant situations (12). During the study training, GPs will be trained to use the 3 main tools: a visit with the OP before returning to work after a sick leave (referred to as the "pre-return-to-work visit"), a progressive return to work based on part-time work for therapeutic reasons (referred to as "therapeutic part-time work"), and the "recognition of handicapped worker status." These tools will be discussed in detail, including their usefulness, their limitations, and how to implement them in practice, considering local resources and the healthcare organization.

- Increased cooperation among healthcare professionals for a coordinated care for patients

The cooperation between healthcare professionals within a cluster, allocated the study interventions, will be initiated during the study training as an explicit component of the intervention. The cooperation will be facilitated by the proximity of healthcare professionals in the study. At the portion of the training session dedicated to the collaboration between healthcare professionals, time will be allocated for the professionals to discuss obstacles, opportunities for and modalities to collaborate. The use of tools available locally, but underused, including shared information systems and multidisciplinary meetings, will be encouraged for patients included in the study. The GPs will be instructed, with permission from the patient, to provide the physiotherapists not only with the prescription but also the relevant clinical information at the start of treatment. The physiotherapists will be instructed to provide the GP with a final report including an assessment of the patient's condition once the patient completed the reeducation program. Also, when justified by the patient's clinical situation, communication between GPs and physiotherapists will be encouraged throughout the reeducation program. Furthermore, the healthcare professionals will be encouraged to correspond or initiate communication with all healthcare professional implicated in the patient's treatment and return to work, even those not participating in the study. Finally, the following 3 templates for letters will be provided by the research team: a reference letter template from the GP to the physiotherapist, a final report template from the physiotherapist to the GP at the end of reeducation program, and a template from the GP to the OP or occupational nurse. Professionals in the clusters allocated to the Coordinated-care group will be instructed to locally adapt these templates as required and/or to use their own templates.

This multi-faceted study intervention was designed as a coordinated and comprehensive biopsychosocial healthcare strategy. The intervention is fundamentally patient centered: adapted to the needs and preferences of each patient. The healthcare professionals must evaluate the pertinence of each part of intervention according to the patient's specific situation, and to incorporate the patient's preferences in the treatment decision, following a shared decision approach. The patient will remain free to accept or not, or to delay, any proposed part of intervention without being excluded from the study.

Patients in clusters allocated usual care are treated according to the GP's usual practice.

To avoid creating a feeling of injustice in healthcare professionals allocated the non-intervention group and to motivate them to actively participate in the study, the 2-session training will be offered to physicians and physiotherapists of these clusters after the end of the study.

Primary objective and outcome

The primary objective is to assess the benefit of coordinated care for reducing disability, compared to usual care, in patients, aged between 18 and 60 years, consulting for subacute or recurrent acute LBP. The primary objective will be measured using the validated French version of the Roland Morris Disability Questionnaire (RMDQ) (20–22). The questionnaire comprises 24 questions and is scored from 0 (without disability) to 24 (with maximum disability). The primary outcome measure is the proportion of patients that has an improvement (lower score) of at least 4 points at 12 months after enrollment.

Secondary objectives and outcomes

The benefit of coordinated primary care, in terms of patients' clinical improvement and employment status will also be assessed using the following secondary outcome measures:

1. The proportion of patients that have improved RMDQ scores by at least 4 points, relative to baseline, at 3 and 6 months after enrollment.
2. The evolution of the RMDQ scores measured at baseline and then at 3, 6, and 12 months after enrollment.
3. The proportion of patients that improved by at least 2 points on the numerical pain scale, relative to baseline, at 3, 6, and 12 months after enrollment. The numerical pain scale is widely used and validated by the French Health Authority ("Haute Autorité de Santé") (23). The scale is assessed from 0 (no pain) to 10 (maximum pain). In the literature an improvement of 1.5 points is considered to the minimum improvement to be of clinical significance (24).
4. The evolution of the numerical pain scale scores measured at baseline and then at 3, 6, and 12 months after enrollment.
5. The proportion of patients that are "actively employed," defined as being employed and being at work (not on sick leave), at 3, 6, and 12 months after enrollment. Patients on sick leave will not be considered as being actively employed.
6. The number of days of sick leave during the 12 months after enrollment.
7. The proportion of patients considered as having "improved overall." Patients will be considered to have "improved overall" if they have improved their RMDQ scores by at least 4 points,

improved their numerical pain scale by at least 2 points, and are actively employed. The outcome will be measured at 3, 6, and 12 months after enrollment.

8. The change in the physical and mental quality of life of patients during the study measured using the Short-form 12 (SF-12). The SF-12 consists of physical and mental dimensions. Each dimension has 4 categories measure between 0 and a maximum value of 100. The higher the score the better the quality of life. The SF-12 is extensively used with a validated French version (25, 26). The SF-12 will be measured at baseline and at 3, 6, and 12 months after enrollment.
9. The changes in the anxiety and depression scores of the Hospital Anxiety and Depression Scale (HAS). The HAS comprises 14 items: 7 for anxiety and 7 for depression (27). Each item is scored from 0 to 3. The HAS provides anxiety and depression scores ranging from 0 to 21. The study will use the validated French version and will be completed by patients at baseline and at 3 and 12 months (28).

The benefit of coordinated primary care, in terms of the beliefs, feelings, and satisfaction of patients and healthcare professionals will also be assessed using the following secondary outcome measures:

1. The changes in the occupational and physical scores of the Fear Avoidance Beliefs Questionnaire (FABQ). The self-administered FABQ evaluates the patient's fears and beliefs surrounding LBP (29). The validated French version of the FABQ was used during the study (30). The FABQ comprises 16 items divided into two dimensions: the physical (items 1–6) and the occupational (items 7–16). Each item is scored from "0" (completely disagree with the statement) to "6" (completely agree with the statement). Thus, the maximum score is 36 for the physical dimension and 60 for the occupational dimension. The FABQ will be completed by patients at baseline, and at 3 and 12 months.
2. The change in the Patient-Centered Coordination by a Care Team (PCCCT) questionnaire. The PCCCT instrument measures the quality of primary care from the patient's perspective. The questionnaire is composed of 14 items each scored from 0 to 3 (31). The overall score will range from 0 (worst coordination) to 42 (best coordination). The PCCCT questionnaire will be completed by patients at baseline and at 3 and 12 months.
3. The change in the GPs' satisfaction with the healthcare provided for their patients' LBP.
4. The change in the physiotherapists' satisfaction (only in the Coordinated-care group) with the healthcare provided for their patients' LBP.

The GPs' and physiotherapists' satisfaction will be measured, on a scale from 0 (not satisfied) to 10 (completely satisfied), at the following timepoints: when the cluster is initiated, at 6 months after the 5th patient is included in each cluster, and at the end of the follow up of the last patient in each cluster. The GPs' satisfaction will be compared between the study groups.

The level of implementation of coordinated primary care (the study intervention) will be assessed using the following secondary outcome measures:

1. The number of healthcare professionals, in the interventional group, that performed both training sessions.
2. The change in the attitudes and beliefs of physiotherapists (only in the Coordinated-care group) toward LBP. This will be measured using the Pain Attitude and Belief Score (PABS) (32). This instrument assesses treatment orientations (either biomechanical or biopsychosocial). The PABS comprises 36 items: 10 in the biomechanical and 9 in the biopsychosocial dimension. Each item is score using a 6-point Likert scale: 1 (disagree) to 6 (totally agree). This data will be collected when the cluster is initiated, at 6 months after the 5th patient is included in each cluster, and at the end of the follow up of the last patient in each cluster.
3. The change in the attitudes and beliefs of GPs (in both study groups) toward LBP. This will be measured using the biomechanical and biopsychosocial dimensions of the PABS. The GPs will complete the instrument when the cluster is initiated, at 6 months after the 5th patient is included in each cluster, and at the end of the follow up of the last patient in each cluster.
4. The numbers and modes of communication (letters, emails, facsimiles, and telephone calls), in both study groups, between GPs and other healthcare professionals (whether or not they are participating in the study) implicated in the patients' management.
5. Number of consultations/visits/examinations for patients, in both study groups, according to the type of healthcare professional (GPs, physiotherapists, OP or occupational nurse, rheumatologists, other medical specialists, other paramedical healthcare professionals, osteopaths, emergency room visits, imagery, and other examinations), whether or not the healthcare professionals are participating in the study.

Data collection

The schedule for collecting patient data is shown in Table 1 and that for collecting healthcare professional data in Table 2.

At baseline, all data will be collected using a paper version of the case report form. After baseline, all participants (patients, GPs, and physiotherapists) will collect data either via the internet (electronic case report form) or using a paper version, at their discretion.

Patients' data

The baseline visit for patients is the only study-specific visit required by the protocol (Table 1). After the enrollment of patients during GP consultations, patients' data will be collected using self-administered questionnaires completed at home. The patients will be invited by the study coordination team to complete the questionnaires during a period from 7 days before to 21 days after each evaluation endpoint. Reminders will be sent during this period in cases of non-completion. The patients will complete the standardized instruments, as well as questions concerning their LBP management and employment (including their employment

TABLE 1 Schedule for collecting patient data.

Study procedures	Study time points			
	Baseline	3 months*	6 months*	12 months*
Delay allowed (days)		−7 to +21	−7 to +21	−7 to +21
Baseline procedures				
Verification of eligibility	X			
Providing study information and obtaining signed informed consent	X			
Collection of patient data				
Sociodemographic data	X			
Medical history (LBP and concomitant conditions)	X			
Details concerning LBP	X	X	X	X
Work and employment data (including sick leave)	X	X	X	X
Completion of instruments by patients				
Roland Morris Disability Questionnaire (RMDQ)	X	X	X	X
Numerical pain scale (scored from 0 to 10)	X	X	X	X
Short-form 12 (measure of the physical and mental quality of life)	X	X	X	X
Fear Avoidance Belief Questionnaire (FABQ)	X	X		X
Hospital Anxiety and Depression Scale (HADS)	X	X		X
Patient-Centered Coordination of Care Team (PCCCT) questionnaire	X	X		X
Nordic musculoskeletal questionnaire	X			X

LBP, low back pain.
*A medical visit will not be required for these study time points, since patients' data will be collected using self-administered questionnaires completed at home.

status, sick leave, and/or the assistance provide to maintain active employment) since the last evaluation performed. Patients will provide data at 3, 6, and 12 months after enrollment.

During the study, data will also be collected from GPs whenever a participant consults them during the planned 12 months of follow up. The following data will be collected:

- The number of consultations/visits/examinations performed by healthcare professionals (including other GPs, physiotherapists, and OP), since the previous evaluation.
- The number and modes of communication between GPs and other healthcare professionals since the previous evaluation, including which healthcare professional initiated the exchange.
- Employment data, including details concerning sick leave.

Finally, at 12 months after enrollment of each patient, the data collected during follow up will be updated so that all information required for analyses have been provided.

Professionals' data

At initiation of the clusters, sociodemographic and healthcare practice data will be collected from all GPs and only physiotherapists in the interventional group (Table 2). Furthermore, all GPs and only physiotherapists in the interventional group will assess their satisfaction with the healthcare provided for their patients' LBP and complete the PABS at initiation of their cluster, at 6 months after the 5th patient is included in their cluster, and at the end of the follow up of the last patient in their cluster.

Sample size

To calculate the sample size required for the study we hypothesize that 50% of patients in the control group (Usual-care group) and 70% of those in the interventional group (Coordinated-care group) will have a significantly reduced disability at 12 months after being enrolled (3, 33). Considering a cluster randomized study with the following statistical characteristics:

- A power of 80%.
- A type 1 error (α-risk) of 0.05.
- A mean cluster size of 25 patients.
- A coefficient of variation in the cluster size of 0.2.
- An intraclass correlation coefficient of 0.03.
- An attrition rate of 20%.

To show a difference of 20% between the study groups (70% vs. 50%) the study needs to include 10 clusters of 25 patients in each study group. Therefore, a total of 20 clusters of 25 patients: 500 patients are required for the study. The sample size was calculated using Stata (Stata 13.1 software, package clustersamplsi).

This sample size is realistic considering that GPs on average perform 2,500 consultations per year in patients aged between 18 and 60 years (34). Among these 1 of every 200 consultations concerns subacute LBP (35). Therefore, on average 12–13 patients per year with subacute LBP consult each GP in France. The number of consultations for recurrent acute LBP is more difficult to estimate but is about as frequent as those for subacute LBP. The planned patient enrollment period is 24 months for any given cluster. Each cluster will consist of at

TABLE 2 Schedule for collecting healthcare professional data.

Study procedures	Study time points		
	At cluster initiation	At 6 months after the 5th patients is enrolled in the cluster	At the end of follow up of the last patient in the cluster
Baseline procedures			
Sociodemographic and details concerning their healthcare practices will be collected from all GPs and only physiotherapists in the Coordinated-care group	X		
The number of healthcare professionals that underwent study training (Coordinated-care group only)	X		
Completion of instruments by general practitioners (GPs)			
GPs' satisfaction with healthcare provided for their patients' LBP (score from 0 to10)	X	X	X
Pain Attitude and Belief Score (PABS)	X	X	X
Completion of instruments by physiotherapists (coordinated care group only)			
Physiotherapists' satisfaction with healthcare provided for their patients' LBP (score from 0 to10)	X	X	X
Pain Attitude and Belief Score (PABS)	X	X	X

LBP: low back pain.

least 4 GPs. Therefore, the study target of recruiting 25 patients per cluster is feasible. The total planned enrollment period is 36 months, comprising an initial 12-month period during which the clusters will be initiated followed by a 24-month patient enrollment period.

The "Lasagna law," suggests that previsions of recruitment are generally optimistic for various reasons, including but not limiting to inclusion criteria (36). Therefore, in our study, to anticipate the risk of lower than expected and/or differential recruitment levels between the control and interventional groups, we developed various strategies to support patient recruitment. These include communication strategies, that were adapted according to the study group and according to each GPs recruitment activity. Moreover, the recruitment status and other study information will be communicated to GPs via newsletters and an online platform. The study team will also maintain contact will all GPs throughout the study to ensure that they remain motivated and that they recruit patients.

The coefficient of variation in the cluster size was set at 0.02. This corresponds with a mean cluster size of 25 patients, and an interquartile range of 20–30 patients. The intraclass correlation coefficient of 0.03 is conservative. Indeed, the median intraclass correlation coefficient considering the various outcome measures, including disability, have been estimated in primary care to be 0.01, with an interquartile range of 0–0.032 (37).

If patients are lost to follow-up, the GP will make all attempts to contact the patients and ensure follow-up. Patients lost to follow-up will not be replaced.

Statistics

Quantitative data will be presented as means with standard deviations and will be compared using Mann–Whitney tests. Qualitative data will be presented as numbers with percentages and compared using Fisher's exact tests.

For the primary objective, the proportion of patients that have an improved (lower score) of at least 4 points, in the RMDQ, at 12 months after enrollment will be compared in the study groups. The analysis will be performed using a multilevel logistic mixed model that will allow the clustering effect to be considered as random.

Similarly, the secondary outcome measures with binary outcomes compared between the study groups (e.g., the proportion of patients that improved by at least 2 points on the numerical pain scale at 12 months) will be analyzed by multilevel logistic mixed regression models.

Secondary outcome measures assessing changes in a quantitative parameter over time (e.g., the evolution of the RMDQ scores measured at baseline and then at 3, 6, and 12 months after enrollment) will be analyzed using linear multilevel mixed regression models. The individual effect will be included in the cluster effect. Time will be considered as qualitative variables with a varying number of modalities, e.g., 4 modalities for outcomes assessed at baseline, and then at 3, 6, and 12 months, and 3 modalities for outcomes assessed at baseline, and then at 3 and 6 months. The effect of the intervention will be evaluated by including an interaction between the variables for time and for the study group. The effect of the intervention will be assessed at each time point. The increased alpha-risk, due to multiple analyses, will be accounted for using the Bonferroni correction.

For these various multilevel models, the variance–covariance matrices will be considered as unstructured. Missing data will be treated using a set of 10 multiple imputations based on chained equations (38, 39). The analyses will be performed bilaterally with the alpha-risk set at 5%, except in cases where the Bonferroni correction was used. The data will be analyzed on an intent-to-treat basis. Thus, all patients with data will be included in the analysis unless they specifically indicate that they do not want their data analyzed.

Discussion

Our study assesses a multi-faceted coordinated patient-centered strategy for treating LBP that incorporates the 4 main factors identified in the literature:

1. The management of psychosocial risk factors (10, 14).
2. Active exercise reeducation program (40, 41).
3. Tools for maintaining employment (12).
4. Reinforced cooperation between primary healthcare professionals.

These factors are supposed to be clinically relevant for reducing the risk of persistent incapacity and extended sick leave and/or job loss in people presenting with LBP. At the chronic LBP stage, the benefits of strategies based on these factors remain modest and are often short-lived. The literature suggests that implementing these strategies at an earlier stage, when LBP is subacute or acute recurrent, may be more effective in reducing the risk of chronic incapacity. Thus, strategies need to be implemented in primary care (and not in the hospital setting) where early symptoms of LBP are managed. Furthermore, primary healthcare workers have the required competence to implement these strategies. Although, at present, there is not sufficient data to confirm this hypothesis. The French (13) and International recommendations (42–44) for treating patients with a risk of chronic LBP incorporate the 4 factors mentioned above. However, these recommendations are often based on expert consensus and not on evidence-based research. To date, the results of implementing strategies in primary care, only based on certain factors, have proved to be disappointing (45–48). We hypothesize that only the simultaneous implementation of strategies based on these 4 factors will significantly reduce the risk of chronic incapacity considered to be clinically relevant.

We decided to limit our study eligibility to adults younger than 60 years old. Indeed, the etiology of LBP varies with age. In adults younger than 60, the cause of LBP is mostly general and unspecific, becoming more specific with age. Beyond 70, the specific origin of LBP becomes clinically significant (33). Moreover, a critical portion of our study concerns the occupational impact of LBP. This impact becomes more difficult and/or less relevant to assess in patients older than 60 years because of the high probability of them being unemployed or retired.

GPs in the interventional group may preferentially include patients with severe LBP instead of enrolling all eligible patients if they consider the intervention to be better than usual care, and that this improved care may benefit patients with severe LBP more than patients with less severe LBP. This phenomenon may also occur in the control group, where GPs may be reluctant to suggest study participation because of the protocol's constraints, to patients with non-severe LBP. We have examined this issue and will address this by providing continuous support for GPs during the study. Where a significant difference between groups in terms of patient's LBP status at baseline is observed, we planned to adjust analyses to limit the impact of this bias on the results.

Most studies that have assessed the clinical evolution of LBP have used either pain, incapacity, and/or returning to work to measure the effectiveness of interventions (33, 49). However, from a patient's perspective, reduced LBP is mainly comprised of three dimensions: attenuated pain, improved functional capacity, and combined with an acceptable quality of life, which includes the capacity to work (24). In our study, we chose perceived disability, considered by patients to be of utmost importance, as our primary outcome measure. However, we have included several secondary outcome measures, including measures to assess pain, quality of life, and the patients' occupational status—other important facets of LBP.

Currently, in France, primary healthcare professionals, working in the same geographical region, are encouraged to group together in multidisciplinary practices. Our study is consistent with this evolution of primary healthcare, evaluating a coordinated strategy composed of a multidisciplinary team. Moreover, our study allows healthcare professionals in each region to form networks that hopefully will persist after the study has been completed. Consequently, we will cluster randomized GPs in the same region to promote local cooperation among professionals.

It has been reported that patient's and healthcare provider's expectations, based on previous experiences and representations, are associated with prognosis of patients with nonspecific LBP (50–52). Regarding patients, we believe that our randomized study design will limit the confusion bias from the heterogeneity in baseline patients' expectations. Similarly, concerning healthcare providers, we expect that the randomized study design will equally distribute the healthcare providers' expectations between the study groups at baseline. In addition, our study has been designed to evaluate whether the intervention will significantly change beliefs in healthcare provider's, allocated to the Coordinated care group. This will be measured using the PABS (53). If required, an adjustment according to baseline levels has been planned.

In our study, the study intervention does not allow either the patients or providers to be completely blinded to the study group. Indeed, the study intervention involves not only specific actions from the GP but also informed patient participation, as an active partner in their care. We have done our best to limit information about the alternative group. For example, we created two different patients' information and consent letters: one for each group. The information provided to patients has been adapted to the group allocated. In addition, the flow of information between groups are unlikely since GPs and their patients allocated the same cluster share the same geographical area, which differs to that of other clusters.

As in most clinical trials, our study may be affected by the "Hawthorne effect" or "trial effect" (54, 55). This effect concerns the changing of behavior due to study participation and the feeling of being observed. This may affect GPs in the control group, performing more careful treatment than usual, but may also occur in GPs allocated to the intervention group, with them having higher expectations and increased motivation. Therefore, it is difficult to estimate how, and to what extent, this effect could bias the study results.

This study will provide valuable data concerning the management of LBP in primary care in France. Overall, it will allow us to evaluate the benefit of a coordinated approach to LBP management, from the patients' perspective, among other outcomes: to alleviate the associated disability, attenuate the pain, and to promote the return to work in patients suffering from subacute or recurrent acute LBP.

Future directions and clinical implications

Our study design is pragmatic and based on current healthcare practices in French primary care. Consequently, our results will have a high potential for transferability. They may support early collaboration between GPs, physiotherapists, and OPs for treating patients with subacute or recurrent acute LBP in primary care. More largely, they may also advocate for reinforcing interdisciplinary collaborative practices around patients having musculoskeletal disorders, pain syndromes, or other types of chronic conditions.

Trial status

On the 5th of May 2023, 19 clusters have been initiated with the approval to include patients: 41 patients have been enrolled.

Ethics statement

The CO.LOMB study was conducted in accordance with the guidelines of the Declaration of Helsinki, and respecting French and European regulations, including the European General Data Protection Regulation and the requirements of the French "Commission Nationale de l'Informatique et des Libertés". The study has been approved by an independent French ethics committee, the "CPP Ile de France XI" (Study number 20.01298.067400-MS02). All participants provided written informed consent before participating in the study.

Author contributions

AR-R, CyB, EP-S, AP, MP, and CéB: study concept and design. AR-R, SC, TB, MG, MP, and CéB: acquisition of data. AR-R and MP: drafting of the manuscript. AR-R, EP-S, SC, TB, JV, and CéB: critical revision of the manuscript for important intellectual content. AR-R, CyB, SC, TB, EP-S, and CéB: obtaining funding. AL: administrative, technical, or material support. AR-R: supervision. CyB and JV: clinical training. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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Virtual reality to improve low-back pain and pelvic pain during pregnancy: a pilot RCT for a multicenter randomized controlled trial

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A significant proportion of women experience low back and pelvic pain during and after pregnancy, which can negatively impact their daily lives. Various factors are attributed to these complaints, and many affected women do not receive adequate healthcare. However, there is evidence to support the use of different physiotherapeutic interventions to alleviate these conditions. Virtual reality is a promising complementary treatment to physiotherapy, particularly in improving pain perception and avoidance. The primary objective of this study is to evaluate the efficacy of a four-week program combining VR and physiotherapy compared to standard physiotherapy in pregnant women with low back and pelvic pain, in terms of improving pain avoidance, intensity, disability, and functional level. The study also aims to investigate patient satisfaction with the VR intervention. This research will be conducted through a multi-center randomized controlled clinical trial involving pregnant patients residing in the provinces of Seville and Malaga with a diagnosis of low back and pelvic pain during pregnancy. The alternative hypothesis is that the implementation of a Virtual Reality program in combination with standard physiotherapy will result in better clinical outcomes compared to the current standard intervention, which could lead to the development of new policies and interventions for these pathologies and their consequences.

Clinical trial registration: clinicaltrials.gov, identifier NCT05571358.

KEYWORDS

virtual reality, physiotherapy, low-back pain, pelvic pain, pregnancy

1. Introduction

Roughly 50% of women experience low back pain (LBP) during pregnancy, and approximately 25% still suffer from pain 1 year after giving birth (1). LBP and pelvic pain (PP) are common complaints during pregnancy, which may worsen as pregnancy progresses and in some cases may even radiate to the buttocks, legs, and feet (2). The reported global prevalence rates for these conditions vary widely, ranging from 24 to 90%, mainly due to the lack of a universally accepted disease classification system (3). For many women, the pain can become

severe enough to interfere with daily activities, disrupt sleep, and have negative impacts on social and sexual life, work capacity, and psychological well-being and contributes to high levels of sick leave (4). There are various reasons that can be associated with back pain during pregnancy. One of the factors is mechanical stress due to the growing uterus, resulting in lumbar lordosis (5). Additionally, the separation of abdominal muscles during pregnancy can also cause strain on the paraspinal muscles. The hormone relaxin, which is increased during pregnancy, is also a contributing factor, as it leads to joint laxity and instability, which can cause rotational movements in the sacroiliac joints. These factors have been identified as possible causes of back pain during pregnancy (6, 7).

According to estimates, more than half of women receive insufficient or no healthcare intervention for conditions such as LBP and PP (8). Guidelines in Europe recommend managing LBP and PP by providing patients with sufficient information and a sense of security are necessary to enable individuals to carry out their daily tasks without disruption, staying active and working where possible, and offering tailored exercises as needed. Prenatal healthcare providers in the United Kingdom and Nordic countries typically educate pregnant women about effective ways to handle lower back pain, pelvic pain, or both during pregnancy and may suggest they seek physiotherapy for targeted treatment (9). In contrast, women in the United States are frequently informed that experiencing lower back pain during pregnancy is a normal occurrence. To alleviate such pain, a range of approaches have been implemented, including exercise, rest, hot and cold compresses, support belts, massage, acupuncture, chiropractic care, aromatherapy, relaxation techniques, herbal remedies, yoga, Reiki, paracetamol, and nonsteroidal anti-inflammatory drugs (3, 4, 8, 9). Other therapies have also been studied, such as exercise, yoga, manual therapy, acupuncture, and multi-modal approaches. A 2015 Cochrane systematic review and meta-analysis found that regular exercise has been shown to potentially lower pregnancy-related LBP, enhance functional ability, and decrease the need for sick leave compared to usual prenatal care (2). A 2018 systematic review of 32 studies concluded that prenatal exercise can reduce the severity of LBP and PP during and after pregnancy compared to not exercising (1).

Some studies addressed the issue of sick leave during pregnancy, presenting positive results through exercise programs, reducing healthcare costs and promoting women's health (10, 11). For persistent LBP lasting more than 12 weeks, recommended physical treatments include an activity or exercise program that is gradually increased in intensity and aimed at enhancing functionality and preventing additional disability. Current evidence does not support the superiority of any particular type of exercise for managing pregnancy-related lower back pain, and therefore, guidelines suggest customizing exercise programs based on individual needs, preferences, and abilities. While some guidelines do not recommend passive therapies such as spinal manipulation or mobilization, massage, and acupuncture, others consider them optional and may recommend a brief course of treatment for individuals who do not respond to other interventions (12). For individuals with persistent lower back pain that has not responded to previous treatments, other passive therapies like ultrasound, transcutaneous electrical nerve stimulation, progressive relaxation, mindfulness-based stress reduction, and combined physical and psychological treatments may be options to consider (13–15). In cases where patients have not responded to initial treatments and are significantly functionally impaired by pain, multidisciplinary rehabilitation programs may be more effective than standard treatments. These programs typically include supervised exercise therapy, cognitive-behavioral therapy, and medication to help manage pain and improve function (13–18).

A clinical practice guidelines in LBP during pregnancy in Spain suggests the use of aquatic exercises and other individualized exercise programs, as well as therapeutic massage to relieve LBP during pregnancy (19). In addition, strengthening the muscles of the lumbo-sacral joint and pelvic girdle through physiotherapy has been shown to effectively alleviate back pain (20). Incorporating exercise as a treatment option for pregnant women with back pain aims to reduce their pain levels and mitigate associated health complications. This approach also seeks to enhance their overall quality of life (6).

Virtual Reality: In the last 20 years, virtual reality (VR) technology has advanced rapidly and is now widely used (21). VR refers to computer simulations that utilize interaction devices and sensory display systems (22, 23). This technology has been applied to various fields, including healthcare, where it has been used to provide treatment, aid in pain management, and support rehabilitation programs (12, 24, 25), among other clinical applications.

A systematic review from 2019 conclude that VR has the potential to improve outcomes for spinal pain with demonstrated statistical and clinical significance (26). Additional patient populations VR interventions may be particulary beneficial for individuals who are experiencing higher levels of pain, and physical dysfunction, as well as anxiety, an alternative treatment to opioid analgesics (26). A study conducted on 80 female breast cancer patients at a specialized cancer center in Jordan revealed that VRi can be an effective intervention for managing pain and anxiety. The study found that using immersive VR in conjunction with other interventions is more effective than using morphine alone for relieving pain and anxiety (27). In stroke patients VR show promise as a future tool in the rehabilitation of daily live activities, particularly in the subacute phase (27).

VR enables users to engage with computer-generated environments and simulate real-life exercises and situations. In the context of rehabilitation, motivation is a crucial factor that affects the outcome of a patient's performance (26). By providing enriched environments with multiple sensory feedbacks (auditory, visual, tactile) and moving avatars, VR stimulates various neural circuits that enhance a patient's learning and recovery process (28–30). Therefore, VR has the potential to aid patients in improving their movements and perception of body position and reducing pain during the VR exercises (31). In turn, VR is a tool with a powerful contextual factor with the capacity to modify the patient's context, that is, it can modify dysfunctional expectations and beliefs to improve musculoskeletal pain. Mainly they find it useful with violation strategies when our patients have a negative expectation with prior with low presicion. On the other hand, besides VR, other tools also used are exercise and manual therapy. All these tools used appropriately are very useful for the modification of expectations and beliefs (32). We know that contextual factors can trigger positive or negative effects on the achievement of goals, therefore attending to these factors can improve daily clinical practice (33).

A review suggests that VR may be a tool capable of modifying patients' body perception. That is, VR has the ability to explicitly or implicitly modify the body and spatial perception of patients with musculoskeletal pain (34). Thus it can be presented as a very

interesting tool on a perceptual level (32, 33). This supports and relates it to the modification of the patient's expectations and perception.

A systematic review from 2019 focus on orthopedic rehabilitation conclude that the promising evidence suggests that VR can be effective in treating chronic neck pain and shoulder impingement syndrome. In cases of rheumatoid arthritis, knee arthritis, ankle instability, and post-anterior cruciate reconstruction, VR and exercise have similar effects. However, the evidence regarding the effectiveness of VR in comparison to exercise in cases of fibromyalgia and knee arthroplasty is either inconclusive or absent (35). A recent systematic review conducted in 2020 indicates that VR exercises have the potential to produce positive physiological, psychological, and rehabilitative outcomes in individuals when compared to traditional exercise (36). VR technology can also be utilized for a variety of purposes during different stages of pregnancy such as reducing anxiety levels, training individuals to manage pain during labor effectively (37), lowering anxiety levels before cesarean, episiotomy repair, dilation, and curettage (38–41), reducing pain (28), and managing exercise training (24). The importance of external focus in exercise management was picked up in the review by Piccoli et al. (42). VR makes it possible to administer exercise by shifting the patient's attention with musculoeskeletal disorder to the objetive of the task facilitating motor performance and learning. This implies that VR is a useful tool for managing externally focused exercises (42).

In addition to all these positive effects, it is important to note that VR has adverse effects such as motion sickness (MS). MS is a pathology that can cause various signs and symptoms such as nausea, vomiting, disorientation, sweating, fatigue, and headache. Currently, MS is being studied in the context of two main technologies, automated cars and VR, and is a pathology to be taken into account as it represents a threat to the success of therapy and acceptance (43).

Although VR has shown effectiveness in treating some orthopedic conditions, currently, there is no conclusive evidence available on the effectiveness of interventions utilizing VR in treating LBP and PP during pregnancy. Therefore, it is advisable to conduct further studies to evaluate the effectiveness of VR interventions in this population both in hospital environments and other areas of care, considering the current health scenario. The primary aim of this study is to assess the efficacy of a combined VR and Physiotherapy 4-weeks program compared to a standard physiotherapy intervention in LBP and PP in pregnant women to improve pain-related fear avoidance, pain intensity, disability and functional level. As secondary aim is to investigate patient satisfaction with the VR intervention.

2. Materials and methods

2.1. Design

This research is a 4-week prospective multicentre randomized clinical trial. Participant recruitment and the supervised VR program component will be provided by clinical setting at department of Physiotherapy at University of Sevilla and Málaga (Spain). This study encompasses various departments of gynecology rehabilitation, physiotherapy, and researchers from the University of Granada, University of Málaga, and University of Sevilla. All participants in this study will be treated in academic centers and facilities, in both cases belonging to the universities of Seville and Malaga city. The study adheres to the Standards for Quality Improvement and Excellence in Reporting (SQUIRE) guidelines (44) and is conducted in accordance with (CONSORT) Consolidated Standards of Reporting Trials criteria (45). In addition, it is based on Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 explanation and elaboration: guidance for protocols of clinical trial (46). More information in Supplementary Material.

The study was approved by the institutional ethics committee of Andalucía with internal code 1928-N-21. It has also been registered in the clinicaltrials.gov database under the trial registration number NCT05571358. All female participants must provide informed consent prior to enrollment in the study (Supplementary Material).

2.2. Participants and eligibility criteria

The trial will enroll pregnant women who report or have been clinically diagnosed with LBP, PP, or a combination of both.

To be eligible, patients must reside in Sevilla or Málaga during the intervention phase, and must not have had a history of LBP or lumbar pathology prior to pregnancy, or have experienced LBP or PP events before their first contact with the research team. Patients with absolute or relative contraindications such as heart disease, chronic obstructive lung disease, diabetes mellitus, incompetent cervix/cerclage, multiple gestation, risk of premature labor, preeclampsia/pregnancy-induced hypertension, thrombophlebitis, pulmonary embolism, intrauterine growth restriction, or serious blood disease, history of abortion or curettage will be excluded. Additionally, excluding patients who lack the cognitive ability to utilize modern technological tools will be necessary. The inclusion and exclusion criteria can be found in Table 1. The trial involves the participation of gynecology rehabilitation and physiotherapy departments, as well as researchers from the University of Granada, University of Málaga, and University of Sevilla.

TABLE 1 Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Adult woman over 18 years old	Patients who had LBP or PP prior to their pregnancy.
Pregnant women experiencing symptomatic LBP, PP, or both conditions (47)	Patients who do not possess the cognitive ability required for the use of technological tools
Pregnant women in their second or third trimester, between the 12th and 38th week of gestation (2)	Patients with either absolute or relative contraindications.
Pain intensity rated as greater than 4 out of 10 on the VAS, indicating moderate to severe pain (47)	
Participants must reside in either Sevilla or Málaga during the research period	

LBP, Low Back Pain; PP, Pelvic Pain; VAS, Visual Analogy Scale.

2.3. Recruitment

To gather sufficient data for the development of this study, a sample size of 66 patients ($n = 66$) will be enlisted. To date, no studies have reported on the use of VR and LBP in pregnant in low resource setting; so that this randomized, blinded clinical trial will provide evidence for the effect size. However, an online sample size calculator was used[1] to determine minimal sample size (accessed on 26 July 2023). Included in the calculation was a one-tailed test, we assumed a medium effect size of 0.65 based on related study on a similar topic (1, 47–50), a significance level of 0.05 and power of 0.8. As the first estimate of effect size, a sample size of 66 participants has been calculated, with an expected proportion of losses (10%), and a proportional distribution for each arm of the study (EG = 30 and CG = 30). The drop-out rate will be taken into account in the reporting process, as well as the reasons for exclusion, although this information is free to be provided, as it is contained in the initial information presented to the patient, this information is expanded in the Supplementary Material.

To ensure adequate recruitment of participants to achieve the target sample size, a multidisciplinary approach involving the gynecology, rehabilitation, and physiotherapy departments has been adopted. Collaborators have been provided with information on the study through personal interviews and presentations. Patient recruitment will aim to have socio-demographic diversity that reflects the social background, gender, ethnicity, and educational level of the reference population, while taking into account the specific characteristics of the population.

Prior to the inclusion of patients, the research team will devise the allocation sequence and consecutively assign patients into either the Experimental Group (EG) or the Control Group (CG) through the use of opaque sealed numbered envelopes. This assignment will be done using a computerized random number generator to ensure unbiased allocation. Each participant's treatment will be administered separately to maintain the confidentiality of study information.

Due to the nature of the intervention in both groups, blinding of patients and physiotherapists will not be feasible. As a result, this study will adopt a single-blind approach, where the evaluator responsible for assessments will remain unaware of the nature of the intervention. Throughout the entire study process, the evaluator will be kept blinded, being unaware of the study objectives and the randomized distribution of patients into study groups. Additionally, access to the randomization sequence will not be provided to the evaluator.

Subjects will undergo an initial evaluation based on clinical parameters, and subsequent follow-up discharge reports will be documented. The collection of data will be performed by the principal investigator and integrated into dedicated research databases.

2.4. Intervention

Random allocation will be utilized to assign participants to either the intervention or control groups, which will be achieved by utilizing a random number table. Both groups will receive 3 sessions per week during the 4 weeks of intervention (51).

2.4.1. Control group (CG)

In adherence with clinical practice guidelines, participants assigned to the control group will be provided multidisciplinary rehabilitation programs that involve coordinated delivery of supervised exercise therapy, cognitive-behavioral therapy (including education on pain), as well as therapeutic massage to alleviate LBP during pregnancy. Typical physiotherapy session:

- Control of daily health.
- Analgesic and muscle-relaxing (thermotherapy, tens, therapeutic massage).
- Exercise session:

Initial warm-up: 5–10 min (thoracic, lumbar and pelvic joint mobility exercises adapted to the pregnancy progress).

Strengthening and flexibility exercises (thoracic, lumbar and pelvic joint exercises adapted to the pregnancy progress).

Return to calm: 5 min breath and stretching exercises.

Recording of incidents and patient/physiotherapist feedback.

2.4.2. Experimental group (EG): VR intervention

The experimental group will be treated with the same approach as the control group, as described in the previous section. In addition to the aforementioned treatment, the experimental group will also receive a virtual reality intervention.

The immersive virtual reality (VRi) system is composed by a head mounted display (Oculus Quest, Facebook Inc.) and two controllers. Oculus Quest headset is a wireless and portable Android-based device which supports positional tracking with six degrees of freedom (360°). The internal cameras allow to show an external signal with the user view, which helps to monitoring the patient execution. A Wi-Fi connection and a training area of 2×2 meters are needed.

After each session, participants will be immersed in a virtual reality landscape provided by the Nature Trek VR software.[2] Initially, participants will be seated and guided through a five-minute breathing exercise, also known as the "meditation Lotus option." Subsequently, participants will be encouraged to move freely within a relaxing virtual environment for 15 min, while paying close attention to the calming sounds of nature. The specific themed environment will be selected based on the individual preferences of the participants.

At the start of the research, general care advice, including physical activity and medication intake (the intake of medication shall be permitted, monitored and supervised), is provided to participants. They are also instructed not to engage in any other training programs during the intervention phase. If any participant deviates from the VRi program or experiences any negative incidents, such occurrences are recorded daily. Also, Participants undertaking other training programs during the intervention will be excluded.

1 https://www.ai-therapy.com/psychology-statistics/sample-size-calculator

2 https://naturetreksvr.com/

2.5. Outcomes and instruments

2.5.1. Primary research outcomes

2.5.1.1. Pain related fear avoidance

A new scale called the Fear-Avoidance Components Scale (FACS) was created, which includes important components of previous measures related to fear-avoidance (FA) and additional components of the FA model that were not considered in previous questionnaires. The FACS is based on the most current FA model developed by Vlaeyen (52, 53). The reliability of the FACS was tested, and it demonstrated acceptable test/retest reliability with a correlation coefficient of 0.90–0.94 and high internal consistency (Cronbach $\alpha = 0.92$) (54). Scale validated in Spanish (54). Pain-related fear avoidance (FA) is a frequently encountered issue among patients who suffer from painful medical conditions and exhibit pain-related catastrophic cognitions, hypervigilance, and avoidance behaviors, which can result in reduced functioning, depression, and disability (55).

2.5.1.2. Pain intensity

The Visual Analog Scale (VAS) has been utilized in earlier research examining alterations in pain, particularly in all randomized trials of treatments for back pain during pregnancy published in or included in the Cochrane and systematic reviews (48). The pain assessment before and after the intervention will be conducted using the visual analog scale (VAS), which consists of a 10-cm scale with 1-cm increments. The participants will be asked to rate their pain on the scale and the score will be recorded. The scale ranges from 0 to 10, where 10 represents the most intense pain. The score indicated by the participants on the scale will be considered as the pain score. Past research has demonstrated that the VAS has a high level of reliability ($r = 0.76$–0.84) (54). VAS is used in Spanish version and validated in LBP (56, 57).

2.5.1.3. Disability and physical function

In this paper, our focus is on the two back-specific functional measures recommended in the "core-set," namely the Roland-Morris Disability Questionnaire (RMDQ), in Spanish scale validated (58) and the Oswestry Disability Index (ODI), in Spanish scale validated (59). They are the most commonly used measures of function in back pain research (54).

To measure the severity of disability in participants with less severe LBP, the researchers will use the RMDQ, which consists of 24 categories with yes or no questions. A score of up to 24 can be achieved, with higher scores indicating greater functional disability. The test–retest reliability of the RMDQ has been found to be high, with correlations of 0.91 (same day), 0.88 (1 week), and 0.83 (3 weeks) reported (60, 61).

Participants will complete the Oswestry low-back pain disability index (ODI) to evaluate their functional level during LBP, which consists of 10 questions assessing daily activities. The severity of disability in each category will be scored from zero to five. The validation of the ODI showed high intraclass correlation coefficient ($r = 0.938$) and internal consistency with Cronbach's alpha of 0.918 (day 1) and 0.895 (day 7) (52, 53).

2.5.2. Secondary research outcomes

2.5.2.1. Satisfaction with virtual reality intervention

The User Satisfaction Evaluation Questionnaire (USEQ) will be used to evaluate participants' satisfaction with the Virtual Rehabilitation Systems. The USEQ is a questionnaire that measures user satisfaction, a component of usability, in virtual rehabilitation systems. The questionnaire is considered reliable with satisfactory internal consistency (Cronbach alpha coefficient of 0.716), and participants have reported finding it easy to understand with an appropriate number of questions (55). USEQ has been validated in Spanish population (62).

A summary of the variables has been included in Table 2.

2.6. Data collection, monitoring and management

After informing and obtaining consent from participants, the study will collect data by the end of the year 2023, which will be analyzed statistically. The research team, including the rehabilitation and physiotherapy department, will conduct an initial assessment (Pre) and a final 4-week assessment (Post). Schedule of enrollment, interventions, and assessments is shown in Figure 1. The collected data will be aggregated into a research database specifically created for this study, which will be managed by the principal researchers will be conducted using exportable data tables.

The study has been structured into four stages, which are illustrated in the study design flow diagram depicted in Figure 2:

Stage 1 consists of two processes: the first stage involves identifying potential candidates, providing them with prior information, and obtaining their informed consent to participate. Secondly, the physiotherapy department will conduct assessments, which will include a self-made clinical interview for anamnesis, along with self-administered questionnaires such as FACS, RMDQ, ODI, and 2VAS (T0-Pre). This stage will conclude with a referral to the physiotherapy intervention team.

Stage 2 includes: Design of a personalized physiotherapy program (CG and EG) according with Physiotherapy department plus VRi intervention in the (EG).

Stage 3 includes: participants will receive a 4-week physiotherapy intervention along with a VRi program that is supervised by the

TABLE 2 Primary and secondary outcomes.

Primary and Secondary Outcomes	Definition	Type
Pain related fear avoidance	FACS	Self-reported
Pain intensity	VAS	Registered / Self-reported
Disability and physical function	RMDQ, ODI	Registered / self-reported
Satisfaction and usability	USEQ	Self-reported

FACS, Fear-Avoidance Component Scale; VAS, Visual Analog Scale; RMDQ, Roland-Morris Disalibity Questionnaire; ODI, Oswestry Disability Index; USEQ, User Satisfaction Evaluation Questionnaire.

	ENROL-MENT	ALLOCATION	POST ALLOCA-TION	CLOSE OUT
Time Point	- T 1	T 0 (Baseline) PRE	T.1 (4 Weeks) POST	
ENROLMENT				
Eligibility screen	X			
Informed consent	X			
Advance Info	X			
Allocation		X		
INTERVENTION				
Virtual Reality Interven-tion		X	X	
Control Group		X	X	
ASSESMENT				
List Baseline Variable	X			
Initial Assessments		X		
FACS		X	X	X
VAS		X	X	X
RMDQ		X	X	X
ODI		X	X	X
USEQ			X	X
Data Collection		X	X	
Statistical and Data Analysis				X

FIGURE 1
Schedule of enrolment, interventions, and assessments. FACS, Fear-Avoidance Component Scale; VAS, Visual Analog Scale; RMDQ, Roland-Morris Disalibity Questionnaire; ODI, Oswestry Disability Index; USEQ, User Satisfaction Evaluation Questionnaire.

physiotherapy department. The intervention will start with a one-on-one session to provide patients with education and training on the use of technology. Daily follow-up sessions will be conducted to monitor the progression of the program and to record any adverse events. Based on the feedback received from the participants, the physiotherapy team will make updates to the program.

Stage 4 includes: the final assessments and evaluation (T1-Post) will be conducted. The physiotherapy team and principal researchers will compile the results of the outcomes after 4 weeks, which will include FACS, RMDQ, ODI, VAS, and USEQ. A satisfaction questionnaire, additionally, it is planned to include the aforementioned data in the research dataset for statistical analysis purposes.

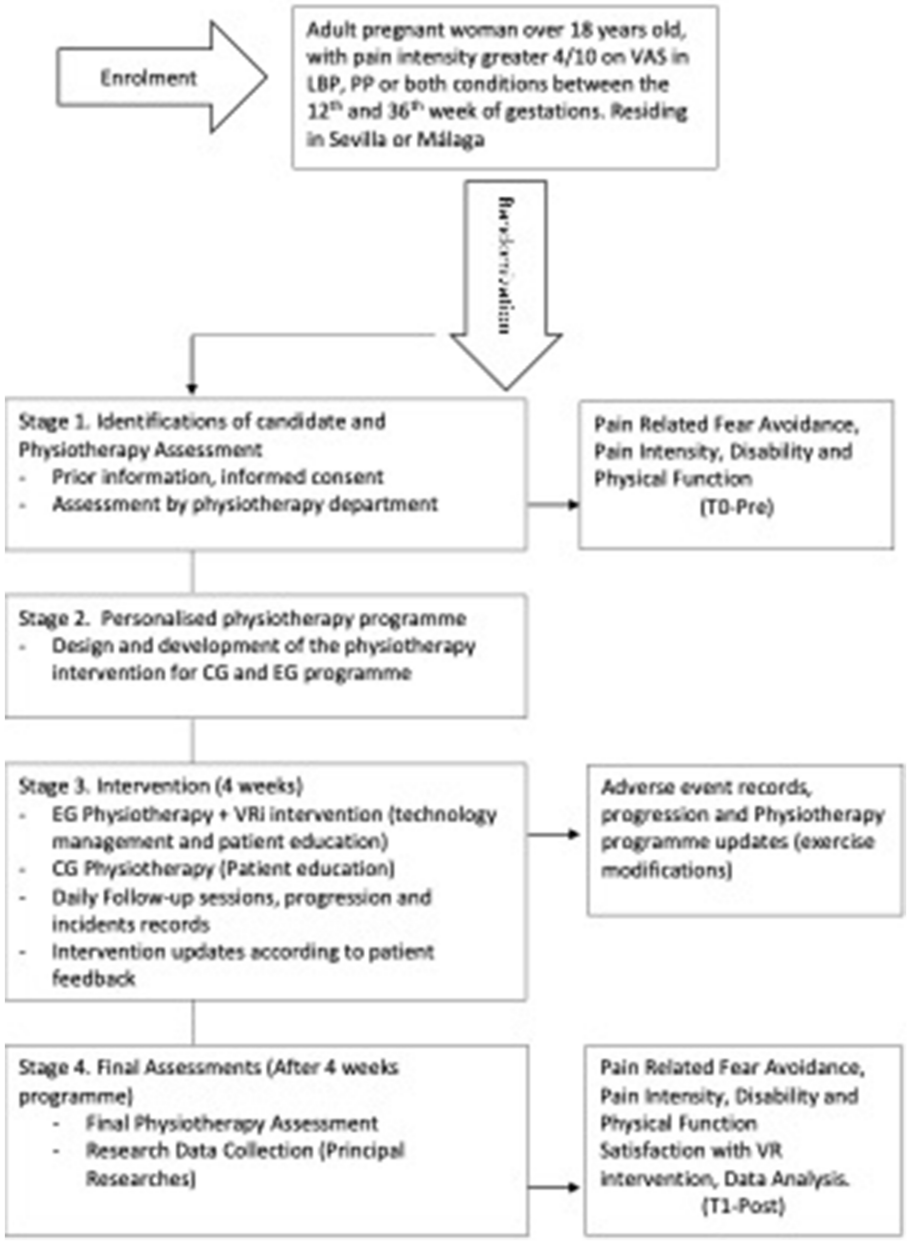

FIGURE 2
Study design. VAS, Visual Analog Scale; LBP, Low Back Pain; PP, Pelvic Pain: VR, Virtual Reality.

2.7. Statistical analysis

The research is a prospective controlled trial with a pre/post design that will be conducted in multiple centers. The results of the trial are intended to be presented in the form of a summary of outcome measures, including estimated effect size and precision. Statistical analysis will be carried out using the "intention to treat" method and for missing data multiple imputation will be used; all data will be collected in a single database and analyzed to evaluate any differences between the randomized groups both for primary outcomes and for secondary outcomes. Patient characteristics will be presented using frequencies and percentages for categorical factors and means and standard deviations for continuous measures to provide comprehensive information for exploration and analysis. Cohen's d will be used to calculate the effect sizes, which will enable the comparison of results with other studies.

The results will be evaluated by comparing the differences between EG and CG with mixed linear model and T-test statistics to test the hypothesis that the means of two groups are or are not significantly different from each other. The outcome measures will be compared before and after the completion of the 4-week intervention. All statistical analyzes will be carried out using SPSS sofware. Statistical significance will set ap $p < 0.05$ and a unilateral analysis will be made.

3. Results

Enrollment first three quarters of 2023. First study results will be reported at the end of the first quarter of the year 2024. The findings from this research will ascertain the viability of implementing a larger intervention on a broader scale. Additionally, this initial study will serve as a pioneering investigation into the impact of the VR intervention on LBP and PP in pregnant women. If the results confirm beneficial effects in the outcomes, this investigation will contribute additional evidence to substantiate the efficacy of utilizing a VR program as a powerful tool in pregnancy with LBP and PP rehabilitation programs. This is the first study that investigates this cause, giving positive results, this study will serve as a basis to extrapolate it to multi-centers, thus being able to carry it out in larger samples, which will allow us to standardize processes.

4. Discussion

The results obtained from individual studies propose that certain therapy modalities or a combination of multiple interventions (such as manual therapy, exercise, and education) may be effective to improve pelvic pain and pregnancy related outcomes. However, the current scientific evidence leaves many issues unresolved like type and intensity of exercise and physiotherapy intervention effectiveness for different outcomes. As there is currently no available evidence indicating the superiority of one form of exercise over another, the guidelines suggest exercise programs that take into account individual requirements, inclinations, and capabilities when determining the most appropriate type of exercise. This lack of standardized exercise programs may lead to significant intervention biases in the different studies and consequently the low or moderate level of evidence.

Due to the high prevalence, the recurrence, the interference on daily activities, work capacity and sick leaves, and the increased psychological stress (1–4), LBP is undoubtedly the key clinical sign to address in this population.

The use of immersive virtual reality (VRi) in this case may help alleviate pain by diverting the patient's attention away from the pain. This is believed to be the psychological effect of being immersed in the virtual space created by VR technology, which can alleviate pain. (63, 64). Additionally, the VR program can create a relaxing atmosphere that may positively affect the patient's emotional state, thereby reducing their perception of pain (65). There are studies that show how VR can change the patient's perception due to the focus of attention on the external focus, this approach is very interesting as it can improve their ability to learn (42).

There is evidence that muscle relaxation techniques such as TENS can reduce LBP in pregnant women, however, this is not true of the benefits of yoga for LBP in pregnant women (66, 67). Our approach with Nature Trek VR is to bring relaxation techniques into a virtual environment and test their effects.

Regarding the moment of application of the tear therapy, one of the reasons for putting the relaxation therapy at the end is the ease of use for the physiotherapist as well as for reasons of expectation, as we normally associate the most relaxing techniques at the end of the session. However, there are studies that can be applied during the exercise session itself, which is also appropriate. In both cases, the use is correct, regardless of the moment.

This research aims to gather new information and insights on the practicality of integrating VR programs into clinical environments, with a particular emphasis on discovering new opportunities for interventions that could benefit patients.

However, the use of VR technology may encounter technical challenges such as device malfunctions and technological difficulties. Nevertheless, technical support staff will be available to address these issues. Possible adverse events that may occur include a lack of improvement or positive outcomes for the patient, as well as excessive exercise workload. Among these adverse effects that we may encounter is MS, a pathology that can cause dizziness, vomiting, headache, etc. In particular, we must bear in mind that MS can affect the course of therapy and therefore the success of the treatment. It has been seen that there is a threshold time of onset and that the symptoms may decrease or increase, when the exposure is of slow speed, it may happen that when checked in the Simulator Sickness Questionnaire (SSQ) this is not altered. Therefore, we must take this into account, but we cannot know the degree to which it affects therapeutic success (68, 69). Adverse effects and drop-outs will be taken into account in our case. An important aspect to discuss is the importance of usability and patient satisfaction, i.e., the user experience when using this type of device. We know that this kind of tools can improve adherence, but they also have negative aspects that have to be taken into account such as: cognitive capacity that can interfere directly in usability or simply facts that come from the use of the tool such as motion stinecks. In this case, there are questionnaires to detect this pathology (62). In our study this questionnaire has not been added since the exposure time is short and we do not consider that it can provide us with extra information. Rossettini et al., in their recent reviews, it is shown that patient satisfaction in musculoskeletal pathology is a multidimensional construct influenced by individual patient, clinical and contextual factors. This means that satisfaction can be affected by multifactorial components, not only by the device used (70). Another important aspect to consider is the relationship between the virtual device and its influence as a placebo/nocebo in treatment. This study shows how contextual factors can affect therapeutic success (34). One of the most studied factors is the pain symptom and its relationship to placebo (32, 33). In our case, we might ask ourselves how much influence can the use of virtual devices have on placebo level? If pain is improved, is it really because of the therapy or is it because of the effect? These are questions we do not know how to answer, as future research in our field would be of great interest. Patients will be informed about the importance of reporting any incidents or setbacks in their recovery and their right to withdraw from the research at any time.

Future research directions may involve conducting clinical trials with larger sample sizes and the opportunity to develop a multicenter randomized clinical trial with standardize physiotherapy and exercise programs. The feasibility of this pilot study will serve as a basis for future research in which we would replicate the basic study design, expanding the sample size in different centers, trying to standardize the intervention protocols.

This study protocol represents the first attempt to investigate the impact of VR intervention, combined with physiotherapy, on LBP and PP in a multi-center clinical setting. The effectiveness of this intervention, as well as patient satisfaction, will serve as important indicators of whether this study provides further evidence supporting the use of VR as an effective tool for pregnant women.

4.1. Institutional review board statement

This project will adhere to the guidelines outlined in the Declaration of Helsinki (Fortress 2013) and the Standards of Good Clinical Practice. The handling of personal data will comply with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, which pertains to the protection of natural persons regarding the processing of personal data and the free movement of such data, as well as Organic Law 3/2018 of 5 December on the Protection of Personal Data and Guarantee of Digital Rights (71). Only researchers involved in the project will be permitted to access the research data. Each subject's information will be linked with a unique numerical identification code and will be the sole means of identifying the patient for the purposes of data processing and analysis. This trial has been approved by the Andalucía Ethics Committee with HIP version 1928-N-21. It has also been registered in the clinicaltrials.gov database under the trial registration number NCT05571358.

4.2. Informed consent statement

All subjects participating in the study provided informed consent prior to their inclusion. To do so, participants were asked to read and sign the patient information sheet and consent form. They were also informed of their right to revoke their consent at any time without having to provide a reason and without any adverse consequences.

Dissemination

The results of this study will be published in academic journals and presented in both the academic and public domain, including at scientific conferences and in the media in public engagement forums. Patient confidentiality will be maintained in all of the above.

Ethics statement

The studies involving human participants were reviewed and approved by the institutional ethics committee of Andalucía with internal code 1928-N-21. Participants gave written informed consent before enrolling in the study.

Author contributions

F-JG-L, J-MP-B, NM-M, M-JE-P, AL-G, and RM-V have played important roles in the development of this article. Specifically, F-JG-L, J-MP-B, and NM-M coordinated the project, contributed to the conception and design of the study, and were involved in writing the manuscript. M-JE-P and RM-V provided methodological guidance. F-JG-L and AL-G were responsible for coordinating the intervention protocols, patient recruitment, and reviewing the manuscript for spelling and grammar. All authors contributed to the article and approved the submitted version.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fmed.2023.1206799/full#supplementary-material

SUPPLEMENTARY DATA SHEET S1
Minimal sample size.

SUPPLEMENTARY DATA SHEET S2
Informed consent.

SUPPLEMENTARY DATA SHEET S3
Prior information for the patient.

SUPPLEMENTARY DATA SHEET S4
SPIRIT 2013 checklist.

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Glossary

LBP	Low Back Pain
PP	Pelvic Pain
VR	Virtual Reality
TENS	Transcutaneous electrircal nerve stimulation
SQUIRE	Standards for Quality Improvement and Excellence in Reporting
CONSORT	Consolidated Standards of Reporting Trials
VAS	Visual Analog Scale
CG	Control Group
EG	Experimental Group
VRi	Immersive Virtual Reality
FACS	The Fear-Avoidance Components Scale
ODI	Oswestry Disability Index
RMDQ	Roland-Morris disability Questionnaire
USEQ	User Satisfaction Evaluation Questionnaire
MS	Motion Sickness
SSQ	Simulator Sickness Questionnaire

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Prevalence and risk factors of work-related musculoskeletal disorders among emerging manufacturing workers in Beijing, China

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Objective: The workers in emerging manufacturing are at decreased risk of traditional occupational diseases, while probably at increased risk of work-related musculoskeletal disorders (WMSDs). This study aimed to investigate the prevalence and risk factors of WMSDs among emerging manufacturing workers in Beijing.

Methods: A total of 3,359 valid questionnaires were collected from 10 enterprises in the electronics, pharmaceutical, and motor manufacturing industries. The prevalence of WMSDs was assessed using the Nordic Musculoskeletal Questionnaire. The work posture load was evaluated through a questionnaire.

Results: The results showed that the highest prevalence of WMSDs was observed in part of the neck (15.0%), followed by the lower back (12.5%), shoulders (11.2%), and upper back (7.1%). Female workers, workers aged older than 35 years, workers with a BMI of ≥28 kg/m^2, longer working experience, never exercised had a higher prevalence of WMSDs. Logistic regression analysis showed that female workers, workers aged older than 35 years, with a middle school education and college degree, and workers who never exercised had a higher risk of WMSDs. In addition, workers who sat for long during work, worked hard with upper limbs or hands, worked in uncomfortable postures, and performed repetitive operations were positively related with the increased risk of WMSDs.

Conclusion: These findings suggested that WMSDs were prevalent among emerging manufacturing workers in Beijing, China, while efforts should be made to reshape the risk factors associated with WMSDs, such as prolonged sitting, uncomfortable positions, and repetitive operations. Encouraging exercise and promoting ergonomic interventions probably be also benefit to induce the risk of WMSDs.

KEYWORDS

work-related musculoskeletal disorders (WMSDs), worker, cross-sectional study, manufacturing workers, risk factors

1. Introduction

Work-related musculoskeletal disorders (WMSDs) refer to injuries to local muscles, tendons, bones, cartilage, ligaments, nerves, and other parts of the body caused or aggravated by occupational activities, resulting in varying degrees of damage. Approximately 1.71 billion people have musculoskeletal conditions worldwide (1). WMSDs are the leading contributor to disability worldwide, with low back WMSDs being the single leading cause of disability in 160 countries (2, 3). WMSDs significantly limit mobility and dexterity, leading to early retirement from work, lower levels of well-being and reduced ability to participate in society. Because of population growth and ageing, the number of people living with WMSDs and associated functional limitations, is rapidly increasing which has become a major occupational-related disease affecting the health of the working population. Many countries, including the United States, the United Kingdom, Germany, and Japan, had included WMSDs in their list of legally recognized occupational diseases or compensable diseases (4, 5). Therefore, it is necessary to conduct research on the prevalence and risk factors of WMSDs, which is of great significance for the prevention and treatment of WMSDs and the health protection of the working population.

Beijing, as the capital of China, is undergoing a major restructuring of its industrial structure. Currently, there are large number of workers worked in emerging industries, such as electronics, pharmaceutical, and motor manufacturing industries (6). Risk factors such as forced postures, unreasonable work systems, repetitive tasks, and long working hours were common in these industries (7, 8), which were widely presented and can easily result to local muscle fatigue and increase the risk of WMSDs (9, 10), which was significant different to the traditional risk factors, such as carry heavy objects. Electronics, pharmaceutical, and motor manufacturing industries were typical emerging manufacturing industries. The main characteristics of those enterprises were the high degree of automation and light manual labor, which was the future development direction of most enterprises. The characteristics and prevalence of WMSDs probably be different from traditional manufacturing workers, such as building industry, iron and steel industry. Therefore, it is necessary to evaluate the prevalence of WMSDs in these types of enterprises to light the other developing countries in the future. However, there are no reports on the prevalence and risk factors of WMSDs among emerging manufacturing workers in China. The objective of this study was to evaluate the prevalence of WMSDs among emerging manufacturing workers in Beijing, China. Therefore, a cross-sectional survey included 3,359 workers to determine the prevalence of WMSDs and risk factors was conducted in Beijing, which can be benefit to improve the prevention measures and occupational health status of workers, reduce the incidence of WMSDs, and alleviate the social burden.

2. Methods

2.1. Study design and participants

Ten enterprises, including electronics, pharmaceutical, and motor manufacturing industries in Beijing, China, were selected in this cross-sectional study between September 2021 and December 2022. The characteristics of each enterprises were showed in Supplementary Table S1. Among these enterprises, workers from the frontline production positions were included in this study. The inclusion criteria were as followed: (a) age more than 18 years old; (b) worked for at least 1 year in this present position; (c) volunteer to participate in this study. The exclusion criteria were that individuals who had musculoskeletal pain or discomfort in the affected area before starting the present job, those with a history of injury, and those with WMSDs caused by accident. Finally, 3,359 workers were included in this study. On the majority of working days throughout the year, these workers were on an eight-hour daily work schedule, working 5 days a week, without shifts or night shifts. Although the primary job tasks may vary, the workers were primarily engaged in frontline basic production. For example, workers in pharmaceutical companies are mainly involved in drug formulation and packaging, while those in electronic companies were responsible for product quality testing. In summary, these workers represented the most fundamental characteristics of frontline production, which were characterized by low technical complexity and high repetitiveness. This study complied with the Helsinki Declaration and was approved by the Ethics Committee of the Beijing Institute of Occupational Disease Prevention and Treatment (No. C2022006). All participants were informed and gave their consent. Due to the COVID-19 epidemic, face-to-face surveys were not feasible, so the survey was conducted online.[1] Only one questionnaire can be submitted for per participants through technical settings. The link of questionnaire was distributed throughout the organization network to ensure that other individuals not belonged to the 10 specific enterprises do not fill out the questionnaire.

2.2. Independent variables

Information on the demographic characteristics and work posture load of the participants was collected through a questionnaire. (a) The demographic characteristics included gender (male and female), birth date, height (m), weight (kg), education level (junior school and below, middle school, college degree), smoking (never, seldom, sometimes, and quit smoking), drinking (never, seldom, sometimes, and quit drinking), present job tenure (years), and exercise habits (never, 1–3 times/quarter, 2–3 times/month, 1–2 times/week, and >2 times/week). The variable of age was classified into ≤35 and >35 years old. The body mass index (BMI) was calculated by the formula: BMI = weight (kg)/height squared (m^2), which was further divided into three categories: ≤23.9, 24.0–27.9, and ≥28.0 kg/m^2. The variable of current station was divided into four categories: <5, 5–10, 10–15, and >15 years. The work posture load mainly included information on whether the participants had long-term standing, sitting, squatting, and kneeling, carrying heavy loads, vibration, driving, repetitive work, and other adverse postures during work. The frequency of adverse posture was classified into "seldom, sometimes, often, and always." The answer of "always" of these questions was defined as adverse postures during work, while the other answers of these questions was defined as no adverse posture during work.

Abbreviations: WMSDs, Work-related musculoskeletal disorders; OR, Odds ratio; CI, Confidence interval.

1 https://www.wjx.cn/newwjx/manage/myquestionnaires.aspx

2.3. Definition of WMSDs

The WMSDs was assessed using the Nordic Musculoskeletal Questionnaire, which mainly included information on whether musculoskeletal pain or discomfort symptoms occurred in neck, low back, shoulders, upper back, knee, wrist, leg, ankle, and elbow in the past 7 days and 12 months, the frequency of pain or discomfort, and the total duration of pain or discomfort throughout the year. The reliability and validity of this questionnaire has been tested previously, 0.87 and 0.80, respectively (11, 12). Specifically, when discomfort symptoms such as pain, stiffness, burning sensation, numbness, or tingling occur in the muscles or joints of various body parts, and meet the following criteria: (1) discomfort within the 12 months, (2) discomfort began after starting current work, (3) no accidents or sudden injuries affecting the affected area in the past, and (4) discomfort symptoms occur every month or last for more than 7 days, then it is considered as a WMSDs. Any of the following body parts: neck, lower back, shoulders, upper back, knee, wrist, leg, ankle, and elbow, with the discomfort symptoms, were defined as WMSDs. This study followed the diagnostic criteria for WMSDs established by the US National Institute for Occupational Safety and Health (NIOSH).

2.4. Statistical analysis

After downloading the data collected online, clean and logical error correction were performed. A database was established using Excel 2019 software for Mac. SPSS 26.0 software for Windows 10 was used for statistical analysis. Categorical variables were expressed as number (percent) [*n* (%)]. In the univariate analysis, the chi-square (χ^2) test was used to analyze the differences in the prevalence of WMSDs among different industries and characteristic individuals. Furthermore, logistic regression analysis was performed to identify the influencing factors of WMSDs among the factors with statistical significance in the univariate analysis with sex, age category, BMI category, current station experience, education level, exercise frequency, work load, and categories of industries adjusted, which were found to be associated with WMSDs in single factor analysis or reported to be related with those (13, 14). A *p*-value less than 0.05 was defined statistically significant.

3. Results

3.1. Demographic characteristics

The demographic characteristics of the workers across industry categories were showed in Table 1. There were 367 (10.9%), 1,448 (43.1%), and 1,544 (46.0%) workers from electronics, motor, and pharmaceutical manufacturing enterprises, respectively in this study. Significant differences were observed in sex, age, BMI, current station, working years, education, exercise, smoking, and drinking across the three industries ($p < 0.05$). The electronics manufacturing industry had the highest proportion of male workers (86.1%), while the pharmaceutical industry had the highest proportion of female workers (54.0%). The pharmaceutical manufacturing industry had the highest proportion of workers aged 35 years and above (44.8%), while the electronics manufacturing industry had the highest proportion of workers with a college degree (83.8%). The motor industry had the highest proportion of workers who never exercised (47.1%), while the pharmaceutical manufacturing industry had the highest proportion of workers who exercised >2 times per week (12.0%).

TABLE 1 The demographic characteristics across industries categories.

Characteristics	E industry	M industry	P industry	*p*-value
n	367 (10.9)	1,448 (43.1)	1,544 (46.0)	—
Sex				<0.01*
Male	320 (87.2)	1,309 (90.4)	704 (45.6)	
Female	47 (12.8)	139 (9.6)	840 (54.4)	
Age (years old)				<0.01*
≤35	287 (78.2)	1,093 (75.5)	852 (55.2)	
>35	80 (21.8)	355 (24.5)	692 (44.8)	
BMI (kg/m^2)				<0.01*
≤23.9	151 (41.2)	652 (45.0)	797 (51.6)	
24.0–27.9	152 (41.4)	457 (31.6)	507 (32.8)	
≥28.0	64 (17.4)	339 (23.4)	240 (15.6)	
Current station (years)				<0.01*
<5	198 (54.0)	614 (42.4)	809 (52.4)	
5–10	90 (24.5)	662 (45.7)	401 (22.4)	
10–15	42 (11.4)	144 (9.9)	213 (13.8)	
>15	37 (10.1)	28 (1.9)	121 (7.8)	
Education				<0.01*
Junior school and below	16 (4.2)	49 (3.4)	104 (6.7)	
Middle school	31 (8.1)	849 (58.6)	371 (24.0)	
College degree	320 (83.8)	550 (38.0)	1,069 (69.2)	
Exercise				<0.01*
Never	99 (25.9)	682 (47.1)	418 (27.1)	
1–3 times/quarter	63 (16.5)	242 (16.7)	253 (16.4)	
2–3 times/month	105 (27.5)	189 (13.1)	313 (20.3)	
1–2 times/week	61 (16.0)	253 (17.5)	374 (24.2)	
>2 times/week	39 (10.2)	82 (5.7)	186 (12.0)	

*$p < 0.05$. M industry, motor industry; E industry, electronics manufacturing; P industry, pharmaceutical industry.

3.2. Prevalence of WMSDs

The prevalence of WMSDs by body part among 3,359 manufacturing workers was showed in Figure 1. The highest prevalence of WMSDs was observed in the neck (15.0%), followed by the lower back (12.5%), shoulders (11.2%), and upper back (7.1%). The prevalence of WMSDs in the wrist and knee was 6.3% and 4.5%, respectively. The prevalence of WMSDs in the legs, ankles, and elbow was 4.1%, 3.9%, and 2.8%, respectively. In addition, approximately one-fourth of the workers suffered from at least one WMSDs in any body part.

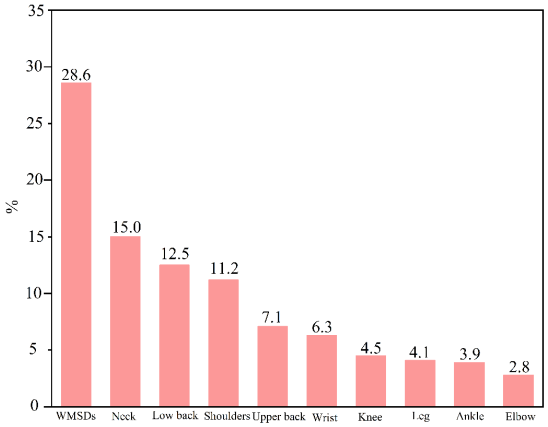

FIGURE 1
The prevalence of work-related musculoskeletal disorders (WMSDs) among workers.

The prevalence of WMSDs across demographic characteristics among the manufacturing workers was showed in Table 2. Significant differences were observed in the prevalence of WMSDs across sex, age, current work experience, education level, exercise, and industry categories ($p < 0.05$). The prevalence of WMSDs was higher among female workers (33.5%) than male workers (24.0%). Workers aged 35 years and above had higher prevalence of WMSDs (33.7%) than aged ≤35 years old (23.4%). Workers with the BMI of ≥28 kg/m^2 had the highest prevalence of WMSDs (28.8%). Workers with less than 5 years of work experience had the lowest prevalence of WMSDs (22.8%), while those with 15 years or more work experience had the highest prevalence (31.8%). Workers who never exercised had the highest prevalence of WMSDs (31.2%). The pharmaceutical manufacturing industry had the highest prevalence of WMSDs (29.1%), while the electronics manufacturing industry had the lowest prevalence (24.8%).

TABLE 2 The prevalence of WMSDs across demographic characteristics.

Characteristics	Number of workers *n* (%)	WMSDs *n* (%)	χ^2	*p*-value
Sex			33.187	<0.01*
Male	2,333 (69.5)	559 (24.0)		
Female	1,026 (30.5)	344 (33.5)		
Age (years old)			40.309	<0.01*
≤35	2,232 (66.4)	523 (23.4)		
>35	1,127 (33.6)	380 (33.7)		
BMI (kg/m^2)			2.383	0.304
≤23.9	1,600 (47.6)	434 (27.1)		
24.0–27.9	1,116 (33.2)	284 (25.4)		
≥28.0	643 (19.2)	185 (28.8)		
Current work experience (years)			26.811	<0.01*
<5	1,621 (48.3)	370 (22.8)		
5–10	1,153 (34.3)	347 (30.1)		
>10	585 (17.4)	117 (31.8)		
Education level			22.670	<0.01*
Junior school or below	169 (5.0)	28 (16.6)		
Senior high school	1,251 (37.2)	299 (23.9)		
College and above	1,939 (57.8)	576 (29.7)		
Sports				<0.01*
Never	1,199 (35.7)	374 (31.2)		
1–3 times/quarter	558 (16.6)	147 (26.3)		
2–3 times/month	607 (18.1)	148 (24.4)		
1–2 times/week	688 (20.5)	161 (23.4)		
>2 times/week	307 (9.1)	73 (23.8)		
Categories of industries			7.445	0.02*
E industry	367 (10.9)	91 (24.8)		
M industry	1,448 (43.1)	362 (25.0)		
P industry	1,544 (46.0)	450 (29.1)		

*$p < 0.05$. E industry, electronics manufacturing; M industry, motor industry; P industry, pharmaceutical industry.

3.3. Labor load

Table 3 presented the working posture across three industries among the manufacturing workers. Significant differences were observed in the working posture across the three industries for all the nine risk factors ($p < 0.05$). The motor industry had the highest proportion of workers who stood for long periods (34.7%), while the pharmaceutical industry had the lowest proportion (8.1%). The transportation electronics industry had the highest proportion of workers who sat for long periods (30.7%), while the motor manufacturing industry had the highest proportion of workers who squatted or kneeled for long periods (3.2%). The motor and pharmaceutical industry had the highest proportion of workers who carried objects weighing more than 5 kg (7.8%) and more than 20 kg (3.3%), respectively. The motor manufacturing industry had the highest proportion of workers who worked hard with their upper limbs or hands (27.1%). The motor industry had the highest proportion of workers who were exposed to vibration (12.0%). The motor manufacturing industry had the highest proportion of workers who drove a vehicle (9.3%). The motor industry had the highest proportion of workers who worked in uncomfortable positions (6.1%). The motor manufacturing industry had the highest proportion of workers who performed repetitive operations (31.8%).

3.4. Influencing factors of WMSDs

Univariate logistic regression was performed firstly to evaluate the association between risk factors of working posture and WMSDs, which indicated that all the postures were related with WMSDs (Supplementary Table S2). Multiple logistic regression was performed to further evaluate the association risk factors between WMSDs, which were showed in Figure 2. The associations between WMSDs

TABLE 3 The working posture across three industries.

Risk factors	E industry	M industry	P industry	*p*-value
Stand for long	41 (11.2)	503 (34.7)	125 (8.1)	<0.01*
Sit for long	76 (20.7)	111 (7.7)	231 (15.0)	<0.01*
Squat or kneeling for long	3 (0.8)	47 (3.2)	231 (0.6)	<0.01*
Carry objects >5 kg	10 (2.7)	113 (7.8)	106 (6.9)	<0.01*
Carry objects >20 kg	6 (1.6)	46 (3.2)	51 (3.3)	<0.01*
Working hard with upper limbs or hands	32 (8.7)	393 (27.1)	188 (12.2)	<0.01*
Vibration	2 (0.5)	174 (12.0)	36 (2.3)	<0.01*
Driving a vehicle	12 (3.3)	135 (9.3)	108 (7.0)	<0.01*
Uncomfortable positions	8 (2.2)	89 (6.1)	28 (1.8)	<0.01*
Repetitive operation	42 (11.4)	460 (31.8)	187 (12.1)	<0.01*

*$p < 0.05$. E industry, electronics manufacturing; M industry, motor industry; P industry, pharmaceutical industry.

and sex, age, current station, education level, exercise, sit for long, working hard with upper limbs or hands, uncomfortable positions, and repetitive operations were statistically significant ($p < 0.05$). Female workers had a higher odds ratio (OR) of WMSDs (OR = 1.442, 95% CI: 1.183, 1.758) than that among male workers. Workers aged 35 years old and above had higher ORs of WMSDs than those aged under 35 years old ($p < 0.05$). Workers with a middle school education and college degree had higher ORs of WMSDs than those with a junior school education or below ($p < 0.05$). In addition, exercise was found to be a protective factor to WMSDs. Workers who exercised 2–3 times per month and 1–2 times per week had lower ORs of WMSDs than those who never exercised ($p < 0.05$). Workers who sat for long during work had a higher OR of WMSDs (OR = 1.632, 95% CI: 1.332, 1.999) than those who did not. Workers who worked sitting for long, with upper limbs or hands, in uncomfortable positions, and performed repetitive operations had higher ORs of WMSDs than those who did not ($p < 0.05$). No significant association was observed between WMSDs and standing for long periods, kneeling or squatting for long periods, carrying objects weighing more than 20 kg, vibration, or driving a vehicle ($p > 0.05$).

4. Discussion

This study aimed to investigate the prevalence and risk factors of WMSDs among emerging manufacturing workers in Beijing, China. The results showed that the prevalence of WMSDs was high among the workers, with the neck, lower back, shoulders, and upper back being the most commonly affected body parts. Female workers, older workers, workers with higher education levels, and those who never exercised were more likely to suffer from WMSDs. In addition, sitting for long periods, working in uncomfortable positions, and performing repetitive operations were identified as risk factors for WMSDs.

The prevalence of WMSDs in this study was 28.6%, which was lower than that among 7,908 manufacturing workers in Henan and Hubei Provinces, China (10), consistent with that among workers in manufacturing factories in Guangdong Province, China (15). The WMSDs prevalence of the neck, low back, shoulders, and upper back was the highest among all the body parts, which was consistent with other studies (16, 17). The work of manufacturing often involved risk factors of repetitive tasks, prolonged sitting or standing, and awkward postures, which could lead to local muscle fatigue and increase the risk of WMSDs (5). Female workers were found to be more likely to suffer from WMSDs than male workers, which is consistent with previous studies (5, 18). Women generally have smaller muscle mass and lower strength than men, which may make them more vulnerable to WMSDs (5). In addition, women were more likely to work in jobs that require repetitive tasks and prolonged standing or sitting, which are risk factors for WMSDs (19, 20). The older workers were also found to be more susceptible to WMSDs than young workers, which was consistent with previous studies (21). This may be due to age-related changes in the musculoskeletal system, such as decreased muscle strength and flexibility, soft tissue rheumatism, osteoarthritis, inflammatory arthritis, large joint prostheses, and age-related co-morbidities, which can increase the risk of WMSDs (21, 22). In addition, older workers may have accumulated more work-related physical stress over time, which can also increase the risk of WMSDs (18, 23). Furthermore, workers with higher education levels were found to be more likely to suffer from WMSDs (24), which probably be resulted to the fact that workers with higher education levels were more likely to work in jobs that require prolonged sitting, breaks less, which were risk factors for WMSDs (17). In addition, high workloads probably be another reason to increase the risk of WMSDs (25). Sitting for long periods, working in uncomfortable positions, and performing repetitive operations were identified as risk factors for WMSDs, which was consistent with previous studies (5, 8). These factors can lead to local muscle fatigue and increase the risk of WMSDs (5). Therefore, it is important to implement ergonomic interventions, such as adjusting workstations, providing rest breaks, and rotating tasks, to reduce the risk of WMSDs (8). As for the factors of work posture load, sitting for long periods, working in uncomfortable posture, and performing repetitive operations were identified as risk factors for WMSDs, factors of which could lead to local muscle fatigue and increase the risk of WMSDs (26–29). Therefore, it was crucial to implement ergonomic interventions, such as adjusting workstations, providing rest breaks, and rotating tasks, to reduce the risk of WMSDs.

Exercise was found to be a protective factor for WMSDs, which was consistent with previous studies (30, 31). Exercise can improve muscle strength and flexibility, reduce fatigue, and prevent WMSDs

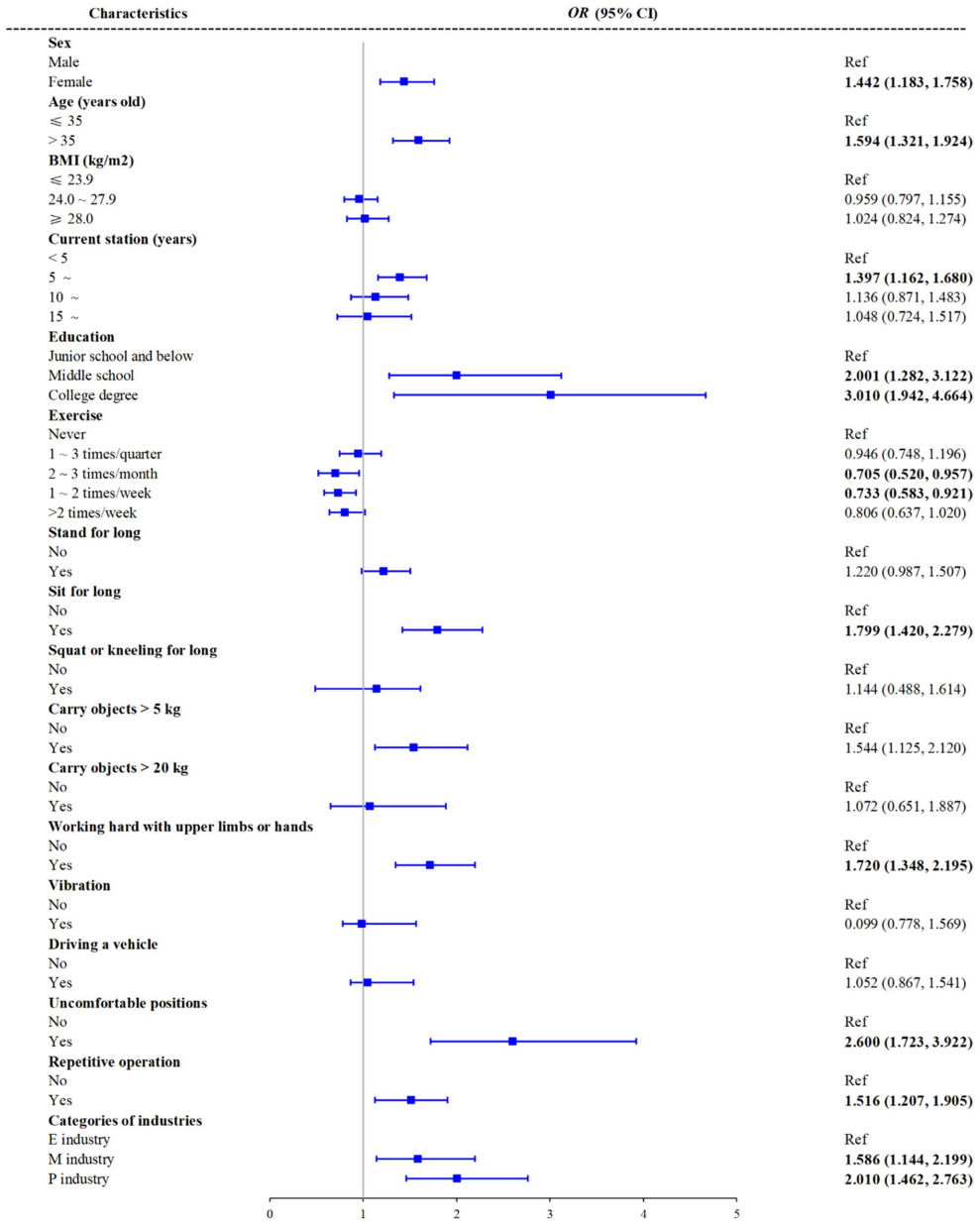

FIGURE 2
Associations between risk factors and WMSDs in multivariate logistic regression. E industry, electronics manufacturing; M industry, motor industry; P industry, pharmaceutical industry.

(32, 33). Workers who never exercised had the highest prevalence of WMSDs, while those who exercised 2–3 times per month and 1–2 times per week had lower odds of WMSDs, which suggested that even moderate levels of exercise can be beneficial for preventing WMSDs.

However, it was not easily to engage in physical exercise, even if it was only mild exercise, which was benefit to prevent the occurrence of WMSDs.

To the best of our knowledge, this is the first study to illustrated the prevalence of WMSDs among the emerging manufacturing enterprises workers and to explore the risk factors in large samples in Beijing, China. The current study illustrated that workers in the emerging manufacturing enterprises were at high risk of WMSDs although whose labor load was not as strong. Work load risk factors of siting for long, carry objects, uncomfortable positions were associated with the risk of WMSDs, while the demographic and habits of female, age, educational level, and sports were also associated with the happen of WMSDs. Therefore, ergonomic interventions, including implement ergonomic interventions to address work load risk factors such as prolonged sitting, carrying heavy objects, and uncomfortable positions, could be applied in the workplace. In addition, providing training and education programs to raise awareness among workers about the importance of maintaining good posture, using proper body mechanics, and adopting ergonomic practices probably be benefit to reshape the WMSDs, which can help them understand the risks associated with WMSDs and learn preventive measures. By implementing these measures, it is possible to reduce the prevalence

of WMSDs among workers in emerging manufacturing enterprises and improve their overall musculoskeletal health.

This study had notable strengths due to its large sample size. Nevertheless, it was important to acknowledge several limitations that were present in this study. First, the study was conducted based on a cross-sectional design, which limited the ability to establish causality between risk factors and WMSDs. Second, the study relied on self-reported data, which may be subject to recall bias and social desirability bias. There may be inaccuracies when participants recalled WMSD or not over a year. In addition, some participants tended to exaggerate the severity of WMSDs when they were dissatisfied with the enterprises. Third, only three types of industries workers in Beijing were included, especially the disproportionally small sample size of the electronics group, which may limit the generalizability of the findings to other regions and industries in China and other regions. Forth, the data were collected online since the epidemic of COVID-19, while the information bias was common for that. Therefore, it is necessary to further verify the conclusions of this study.

5. Conclusion

This study provides important insights into the prevalence and risk factors of WMSDs among manufacturing workers in Beijing, China. The high prevalence of WMSDs and the identified risk factors highlight the need for targeted prevention measures, such as ergonomic interventions and exercise. In addition, there is currently a lack of objective and reliable diagnostic methods for WMSDs. It is necessary to conduct research in the future to address this gap.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by the Medical Ethics Committee of the Beijing Institute of Occupational Disease Prevention and Treatment. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

XD: Conceptualization, Formal analysis, Methodology, Writing – original draft. ZG: Data curation, Methodology, Software, Writing – review & editing. NL: Supervision, Writing – original draft. MB: Data curation, Investigation, Methodology, Writing – review & editing. FJ: Supervision, Writing – review & editing. HW: Supervision, Writing – review & editing. XZ: Project administration, Writing – original draft. BL: Resources, Supervision, Writing – review & editing. DN: Supervision, Writing – review & editing. TL: Project administration, Resources, Writing – original draft. TX: Project administration, Writing – original draft. JL: Funding acquisition, Supervision, Writing – review & editing. TY: Conceptualization, Funding acquisition, Investigation, Resources, Supervision, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fmed.2023.1289046/full#supplementary-material

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Evaluation of multidetector CT Hounsfield unit measurements as a predictor of efficacy and complications in percutaneous vertebroplasty for osteoporotic vertebral compression fractures

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Introduction: More than 30 years after the initial experience of Galibert and Deramond with percutaneous vertebroplasty, the procedure has gone through countless refinements and clinical evaluations. Predictors for the success and failure of the procedure in the literature vary and are focused on the duration of complaints, type of fracture, presence of edema on MRI scans, etc. We propose using a quantitative method based on a standard CT examination of the thoracic or lumbar spine to assess the risks and potential success of performing vertebroplasty.

Materials and methods: This is a single-center prospective observational study on 139 patients treated with percutaneous vertebroplasty (pVPL) for a single symptomatic osteoporotic vertebral compression fracture (OVCF). We measured the levels of disability and pain preoperatively and again at the 3-, 6- and 12-month marks using the standardized VAS and ODI questionnaires. Every patient in the study was evaluated with postoperative multidetector CT (MDCT) to determine the presence, extent, and localization of vertebral cement leakage and to measure the adjacent vertebrae's minimal and mean density in Hounsfield units (HU_{min} and HU_{mean}, respectively).

Results: We determined that a slight ($r = -0.201$) but statistically significant ($p = 0.018$) correlation existed between HU measurements taken from radiologically intact adjacent vertebrae and the procedure's effect concerning the pain levels at the 3-month follow-up. This correlation failed to reach statistical significance at 12 months ($p = 0.072$). We found no statistically significant relationship between low vertebral cancellous bone density and cement leakage on postoperative scans ($p = 0.6$ for HU_{min} and $p = 0.74$ for HU_{mean}).

Conclusion: We have moderately strong data that show a negative correlation between the mean values of vertebral cancellous bone density in patients with OVCF and the effect of pVPL in reducing pain. Lower bone densities, measured this way, showed no increased risk of cement leakage.

KEYWORDS

percutaneous vertebroplasty, Hounsfield units, cement leakage, VAS, ODI

Introduction

Percutaneous vertebroplasty (pVPL) was initially applied in the treatment of symptomatic spinal hemangioma (1) and subsequently used in various other pathologies, including spinal osteolytic neoplasms (2) and simple osteoporotic vertebral compression fractures (OVCFs) (3). The procedure has been through the gauntlet of the RCT multiple times with varying results and recommendations (4–7). To date, most authors agree that pVPL is a viable alternative after conservative management has failed to produce pain control (8–14).

Like most other invasive medical procedures, percutaneous vertebroplasty is not without complications. A systematic review conducted by Hulme et al. (15) suggests that these should be separated into two categories:

1. Procedural – bone fractures, nerve, and pressure injuries due to improper positioning of the patient on the operating table; intervention site infection; cardiopulmonary suppression due to intraoperative use of opioids; iatrogenic injury of neural and vascular structures due to suboptimal placement of working cannulas, and others.
2. Complications secondary to cement leakage outside the vertebral body include pulmonary artery embolization, spinal canal occlusion, thermal and compression injuries due to exothermal polymerization, and hardening of the compound near neural structures.

Since the first category is not exclusive to pVPL and these complications can be observed in any surgery performed in the prone position (16), we will evaluate the risk factors affecting cement leakage, a complication that is bespoke to vertebral augmentation procedures.

Even though cement leakage following pVPL is frequent, actual adverse clinical events are very few and quite rare (17). The current literature on the evaluation of risk factors for cement leakage is focused on fracture severity, bone cement dispersion types, puncture approach, presence of cortical surface disruption, and others (18). A recent study by Jun Liu et al. suggests that bone mineral density, measured with dual-energy X-ray absorptiometry (DXA), can predict the dispersion pattern of cement during the procedure (19). Another study has shown a causal link between low bone mineral density and a higher incidence of cement leakage during pVPL (20).

Multiple studies have shown a strong relationship between bone mineral density values from DXA and HU measurements taken from vertebrae, thorax, pelvis, cranium and other bones (21–24). Additionally, quantitative computed tomography (qCT) has been recognized as an alternative to DXA in diagnosing osteoporosis since the latter half of the 1970s (25). Building further on these well-established dependencies, we aim to investigate any existing relationship between HU measurements obtained via MDCT and the therapeutic effect of pVPL and the incidence and complications stemming from cement leakage.

Materials and methods

Patient selection and data collection

The present study is a single-center prospective observational study on 139 patients. The inclusion criteria for the study were as follows: single symptomatic OVCF determined by the presence of bone marrow edema on STIR MRI images or by bone scintigraphy when MRI was contraindicated. VAS pain score ≥ 5 after optimal conservative management, including physiotherapy; duration of symptoms no more than six months; spontaneously occurring fractures due to fragility or minimal traumatic etiology (e.g., during otherwise physiological physical exertion, improper movements, lifting a heavy object, minor daily injuries that would not lead to a fracture in the absence of osteoporosis). Exclusion criteria: evidence of malignancy in any of the scanned vertebrae; dementia or inability to understand or complete the needed forms; history of significant back pain before the incidence of OVCF; history of rheumatological disease affecting the spine other than osteoporosis; lack of radiologically intact adjacent vertebrae on the postoperative CT scans.

Between January 2018 and January 2022, a total of 1,025 vertebroplasty procedures were performed for the treatment of various pathologies in the Clinic of Neurosurgery at St. Ivan Rilski University Hospital, Sofia, Bulgaria. Of those, 157 patients fit the inclusion criteria. Participants were required to consent to postoperative CT imaging. N = 18 declined participation, most of them citing unnecessary ionizing radiation exposure as the main reason. The remaining 139 patients who underwent pVPL for a single-level OVCF were enrolled in the study.

The patient data recorded were age, sex, level of the fractured vertebra, degree of vertebral fracture, pain, and disability levels, measured by the standardized VAS and ODI questionnaires, (26, 27) – before surgery and at 3-month intervals during the 12-month follow-up. Additionally direct pain control was assessed at 24 h after the procedure. A postoperative, noncontrast CT scan of the affected spinal segment was taken to assess the presence and location of cement leakage and to measure HU_{min} and HU_{mean} from radiologically intact adjacent vertebrae. The severity of the fractures was determined via intraprocedural fluoroscopy using the semiquantitative grading method described by Genant et al.: Grade 1: mild, ≤25% loss of body height; Grade 2: moderate, 25–40% loss; Grade 3: severe, >40% loss (28). These were then further subcategorized to account for the presence of an intravertebral cleft sign, a.k.a. Kümmell disease (29).

All 139 patients received a thoracic and lumbar spine X-rays at the end of the follow-up to assess for the presence new OVCFs. If findings were inconclusive, an MRI of the suspected segment was also performed.

MDCT examination

All postoperative scans were performed on a 16-slice MDCT scanner (GE BrightSpeed) at the St Ivan Rilski University Hospital. The CT parameters for the study were as follows: peak potential 120

Abbreviations: pVPL, percutaneous vertebroplasty; OVCF, osteoporotic compression fracture; MDCT, multidetector computed tomography; HU, Hounsfield units; DXA, dual-energy X-ray absorptiometry; VAS, Visual analogue scale; ODI, Oswestry disability index; IVC, intravertebral vacuum cleft.

kVp, slice thickness of 1.25 mm, and 2–3 mm increments. A radiologist and two neurosurgeons independently performed the image evaluation. Complete unanimity was required to classify a radiological artifact as a cement leakage since it could be minuscule in volume.

The study's main variables, HU_{min} and HU_{mean}, were measured using standard DICOM viewing software to draw oval regions of interest (ROIs) inside the body of the two closest, radiologically intact, adjacent vertebrae, excluding their cortical surfaces. HU_{mean} was estimated arithmetically from the value taken using six axial cut slices, three from each vertebra. A technique similar to the one described by Schreiber et al. (22). In the original paper, the authors observe a statistically significant correlation in the values taken from a single intact vertebra and BMD scores obtained via DXA. However, we propose that modifying the technique by using 2 immediately adjacent vertebrae (one above and one below) would yield measurements that more closely represent the density within the fractured vertebrae before vertebral body collapse and secondary compaction of the cancellous structure had occurred (Figure 1).

The minimal observed HU (HU_{min}) values were also used in the subsequent statistical analysis; these were often lower by more than 50% from the observed HU_{mean}. The HU_{min} quoted here is the lowest of all six measures and not the minimal value of radiodensity inside each separate ROI. In instances where subchondral osteosclerosis was present in the adjacent vertebrae, we took measurements from the two closest vertebrae that appeared radiologically intact. This approach eliminates the artificially heightened HU_{mean} results that these radiologically denser lesions would cause.

Any presence of vertebral cement outside of the cortical contour of the target vertebra on the CT scan was noted and further subclassified into five categories (Figures 2A–E).

Percutaneous vertebroplasty was performed using local anesthesia under fluoroscopic guidance via a bipedicular approach. A standard high-viscosity cement was used in all procedures. Cement injection is carried out until optimal vertebral body fill is observed (30) or there is fluoroscopic evidence of extravertebral cement leakage. Note that isolated leakage into the intervertebral disk was not considered grounds to terminate the procedure, as current evidence suggests that this type of cement leak has no negative predictive value for the overall success of the procedure and does not contribute to any clinically significant complications (31). The volume of cement applied was recorded at the end of the procedure.

Statistical analysis

Univariate analysis was used to determine the relationship between HU_{min} and HU_{mean} values and the development of specific grade fractures, pain (VAS), and disability (ODI) levels. Furthermore, logistic regression analysis was used to determine the relationship between these variables and bone cement leakage on postoperative CT scans. These tests were then subcategorized for each distinctive type of cement leak. The following risk factors were evaluated: severity of fracture and the presence of Kümmell disease. The statistical analyses were conducted using SPSS Version 19 (IBM, NY, United States). *p*-values at or below 0.05 were regarded as significant.

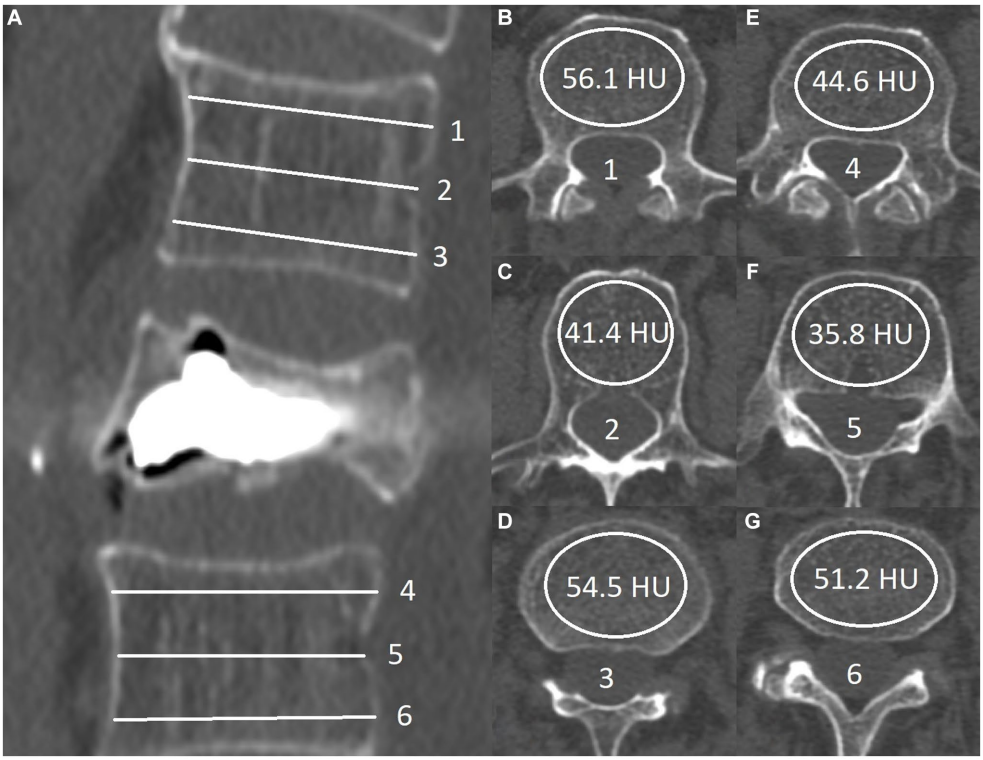

FIGURE 1
Sagittal view of postprocedural computed tomography: **(A)** Six transverse lines represent the level of the ROI measurement **(B-G)**. HU_{mean} values are calculated by the formula (56.1 + 41.4 + 54.5 + 44.6 + 35.8 + 51.2)/6 = 47.3. The HU_{min} value in this patient was 35.8 **(F)**.

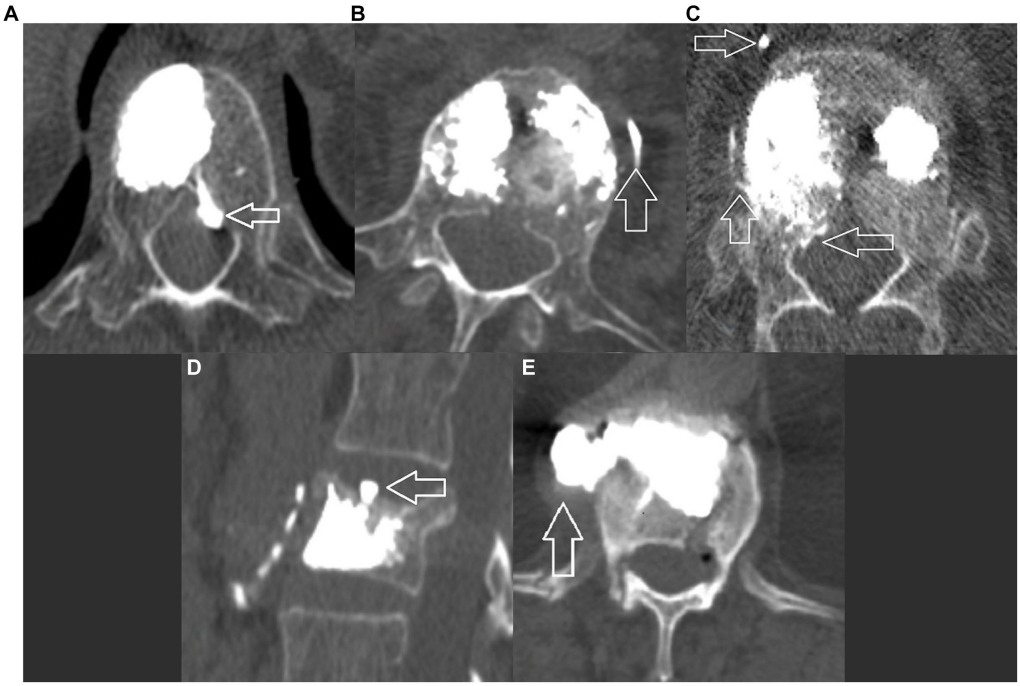

FIGURE 2
Postoperative CT, axial view showing different categories of leakage: **(A)** Type A – inside the spinal canal through the basivertebral vein; **(B)** Type B – inside the segmental veinous outflow; **(C)** Type C – inside the spinal canal and the segmental veinous outflow; **(D)** Type D inside the intervertebral disk; and **(E)** Type E – in the paravertebral space, leak occurs through a cortical defect.

TABLE 1 **Demographic characteristics of all patients, baseline pain (VAS) and disability (ODI), immediate postoperative pain (VAS), and type of fracture (mean ± SD).**

	All patients, *N* = 139	Female, *N* = 104	Male, *N* = 35	Presence of IVC sign, *N* = 35	Fracture grade		
					Grade I, *N* = 27	Grade II, *N* = 60	Grade III, *N* = 52
Age	70.8 ± 9.6	70.2 ± 10.1	72.7 ± 7.8	72.7 ± 10.6	67.4 ± 8.9	71.9 ± 9.4	71.3 ± 10.0
VAS pre	7.7 ± 1.6	7.6 ± 1.6	7.9 ± 1.5	8.9 ± 1.2	6.7 ± 1.4	72.3 ± 1.5	8.6 ± 1.2
VAS post	2.9 ± 1.6	2.9 ± 1.6	2.8 ± 1.4	2.6 ± 1.3	2.9 ± 2.1	2.8 ± 1.6	3.1 ± 1.2
ODI(%) pre	52.9 ± 12.3	52.7 ± 12.5	53.4 ± 11.8	60.5 ± 10.1	45.3 ± 8.1	50.5 ± 12.0	59.6 ± 11.3
Cement leak, *N* (%)	54 (38.9%)	40 (38.5%)	14 (40.0%)	8 (22.9%)	10 (37.0%)	27 (45.0%)	17 (32.7%)
Type A	3	2	1	0	1	3	0
Type B	12	9	3	0	2	5	5
Type C	8	6	2	0	4	4	0
Type D	27	20	7	6	4	13	10
Type E	4	3	1	2	0	2	2

Results

Baseline VAS pain and ODI disability levels were established for all 139 participants. The mean duration of complaints was 11 weeks (±9; 2–26). In addition to receiving a postoperative CT scan on the following day, VAS levels were also reassessed to determine the immediate effect of the procedure. We performed neurological examination and re-evaluation of VAS and ODI at 3-, 6- and 12-month time points. The demographics, baseline scores and immediate postoperative results of all patients enrolled in the study (N = 139) are presented in Table 1. The HU_{min} and HU_{mean} values measured for each age group are summarized in Table 2.

Thirty-seven of the 139 patients did not complete the predetermined 12-month follow-up: N = 10 completed the 3-month follow-up but were later lost without contact (N = 7) or were reported as deceased (N = 3); N = 17 completed the 6-month follow-up, subsequently N = 12 were lost without contact, two were diagnosed with a primary malignancy, two were reported as deceased, and one was diagnosed with fibromyalgia. 10 patients had evidence of a new OVCF on the X-ray reevaluation taken at the 12-month mark. They

TABLE 2 Hounsfield unit (HU) measurements by age group.

			HU_{min} values		HU_{mean} values	
Age group	Female, N = 104	Male, N = 35	Female	Male	Female	Male
50–59	20 (19.2%)	2 (5.7%)	59.2	61.3	99.1	117.7
60–69	29 (27.9%)	9 (25.7%)	38.4	42.4	71.6	95.8
70–79	33 (31.7%)	17 (48.6%)	5.1	39.8	43.3	62.3
≥80	22 (21.2%)	7 (20.0%)	−24.7	19.5	34.2	54.2

were excluded from the statistical analysis at the 12-month mark since they no longer fit the criteria for a single symptomatic OVCF. The demographic data, CT data, and direct postoperative results for the patients who did not complete the 12-month follow-up (N = 37) were used in the statistical analysis wherever appropriate, e.g., immediate postoperative results for pain control and cement leakage.

None of the patients (N = 139) exhibited any intra- or postoperative adverse events. Everyone who went through the 12-month follow-up (N = 102) revealed a significant reduction in overall VAS and ODI scores (Figure 3). The mean preoperative VAS score was 7.7 (±1.5; range 5–10). On the first postoperative day, this score was 2.8 (±1.5; 0–7). The 3- and 6-month follow-up results became more linear, with mean scores of 1.9 (±1.6; 0–8) and 1.5 (±1.5; 0–6), respectively. The mean total reduction (ΔVAS) for the follow-up was 6.4 ± 1.7. Disability scoring followed a similar trend: the preoperative mean scores were 52 ± 12.5, 17 ± 10.7% at 3 months, 11% ± 9.2% at 6 months, and 9.0% ± 10.7% at 12 months. The overall mean reduction in ΔODI was 42.0% ± 13.3%.

We found a correlation near statistical significance ($p = 0.056$) between the mean values and the preoperative VAS scores ($r = -0.190$). This would suggest that a decrease in overall density is a predictor for higher VAS scores before the procedure. This correlation was significant when comparing HU mean and VAS scores at the 3-month follow-up ($p = 0.018$; $r = -0{,}201$). However, these correlations failed to reach statistical significance when measuring preoperative disability ($p = 0.223$) or the effect of the procedure in reducing pain (ΔVAS) and disability (ΔODI) scores at the end of 12 months ($p = 0.516$ and $p = 0.968$, respectively) (Table 3).

Fifty-four patients had evidence of cement leakage on postoperative CT. These were subclassified as type A ($N = 3$) - through the basivertebral vein inside the spinal canal; type B ($N = 12$) in the segmental venous outflows; type C ($N = 8$) as a combination of A and B; type D ($N = 27$) inside the intervertebral disk; and type E ($N = 4$) – paravertebral through a defect in the cortical surface of the vertebrae.

We observed that the presence of the intravertebral vacuum clef (IVC sign, a.k.a. Kümmell's disease) was a protective factor against cement leakage ($p = 0.048$; $x^2 = 11{,}165$) and further protective against subtypes A-C, since all patients in the study with evidence of clefts on preoperative images only exhibited D- and E-type cement leakage. Grade 3 fracture severity was determined to be a protective factor against type A leakage. None of these patients (N = 52) exhibited PMMA leakage through the basivertebral vein toward the spinal canal. The volume of injected bone cement was a risk factor for these complications overall ($p < 0.05$) but was not significant ($p = 0.215$) in the presence of the IVC sign. The latter is only valid with volumes of PMMA $\leq 12\,cm^3$ since commercially available systems used in this trial are limited to this amount.

Cancellous bone density, measured in HU_{min} and HU_{mean}, showed no correlation to the incidence of cement leakage overall ($p = 0.233$, $x^2 = 6.842$, and $p = 0.415$, $x^2 = 5.005$, respectively) or to the likelihood of developing each of the subtypes (Table 4).

Discussion

To our knowledge, this is the first study that evaluates the correlation of quantitative Hounsfield unit measurements to postoperative results from percutaneous vertebroplasty and the risk of cement leakage. Previously reported risk factors for this complication as well as suboptimal pain control from the procedure include patient age, duration of complaints, the volume of applied bone cement, cement dispersion patterns, the severity of the fracture, bone mineral density measurements by DXA, and others (18, 32–34).

In the present study, bone cement leakage was observed in 43 cases (~27%) via intraoperative fluoroscopy. Postoperative CT showed evidence of extravertebral PMMA leakage in another 11 patients for a total of 54 (~40%) cases of PMMA leakage. The difference in reporting by intraoperative fluoroscopy and postoperative CT is well established. This study falls within the average incidence of cement leakage (31, 33). However, there is ambiguity in the literature and no threshold is determined as to what should be considered noteworthy PMMA leak. Therefore, these results should be observed, considering that in some cases this volume is minuscule. Additionally, we must note that postoperative CT was performed for the region of interest, either the thoracic or lumbar spine, and in most cases was not representative of the distal venous outflows and pulmonary arteries. We cannot definitively conclude that distal embolic complications were not present away from the site of intervention/scanning.

We observed that the presence of an IVC sign was a protective factor against all forms of transvenous cement leakage (Figures 2A–C). As described by Tome-Bermejo et al., these clefts are secondary to avascular necrosis of the bone, resulting in a low pressure-low density zone, similar to that created by inflating the balloon during percutaneous kyphoplasty. The PMMA fill pressure is considerably lower than that needed in intact and/or secondarily compacted cancellous bone. The authors hypothesize that the collapse of the normal trabecular structure inside the body destroys any venous channels or interrupts their connection to the basivertebral and segmental veins (34).

Lower densities measured by CT did not appear to correlate to a higher incidence of PMMA cement leakage. This finding contradicts previous reports that used DXA scans to measure bone density (20). While we cannot be certain why such a discrepancy exists, most other authors agree that the severity of the fracture, presence of IVCs and disruption of the cortical wall of the vertebrae are the major predictive

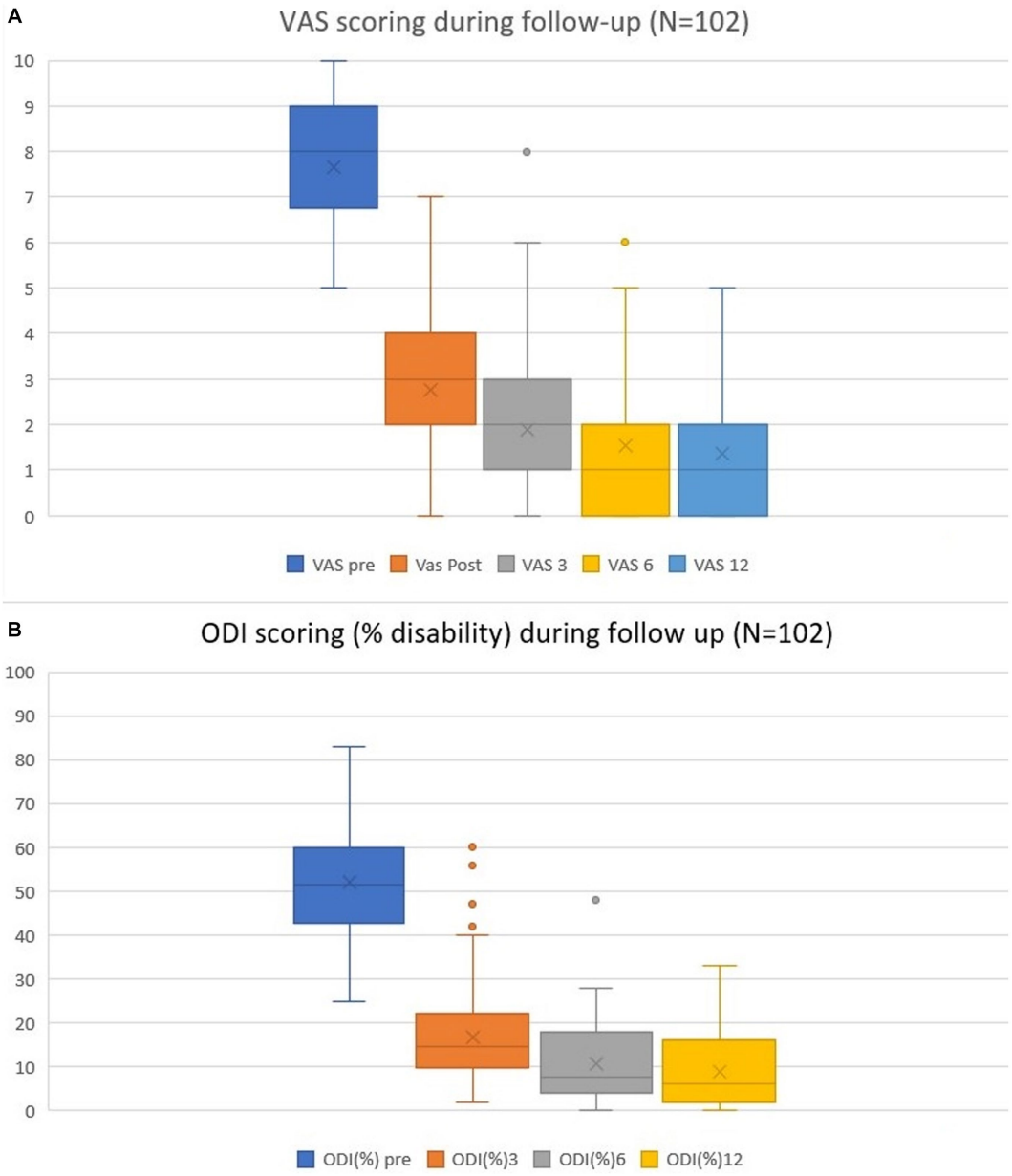

FIGURE 3
Pain VAS **(A)** and disability ODI **(B)** scores preoperatively and during follow-up at the 1-day, 3-, 6- and 12-month time points. Mean values, ranges, and standard deviations are given.

factors for cement leakage, and bone mineral density does not play a major role (18, 32, 34).

These measurements did not correlate significantly with the overall reduction in pain and disability scores. However, there was a slight ($r = -0{,}201$) statistically significant ($p = 0.018$) correlation between the HU_{mean} measurements and VAS score at the 3-month follow-up, i.e., patients with lower density scores could be at a higher risk for inadequate pain control in the short term. This correlation is not strong enough to constitute a clinical guideline or predictive model.

The current study has a new fracture rate of approximately 7%. These patients were excluded from the statistical analysis overall, apart from direct postoperative pain control and CT-defined cement leakage. The relatively small number of patients in the current study (N = 139) and the low rate of new OVCFs ($N = 10$) prohibit us from drawing any statistically significant conclusions on the correlation between HU_{min} and HU_{mean} values and new fractures. However, there is ample evidence in the literature linking low BMD and patient age to the incidence of new fractures. The meta-analysis conducted by Hui Zhang et al., published in 2017, decisively dissociated pVPL as a risk factor in the occurrence of new OVCFs. The authors conclude that persisting low BMD T scores <−3 SD and patient age > 80 constitute the major risk factors, while BMI, tobacco smoking, low serum vitamin D and others are secondary and do not contribute as much to the overall risk (35).

TABLE 3 Univariate analysis for all patients who completed the 12-month follow-up (N = 102).

		Pearson Correlation test		Spearman's rho		Kendall's tau B	
		HUmin	HUmean	HUmin	HUmean	HUmin	HUmean
VAS preoperative	r	−0.141	−0.190	−0.150	−0.190	−0.110	−0.137
	p - value	0.158	0.056	0.133	0.056	0.130	0.058
VAS on postoperative day one	r	0.040	−0.007	0.031	−0.015	0.025	−0.012
	p - value	0.688	0.943	0.759	0.884	0.732	0.871
VAS at 3-month follow-up	r	−0.152	−0.201	−0.143	−0.185	−0.101	−0.132
	p - value	0.075	0.018	0.095	0.030	0.104	0.034
VAS at 12-month follow-up	r	−0.174	−0.179	−0.166	−0.186	−0.127	−0.139
	p - value	0.081	0.072	0.095	0.061	0.088	0.062
Total reduction in pain – ΔVAS	r	−0.026	−0.065	−0.068	−0.092	−0.050	−0.075
	p - value	0.797	0.516	0.495	0.357	0.488	0.296
ODI(%) preoperative	r	−0.096	−0.122	−0.110	−0.135	−0.077	−0.093
	p - value	0.338	0.223	0.271	0.175	0.259	0.175
Total reduction in disability – ΔODI(%) at 12-month follow-up	r	0.041	0.004	0.011	−0.030	0.001	−0.026
	p - value	0.682	0.968	0.914	0.761	0.988	0.705

TABLE 4 Multivariate logistic regression analysis for the development of each fracture subtype.

Cement leak category		B	Standard error	Wald	*p*	Exp(B)	95% CI	
							Lower bound	Upper bound
A	Intercept	−5.149	1.693	9.254	0.002			
	HU_{min}	0.042	0.066	0.401	0.526	1.043	0.916	1.187
	HU_{mean}	−0.004	0.062	0.004	0.948	0.996	0.881	1.126
B	Intercept	−2.578	0.945	7.451	0.006			
	HU_{min}	0.072	0.046	2.440	0.118	1.075	0.982	1.176
	HU_{mean}	−0.047	0.045	1.107	0.293	0.954	0.874	1.041
C	Intercept	−4.130	1.154	12.816	0.000			
	HU_{min}	0.017	0.047	0.138	0.711	1.017	0.929	1.115
	HU_{mean}	0.012	0.044	0.078	0.780	1.012	0.929	1.103
D	Intercept	−2.115	0.616	11.773	0.001			
	HU_{min}	−0.026	0.028	0.875	0.349	0.974	0.922	1.029
	HU_{mean}	0.035	0.026	1.774	0.183	1.036	0.984	1.091
E	Intercept	−3.295	1.435	5.271	0.022			
	HU_{min}	0.096	0.072	1.773	0.183	1.100	0.956	1.267
	HU_{mean}	−0.069	0.070	0.961	0.327	0.933	0.813	1.071

Limitations of the study

This prospective study's relatively small number of patients limits its significance. Thus, we cannot propose a guideline based on these findings. Further investigation within a larger demographic could influence the strength of these statistical correlations. Additionally, this single-center study is susceptible to observational bias, and using semiquantitative methods to subcategorize fracture types presents observer bias. The tools used to evaluate patient well-being and procedural success (VAS and ODI) are subjective and are prone to reporting biases.

Conclusion

Our findings suggest a correlation between low bone density measurements and poorer results after percutaneous vertebroplasty in

the first three months after the procedure. This correlation is not present at one year. The existence of an intravertebral vacuum cleft sign is a protective factor against cement leakage overall and transvenous cement embolization. Lower HU_{min} and HU_{mean} values did not contribute to a higher incidence of cement leaks. These metrics remained statistically irrelevant to the overall disability of the patients on presentation or at any point during the 12-month follow-up.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by Institutional Ethical Review at St. Ivan Rilski University Hospital, Sofia, Bulgaria. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

DY: Writing – review & editing, Conceptualization, Formal analysis, Investigation, Methodology, Visualization, Writing – original draft. AB: Methodology, Project administration, Supervision, Writing – review & editing. VK: Project administration, Resources, Supervision, Writing – original draft. AS: Data curation, Formal analysis, Software, Visualization, Writing – original draft. DF: Investigation, Project administration, Resources, Supervision, Visualization, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Gait analysis using digital biomarkers including smart shoes in lumbar spinal canal stenosis: a scoping review

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Lumbar spinal canal stenosis (LSS) is characterized by gait abnormalities, and objective quantitative gait analysis is useful for diagnosis and treatment. This review aimed to provide a review of objective quantitative gait analysis in LSS and note the current status and potential of smart shoes in diagnosing and treating LSS. The characteristics of gait deterioration in LSS include decreased gait velocity and asymmetry due to neuropathy (muscle weakness and pain) in the lower extremities. Previous laboratory objective and quantitative gait analyses mainly comprised marker-based three-dimensional motion analysis and ground reaction force. However, workforce, time, and costs pose some challenges. Recent developments in wearable sensor technology and markerless motion analysis systems have made gait analysis faster, easier, and less expensive outside the laboratory. Smart shoes can provide more accurate gait information than other wearable sensors. As only a few reports exist on gait disorders in patients with LSS, future studies should focus on the accuracy and cost-effectiveness of gait analysis using smart shoes.

KEYWORDS

gait analysis, smart shoes, lumbar spinal canal stenosis, digital biomarker, wearable sensor

1 Introduction

With the advent of an aging society, lumbar spinal canal stenosis (LSS) is a growing and common problem, causing a major health burden worldwide, clinically and socioeconomically (1–8). Although the natural history of LSS is diverse, a progressive loss of function often occurs over time (3, 4). Therefore, early diagnosis and treatment may improve the prognosis of this disease (3, 4).

For early diagnosis of LSS, it is necessary to combine data from various objective biomarkers with self-reported symptoms, standard neurological findings (sensory, motor and reflexes) and imaging studies to improve the accuracy of the diagnostic algorithm. In the further development of digitization throughout healthcare, the more objective term "digital biomarker" has been used to describe this approach in medicine (9–11). Digital biomarkers are classified as physiological indicators (heart rate, pulse, and blood pressure) and behavioral indicators (gait and posture). They are used in fields ranging from sports support to medicine (9–11). Gait is an important biomarker for diagnosing and assessing disease status, as gait patterns are altered in patients with LSS. Objective gait analysis has traditionally been performed in a laboratory, and the recent

development and availability of wearable sensor technology have provided a faster, easier, and less expensive method for analysis (3–5). An increasing number of reports have shown that gait analysis using digital biomarkers with wearable sensors can aid in LSS diagnosis, severity, and prognosis (3–5). Wearable sensors, including smartphones, smartwatches, and smart shoes, also known as the Internet of Medical Things (IoMT), are used in medicine and sports owing to their high adherence to daily portable products. Because smart shoes enable a more accurate biomechanical analysis of the ankle joint than smartphones or smart watches owing to the predefined rigid sensor positions in the shoes, studies on gait analysis using smart shoes have increased dramatically in recent years [(12); Figure 1].

However, studies using smart shoes have focused on cardiovascular diseases, sports medicine, and neurological diseases (stroke and Parkinson's disease), with only a few reports on LSS, although gait abnormalities is a major symptom (4, 5, 13).

This review aimed to provide a scoping review of objective quantitative gait analysis using digital biomarkers in LSS and to note the current status and potential of smart shoes in diagnosing and treating LSS. The scarcity of reports on smart shoes for gait analysis in spinal disease and the heterogeneity of study designs, outcome measures, and variability prevents meta-analyses and adequate systematic reviews. A scoping review cannot locate all relevant literature and cover the scientific literature without bias. Instead, it will discuss the important papers that the authors know about. Thus, this study employed the scoping review method, which allows for a broader, more flexible, and more comprehensive organization and analysis of the existing literature compared to a systematic review.

For this purpose, we also selected many important papers published in peer-reviewed scientific journals and cited extensively the major papers in LSS gait analysis without any deadline restrictions.

2 Digital biomarkers in gait analysis

Digital biomarkers that objectively and temporally measure the physiological data of daily life, which were previously difficult to obtain using wearable sensors such as smartphones, smartwatches, and smart shoes, have been attracting attention (9–11). The emergence of digital biomarkers has revolutionized the measurement of physiological data in daily life. Typical digital biomarkers obtained from wearable sensors include vital signs, electrocardiogram, sleep, activity (daily steps, running distance, and calories burned), and gait analysis (9–11). Digital biomarkers obtained from wearable sensors are characterized by their noninvasiveness, long duration (outside the hospital), variety, and large volume of data. Biomarkers are classified according to the timing of the medical intervention: susceptibility/risk biomarkers and diagnostic biomarkers before diagnosis, prognostic/predictive biomarkers and pharmacodynamic/response biomarkers during diagnosis, safety biomarkers during treatment, and endpoint (surrogate) biomarkers and monitoring biomarkers from diagnosis to treatment efficacy (9–11). Therefore, various digital biomarkers derived from gait analysis have the potential to create new clinical value for the diagnosis, treatment, monitoring, and prognostic inference of LSS.

3 Trends in gait analysis in the laboratory and beyond

Gait analysis has evolved with technological advances, from purely observational to instrumental methods. Characteristic gait abnormalities observed in LSS include painful claudication and a steppage gait. Observational gait analysis is simple and equipment-free; however, it is inherently subjective, and its validity and reliability

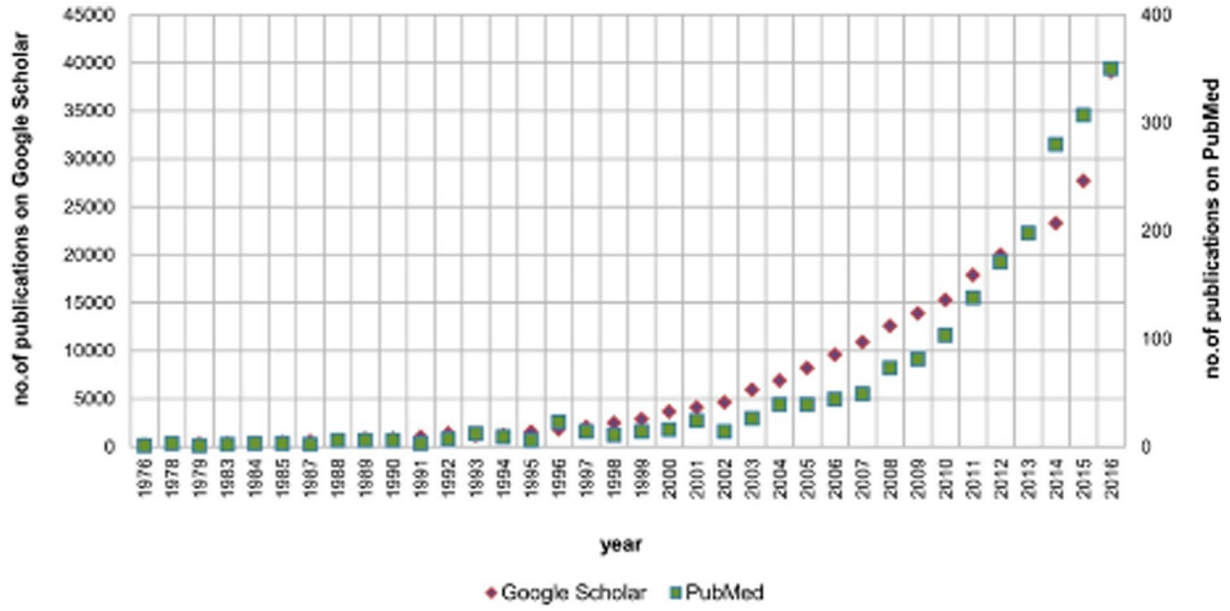

FIGURE 1
The annual number of publications on gait monitoring with smart shoes using PubMed and Google Scholar. The search criteria included "(gait OR shoe OR walking) AND (inertial OR IMU OR sensor OR wearable)." IMU, inertial measurement unit. Adapted from reference (12) with permission from MDPI.

depend on the examiner's skill and experience (14). Objective and quantitative gait analysis helps in understanding the pathophysiology of bipedal walking, identifying treatment focus areas, and optimally monitoring changes in the patient's condition (15). In the clinical and research fields, the most commonly used simple quantitative assessments are the 10-meter walk test for the most comprehensive index of walking speed, the 6-min walk test for assessing walking endurance, and the Timed Up and Go test for applied walking ability (16, 17). Walking speed affects daily mobility functions directly. Furthermore, walking speed and range of motion of the lower limbs were positively correlated, with 1.0 m/s being the speed at which a person can cross a pedestrian crossing and 0.7 m/s indicating a high risk of falling (15–17). The 6-min walk test and the Time Up and Go test can now be easily measured using free smartphone apps. However, these simple assessments do not specifically identify the aspects of gait that differ from those of a healthy gait.

In contrast to performance measures such as gait speed, instrumental quantitative gait analysis contributes to identifying causes that impair bipedal stability and efficiency and events and conditions that should be focused on during treatment. Instrumental quantitative gait analysis is commonly performed according to standard methods based on kinematic analysis of the displacement of body parts during walking (three-dimensional (3D) motion analysis), kinematic analysis of the external forces acting on the body (ground reaction forces), and electromyographic analysis of the muscle activity involved in the walking movement to examine gait parameters, such as spatial (length), temporal (duration), or derived indices (asymmetry, variability) (3, 15). Because these measures can be obtained using multiple inputs from different gait sites, they show high recognition rates and are crucial for classifying and quantifying gait disorders (3, 15, 16). Kinematic measurements can be obtained from any recording device linked to a computer (e.g., motion capture systems or inertial measurement units). The 3D analysis focuses on body movements, and the mainstream approach is optical. Markers attached to various body parts are photographed using a semiconductor camera, and the displacement, angular velocity, angular acceleration, stride length, and stride width of joint movements are calculated (18). Commonly used spatiotemporal gait metrics for quantitative evaluation include spatial (step and stride length) and temporal (step and stride time) parameters, spatiotemporal (walking speed and cadence: composite parameters derived from spatial and temporal variables) parameters, gait asymmetry, gait variability (Table 1), and joint angles (3).

For kinetic analysis, ground (foot) force reaction (GRF) analysis, including foot pressure analysis, was used to measure the magnitude, direction, and location of the application (19, 20). Adding 3D analysis data to GRF or electromyography data can provide a more comprehensive depiction of the gait. The marker-based system device is the traditionally used and highly accurate method, which combines 3D motion analysis (video analysis, optical motion tracking and analysis, multi-sensor, or gyroscope), electromyography, and GRF analysis in the laboratory for gait analysis (i.e., VICON) [Figure 2; (19, 20)].

A combined analysis of 3D motion and digital biomarker data obtained from ground reaction forces and electromyograms will improve understanding of the indices of spatial and temporal factors in the gait cycle, characteristics of the center of gravity movement that contribute to gait efficiency, and the relationship between joint motion and muscle activity in the lower limbs and trunk. However, laboratory gait analyses, including marker-based 3D motion capture systems, GRF, and electromyography, have disadvantages regarding space, equipment, time, workforce, cost, technical expertise, and exhaustive data analysis, making their clinical application difficult (21). There is also the problem of the "Hawthorne effect" in which people consciously alter their gait because they know that they were monitored (21) and the "white coat effect" (22), in which tension in an unfamiliar environment can alter patient performance. In addition, marker-based gait analysis requires subjects to expose their skin for accurate marker placement to obtain more accurate data, which may cause inconvenience (23). Recently, the accuracy of markerless 3D

TABLE 1 Spatiotemporal gait metrics: spatial, temporal, spatiotemporal, gait asymmetry, gait variability.

Type	Parameters	Definition	Units
Spatial	Step length	Average distance between two consecutive contacts of any foot with the ground	Meters (m)
Spatial	Stride length	Average distance between two consecutive contacts of the same foot with the ground	Meters (m)
Temporal	Step time	Average time between two consecutive contacts of any foot with the ground	Seconds (s)
Temporal	Stride time	Average time between two consecutive contacts of the same foot with the ground	Seconds (s)
Spatiotemporal	Walking speed (or gait velocity)	Average distance traveled per second	Meters/second (m/s)
Spatiotemporal	Cadence	Average rate (or frequency) of steps	Steps/minute
Gait asymmetry	Step time asymmetry	Average difference in time taken for successive steps on the left and right foot	Seconds (s)
Gait asymmetry	Step length asymmetry	Average difference in length for successive steps on the left and right foot	Meters (m)
Gait variability	Step time variability	Step-to-step variability of step time	Standard deviation (SD) coefficient of variance (cov = SD/mean)
Gait variability	Step length variability	Step-to-step variability of step length	Standard deviation (SD) coefficient of variance (cov = SD/mean)
Gait variability	Walking speed (or gait velocity) variability	Step-to-step variability of walking speed	Coefficient of variance (cov = SD/mean)

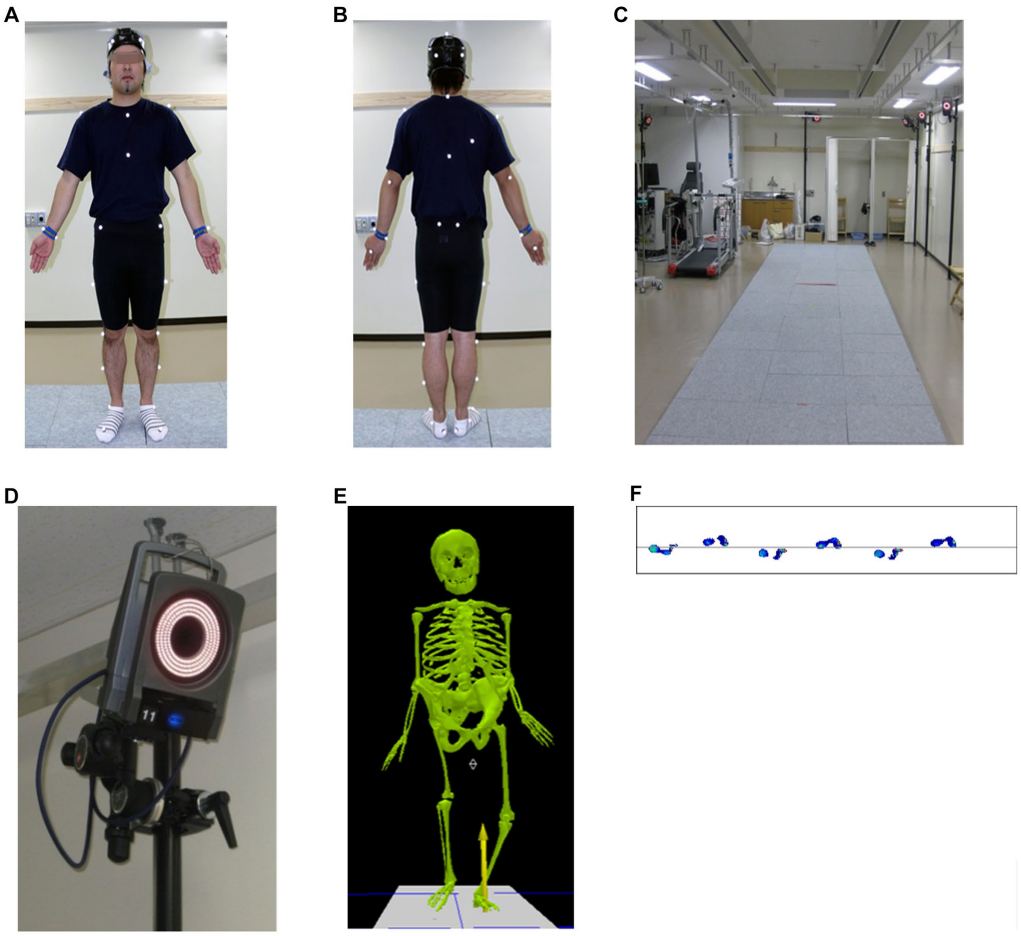

FIGURE 2
Vicon Motion System™, Oxford, UK. **(A,B)** Thirty-five infrared reflective markers are attached to the body surface. **(C)** Patients were asked to walk freely on an approximately 8 m walking path with a ground reaction force meter installed in the center of the path **(D)** and photographed by 14 infrared cameras. The infrared reflective markers were positioned using the plug-in-gait model at Saga University. The video motion and ground (foot) force reaction data were seamlessly merged to enable spatiotemporal and dynamic evaluation of gait abnormalities **(E,F)**.

measurements, such as Media Pipe[1] and OpenPose,[2] has improved; these require no expertise or special cameras, are free for noncommercial use, and are expected to expand opportunities for clinical applications (23). Notably, lower limb range of motion (ROM) was measured in the sagittal plane using OpenPose from images taken with a single digital camera (23). Although OpenPose cannot substitute a complete 3D motion analysis system, it can be used for gait analysis (23). OpenPose is a markerless system without special cameras, thus reducing analysis costs and time. Thus, the development and increased availability of wearable sensor and video analysis technology, especially markerless systems using human posture tracking algorithms, has provided a faster, easier, less expensive, and more representative way to measure regular walking patterns (or 'free-living' gait) outside the laboratory as an alternative to marker-based gait analysis in the laboratory (3–5, 24).

Wearable sensors and markerless 3D measurement can provide a more accurate assessment of a patient's gait and posture in "everyday life," which may not be reflected in tests performed by a physician in the hospital or outside the laboratory. Therefore, combining wearable sensors and markerless 3D measurement (OpenPose, Media Pipe) could be a "game changer" in motion and gait analysis.

4 Summary of publications on objective quantitative gait analysis using digital biomarkers in LSS

The most characteristic clinical presentation of LSS is neurogenic intermittent claudication, which causes pain and numbness from the buttocks to the lower extremities on one or both sides during walking, resulting in a slower walking speed and shorter total walking distance (3, 25). A systematic literature review by Wang et al. in 2022 revealed that most conventional quantitative gait analyses of LSS were performance-oriented studies on walking speed and distance, such as motorized treadmill trials (24 publications) and timed up-and-go trials (19 publications) (24).

1 https://google.github.io/mediapipe/

2 https://cmu-perceptual-computing-lab.github.io/openpose/web/html/doc/index.html

Patients with LSS often have postures that cause the lumbar spine to flex more to maximize spinal canal volume and minimize pain and symptoms during walking, leading to postural abnormalities (25, 26). In addition to lower-extremity pain, muscle weakness and sensory disturbances can result in balance dysfunction (24, 26, 27). Furthermore, changes in sagittal spinal alignment may affect the hips (28, 29) and knees (30). Kinematic (3D motion analysis), kinetic (GRF), and electromyographic (EMG) analyses of gait can produce abnormalities in spatial, temporal, or derived indices (asymmetry and variability) of gait. These observations were made upon reflecting on these LSS-induced lower-extremity neuropathies and alignment abnormalities in the spine and lower-extremity joints from objective quantitative gait analysis using instruments (3, 16).

Table 2 summarizes the publications on objective quantitative gait analysis using digital biomarkers in LSS. Although most studies have investigated spatiotemporal gait metrics (spatial, temporal, spatiotemporal, gait asymmetry, gait variability), only a few investigated trunk and lower-extremity joint angles, plantar pressure distribution, and EMG (Table 3).

The characteristics of gait deterioration in patients with LSS compared to those in healthy subjects include decreased gait velocity (35, 38, 42, 44, 46), decreased time or length of gait (step or stride) (21, 22, 28, 32, 33, 35, 38, 40, 44), decreased cadence (21, 22, 35, 42), gait asymmetry (38), and prolonged gait duration (21, 22, 32, 35, 38). Kinematic analysis showed that LSS decreased hip ROM (42), increased knee ROM (42) and lumbar flexion (anterior trunk tilt) in the sagittal plane (44), and increased the foot contact time and progression angle (34). This observation may be due to neuropathy (muscle weakness and pain) in the lower extremities caused by LSS. For the EMG variables, muscle activity in the LSS was higher in the tensor fascia, quadriceps (37), and vastus lateralis muscles (20). Additionally, muscle activity was lower in the paravertebral muscles (20) of patients with LSS than in healthy controls (Table 4). Although the number of reports on the gait analysis of LSS using wearable sensors has increased (33, 44), only two studies on smart shoes were written by the same authors (4, 5).

5 Smart shoes: status quo and quo vadis

Smart shoes are ordinary shoes with technological innovations, such as biometric data recording and automatic size adjustment according to the individual (13). Shoes with at least one actuator or sensor built in are "smart." Leading companies have developed smart shoes incorporating various technologies, including pressure sensors, accelerometers, gyro sensors, piezoelectric pedometers, and Bluetooth. These smart shoes can analyze posture, gait patterns, and ankle momentum and measure the number of steps and calories burned via a smart app (13); they include Lechal Shoes that navigate using GPS (13, 47), Google's talking shoes (48), Adidas' Micropacer (49), Nike's Adapt BB, Puma's Fit Intelligence, Samsung's IOFIT, and Asics' EVORIDE ORPHE.

The shoe incorporates pressure, acceleration, and gyroscope sensors to track the user's activity. Real-time feedback can be provided by connecting it to a personal computer or smartphone. Asics' EVORIDE ORPHE enables multifaceted gait analysis by linking 3D motion analysis using OpenPose from videos captured by a single digital camera with kinematics and GRF data obtained from smart shoes (Figure 3). However, no comparisons have been made between marker-based 3D movement analysis (numerous video cameras and infrared markers) combined with GRF measurements in the laboratory (Figure 2) and markerless 3D movement analysis outside the laboratory using low-cost and convenient smart shoes and a single digital camera on a smartphone in patients with LSS. This aspect requires further exploration.

Biofeedback systems combined with smart shoes can prevent injuries in runners (50, 51), prevent and detect falls in older patients (50, 52), monitor posture in patients with back pain (52), and detect gait abnormalities in osteoarthritis to prevent joint damage (53). Moreover, Bluetooth-and Wi-Fi-capable smart shoes can help the visually impaired navigate their destinations using Google Maps functionality (13, 54). Smart shoes are a useful tool for evaluating gait analysis because they (1) have predefined rigid sensor positions on the soles for accurate and flexible biomechanical analysis, (2) can monitor the highly fixed movement of gait and automatically assess functional biomechanics, and (3) are discreet and non-stigmatizing to incorporate, improve patient acceptance and long-term adherence, and allow gait to be assessed spatiotemporally and mechanically (12). When comparing the accuracy of the number of steps by wearing the sites at the hip, buttock, thigh, ankle, and wrist, the ankle joint showed the highest accuracy (55). Therefore, smart shoes are more suitable as wearable sensors for gait analysis than smartphones or smartwatches because they provide more gait information (gait asymmetry and GRF) (4, 5, 12, 56).

Studies on smart shoe gait analyses have increased dramatically in recent years (12). However, they have focused on cardiovascular diseases, sports medicine, and neurological diseases (stroke and Parkinson's disease), with only a few on degenerative spinal diseases, although gait abnormalities is a major symptom (4, 5, 12). This may be because wearables have only recently emerged as practical tools to assist health management. Smart shoes enable the long-term recording and analysis of superficial information, including walking distance, walking time, and calories burned, which can be obtained from smartphones and smartwatches, and stride length, landing angle and impact, the area where the foot touches the ground, and changes in walking style (4, 5, 12, 56). Smartphones may motivate runners and patients to exercise by encouraging behavioral changes through daily step challenges and goal setting. Furthermore, insole-based systems can easily measure several parameters related to lower-extremity health, such as plantar pressure, body temperature, pulse rate, and gait dynamics (4, 5, 12). Thus, these data-collecting smart shoes are similar to the IoMT.

Accumulating gait data and machine learning algorithms may help establish a warning system for faster and better fall response. Therefore, accurate gait analysis data from smart shoes can help in the early detection, assessment of fall risk, treatment decisions, monitoring of treatment, and outcome evaluation of diseases that cause gait disorders, including LSS. Outcome measurements will shift from being subjective to combining subjective and objective measurement tools derived from digital biomarkers. Information from wearable sensors other than smart shoes will be integrated with artificial

TABLE 2 Summary of publications on objective quantitative gait analysis using digital biomarkers in LSS.

Reference	Year	Nationality	Product	Instrumentation	Wearable sensor location	Environment
(31)	2022	China	Footscan® pressure plate 13 (RSscan International, Olen, Belgium)	GRF plate		Indoor 10 m circular track
(32)	2022	Czech Republic	11 infrared cameras Oqus 300 and 300+, two force platforms (Kistler type 9281EA, Kistler Group, Winterthur, Switzerland)	Motion capture, GRF plate		Laboratory
(22)	2021	Australia	MetaMotion C (MbientLab Inc., CA, USA)	Motion capture, accelerometer, gyroscope, magnetometer	Sternal	Indoor hospital ward
(33)	2021	China	IDEEA (MiniSun, LLC, Fresno, CA, USA)	Accelerometer (acceleration electronic sensors)	fourth metatarsal, thigh, sternal	Indoor horizontal walkway
(34)	2020	China	Footscan® 3D pressure system (RSscan International, Olen, Belgium)	GRF plate		Indoor 10 m circular track
(35)	2020	USA	Shimmer3 wearable sensor platform (Shimmer Sensing, Dublin, Ireland)	Accelerometer, gyroscope, magnetometer		NA
(36)	2020	Switzerland	RehaGait® system (Hasomed GmbH, Magdeburg, Germany)	Accelerometer		Indoor hospital ward
(37)	2020	Korea	Human Track®, Gait & Motion Analysis System (RBiotech Co., Ltd., Seoul, Korea), FreeStep software® (Sensor Medica, Rome, Italy)	Accelerometer, gyroscope, magnetometer		Laboratory
(21)	2020	Australia	NA	Videography		NA
(38)	2018	Switzerland	RehaGait® system (Hasomed GmbH, Magdeburg, Germany)	Accelerometer, gyroscope, magnetometer	Lateral shoe, lower and upper legs, pelvis	Indoors (clinic)
(39)	2018	Switzerland	RehaGait® system (Hasomed GmbH, Magdeburg, Germany)	Accelerometer, gyroscope, magnetometer	Lateral shoe, lower and upper legs, pelvis	NA
(40)	2018	China	IDEEA3; MiniSun (LLC, Fresno, CA, USA), GoPro Hero3 high-speed camera (GoPro, San Mateo, CA, USA)	Accelerometer, gyroscope, magnetometer	Chest, thigh, ankles, and plantar surface of foot	Indoor hospital ward
(4)	2017	USA	Smart shoes (UCLA Wireless Health Institute) with pressure sensors (FSR400, Interlink Electronics, USA)	GRF (smart shoes)	Shoe (heel, lateral plantar, toe)	Laboratory
(41)	2017	Japan	Vicon MX system® (Vicon Motion Systems, Oxford, United Kingdom) 8cameras, round force platform (AMTI, model OR-06; Advanced Mechanical Technology, Watertown, MA, USA); Telemyo 2,400 T (Noraxon, Scottsdale, AZ, USA)	Motion capture, GRF plate		Laboratory
(42)	2015	Japan	NA	Videography		Laboratory
(43)	2014	Brazil	MX40 Vicon system (Vicon, Oxford, UK)	Motion capture		Indoor horizontal walkway
(44)	2014	Japan	Triaxial accelerometer (WAA-066, ATR Promotions Co., Japan)	Accelerometer	Lumbar and cervical spines	Laboratory
(45)	2013	USA	Long instrumented walkway (GaitRite®; CIR Systems, Inc., Havertown, PA, USA); electromagnetic tracking system (Liberty, Polhemus Inc., Colchester, VT, USA).	GRF plate		Laboratory
(46)	2002	Japan	NA	GRF plate		Indoor 10 m circular track

NA, not applicable; m/w, men/ women; yrs, years old; GRF, Ground reaction force; SGM, Spatiotemporal gait metrics (spatial, temporal, spatiotemporal, gait asymmetry, gait variability); Kinematic variable, Trunk or Lower joint angle and range of motion; Kinetic variable, Vertical force, pressure distribution, and center of force on foot; EMG, Electromyography.

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TABLE 3 Summary of publications on spatiotemporal gait metrics, Kinematic and Kinetic variable and EMG in LSS.

Reference	Patient characteristics (N), gender (m/w), Mean age (yrs), study	Variable	Study findings
(31)	*N* = 31 (NA), 60 yrs, LSS patients vs. controls	SGM	↑The medial-lateral center of pressure with increasing distance
(32)	*N* = 15 (11/4), 62 yrs, LSS patients vs. controls	SGM Kinematic variable, Kinetic variable	↓stride length, step length, step times, cadence, swing times ↑stride width, stance times, initial double limb support
(22)	*N* = 25 (17/8), 59 yrs, LSS patients vs. controls	SGM	↑ step length and step time asymmetry ↓stride time, step time, and cadence, stride length and step length
(33)	*N* = 49 (18/31), 80 yrs, LSS patients vs. controls	SGM Kinetic variable	↑small intermittent claudication, single support, double support, step duration, and pulling accel ↓Push off, speed, step length, and Stride length
(34)	*N* = 20 (12/8), 60 yrs, LSS patients vs. controls	Kinematic variable, Kinetic variable	↑foot contact time for LSS,↑foot progression angle for LSS, ↑pressure time integral in forefoot, medial and lateral heal for LSS
(35)	*N* = 10 (3/7), 70 yrs, LSS patients vs. controls, Knee osteoarthritis vs. controls	SGM	Foot flat ratio, gait speed, stride length and cadence were identified as the best gait characteristics for the LSS population discrimination. Normal paced walking tests (6MWT, SPWT) are better suited for distinguishing gait characteristics
(36)	*N* = 29 (17/12), 73 yrs, LSS patients vs. controls	Kinematic variable	↑ vertical pelvis acceleration for pre-op, 10wks, and 1 yr. ↓ AP and ML pelvis acceleration for pre-op, 10wks, and 1 yr
(37)	*N* = 17 (3/14), 66 yrs, LSS patients vs. controls	Kinematic variable, EMG	↑peak knee varus angle for LSS ↑tensor fascia and↓ quadriceps muscle activity for LSS: LSS patients required increased activation of hip abductors and recruited neighboring quadriceps muscle fibers when performing hip abduction.
(21)	*N* = 15 (8/7),73 yrs, LSS patients vs. controls	SGM	↓cadence, step length, gait velocity, ↑step time(a decrease in gait speed and cadence is caused by the presence of lower limb pain and dysesthesias)
(38)	*N* = 29 (17/12), 73 yrs, LSS patients vs. controls	SGM	↓gait velocity, gait length, ↑gait duration and gait asymmetry
(39)	*N* = 19 (11/8), 74 yrs, LSS patients vs. controls	SGM	↑change in acceleration pattern for 1 yr. ↑ change in acceleration variability for pre-op, 10wks, 1 yr. ↑ change in acceleration pattern and quality for pre-op, 10wks, 1 yr
(40)	*N* = 20 (NA), 58 yrs, LSS patients vs. controls	SGM	↓step length and stride length
(5)	*N* = 15 (4/11), 58 yrs, LSS patients	SGM, Plantar pressure distribution	
(20)	*N* = 6 (5/1), 69 yrs, LSS patients (pre-, post operation)	SGM, Plantar pressure distribution, EMG	↓ (Kinematic analyses) thorax angle, pelvic angle(tendency, not significant), (EMG)the activity of the PVM ↑ (Kinematic analyses) Cadence, gait velocity, knee flexion angle,(Kinetic analyses),Hip and Knee flexion torques, (EMG)The activity of the VL
(42)	*N* = 7 (5/2), 71 yrs, LSS patients vs. Hip oseoarthritis	SGM	↑sagittal plane knee ROM during stance
(43)	*N* = 14 (10/4),75 yrs, LSS patients vs. controls	SGM	↓stride length and gait velocity ↑anterior trunk tilt
(44)	*N* = 11 (8/2), 73 yrs, LSS patients	SGM	↑postural sway
(45)	*N* = 25 (11/14), 73 yrs, LSS patients	SGM	↓gait velocity
(46)	*N* = 60 (11/29), 63 yrs, LSS patients (cauda equina and radicular type)	SGM	Abnormalities of various factors related to the style of walking soon after the patients began to walk

NA, not applicable; SGM, Spatiotemporal gait metrics (spatial, temporal, spatiotemporal, gait asymmetry, gait variability); Kinematic variable, Trunk or Joint angle and range of motion; Kinetic variable, Vertical force, pressure distribution, and center of force on foot; EMG, Electromyography.

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TABLE 4 Characteristic of gait analysis on patients with lumbar spinal canal stenosis.

Gait type	Neurogenic intermittent claudication, painful limp, steppage gait
Spatiotemporal gait metrics	Decreased gait velocity (21, 35, 38, 42, 44, 46), decreased time or length of gait (step or stride) (21, 22, 32, 33, 35, 38, 40, 44), and decreased cadence (42), prolonged gait duration
Kinematic variable	Decreased hip and knee range of motion (42) Lumbar flexion (anterior trunk tilt) in the sagittal plane (20, 43, 44)
Kinetic variable	Increased knee flexion torques (20)
Electromyography	Muscle activity in the LSS was higher in the tensor fascia, quadriceps (37), and vastus lateralis muscles (20) and lower in the paravertebral muscles (20).

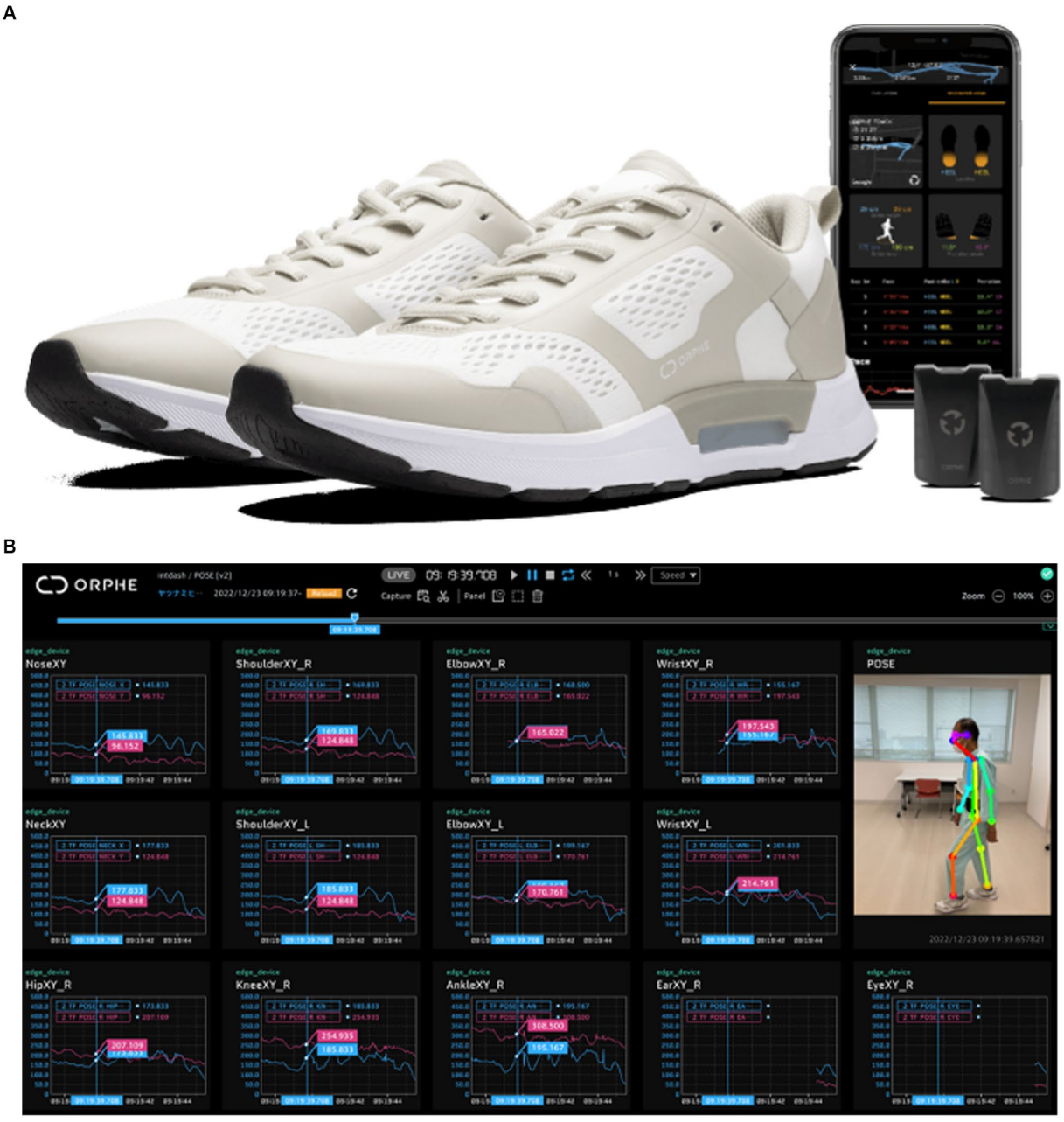

FIGURE 3
Asics' EVORIDE ORPHE smart shoes can measure the time of each segment of the gait cycle, landing and departure angles, spatiotemporal evaluation of gait using 6-axis (3-axis acceleration, 3-axis angular velocity) motion sensors built into the plantar surface, and indicators for gait evaluation such as ankle joint angle and plantar pressure [landing impact, ground (foot) force reaction]. **(A)** Is adapted from https://orphe.io/presswith permission of ORPHE. **(B)** Linkage with 3D motion analysis was done by linking the videos captured by a single digital camera with multifaceted gait analysis using OpenPose.

intelligence to provide useful information for healthcare providers regarding treatment. With the entry of major shoe companies, market penetration of smart shoes with high comfort and convenience is expected to increase rapidly. However, reports on the efficacy of smart shoes for gait analysis in LSS, usability, data security, and cost-effectiveness are lacking (57). The legal system may be unable to keep pace with advances in connected medical product technology, and data security must be a top priority, particularly concerning patient information.

6 Conclusion

Proper diagnosis and treatment of LSS require objective and subjective methods of assessment. Objective quantitative gait analysis and subjective patient assessment are useful for diagnosis, prevention, therapeutic intervention, treatment management, and outcome assessment. Although objective quantitative methods of gait analysis have been performed using laboratory-based 3D motion analysis, ground reaction force, and electromyography, challenges may occur regarding workforce, time, expertise, and cost. Wearable sensor technology (especially smart shoes) and markerless motion analysis systems have made it possible to replace conventional gait analysis with markers in the laboratory, which is faster, simpler, cheaper, and more reflective of everyday life. Using smart shoes for gait analysis shows great potential; however, evaluating their accuracy and cost-effectiveness is crucial. Future studies should aim to address these concerns and provide more insight into the use of smart shoes for gait analysis in the diagnosis, treatment management, and outcome assessment of LSS. These advances in technology and methods will help healthcare professionals provide better care for patients with LSS.

Author contributions

TM: Conceptualization, Data curation, Investigation, Writing – original draft. HH: Conceptualization, Methodology, Supervision, Visualization, Writing – original draft. TK: Data curation, Formal analysis, Writing – original draft. MT: Supervision, Validation, Visualization, Writing – original draft. TY: Supervision, Validation, Writing – original draft. YT: Investigation, Methodology, Writing – original draft. MM: Supervision, Validation, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Appropriateness of specialized care referrals for LBP: a cross-sectional analysis

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Background: Low back pain (LBP) accounts for a significant proportion of primary care visits. Despite the development of evidence-based guidelines, studies point to the inefficient use of healthcare resources, resulting in over 60.0% of patients with LBP being referred to spine surgeons without any surgical indication. Centralized waiting lists (CWLs) have been implemented to improve access to specialized care by managing asymmetry between supply and demands. To date, no study has provided data on patients' clinical profiles and referral patterns to medical specialists for LBP in the context of a publicly funded healthcare system operating a prioritization model. The objective of this study was to evaluate the appropriateness of specialized care referrals for LBP after the implementation of a CWL.

Methods: A retrospective cross-sectional analysis of 500 randomly selected electronic health records of patients who attended the outpatient neurosurgery clinic of the administrative Mauricie-et-Centre-du-Québec region was performed. Inclusion criteria were neurosurgery consultation referrals for adults ≥18 years suffering from a primary complaint of LBP, and performed between September 1st, 2018, and September 1st, 2021. Data relevant for drawing a comprehensive portrait of patients referred to the neurosurgery service and for judging referrals appropriateness were manually extracted.

Results: Of the 500 cases analyzed, only 112 (22.4%) were surgical candidates, while 221 (44.2%) were discharge from the neurosurgery service upon initial assessment. Key information was inconsistently documented in medical files, thus preventing the establishment of a comprehensive portrait of patients referred to the neurosurgery service for LBP. Nevertheless, over 80.0% of referrals made during the study period were deemed inappropriate. Inappropriate referrals were characterized by higher proportion of patients symptomatically improved, presenting a back-dominant chief complaint, exhibiting no objective neurological symptoms, and diagnosed with non-specific LBP.

Conclusion: This study reveals a significant proportion of inappropriate referrals to specialized care for LBP. Further research is needed to better understand the factors that prompt referrals to medical specialists for LBP, and the criteria considered by neurosurgeons when selecting the appropriate management strategy. Recent studies suggest that triaging approaches led by musculoskeletal experts may improve referral appropriateness to specialized care.

KEYWORDS

low back pain, referral appropriateness, specialized services, wait time, cross-sectional study

1 Introduction

Canada's publicly funded health care system is organized around a 3-level of care delivery model, providing access to a broad range of health services (1). Primary health care serves a dual function, being the first point of contact with health care services, while ensuring continuity of care and coordination with secondary and tertiary care providers when specialized services are needed (1). Access to specialized care poses a challenge, as it relies on highly qualified personnel and equipment that may not be readily available, particularly in remote areas, and in underserved communities (2).

In 2016, Quebec's Ministry of Health and Social Services (MSSS) launched the *Prioritized Access to Specialized Services* (PASS) program (3), characterized by a set of strategies designed to improve access to specialized care by managing asymmetry between supply and demands (4). Among those strategies, centralized waiting lists (CWLs) have been implemented and consolidate multiple service providers' and organizations' waiting lists into a single waiting list for a given specialized service. A CWL operates under a prioritization model, where patients are placed into a queue, through a central intake point, and assigned to medical providers according to their level of need (4). The Service Request Management Center (*Centre de répartition des demandes de services*-CRDS) falls into CWLs' definition, managing all new referrals sent from primary health care providers to specialized services. The province of Quebec counts 15 CRDSs, distributed across its territory (3). Although promising, the latest MSSS report for the year 2021–2022 indicated that 33.0% of specialist consultations, after referral from a family physician, were not carried out within the expected delay (5). As the public health care system struggles with limited health care resources, this reinforces the importance of the quality of referrals (i.e., referring the right patient, at the right time, to the right service, with the right information) (6) in enabling patients to get a timely access to medical specialists.

As the leading cause of years lived with disability worldwide (7), low back pain (LBP) accounts for a significant proportion of outpatient physician visits (8), and for a significant share of Canada's health care spending (9). Although several evidence-based clinical guidelines have been published over the years to assist primary care providers with the prevention, evaluation and management of LBP, preventing the use of practices that are harmful or wasteful, while ensuring equitable access to effective and affordable health care for patients with LBP remains a national challenge (10). In most healthcare systems from developed countries, general practitioners are the primary contacts responsible for referring patients with MSK conditions to secondary and tertiary care services, and sometimes to other healthcare professionals (11). However, evidence suggests that usual care for patients with LBP often does not match care endorsed in evidence-based guidelines, leading to overuse of imaging and opioids prescriptions at the expense of self-management strategies and patient education (12–14). Several studies (15–19) also suggest an overreliance on the expertise of medical specialists, indicating that between 62.0 to 85.0% of patients referred to spine surgeons for LBP are not surgical candidates, thus delaying access for patients in need of surgical consultation.

In Mauricie-et-Centre-du-Québec, a CRDS has been implemented in 2018 to manage demands for specialized services within the area served by the Centre intégré universitaire de soins de santé et de services sociaux de la Mauricie-et-du-Centre-du Québec (CIUSSS-MCQ). This CRDS is the only CWL within the province of Quebec to manage all referrals from primary care to specialized services, irrespective of referrals source. The CIUSSS-MCQ's neurosurgery department also distinguishes itself by managing all surgical consultations for LBP, except for traumas, whereas patients with LBP are distributed between specialists in other institutions. Such particularities offer a unique opportunity to capture relevant information regarding patients referred to specialized care services for LBP. To date, no study has yielded objective data that provide a clear understanding of patients' clinical profiles and referral patterns to specialized care for LBP following the implementation of a CWL. These data could prove to be an invaluable asset in the development of strategies aimed at improving patients' care trajectories, while promoting optimal use of health care resources and timely access to medical specialists.

Therefore, our objective was to determine the appropriateness of referrals made to the CIUSSS-MCQ's neurosurgery service for LBP. This objective was broken down into 3 specific objectives: [1] quantify and describe patients referred for an initial consultation to the neurosurgery department for a primary complaint of LBP; [2] determine the proportion of referrals made to the neurosurgery department for a primary complaint of LBP that is deemed inappropriate; and [3] identify the characteristics that differentiate inappropriate from appropriate referrals.

2 Methods

The reporting of this study followed the REporting of studies Conducted using Observational Routinely collected Data (RECORD) checklist (20).

2.1 Ethics approval

The Centre intégré universitaire de santé et de services sociaux de la Mauricie-et-du-Centre-du-Québec (CER-2022-600-838) and the Université du Québec à Trois-Rivières (CER-22-288-10.04) Research Ethics Boards have reviewed and approved this study.

2.2 Study design and setting

A retrospective cross-sectional analysis of medical files data was performed, using electronic health records of patients who attended for the first time the CIUSSS-MCQ's outpatient neurosurgery clinic for a

primary complaint of LBP between September 1st, 2018 (CRDS implementation date), and September 1st, 2021. The CIUSSS-MCQ was created following the fusion of regional public health and social establishments, including hospitals, community services and long-term facilities, and serves a population of more than 530,000 people, including 82.5% over the age of 18 (21). During the study period, the neurosurgery department was staffed by 5 neurosurgeons. CRDS's referral form for neurosurgery services (see Supplementary File 1) assigns each patient a clinical priority code from A to E based on their clinical profile. Each priority code is associated with a specific delay to be observed between the referral being sent and the neurosurgery consultation (i.e., code A: ≤ 3 days, code B: ≤ 10 days, code C: ≤ 28 days, code D: ≤ 3 months, and code E: ≤ 12 months). As a prerequisite for the neurosurgery service, patients with LBP must also provide an imaging report dated less than 3 months prior to their surgical consultation.

2.3 Study population and patient selection

An administrative agent proceeded to the identification of potentially eligible medical files by searching the CRDS database based on listed reasons for referral. Inclusion criteria for eligible chart review included: [1] a documented reference to the CIUSSS-MCQ neurosurgery outpatient clinic; [2] a primary chief complaint that prompted consultation consistent with LBP; [3] an initial consult that took place between September 1st, 2018, and September 1st, 2021; and [4] included a patient that was 18 years or older at the time of the initial consult. Exclusion criteria were charts documenting follow-up visits only, and a primary chief complaint of unspecified spinal pain region. Two independent reviewers screened all potentially eligible medical files to confirm eligibility. A third reviewer was involved if consensus could not be reached. From the medical records meeting the inclusion criteria, a random selection of 500 files was made using block stratification to ensure representativeness of time periods (years), sexes and ages in the planned analyses. Those medical records were then subjected to data extraction. The sample size was based on existing literature which generally holds 10 charts per variable as an accepted norm to obtain results that are likely to be clinically useful (22).

2.4 Data collection

The medical record of each randomly selected patient was reviewed, and data were extracted from the neurosurgery outpatient consult request form, and from the consultation note. If more than one neurosurgery consult request form and consultation note were present in the medical file, only data related to the initial consultation were extracted. Data collection was performed using a standardized form with pre-set drop-down fields and free-texts boxes. Five patients meeting inclusion criteria were randomly selected and subsequently contacted by the neurosurgeon research team member (C.É.C) to obtain their consent for their records to be analyzed. This exploratory analysis has allowed to refine the form and confirm the data sets to be extracted. Four medical students were recruited and trained for data extraction. They were advised to extract only information related to the current episode of LBP. Accordingly, dates of clinical examinations performed were retrieved to ensure that they were related to the current episode. Whenever possible, the medical residents were asked to transcribe textually the written referral form and consultation note to avoid any interpretation of the data.

2.5 Data coding and outcomes

Table 1 presents the types and definitions of variables that were extracted to allow the drawing of a comprehensive portrait of patients being referred to the neurosurgery outpatient clinic. The extracted data were coded by four research assistants, using a codebook to ensure consistency. A training exercise was conducted with 15 medical files. Random verifications were subsequently performed by the main author (J.M.) throughout the extraction process to ensure reliability of the extracted data. To minimize subjectivity in codification in relation to personal theories about the study's aims, data extractors were kept blinded to the study hypothesis (23, 24). When necessary, the neurosurgeon research team member (C.É.C) was consulted to provide information on standards of practice, and to clarify some medical terms and abbreviations. The Material and Social Deprivation Index (MSDI) was used as a proxy for lacking information on patients' socioeconomic status in the CRDS database. The MSDI allows for a comprehensive assessment of social inequalities (25), by connecting area-based socioeconomic data to postal codes. The MSDI was carefully chosen due to its well-established associations with health status and deprivation, encompassing both material and social dimensions (26). The material dimension involves deprivation of the goods and conveniences that are part of modern life and marks the consequences of lack of material resources associated to low education, insecure job situation, and insufficient income. The social component refers to the composition and fragility of the social network (26, 27). For both dimensions, areas were ranked in quintiles, with quintile 1 being the most privileged and quintile 5 the most disadvantaged (25).

2.5.1 Referral appropriateness

For the 500 medical files randomly selected, two clinical researchers (J.M, A.A.M.) independently judged the appropriateness of referrals made to the neurosurgery department. Referral appropriateness was judged by considering 3 specific components: [1] the compliance with CRDS's referral form criteria (Supplementary Files 1, 2), such as (a) the presence of a painful or sensory-motor radiculopathy OR neurogenic claudication with either (i) severe symptoms and functional limitations >8 weeks or (ii) moderate chronic symptoms >8 weeks OR (b) the presence of an isolated LBP with structural abnormality; [2] the patient's clinical profile; and [3] the patient's care trajectory. From a clinical perspective, referrals were considered inappropriate if one or more of the following criteria was present: [1] pain pattern consistent with non-specific LBP; [2] acute pain episode or non-progressing or slowly progressing symptoms; and [3] absence of objective neurological symptoms.

Patients' care trajectories were deemed inappropriate if diagnostic tests and conservative treatment options had not been fully exhausted (guideline concordant care for 6–10 weeks) prior to referral for specialized care. These criteria were based on evidence-based guidelines for the management of LBP (28–32) and on factors known to be associated with poor surgical outcomes (33–36). Researchers

TABLE 1 Variables and outcomes.

Category	Extracted variable	Outcome
Sociodemographic data	1. Date of birth 2. Biological sex 3. City of residence, postal code, administrative region	1.1 Age 2.1 Male or Female 3.1 Material and Social Deprivation Index
Administrative data	4. Involvement of workers' compensation board (CNESST) 5. Involvement of public automobile compensation board (SAAQ) 6. Date of referral Date of consult Priority code 7. Referring clinicians	4.1 Yes or No 5.1 Yes or No 6.1 Delay to neurosurgery consult 6.2 Pre-pandemic or pandemic period 6.3 A-B-C-D-E 6.4 Compliance with the priority code 7.1 Primary care referral, medical specialist, emergency unit
Clinical data	8. Medical history 9. Presence of red flags 10. Pain localization and dominance 11. Pain status 12. Pain duration 13. Symptoms progression 14. Presence of neurological deficits 15. Diagnosis from the neurosurgeons	8.1 Type and number of comorbidities 8.2 Pain medication 8.3 History of spinal surgery 8.4 Smoking status 9.1 i.e., bladder and bowel dysfunction, saddle anesthesia, fever, chills, history of trauma 10.1 Back, leg(s) or both 11.1 Intermittent, constant 12.1 Acute (< 4 w), Subacute (4-12w) or chronic (> 12 w) 13.1 Stable, aggravation, improvement 14.1 Sensory, motor, reflex deficits 14.2 Presence of pathological reflexes (i.e., clonus, Babinski sign) 15.1 Type of LBP (i.e., non-specific LBP, radicular syndrome, specific LBP)
Care trajectories data	16. Use of advance imaging and diagnostic testing for LBP prior to the neurosurgery consult 17. Use of conservative care prior to the neurosurgery consult	16.1 Type of diagnostic test 17.1 Type of health professional seen
Consultation outcomes	18. Recommended management strategy	18.1 Proportion of discharges from the neurosurgery service 18.2 Recommendations upon discharge 18.3 Proportion of referrals made to another service 18.4 FUP interventions 18.5 Surgical indication

FUP, Follow-up; LBP, Low back pain; w, weeks.

met to discuss disagreements and to reach consensus. A third researcher (M.D.) was involved if consensus could not be reached.

2.6 Data analysis

The Shapiro–Wilk normality test was performed for all continuous variables to determine data distribution. Patient characteristics, care trajectories and consultation outcomes were summarized using frequency distributions for categorical variables, and means, medians and standard deviations for continuous variables. For between groups comparisons (i.e., appropriate vs. inappropriate referrals; pre-pandemic vs. pandemic period), Mann–Whitney test and independent Student *t* test were used for continuous variables and the chi-square test with pairwise *Z*-tests were used for categorical variables. After comparing the characteristics of appropriate and inappropriate referrals, variables that differed significantly between groups were introduced in the binomial logistic regression model using the enter method (i.e., all variables were entered in the model in a single step) to determine whether they predicted the appropriateness of referrals made to the neurosurgery service. Odds ratios (OR) and 95% confidence intervals (95% CI) were calculated and reported for each included variable. Variables that were missing in more than 20.0% of our sample were not included in logistic regression analyses. All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 18.0.0 (Armonk, NY: IBM Corp.) and considered p values <0.05 statistically significant.

3 Results

3.1 Availability of data

A total of 2,965 medical records met the inclusion criteria, of which 500 were randomly selected. Following a preliminary analysis of our random sample, 118 files had to be replaced by a random selection, since at least one of the three components used to judge the appropriateness of referrals lacked information. Socio-demographic data were available in 100% of selected files. For the MSDI, 10.0% of patients had zip codes for which no corresponding deprivation index

TABLE 2 Sociodemographic characteristics.

Characteristics	*N* (%) or mean ± SD	Missing value, *n* (%)
Age (years)	60.06 ± 15.28	-
Biological sex		
Male	262 (52.4)	-
Female	238 (47.6)	
Administrative region		
Mauricie	279 (55.8)	-
Centre-du-Québec	154 (30.8)	
Lanaudière	44 (8.8)	
Other	23 (4.6)	
Material deprivation index		
5	141 (28.2)	50 (10.0)
4	122 (24.4)	
3	91 (18.2)	
2	53 (10.6)	
1	43 (8.6)	
Social deprivation index		
5	97 (19.4)	50 (10.0)
4	62 (12.4)	
3	98 (19.6)	
2	120 (24.0)	
1	73 (14.6)	

SD, Standard deviation.

value was available. As for administrative data, the clinical priority code was not documented for 16.6% of patients. Several data pertaining to patients' clinical profiles were missing. Pain dominance and pain status were reported for 31.6 and 9.0% of the study sample, respectively, while back or leg pain intensity was only reported for 2.0% of cases. The presence or absence of red flags were not documented for 45.6% of patients. For 13.6% of the sample, none of the neurological examination components were described. The progression of symptoms and patients' medical history were not documented in 45.8 and 41.6%, respectively. While diagnostic tests performed prior to the neurosurgery consultation were reported for almost all patients, conservative treatments received were not documented for 38.2% of the sample.

3.2 Specific objective 1

The following sections outline the characteristics documented in medical files of patients referred to the CIUSSS-MCQ's neurosurgery service for a primary complaint of LBP. Proportions for each characteristic have been computed based on the total number of selected files ($N = 500$). The percentage of missing values for each variable is detailed in corresponding Tables 2–6.

3.2.1 Sociodemographic data

Table 2 presents the sociodemographic characteristics of the 500 patients included in the study. The mean age was 60.06 ± 15.28 years at the time of the initial neurosurgery consultation, and 52.4% of patients were male. More than half (55.8%) of patients were living in the administrative region of Mauricie, and 30.8% in the Centre-du-Québec, while 13.4% of patients originated from regions beyond the territory served by the CIUSSS-MCQ. More than half of our study sample (52.6%) was classified in the 4th and 5th quintiles for material deprivation (i.e., most disadvantaged categories), while 8.6% of patients fell into the first quintile (i.e., most privileged category) for this component. As for social deprivation, 31.8% of patients were ranked in the 4th and 5th quintiles, while only 14.6% fell into the most privileged category.

TABLE 3 Administrative data.

Characteristics	*N* (%)	Missing value, *n* (%)
Involvement of compensation boards		
CNESST (yes)	34 (6.8)	-
SAAQ (yes)	4 (0.8)	
Consultation period		
Pre-pandemic (< 2020-03-13)	306 (61.2)	-
Pandemic (≥ 2020-03-13)	194 (38.8)	
Delay to the neurosurgery consult (days)	Median: 50.50 IQR: 75.75	-
Priority code		
A (≤ 3 days)	5 (1.0)	83 (16.6)
B (≤ 10 days)	10 (2.0)	
C (≤ 28 days)	47 (9.4)	
D (≤ 3 months)	284 (56.8)	
E (≤ 12 months)	71 (14.2)	
Compliance with priority code		
Yes	289 (57.8)	83 (16.6)
No	128 (25.6)	
Referring clinicians		
General physician	442 (88.4)	-
Physiatrist	13 (2.6)	
Orthopedist	8 (3.6)	
Neurologist	5 (1.0)	
Other	32 (6.4)	

CNESST, Commission des normes de l'équité, de la santé et de la sécurité du travail; IQR, Interquartile range; SAAQ, Société de l'assurance automobile du Québec.

3.2.2 Administrative data

Administrative data extracted from patients' medical records are presented in Table 3. In the study sample, 61.2% of initial consultation took place before the COVID-19 pandemic outbreak in Canada. A 63.4% decrease in neurosurgery referrals for LBP was observed between the pre-pandemic and the pandemic period. Most of the neurosurgery outpatient consultation requests came from primary care physicians (88.4%), followed by medical specialists such as orthopedists (3.6%), physiatrists (2.6%), and neurologists (1.0%). The clinical priority code "D" (i.e., ≤ 3 months) was attributed to over half (56.8%) of referred patients, while the priority code "E" (i.e., ≤ 12 months) was attributed to 14.2% of the sample, and "C" (i.e., ≤ 28 days) to 9.4%. Slightly more than a quarter

TABLE 4 Clinical profiles.

Characteristics	*N* (%) or mean ± SD	Missing value, *n* (%)
Presence of red flags		
Yes	39 (7.8)	228 (45.6)
No	233 (46.6)	
Neurological status		
Motor deficits	92 (18.4)	100 (20.0)
Sensory deficits	144 (28.8)	157 (31.4)
Reflexes deficits	109 (21.8)	215 (43.0)
Pathological reflexes	10 (2.0)	391 (78.2)
Pain location		
Back (yes)	403 (80.6)	78 (15.6)
Leg(s) (yes)	407 (81.4)	35 (7.0)
Pain dominance		
Back	97 (19.4)	342 (68.4)
Leg(s)	61 (12.2)	
Pain status		
Intermittent	33 (6.6)	455 (91.0)
Constant	12 (2.4)	
Pain intensity		
Back pain	7.0 ± 2.7	491 (98.2)
Leg(s) pain	5.4 ± 3.6	495 (99.0)
Pain duration		
Acute (< 4 weeks)	4 (0.8)	33 (6.6)
Subacute (4–12 weeks)	40 (8.0)	
Chronic (> 12 weeks)	423 (84.6)	
Progression of symptoms		
Stable	34 (6.8)	229 (45.8)
Aggravation	129 (25.8)	
Improvement	108 (21.6)	
Smoking status		
Smoker	59 (11.8)	353 (70.6)
Previous history of spinal surgery		
Yes	87 (17.4)	205 (41.0)
Usage of pain medication		
Yes	247 (49.4)	205 (41.0)
Comorbidities (number)		
0–1	115 (23.0)	208 (41.6)
Multimorbidity (≥2)	177 (35.4)	
Comorbidities (type)		
Cardiovascular (e.g., HTA)	155 (31.0)	208 (41.6)
Endocrine (e.g., DB, Hypo/Hyperthyroidism)	97 (19.4)	
Urogenital (e.g., renal failure)	50 (10.0)	
Pulmonary (e.g., COPD)	47 (9.4)	
Gastrointestinal (e.g., IBS)	46 (9.2)	
Other	145 (29.0)	
Neurosurgeons' diagnoses		
Non-specific LBP	179 (35.8)	-
Radicular syndrome	304 (60.8)	
Specific LBP	9 (1.8)	
Other causes	8 (1.6)	

COPD, Chronic obstructive pulmonary disease; DB, Diabetes; HTA, Hypertension; IBS, Irritable bowel syndrome.

(25.6%) of reviewed consultations were not carried out within the timeframe prescribed by the priority code. The percentage of consultations that failed to take place within the recommended timeframe was significantly higher during the pandemic period (35.1%) than during the pre-pandemic period (19.6%). Only 7.6% of patients were entitled to compensation from the *Commission des normes, de l'équité, de la santé et de la sécurité au travail* (workers' compensation board) and the *Société de l'assurance automobile du Québec* (public automobile compensation board) in relation to their LBP.

3.2.3 Clinical profiles

Patients' clinical characteristics are detailed in Table 4. In 19.4% of medical records, patients suffered from dominant back pain, and 6.6% exhibited intermittent symptoms. Red flags were identified in 7.8% of patients. Most patients (84.6%) were experiencing chronic pain (> 12 weeks) at the time of their initial neurosurgery consultation, 28.8% had objective sensory deficits, 21.8% showed asymmetrically diminished tendon reflexes, and 18.4% had objective motor deficits. Over a quarter (25.8%) of patients presented to the neurosurgery service with deteriorating symptoms, with 21.6% of patients experiencing improvement in symptoms since the neurosurgery referral. A review of patients' medical history revealed that 17.4% had a previous history of lumbar surgery, 49.4% were using pain medication, and 11.8% were smokers. In 35.4% of cases, patients were classified as multimorbid, presenting two or more comorbidities (37), the most frequent being cardiovascular diseases (31.0%), endocrine diseases (19.4%) and urogenital disorders (10.0%) As for neurosurgeons' diagnoses, 60.8% of patients were diagnosed with a radicular syndrome, which included pain patterns consistent with lumbar radiculopathy, lumbar spinal stenosis, and neurogenic claudication. The diagnosis of non-specific LBP was attributed to 35.8% of patients included in the analysis, with the remaining suffering from specific LBP (1.8%) or experiencing symptoms unrelated to a lumbar spine disorder (1.6%) (e.g., cervical myelopathy, peripheral joints disorders, vascular disorders).

3.2.4 Care trajectories data

Detailed information regarding patients' care trajectories is provided in Table 5. Nearly all (97.0%) patients were referred for further diagnostic testing prior to their initial neurosurgery consultation, with MRI (77.4%) and CT-scan (32.6%), being the most frequently prescribed imaging procedures. Over half (56.4%) of patients received conservative treatments prior to the neurosurgery consultation, including 41.8% who received anesthetic injections, 25.6% who underwent physiotherapy treatments, and 3.4% who had seen a chiropractor.

3.2.5 Consultation outcomes

Neurosurgery consultations' outcomes are provided in Table 6. Upon initial assessment, a clear or relative (i.e., potential surgical indication if symptoms persist or worsen after conservative treatment or for clinically stable patients with persistent disabilities) spinal surgery indication was documented in 22.4% of patients. Forty-four percent of patients were discharged from the neurosurgery service, including 18.4% for whom no recommendations were documented, 11.2% who were referred for anesthetic injections, 5.4% for conservative treatments, and 3.2% to another health care professional. For patients non-surgically managed by neurosurgeons (39.8%), 13.4% were also referred for anesthetic injections, 10.6% for advanced imaging, and 7.2% for a combination of conservative treatments, advanced imaging, and anesthetic injections.

TABLE 5 History of diagnostic testing and conservative treatment.

Characteristics	*N* (%)	Missing value, *n* (%)
Diagnostic tests prior to the neurosurgery consult		
Yes	487 (97.4)	13 (2.6)
Diagnostic tests (type)		
MRI	387 (77.4)	13 (2.6)
CT-scan	163 (32.6)	
X-rays	45 (9.0)	
EMG	28 (5.6)	
Other	3 (0.6)	
Conservative care prior to the neurosurgery consult		
Yes	282 (56.4)	191 (38.2)
No	32 (6.4)	
Type of treatment		
Anesthetic injections	209 (41.8)	235 (47.0)
Physiotherapy	128 (25.6)	321 (64.2)
Chiropractic	17 (3.4)	483 (96.6)
Massage therapy	8 (1.6)	492 (98.4)
Occupational therapy	6 (1.2)	-

CT-scan, Tomodensitometry; EMG, Electromyography; MRI, Magnetic resonance imaging; X-rays, Radiographs.

TABLE 6 Outcomes of neurosurgery consultations.

Characteristics	*N* (%)	Missing value, *n* (%)
Recommended management strategy		
A. Discharge from the neurosurgery service (total)	221 (44.2)	3 (0.6)
B. Non-surgically managed by neurosurgeons	199 (39.8)	-
C. Received a clear or relative surgical indication	112 (22.4)	25 (5.0)
A. Recommendations upon discharge ($N = 221$)		
No recommendations	92 (18.4)	-
Anesthetic injections	56 (11.2)	-
Conservative care	27 (5.4)	-
Combination	33 (6.6)	-
Referral to another health professional	16 (3.2)	-
B. FUP interventions ($N = 199$)		
Imaging referral with FUP	53 (10.6)	-
Referral for anesthetic injections with FUP	67 (13.4)	-
Referral for conservative care with FUP	13 (2.6)	-
Referral for treatment combination with FUP	36 (7.2)	-
Referral to another specialist with FUP	5 (1.0)	-
Wait and see	25 (5.0)	-
C. Surgical indication ($N = 112$)		
Clear indication	62 (12.4)	25 (5.0)
Relative indication[a]	50 (10.0)	
Reluctant or refused to undergo surgery despite surgical indication	21(18.8)	-

FUP, Follow-up; LBP, Low back pain. [a]Relative surgical indication: Potential surgical indication if symptoms persist or worsen after conservative treatment or for clinically stable patients with persistent disabilities.

3.3 Specific objective 2

3.3.1 Referral appropriateness

In 80.4% of cases, referrals made to the neurosurgery department for a primary complaint of LBP during the study period were deemed inappropriate. The proportion of inappropriate referrals was similar during the pandemic period when compared to the pre-pandemic period ($p = 0.467$). Table 7 details the number of cases that failed to meet the CRDS, clinical and care trajectories criteria for a neurosurgery consultation. Regarding the CRDS criteria, 6.2% of patients presented to their initial neurosurgery consultation without the appropriate imaging (i.e., MRI or CT) or with imaging performed over 3 months prior to the consultation. For 9.7% of the study sample, patients were deemed inappropriately referred as they exhibited symptoms of acute or subacute duration. From a clinical perspective, 43.0% of patients presented pain patterns consistent with non-specific LBP, and the absence of objective neurological symptoms was reported in 28.1% of cases. Stable or improving symptoms were documented in 32.6% of patients. As for patients' care trajectories, the absence of a conservative care trial prior to the neurosurgery consultation was documented for 7.0% of patients.

3.4 Specific objective 3

3.4.1 Comparison of appropriate and inappropriate referrals

Socio-demographic profiles and the median delay to the neurosurgery consultation were comparable between inappropriately and appropriately referred patients ($p > 0.05$), except for the social deprivation index, for which a higher proportion of patients ranked in the most privileged quintile was found in the appropriate referrals group compared to the inappropriate referrals group (23.5% vs. 14.5%). As for patients' clinical profiles, we found a significantly higher proportion of patients suffering from dominant back pain in the inappropriate referrals group (22.9%) compared to the appropriate referrals group (4.2%). Progression of symptoms differed significantly between groups as the inappropriate referrals group had significantly higher proportion of patients symptomatically improved (24.9% vs. 8.4%), while the appropriate referrals group included a higher proportion of patients with deteriorating symptoms (33.7% vs. 23.6%). Inappropriate referrals group presented significantly higher proportions of patients with no objective sensory deficits (42.5% vs. 28.4%) and no objective motor deficits (64.7% vs. 47.4%). A pain pattern consistent with non-specific LBP has been described in 43.0%

TABLE 7 Referral appropriateness.

Characteristics	*N* (%)	Missing value, *n* (%)
Appropriateness		
Inappropriate	402 (80.4)	2 (0.4)
Non-compliance with CRDS referral form criteria		
Absence of appropriate or up to date (< 3 months) imaging	25 (6.2)	13 (2.6)
Acute (< 4 weeks) or subacute (4–12 weeks) pain episode	39 (9.7)	33 (6.6)
Non-compliance with clinical criteria		
Pain pattern consistent with non-specific LBP	173 (43.0)	-
Stable or improving symptoms	131 (32.6)	229 (45.8)
Absence of objective neurological symptoms	113 (28.1)	68 (13.6)
Non-compliance with care trajectories criteria		
No conservative care trial prior to the neurosurgery referral	28 (7.0)	191 (38.2)
Conservative treatment options have not been exhausted when indicated	219 (56.2)	

LBP, Low back pain.

of patients deemed inappropriately referred, while only 5.3% of patients diagnosed with non-specific LBP were deemed appropriately referred (i.e., patients for whom the predominant clinical profile was consistent with non-specific LBP but who presented intermittent neurological symptoms requiring follow-up). In regression analysis, only two variables could be investigated for inappropriate referencing since the other independent variables with a p value <0.05 exceeded the pre-established 20.0% cut-off for missing values. The absence of motor deficits ($p < 0.001$; OR 2.91; 95% CI 1.62–5.2) and being ranked in the third quintile for social deprivation ($p < 0.039$; OR 2.75; 95% CI 1.05–7.18) both appeared as predictors of inappropriate referencing to the neurosurgery service for LBP. Results of regression analyses are detailed in Supplementary File 3.

4 Discussion

This study aimed to draw a comprehensive portrait of patients referred to specialized care for LBP, to evaluate the appropriateness of referrals, and to identify the characteristics that differentiated inappropriate from appropriate referrals.

The study sample comprised a random selection of 500 patients, with a mean age of 60 years old, reflecting the age-related increase in prevalence of degenerative lumbar conditions, which account for a significant proportion of cases deemed likely to require surgical consultation (38). Our sample included similar proportions of males and females, although the overall mean prevalence of LBP is known to be higher among females than males across all age groups (39). Referrals for LBP decreased significantly between the pre-pandemic and the pandemic period, which might suggest that patients were avoiding healthcare services unless they had critical symptoms (40, 41). Most referrals (88.4%) made during the study period came from general physicians, which is consistent with Canada's healthcare delivery model, whereby patients must first be seen by a primary care provider before they can access specialized care (1). The small but noteworthy proportion (13.4%) of referrals received from administrative regions not served by the CIUSSS-MCQ may be explained, though not exclusively, by long waiting lists affecting surrounding neurosurgery services, which may prompt physicians to send multiple referrals to maximize the patient's likelihood of a timely consultation (42). Nonetheless, more than 25.0% of CIUSSS-MCQ's neurosurgery consultations for LBP during the study period were not carried out within the expected delay. This percentage is, however, lower than the provincial average which was reported at 33.0% for the year 2021–2022 (5).

Evidence-based guidelines recommend diagnostic triage to classify patients into one of three type of LBP (i.e., non-specific LBP, radicular syndrome, or specific LBP) and suggest management strategies tailored to each of these categories (28, 30–32, 43). As an example, patients diagnosed with persistent (> 4–6 months) non-specific LBP should be provided with structured patient education and multimodal conservative care, whereas a diagnosis of persistent lumbar radiculopathy usually calls for referral for further investigation (32). Diagnostic accuracy is therefore considered crucial to determine whether the patient's condition warrants further investigation or a specialist referral. A recent scoping review of systematic reviews (44) identified several clinical features with appropriate diagnostic value, and therefore, suitable for use in primary care settings for the diagnosis of LBP. Overall, dominant site of pain, pain distribution, aggravating and relieving factors, indicators of underlying spinal pathology and the presence of neurological signs should all be assessed or questioned when evaluating LBP patients (44). Various clinical characteristics are also known to predict response to surgical treatment for LBP, such as the level of disability, baseline leg pain intensity, smoking status, psychological complaints, frailty status and comorbidities, previous spinal surgeries, and patient expectations of treatment outcomes (33–36). Surprisingly, many of these variables were inconsistently documented in the CRDS referral form or in the consultation note, thus preventing the establishment of a comprehensive portrait of patients referred to the neurosurgery service for LBP. It remains to be determined whether this reflects a lack of documentation, or if these variables are being overlooked in clinical decision-making in favor of other clinical characteristics that would further inform clinical decisions. These findings are however consistent with a previous review of Canadian spine surgeons referrals (15), which demonstrated that many factors used in surgical decision-making were not routinely documented, and that most referrals to spine surgeons lacked adequate clinical information for triage. Nevertheless, we were able to determine that most of the sample suffered from chronic pain (84.6%), had undergone diagnostic testing prior to their neurosurgery consultation (97.4%), and had been diagnosed with a radicular syndrome (60.8%). Interestingly, of the 271 patients for whom progression of symptoms was documented, 60.1% exhibited stable or improving symptoms at the time of their initial neurosurgery consultation, potentially reflecting the fluctuating and self-limiting nature of LBP (45–48). These findings also support evidence-based guidelines recommendations, which advocate that patients with LBP should undergo a reasonable conservative care trial before contemplating referral to a medical specialist. Although

considered a prerequisite for surgical consultation for LBP, it could not be determined for almost 40.0% of patients whether they had received appropriate conservative treatments before seeking neurosurgery services.

Our analysis revealed that 80.4% of referrals made to the CIUSSS-MCQ's outpatient neurosurgery clinic for LBP during the study period were deemed inappropriate. Our study findings are in line with other Canadian studies, which have previously reported that between 62.0–85% of referrals to spine surgeons for LBP were inappropriate (16–19, 49). Of the 500 medical files reviewed, only 20.4% of patients were identified as surgical candidates, and of these, 18.8% were reluctant or explicitly refused any surgical options. Interestingly, a study by Mayman et al. (18) also reported a small but significant proportion (13.0%) of referred LBP patients who expressed reluctance to undergo surgery regardless of its indication. This reinforces the importance of promoting shared-decision making, in which patients and providers work together to find a mutually agreed-upon treatment plan, as this approach is known to improve quality of care delivery, and to reduce the overuse of surgical procedures (50, 51). Over 40.0% of LBP patients referred to the neurosurgery service during the study period were discharged upon initial assessment, most of them after being advised to initiate or pursue conservative treatments or after being referred for anesthetic injections. Of the 199 patients non-surgically managed by the neurosurgeons, 87.4% were referred for further diagnostic or therapeutic interventions before undergoing further neurosurgical follow-up, suggesting that non-surgical options had not been fully exhausted for these patients. The high proportion of patients referred for anesthetic injections, commonly seen as a therapeutic modality, could also be explained by evidence supporting the ability of spinal injections to predict surgical outcomes (52, 53). In a retrospective analysis of medical files data from patients with LBP referred to the neurosurgery service of 3 European hospitals, Debono et al. (54) raised a similar issue, identifying a significant proportion of patients inappropriately referred who had not properly been treated before being referred to the neurosurgery service or whose imaging tests were incomplete.

Inappropriate referrals were characterized by higher proportion of patients symptomatically improved, presenting a back-dominant chief complaint, exhibiting no objective neurological symptoms, and diagnosed with non-specific LBP. The multivariate analysis also suggested that the absence of motor deficits was associated with a nearly three-fold increase in the odds of being inappropriately referred. In a retrospective review of spine referrals sent to a group of ten neurosurgeons in Edmonton, Canada, over a 3-year period (2007–2009), Deis and Findlay (49) reached similar conclusions, finding that most inappropriate referrals were based on no mention of leg symptoms or signs of neurological deficits rather than on the lack of concordance between lumbar spine imaging findings and the patient's clinical profile. Debono et al. (54) reported similar results, noting that only 5.1% of inappropriate referrals to the neurosurgery service for LBP were attributed to radioclinical discordance. Additionally, a retrospective study of new referrals for LBP to the neurosurgery service of an Australian public hospital found that there was no significant association between MRI findings and the likelihood of undergoing surgery (55). This is of particular interest as it calls into question the value of imaging findings as a component that can serve to justify a referral to the neurosurgery service. In the present study, imaging results were more frequently reported by referring clinicians than any other type of clinical information, while documentation of pain predominance, level of disability, and neurological findings was often overlooked. However, it is known that up to 90.0% of patients over the age of 50 will have evidence of age-related degenerative changes without definite nerve root compression (56) on their lumbar spine MRI or CT reports, and that these imaging findings may even be seen in asymptomatic individuals (57). Overreliance on imaging procedures could, however, be explained by the constraints imposed by the CRDS's referral form, which explicitly requires that patients seeking referral for the neurosurgery service provide an imaging report dated less than 3 months. In addition to potentially increasing the importance placed on imaging results, this requirement also raises a potential issue in the referral process. Indeed, given the extended wait times associated with priority codes D and E, it appears likely that patients assigned to theses codes may struggle to comply with this criterion, thus questioning its relevance. This reinforces evidence-based recommendations according to which decision-making should be informed first and foremost by the patients' clinical profile, and that routine imaging should be avoided and used only in the presence of potential indication for surgical consultation. Furthermore, this also underlines the need to reinforce continuing medical education for primary care providers, focusing on the clinical criteria justifying spinal imaging or referral to a spine surgeon.

Several strategies to improve the appropriateness of referrals to spine surgeons for LBP have been studied. Though currently not implemented on Quebec's territory, triage interventions have shown promising results in managing LBP patients. Two retrospective analyzes of new outpatient referrals for LBP (17, 19) showed that a multidisciplinary triage process led by MSK experts, also known as the *Saskatchewan Spine Pathway,* significantly reduced MRI utilization and inappropriate referrals to spine surgeons compared to the conventional referral process (i.e., patients referred directly by primary physicians). A retrospective audit of data from three Australian public hospital emergency departments (ED) showed that patients with LBP managed by advanced MSK physiotherapists had shorter ED wait times and length of stay and were more effectively discharge compared with patients seen by ED doctors and nurse practitioners (58). Another retrospective review of all new patients visits to eight orthopedic surgeons at a large academic hospital in New York also revealed that patients triaged by MSK healthcare providers were more likely to undergo surgery (59). Isolated surgical decision-making is known to result in suboptimal treatment recommendations (60). Although more research is needed in the field, multidisciplinary approaches, drawing on MSK healthcare providers expertise, seem more likely to improve the selection of surgical candidates, while providing other patients with appropriate nonoperative treatment options. In an in-dept review and critical analysis, Foster et al. (61) evoke compelling arguments for considering other models of first-contact MSK care, notably ones whose point of entry in healthcare are MSK experts such as physiotherapists or chiropractors. Indeed, evidence suggest that access to primary care services run by MSK specialists is associated with higher improvements in patients' outcomes, a reduction in healthcare use, and with fewer days off work related to back pain (62, 63).

4.1 Strengths and limitations

This study stands out for its comprehensive examination of patients referred to specialized care for LBP, providing a detailed

understanding of clinical profiles and referral patterns of patients most likely to benefit from surgical consultation. This is also the first study to explore the appropriateness of referrals to specialized care for LBP in the context of a publicly funded healthcare system operating a CWL, offering insight into the challenges within the existing healthcare infrastructure. Despite a rigorous methodology, this study has some limitations. Although the study provides a detailed description of patients referred to specialized care for LBP and examines referrals appropriateness, its generalizability is limited as it was performed in a single administrative region. The CIUSSS-MCQ covers a vast territory (64) and provides services to diverse populations, including remote and indigenous communities (65). These populations may face additional challenges in terms of availability and accessibility of healthcare resources. Consequently, these results may not be generalizable to large urban centers. The study findings are also limited by the quality of data collected. Indeed, key information was often not documented in medical files, and most information was hand-written, which may have hampered data interpretation. Considering that some medical files were either incomplete, or even had to be excluded for lack of information, it is important to acknowledge the potential presence of selection bias, as the characteristics of the patients who were not included in the analysis may differed from those in our study sample. Several variables could also not be included in the binomial regression model, most of them known for their appropriate diagnostic value or their ability to predict surgical outcomes. Further studies are needed to determine whether these would predict the appropriateness of referrals made to the neurosurgery service. Using a complementary qualitative approach could help fill the gaps in chart documentation and provide a better understanding of both the factors that prompted referrals to medical specialists for LBP, and of the criteria considered by neurosurgeons when selecting the appropriate management strategy.

5 Conclusion

Through a comprehensive analysis of socio-demographic, administrative, and clinical data, this retrospective chart review echoes the findings of previous studies, suggesting that a significant proportion of patients are inappropriately referred to specialized care for a primary complaint of LBP. The generalizability of the study findings is however limited, as the data were sourced from a single administrative region, and several incomplete medical files had to be excluded from the analysis. Back-dominant chief complaints, the absence of objective neurological deficits, and a non-specific LBP diagnosis were identified as characteristic features of inappropriate referrals. While evidence-based guidelines advocate for a thorough clinical assessment for effective diagnostic triage, this analysis unveiled the absence of key clinical information in referral forms and consultation notes, emphasizing the urgent need to enhance documentation practices. Reliance on imaging findings as a criterion for neurosurgery referral was also questioned, as it seemed to further influence clinical decisions to the detriment of factors known to predict surgical outcomes. This study also suggests that an increased focus should be placed on multidisciplinary approaches that enable LBP patients to get a timely access to the appropriate healthcare provider. Collaborative efforts involving MSK experts in triaging patients with LBP have been shown to improve the selection of surgical candidates, while precluding the use of ineffective diagnostic and therapeutic approaches. However, further research is needed to assess the impact of those innovative strategies within Quebec's healthcare delivery model.

Data availability statement

The data analyzed in this study is subject to the following licenses/restrictions: the raw data supporting the conclusions of this article will be made available by the authors, without undue reservation, upon reasonable request. Requests to access these datasets should be directed to JM, janny.mathieu@uqtr.ca.

Ethics statement

The studies involving humans were approved by the Centre intégré universitaire de santé et de services sociaux de la Mauricie-et-du-Centre-du-Québec (CER-2022–600-838) and the Université du Québec à Trois-Rivières (CER-22-288-10.04) Research Ethics Boards. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required from the participants or the participants' legal guardians/next of kin in accordance with the national legislation and institutional requirements.

Author contributions

JM: Formal analysis, Methodology, Writing – original draft, Conceptualization, Project administration, Validation, Visualization. M-ÈR: Investigation, Writing – review & editing. C-ÉC: Validation, Writing – review & editing. MD: Conceptualization, Supervision, Writing – review & editing. A-AM: Conceptualization, Funding acquisition, Supervision, Writing – review & editing, Validation.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

The author(s) declared that they were an editorial board member of Frontiers, at the time of submission. This had no impact on the peer review process and the final decision.

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Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fmed.2023.1292481/full#supplementary-material

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Prevalence of low back pain and disability among secondary school teacher in the eastern province of the Kingdom of Saudi Arabia: a cross-sectional analytical study

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Introduction: Lower back pain is common worldwide and affects over 600,000 people annually, including teachers. The study aimed to investigate the prevalence of low back pain and disability among secondary school teachers in the Eastern Province of the Kingdom of Saudi Arabia.

Materials and methods: This cross-sectional study included secondary school teachers in the eastern province of Saudi Arabia. 34 schools were selected using a multistage stratified sampling approach. Teachers were allotted randomly and proportionally to each school. Data was collected by anonymous questionnaire having three elements: sociodemographic and health-related questions, the Standardized Nordic Questionnaire, and the Oswestry Low Back Pain Disability Questionnaire. The anthropometric data was also included. Both unadjusted and adjusted logistic regression analyses were performed.

Results: A total of 601 teachers participated in the study with 62.56% reported low back pain. The overall mean age was 40.31 ± 8.13 years. The male-to-female ratio was similar. Back pain was significantly higher among females than males (73.36 and 51.52%, respectively). Additionally, back pain will significantly increase when stress levels and the number of classes increases. A positive correlation was found between age with low back pain ($p = 0.001$). There was minimal disability in 64.63% of the 376 teachers who reported low back pain, moderate disability in 29.79%, and severe disability in 4.79%, and only three (0.8%) were considered crippled. Females were more frequently seen in moderate and crippled categories, and perceived stress levels generally increased mean disability scores. Age and female gender were revealed to be significant predictors of low back pain by logistic regression (adjusted odds ratio [OR] = 1.04, 95% confidence interval [CI] = 1.02–1.07) and (adjusted OR = 2.11, 95% CI = 1.45–3.05), respectively. The number of classes per week was also a significant predictor.

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Conclusion: This study adds to the epidemiological evidence that reveals a high prevalence of low back pain and disability among teachers. Identified risk factors in this study may also reinforce the importance of setting different interventions and preventive measures to reduce lower back pain risk.

KEYWORDS

low back pain, disability, teachers, work related, occupational health, epidemiology

1 Introduction

Lower back pain (LBP) is characterized as pain or discomfort between the costal margins and the inferior gluteal folds, with or without leg pain and it may arise from a single traumatic event or it may develop gradually over time as a result of microtrauma caused by repetitive activity. LBP is one of the most frequently reported symptoms in primary care settings worldwide. Most patients seek medical attention for lower back pain because of the obvious limitations it imposes on their daily lives and how it significantly impairs their overall occupational performance. Furthermore, low back pain is one of the most prevalent medical conditions reported in working individuals. One study indicated that up to 80% of individuals experienced back pain at some point in their life (1, 2).

According to the National Institute for Occupational Safety and Health (NIOSH), back disorders affect more than 600,000 employees each year in the United States of America (USA), costing approximately $50 billion annually. Back injuries and disorders are expected to increase in frequency and economic impact on the workforce over the next several decades as the average lifespan of the workforce increases and healthcare costs rise (1).

A study published in 2020 aimed at estimating the burden of LBP globally between the years 1990–2017 concluded that there was a rising trend in years lived with disability (YLDs) attributed to LBP during that time, stating that the global YLDs back in 1990 was 42.5 million, which increased to 64.9 million by 52.7% in 2017 (3).

Teachers are more prone to this condition and its effects. Many studies have shown that a substantial percentage of teachers suffer from low back pain (4–8). Poor posture, prolonged sitting while working on students' homework and preparing for lessons are some of the factors that contribute to low back discomfort in teachers. LBP results in poorer life quality, higher absenteeism, lower labor productivity, and early retirement. Furthermore, LBP has a significant financial impact on the healthcare system (7, 9).

A study conducted in Chile in the year 2021 concluded that there indeed was a strong association between teachers' reporting a lower quality of life and having musculoskeletal pains or disorders acquired through teaching or at the workplace. Two additional studies conducted in 2022 found that female teachers were more prone to this pain-induced reduction in the quality of life (10–12).

Over the last 10 years, several studies have been conducted on the prevalence of LBP among teachers, both globally and in Saudi Arabia. In 2013, Darwish et al. conducted a study in Saudi Arabia to examine the prevalence of Musculoskeletal Pain Disorders among female Saudi secondary school teachers. In Darwish et al.'s study, the prevalence of musculoskeletal pain disorders was 79.17%. The main point of pain was the lower back (63.8%). Another cross-sectional study conducted among secondary school teachers in Hail, Saudi Arabia found that the prevalence of low back pain was 62.55%, making it the most frequent musculoskeletal disorder (13, 14).

A comprehensive review, which included 11 relevant studies with a total of 5,805 schoolteachers to evaluate the pooled prevalence and related variables of low back pain among teachers in Africa, revealed a high prevalence of back pain, indicated to be 59.0% (15).

Up to now, a number of studies have examined the association between different variables and low back pain. The relationship between engaging in physical activity and musculoskeletal disorders has been investigated in Grabara study. The author also noticed that teachers with more musculoskeletal disorders—including back pain—were less likely to participate in both vigorous and overall physical activity than those with fewer painful body parts. The lower back was also shown to be the most frequently affected area and to have the highest average pain intensity (16).

Another risk factor for musculoskeletal disorder -including LBP- among teaching professionals that was proposed by a study published in 2018 is the level of perceived stress, as the study focused on the mind–body connection concluding that occupational stress could in fact lead to the development of physical symptoms, such as low back pain (17).

Some work-related factors such as the number of hours taught while standing, the duration of sitting teaching, working on a head-down posture, and chairs with inadequate back support can increase the odds of developing musculoskeletal disorders including back pain as found in study conducted on teachers in Machakos County, Kenya (18).

A study by Bontrup et al. (19) examined the relationship between sedentary office workers' sitting behavior and low back pain. He noticed a stronger correlation between sitting behavior and chronic low back pain (LBP) than for with acute pain or disability. This finding may be explained by the fact that people with chronic LBP are more aware of pain-free sitting positions and pain-provoking movements than people with acute pain.

To our knowledge, few recent studies have been conducted on our population of interest to study the prevalence of LBP, its related disabilities and related risk factors. Therefore, the current study aimed to investigate the prevalence and level of disability of low back pain among secondary school teachers of both genders in the eastern region of Saudi Arabia, considering several lifestyle and work-related factors as well as a number of demographic variables.

2 Methodology

2.1 Study design and participants

This cross-sectional study was conducted between January and June 2022. It included teachers from both government and private

secondary schools in the Eastern Province of the KSA. The inclusion criteria were male and female teachers aged 22–62 years. Non-Saudis and those with nonteaching responsibilities, such as administrators, were excluded. Participants with histories of back injury, surgery, or inflammation were excluded.

According to the Ministry of Education (MoE), the total number of teachers in secondary schools in the Eastern province was 5,752. Using this number as the total population and the prevalence of 57.3% of the estimated LBP among teachers (20), with a precision of 4% and an alpha level of 0.05, the estimated minimum required sample size was 533. The Eastern Province is home to three large districts: Dammam, Khobar, and Dhahran. Seventeen schools from Dammam and another 17 from both Khobar and Dhahran were chosen using a multistage stratified sampling technique. The total number of teachers was determined through a proportional allocation. Once the school and the number of teachers within that school were determined, a list of all teachers was created and numbered from 1 to n. A simple random sampling technique was used to select teachers for participation.

This study was approved by the Institutional Review Board of the Imam Abdulrahman Bin Faisal University (IRB-2021-01-453). Written permission from the MoE was obtained before starting the data collection process. Individual written informed consent was a prerequisite for data collection. All questionnaires were anonymous and the collected data were kept private and used only for the purposes of this study. To assess the acceptability and applicability of the methods, a pilot study was conducted with 20 teachers who were excluded from the sample.

Data were collected by senior medical students trained and supervised by two occupational physicians. Three elements of the questionnaire, namely sociodemographic and health-related questions, the Standardized Nordic Questionnaire, and the Oswestry Low Back Pain Disability Questionnaire, were included in the training (21–23). The training also included anthropometric data (height and weight of the participants). The questionnaires were reverse-translated to ensure maximum quality and no misunderstanding.

2.2 Questionnaires

2.2.1 Sociodemographic, health and work-related questions

This section included questions on sociodemographic variables such as age, sex, and marital status. Other questions included health-related lifestyle habits such as smoking, perceived levels of physical activity, and perceived stress. Work-related questions included questions on teaching years, number of classes per week, type of school, standing status during teaching, and the subjects taught (7, 21, 24).

2.2.2 Standardized Nordic Questionnaire

This study used valid and reliable low back pain screening and analysis questions from the Standardized Nordic Questionnaire. The focus was primarily on the symptom duration of low back trouble (ache, pain, or discomfort) in the past, including the last 7 days, the past year, and the past lifetime. A response of "yes" to any question was coded as a "yes," whereas a "no" response to all questions was coded as a "no" (21).

2.2.3 Oswestry Low Back Pain Disability Questionnaire

The Oswestry Low Back Pain Disability Questionnaire is a valid and reliable tool for assessing persistent functional impairment caused to low back pain. It consists of 10 sections including six statements on how back pain affects each of the following areas: pain severity, lifting, personal care, walking, sitting, sex life, standing, social life, sleeping, and travel. The total score was computed and converted to a percentage that could then be interpreted based on pre-specified cut-off points as follows: 0–20% minimal disability, 20.1–40% moderate disability, 40.1–60% severe disability, and 60.1–80% crippled. Participants with scores >80% were considered bedridden or had subconsciously exaggerated their symptoms (23).

2.2.4 Anthropometric data

The participants' anthropometric data, including body height (m) and weight (kg), were measured at the time of data collection using four digital scales, with their consent. The Medical Digital Column Scales by Charder Electronic Co, model MS4900 and MS4970, were used. The scales were calibrated to ensure high-quality measurements. Using these measurements, participants were then classified to categories of body mass index (BMI) as follows; underweight less than 18.5 kg/m^2, normal weight is 18.5–24.9 kg/m^2, overweight is 25–29.9 kg/m^2, and obese if BMI was above 30 kg/m^2 (25).

2.2.5 Statistical analysis

The main outcome was the presence of low back pain during the past 12 months, and the secondary outcome was the disability in teachers who had low back pain. Disability was computed by summing all scores and categorizing them according to the questionnaire criteria. Continuous variables are described as means ± standard deviation and categorical variables as frequencies and percentages. Chi-square and Fisher's exact tests were used to assess bivariate associations between categorical variables, whereas t-tests and analysis of variance (ANOVA) were used to assess associations with continuous variables. *Post hoc* analysis was used for significant associations with the Sidak correction due to assumptions of independence. The choice of inclusion of variables into the regression model was based on Directed Acyclic Graph of relationships between explanatory variables and the outcomes. Unadjusted and adjusted binary logistic regression analyses were performed to compute the odds ratios (ORs) for the odds of low back pain and their accompanying 95% confidence intervals (CIs). The level of significance of 5% was considered appropriate. Model fit diagnostics were performed to ensure a good model fit, and the model than minimized both the AIC and BIC was used. Stata statistical software version 15 was used for all analyses.

3 Results

3.1 Sociodemographic, health and teaching related characteristics

A total of 601 teachers participated in the study. The overall mean age was 40.31 ± 8.13 years. The male-to-female ratio was similar. Approximately 82% of the total sample were married, whereas only 1.33% were widowed. Regarding obesity, 38.9% were overweight and 33.9% were obese. Chronic conditions were present in 25.8% of all

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teachers, and 3.16% were current smokers. Only 38.4% of the participants reported exercising regularly. Examining teaching characteristics, most participants taught science subjects (23.96%), followed by language and humanities (22.8 and 22.63%, respectively). Over half of the teachers taught between 11 and 20 classes per week, and the majority belonged to private schools. Only 16.3% of participating teachers had additional jobs (Table 1).

3.2 Low back pain symptoms

Table 2 describes the presence and symptoms of low back pain according to the Nordic questionnaire. Of the total number of teachers, 62.56% reported low back pain. Of those, 25.5% had been previously hospitalized due to that pain and 7.7% had to change the nature of their jobs. Among those with back pain, 16.49% reported that they experienced pain on a daily basis during the past 12 months. Back pain had reduced work activity in 63.56% of complainers, whereas leisure activity was reportedly reduced in 62.9% of complainers. Additionally, 12.5% of those with back pain reported that it had prevented them from usual work for more than 30 days during the past 12 months. Over 38% had visited a doctor due to the pain, and 51.6% reported that the pain had occurred within the 7 days preceding their participation in this study.

3.3 Associations between low back pain, sociodemographic, health and teaching characteristic

The results of the bivariate analyses have showed that a highly statistically significant difference was observed between age and presence of low back pain ($p < 0.001$). Back pain was also significantly higher among females than males (73.36 and 51.52%, respectively). Marital status was associated with back pain; participants who were currently married or had a history of marriage tended to report low back pain more often than single participants ($p = 0.001$). There was also a statistically significant difference in chronic conditions and regular exercise, where participants who had reported a chronic condition and those who did not exercise reported low back pain more than their counterparts (70.32 and 65.95%, respectively) (p-value = 0.02 and p- value = 0.03 respectively). For perceived stress, a highly significant difference was observed, which reflected an increase in the reporting of back pain with increasing stress levels (p-value <0.001). No statistically significant difference were observed between the BMI and smoking status (Table 3).

3.4 Associations between disability due to low back pain, sociodemographic, health and teaching characteristics

Table 4 presents a subgroup analysis of teachers who reported low back pain and level of disability according to the Oswestry Low Back Pain Disability Questionnaire. Among the 376 teachers who reported low back pain, there was minimal disability (64.63%), moderate disability (29.79%), and severe disability (4.79%); only three (0.8%) were considered crippled. Age was highly associated with the disability

TABLE 1 Sociodemographic, health and teaching related characteristics of study sample.

Characteristic	*N* (%) 601 (100.00)
Age (μ, SD)	40.31 (08.13)
Gender	
Males	297 (49.42)
Females	304 (50.58)
Marital status	
Single	75 (12.48)
Married	495 (82.36)
Divorced	23 (03.83)
Widowed	8 (01.33)
Body Mass Index (kg/m^2)	
Underweight	14 (02.33)
Normal weight	149 (24.79)
Overweight	234 (38.94)
Obese	204 (33.94)
Chronic conditions	
No	446 (74.21)
Yes	155 (25.79)
Perceived stress	
Never	122 (20.30)
Sometimes	308 (51.25)
Often	91 (15.14)
Always	80 (13.31)
Smoking status	
Non-smoker	524 (87.19)
Ex-smoker	58 (09.65)
Current smoker	19 (03.16)
Regular exercise	
No	370 (61.56)
Yes	231 (38.44)
Teaching area	
Languages	137 (22.80)
Humanities and social sciences	136 (22.63)
Sciences	144 (23.96)
Mathematics	79 (13.14)
Computer and applied sciences	66 (10.98)
Others	39 (06.49)
Number of classes per week	
≤ 10 classes	80 (13.31)
11 ≤ 20 classes	320 (53.24)
> 21 classes	201 (33.44)
Type of school	
Private	396 (66.67)
Governmental	198 (33.33)

(Continued)

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TABLE 1 (Continued)

Characteristic	*N* (%) 601 (100.00)
Work an extra job	
No	503 (83.69)
Yes	98 (16.31)
Had low back trouble?	
No	225 (37.44)
Yes	376 (62.56)

score, and an increase in age was observed with an increase in severity ($p = 0.002$) (Significant p for trend). A statistically significant difference in the disability score was observed with sex, where females were seen more frequently in the moderate and crippled categories ($p = 0.005$). In addition, the number of teachers in private schools was higher than their counterparts in the moderate, severe, and crippled disability categories (34.09, 5.68, and 1.14%, respectively) ($p = 0.006$). No other significant associations were observed.

Figure 1 shows the mean disability scores for males and females according to the level of perceived stress. In males, a clear and gradual increase in the mean disability score was observed with increasing levels of perceived stress. A general increase was also observed in women.

3.5 Multivariable associations and odds of low back pain

In the simple logistic regression model, age, sex, perceived regular exercise, number of classes and perceived stress were statistically significant. The multiple logistic regression has found that age was a significant predictor of low back pain after adjusting for all other variables (adjusted OR = 1.04, 95% CI = 1.02–1.07). Similarly, sex was a significant predictor; a more than 2-fold increase in odds for females was observed compared to males (adjusted OR 2.11, 95% CI = 1.45–3.05). The number of classes given by participating teachers per week was also a significant predictor, teachers who had 10 to 20 classes per week was higher than that of teachers who had less than 10 classes per week (adjusted OR = 1.77, 95% CI = 1.05–3.00). Moreover, the odds were even greater for teachers who had over 21 classes per week when compared to teachers who had less than 10 classes (adjusted OR = 2.09, 95% CI = 1.19–3.68). A significantly increased odds was observed for teachers who reported stress compared to those who had never reported stress (adjusted OR = 2.1, 95% CI = 1.12–3.93), the odds was similar for those who had perceived stress all the time (95% CI = 2.07, 95% CI = 1.05–4.07) (Table 5).

4 Discussion

In this study, the presence of LBP and its risk factors in the previous 12 months was investigated as a primary outcome among teachers of both sexes at secondary schools in Saudi Arabia's eastern region, and as a secondary outcome to determine the score of disability among those who had reported low back pain.

TABLE 2 Low back pain symptoms among participating teachers.

Standardized Nordic questions	*N* (%) 376 (100.00)
Had been hospitalized?	
No	280 (74.47)
Yes	96 (25.53)
Had to change job?	
No	347 (92.29)
Yes	29 (07.71)
Total length of time of low back pain in the past 12 months?	
0 days	21 (05.59)
1–7 days	130 (34.57)
8–30 days	69 (18.35)
More than 30 days, but not everyday	94 (25.00)
Everyday	62 (16.49)
Reduced work activity in the past 12 months?	
No	137 (36.44)
Yes	239 (63.56)
Reduced leisure activity in the past 12 months?	
No	138 (37.10)
Yes	234 (62.90)
Total length of time of low back pain prevented usual work in the past 12 months?	
0 days	92 (24.47)
1–7 days	179 (47.61)
8–30 days	58 (15.43)
More than 30 days	47 (12.50)
Seen a doctor in the past 12 months?	
No	232 (61.70)
Yes	144 (38.30)
Had low back pain during the last 7 days?	
No	182 (48.40)
Yes	194 (51.60)

Analysis of the data obtained from the surveys showed that 62.56% of the participating teachers had experienced lower back pain at least once in the last 12 months. These results with high prevalence agree with those obtained by Raizah et al. and Abdulmonem et al. (8, 13, 14, 26, 27). The study by Darwish et al. (13), conducted among the secondary school female teachers in the eastern province, concluded that 63.8% of them reported that the lower back was the most common site of pain they experienced, which is very close to the 62.56% reported in our study. The results in the same culture suggest that a few specific factors, such as teaching classes, long work hours, and high levels of perceived stress at work, may have significant effects (17).

However, this result differs from those of certain studies, such as a longitudinal study on secondary school teachers in Malaysia, which

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TABLE 3 Associations between self-reported low back pain and sociodemographic, health and teaching characteristics.

Characteristics	Presence of low back pain		*p*-value
	Absent 225 (37.44)	Present 376 (62.56)	
Age (μ, SD)	38.4 (08.4)	41.5 (07.7)	< 0.001*
Gender			< 0.001**
Males	144 (48.48)	153 (51.52)	
Females	81 (26.64)	223 (73.36)	
Marital status			0.001***
Single	41 (54.67)	34 (45.33)	
Married	176 (35.56)	319 (64.44)	
Divorced	8 (34.78)	15 (65.22)	
Widowed	0	8 (100.00)	
Body Mass Index (kg/m^2)			0.37**
Underweight	6 (42.86)	8 (57.14)	
Normal weight	64 (42.95)	85 (57.05)	
Overweight	81 (34.62)	153 (65.38)	
Obese	74 (36.27)	130 (63.73)	
Chronic conditions			0.02**
No	179 (40.13)	267 (59.87)	
Yes	46 (29.68)	109 (70.32)	
Perceived stress			< 0.001**
Never	62 (50.82)	60 (49.18)	
Sometimes	122 (39.61)	186 (60.39)	
Often	23 (25.27)	68 (74.73)	
Always	18 (22.50)	62 (77.50)	
Smoking status			0.21**
Non-smoker	190 (36.26)	334 (63.74)	
Ex-smoker	25 (43.10)	33 (56.90)	
Current smoker	10 (52.63)	9 (47.37)	
Regular exercise			0.03**
No	126 (34.05)	244 (65.95)	
Yes	99 (42.86)	132 (57.14)	
Teaching area			0.21**
Languages	46 (33.58)	91 (66.42)	
Humanities and social sciences	45 (33.09)	91 (66.91)	
Sciences	54 (37.50)	90 (62.50)	
Mathematics	37 (46.84)	42 (53.16)	
Computer and applied sciences	30 (45.45)	36 (54.55)	
Others	13 (33.33)	26 (66.67)	
Number of classes per week			0.03**
≤ 10 classes	40 (50.00)	40 (50.00)	
11 ≤ 20 classes	118 (36.88)	202 (63.12)	
> 21 classes	67 (33.33)	134 (66.67)	
Type of school			0.004**
Private	132 (33.33)	264 (66.67)	
Governmental	90 (45.45)	108 (54.55)	
Work an extra job			0.94**
No	188 (37.33)	315 (62.62)	
Yes	37 (37.76)	61 (62.24)	

*p-value obtained from a *T*-test.
**p-value obtained from Chi-squared tests.
***p-values obtained from Fisher's exact test.

found a prevalence of 44% (28). The differences could be explained by the type of study and differences in ethnicity.

According to a national study on employees in the US, 10.7% of those with regular and severe LBP and 6.1% of those with any LBP stopped working, changed jobs, or significantly modified their work activities in the previous 3 months as a result of their LBP (29).

In the current study, back pain decreased work activity in 63.56% of complainers, while leisure activity was reduced in 62.9%, adding to the fact that 7.7% of those who complained had to change the nature of their jobs. These findings show a significant burden and negative impact of back pain among teachers, which might impair work performance, and are corroborated by a World Health Organization report. Low back pain is the primary cause of the total burden of musculoskeletal diseases and is responsible for 7.4% of all years lived with disability (YLDs) worldwide (30).

The results of the present study showed, the difference between men and women, with women reporting LBP more frequently than men. These results are consistent with those reported by Althomali et al. and Erick et al. However, other studies did not reveal any significant differences between men and women (6, 7, 14, 28, 31, 32). Notably, this trend of a higher prevalence of lower in women is present worldwide, as confirmed by a systematic review published in 2011 (32). It has been suggested that women may report pain at a higher rate than men due to factors such as lower physical strength, a longer work time, or that male teachers exercised more frequently than female teachers (7, 14, 32).

According to the results of the current study, age has been found to be a significant predictor of low back pain. This result is in line with that of Erick et al., who also found a significant correlation between low back pain and aging. The possibility that they spent more years teaching as they grew older could help to explain this result. People's muscle mass steadily declines with age, their connective tissue loses its elasticity, and the cartilage between their joints thins (7, 33).

Some studies have linked irregular exercise to low back pain (5, 16, 26). In fact, after performing a logistic regression, our study did not clearly demonstrate any association between irregular exercise to low back pain which correlates with the results of the study by Zamri and Yue (6, 28). This indicates that to obtain more informative findings, we need to ask more focused questions on the types and lengths of exercises.

As for occupation-related risk factors, the stressful nature of the occupation had an undeniable adverse impact on the health of the participants, making them more prone to LBP and more exposed to occupational stressors, as statistically proven in our study as well as in a study published by Bogaert et al. (34) supporting this mind–body connection, highlighting the importance of teachers' mental health and their reflection on their physical state of health, many of which

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TABLE 4 Subgroup analyses of disability among teachers with self-reported low back pain.

Characteristic	Minimal 0–20% 243 (64.63)	Moderate 21–40% 112 (29.79)	Severe 41–60% 18 (4.79)	Crippled 61–80% 3 (0.8)	*p*-value
Age (μ, SD) ‡	40 (8.0)	43 (7.0)	45 (6.0)	45 (1.0)	0.002*
Gender					0.005**
Males	114 (74.51)	30 (19.61)	8 (05.23)	1 (00.65)	
Females	129 (57.85)	82 (36.77)	10 (4.48)	2 (00.9)	
Marital status					0.64**
Single	23 (67.65)	11 (32.35)	0	0	
Married	208 (65.2)	93 (29.15)	15 (04.7)	3 (0.94)	
Divorced	7 (46.67)	6 (40.0)	2 (13.33)	0	
Widowed	5 (62.5)	2 (25.0)	1 (12.5)	0	
Body Mass Index (kg/m^2)					0.49**
Underweight	7 (87.5)	1 (12.5)	0	0	
Normal weight	51 (60.0)	31 (36.47)	2 (2.35)	1 (1.18)	
Overweight	102 (66.67)	39 (25.49)	10 (6.54)	2 (1.31)	
Obese	83 (63.85)	41 (31.54)	6 (4.62)	0	
Chronic conditions					0.07**
No	182 (68.16)	71 (26.59)	11 (4.12)	3 (1.12)	
Yes	61 (55.96)	41 (37.61)	7 (6.42)	0	
Perceived stress					0.20**
Never	48 (80.00)	11 (18.33)	1 (1.67)	0	
Sometimes	123 (66.13)	53 (28.49)	9 (4.84)	1 (0.54)	
Often	38 (55.88)	25 (36.76)	4 (5.88)	1 (1.47)	
Always	34 (54.84)	23 (37.1)	4 (6.45)	1 (1.61)	
Smoking status					0.68**
Non-smoker	213 (63.77)	102 (30.54)	16 (4.79)	3 (0.90)	
Ex-smoker	23 (69.7)	9 (27.27)	1 (3.03)	0	
Current smoker	7 (77.78)	1 (11.11)	1 (11.11)	0	
Regular exercise					0.17**
No	155 (63.52)	79 (32.38)	9 (3.69)	1 (0.41)	
Yes	88 (66.67)	33 (25.0)	9 (06.82)	2 (1.52)	
Teaching area					0.95**
Languages	58 (63.74)	27 (29.67)	5 (5.49)	1 (1.1)	
Humanities and social sciences	61 (67.03)	23 (25.27)	5 (5.49)	2 (2.2)	
Sciences	56 (62.22)	30 (33.33)	4 (4.44)	0	
Mathematics	24 (57.14)	15 (35.71)	3 (7.14)	0	
Computer and applied sciences	25 (69.44)	10 (27.78)	1 (2.78)	0	
Others	19 (73.08)	7 (26.92)	0	0	
Number of classes per week					0.21**
≤ 10 classes	30 (75.0)	9 (22.5)	1 (2.50)	0	
11 ≤ 20 classes	130 (64.36)	63 (31.19)	6 (2.97)	3 (1.49)	
> 21 classes	83 (61.94)	40 (29.85)	11 (08.21)	0	
Type of school					
Private	156 (59.09)	90 (34.09)	15 (5.68)	3 (1.14)	0.006**
Governmental	84 (77.78)	21 (19.44)	3 (2.78)	0	

(Continued)

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TABLE 4 (Continued)

Characteristic	Minimal 0–20% 243 (64.63)	Moderate 21–40% 112 (29.79)	Severe 41–60% 18 (4.79)	Crippled 61–80% 3 (0.8)	*p*-value
Work an extra job					0.21**
No	202 (64.13)	98 (31.11)	13 (4.13)	2 (0.63)	
Yes	41 (67.21)	14 (22.95)	5 (8.2)	1 (1.64)	

‡Significant *p* for trend (< 0.001).
**p*-value obtained from an ANOVA – *Post hoc* analysis shows a significant difference between minimal and moderate disability (*p*-value = 0.03).
***p*-value obtained from Fisher's exact test.

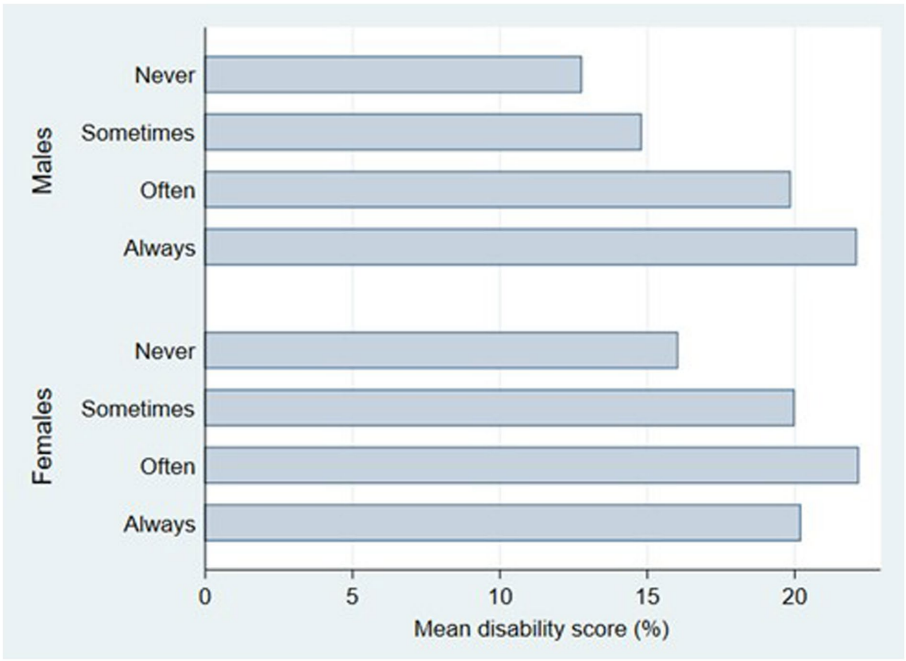

FIGURE 1
Mean score of disability for males and females according to perceived stress.

may not have been realized. This was exactly what we found in our study, with the notable correlation between teachers' back pain and perceived stress being one of the most significant findings. Low back pain becomes more prevalent and disabling as stress levels increase. These findings were consistent with those of previous studies (7, 8, 27, 28).

Several factors may have influenced the teachers' stress. Increased workload, more classes dealing with young adolescents' emotional and behavioral issues, and loss of social support are just a few of the challenges teachers face (28, 35). Therefore, it is important to identify potential workplace issues that contribute to teachers' stress. Specialized stress management programs may help reduce low back pain and disability. We also recommend conducting more research to determine the association between mental illnesses and low back pain in teachers using reliable assessments like PHQ-9 (Patient Health Questionnaire-9) and GAD-7 (General Anxiety Disorder-7) scales, considering the highly significant relationship between perceived stress and low back pain.

Similarly, physical stress, represented in the occupational context of being a teacher by the number of classes taught per week, could be a risk factor for LBP among secondary school teachers, in addition to the nature of the class itself. As predicted, our study found that the greater the number of classes, the greater the LBP risk of low back pain. This study largely confirms the findings of earlier research in this field relating the number of classes to the incidence of low back pain, whether in national or worldwide studies (4, 6, 13, 14, 28, 35). This result might be explained by the prolonged standing or sitting during teaching classes, which could be considered an aggravation factor; while dealing with students during class, teachers often require physical effort or the maintenance of particular postures for an extended period of time just to be on the same level as those students, such as kneeling or bending down when interacting with them (18, 31).

Surprisingly, BMI was not positively correlated with presence of LBP in the current study (34). However, the results of this study disagree with those of other studies (7, 8, 14, 27, 29, 31). Despite many previous studies demonstrating the positive association between BMI and lower back pain through different mechanisms, the insignificant relationship in our study could suggest that the obesity incidence in our study population manifested late and therefore the obesity impact on the lower back will be developed later (36).

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TABLE 5 Unadjusted and adjusted binary logistic regression analysis.

Predictors	Unadjusted model			Adjusted model		
	Unadjusted OR	95% CI	*p*-value	OR	95% CI	*p*-value
Age	1.04	1.02–1.07	< 0.001	1.04	1.02–1.07	< 0.001
Sex						
Males	Ref			Ref		
Females	2.59	1.84–3.64	< 0.001	2.11	1.45–3.05	< 0.001
Exercise						
No	1.45	1.03–2.03	0.03	1.32	0.92–1.89	0.12
Yes	Ref			Ref		
Number of classes per week						
≤ 10 classes	Ref			Ref		
11 ≤ 20 classes	1.71	1.04–2.80	0.03	1.77	1.05–3.00	0.03
> 21 classes	2.00	1.18–3.38	0.01	2.09	1.19–3.68	0.01
Perceived stress						
Never	Ref			Ref		
Sometimes	1.57	1.03–2.40	0.03	1.22	0.78–1.92	0.37
Often	3.05	1.69–5.51	< 0.001	2.10	1.12–3.93	0.02
All the time	3.55	1.88–6.70	0.001	2.07	1.05–4.07	0.03

LBP is one of the main factors contributing to lower quality of life, work loss, and participation restrictions worldwide (33). Work-related LBP due to work affects everyone, including teachers. Therefore, the Oswestry Disability Index was used to assess how this illness impairs a person's capacity for daily tasks. Most Polish teachers who complained in the Rottermund et al. study (86–87%) had only mild impairment, with no significant sex differences. In our study, 64.63% of low back pain sufferers reported minimal disability, which is consistent with the data observed in the study by Eric et al. (7). In contrast to what was seen in Polish teachers, our study had a larger percentage of moderate disabilities (29.79%), with a statistically significantly higher percentage of females. This research revealed sex differences comparable to those reported by Ya et al. in their study of Chinese office workers. High stress levels and the higher prevalence of pain in females may be one of the primary reasons for them having a higher disability levels. For further illustration, Figure 1 demonstrates the positive association between stress and disability levels (4, 37).

The most important finding from our data is the substantial link between age and disability score. This is consistent with a WHO report. It is crucial to increase health awareness and implement preventative measures, such as self-care and ergonomic changes, among teachers (33).

4.1 Limitation

This study has several limitations that must be noted. Four types of electronic weight scales were used to collect the data, which may have led to slightly varied weight readings and, as a result, slightly variable BMI calculations. Furthermore, this study did not consider the stated pregnancy status of the female participants, which could have been a confounding factor if the pregnant participants had lower back discomfort. Participants were also questioned about their symptoms from the previous year, which required them to recall, and may have allowed for recall bias. An additional limitation, the teachers under our study were in the two spectrums of 22 to 62 (low to high age). This could confound our results because did not differentiate between different ages. Also, we did not check the teacher standing hours in our study, which can be effective, because it is difficult to know the precisely standing hours. The use of percieved levels of excercise and percieved stress may have added a level of subjectivity to the results. The study may have benefited more from validated tools for these variables, however this would have greatly increased the number of questions.

4.2 Conclusion

The present study has shown that low back pain is highly prevalent among secondary school teachers in the eastern region of Saudi Arabia, along with having a significant disability index which apparently affects the quality of their lives. The presence of LBP and disability were positively correlated with female sex, advancing age, perceived stress, and the number of classes per week. On other hand, low back pain and disability were not associated with smoking or increased BMI. The variety of LBP risk factors among teachers emphasize the need for implementing different preventative measures, such as promotional campaigns aiming to educate teachers about workplace ergonomics and how to deal with physical and emotional stress, as well as educating decision-makers to reconsider the weekly number of classes assigned to a single teacher and to set a maximum reasonable number of classes per week. Furthermore, early-detection programs aimed at screening for common disorders in a certain work environment are recommended. For example, screening for psychological disorders and lower back pain in teachers.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by the Institutional Review Board of the Imam Abdulrahman Bin Faisal University (IRB-2021-01-453). The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

AA: Conceptualization, Methodology, Supervision, Visualization, Writing – original draft, Writing – review & editing. DA: Data curation, Investigation, Writing – original draft. TA: Data curation, Investigation, Project administration, Writing – original draft. MK: Conceptualization, Investigation, Project administration, Writing – original draft. MA: Data curation, Investigation, Project administration, Writing – original draft. RaA: Data curation, Investigation, Project administration, Writing – original draft. KA: Visualization, Writing – original draft, Writing – review & editing. HA: Conceptualization, Supervision, Visualization, Writing – review & editing. ReA: Conceptualization, Formal analysis, Methodology, Software, Visualization, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Exploring the complexity of commonly held attitudes and beliefs of low back pain—a network analysis

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Objectives: The current study used a network analysis approach to explore the complexity of attitudes and beliefs held in people with and without low back pain (LBP). The study aimed to (1) quantify the adjusted associations between individual items of the Back Pain Attitudes Questionnaire (Back-PAQ), and (2) identify the items with the strongest connectivity within the network.

Methods: This is a secondary data analysis of a previously published survey using the Back-PAQ ($n = 602$). A nonparametric Spearman's rank correlation matrix was used as input to the network analysis. We estimated an unregularised graphical Gaussian model (GGM). Edges were added or removed in a stepwise manner until the extended Bayesian information criterion (EBIC) did not improve. We assessed three measures of centrality measures of betweenness, closeness, and strength.

Results: The two pairwise associations with the greatest magnitude of correlation were between Q30–Q31 [0.54 (95% CI 0.44 to 0.60)] and Q15–Q16 [0.52 (95% CI 0.43 to 0.61)]. These two relationships related to the association between items exploring the influence of attentional focus and expectations (Q30–Q31), and feelings and stress (Q15–Q16). The three items with the greatest average centrality values, were Q22, Q25, and Q10. These items reflect beliefs about damaging the back, exercise, and activity avoidance, respectively.

Conclusion: Beliefs about back damage, exercise, and activity avoidance are factors most connected to all other beliefs within the network. These three factors may represent candidate targets that clinicians can focus their counseling efforts on to manage unhelpful attitudes and beliefs in people experiencing LBP.

KEYWORDS

low back pain, psychological factors, beliefs, network analysis, attitudes

1 Introduction

Low back pain (LBP) is a highly prevalent and costly musculoskeletal pain disorder, which occurs in all countries and affects individuals across the lifespan (1). In 2019, LBP accounted for over half a billion prevalent cases and over 60 million years lived with disability (YLDs) (1). In 2016, LBP was ranked first in healthcare expenditure of US$134.5 billion in the United States (2). Two-thirds of those with an acute painful episode of LBP recover within the

first three months (3), although relapses and remissions are common (4). Approximately 20% of LBP sufferers go on to experience severe, high-impact chronic pain (5), which contributes most to healthcare costs.

The attitudes and beliefs of both patients and clinicians are thought to be important contributors to the development of LBP, its recovery, and how the condition is managed. Harboring negative attitudes and beliefs regarding LBP may elevate catastrophic thoughts and avoidant behaviors (6), which cascade into greater disuse and depression (7), leading to delayed recovery and functional return (8, 9). The beliefs of healthcare practitioners have been reported to explain as much as 20% of the variance in their recommendations to patients suffering from LBP (10). The importance of the relationship between beliefs and clinical management has also been reported across many healthcare professions and in different countries (11). To measure the attitudes and beliefs regarding LBP, the 34-item Back Pain Attitudes Questionnaire (Back-PAQ) was developed (12). Further work on the Back-PAQ resulted in the development of an abbreviated 20-item (13) and also a 10-item version (12).

Regardless of the versions of the Back-PAQ, a summative total score is determined by aggregating the values across all items (12). For example, the original Back-PAQ has a total score ranging from 34 to 170, with higher scores indicating more negative beliefs regarding LBP (12). This aggregate score has been used in clinical trials to determine the effects of different interventions on changes in the patient's attitudes and beliefs (14). Analyzing only the aggregate score of the Back-PAQ does not fully maximize the use of the information. This is because two individuals can have similar aggregate Back-PAQ scores, but have very different scores on individual items. Determining the most important Back-PAQ items could improve its utility for clinical decision-making.

There are potentially many approaches in seeking to understand the most important facets underlying an individual's beliefs about LBP. In a previous study of the Back-PAQ in the general population, items relating to posture (Q8), muscle strength (Q7), and lifting technique (Q5) were the most negatively scored (6); it may be that items with the worse score are considered the most important items. Patients and clinicians are commonly thought to hold negative beliefs about the safety of certain lifting postures (15, 16), and the appropriateness of physical activity during an episode of LBP (17). The importance of the beliefs about posture and activity resumption is evidenced by the development of therapeutic interventions seeking to target these specific beliefs (18, 19). Alternatively, facets of an individual's belief system with strong prognostic value may be deemed as important, including expectations about recovery (20), and self-efficacy (21).

Another approach to determining the importance of items is via network analysis (22). Network analysis focuses on quantifying the multivariate relationships between individual items (23, 24). The importance of any item in network analysis, also termed centrality, is typically defined by the magnitude of association, and the closeness of associations to all other items (22). An item with a very high score may not be central, if it is connected to very few items. In a hypothetical scenario of negative beliefs about posture, a low centrality would mean that this specific belief does not affect the beliefs on other items. From a treatment perspective, targeting a low central item would not be the most efficient approach.

The current study explored the multivariate relationship of the items within the Back-PAQ. The main aims of the study were to (1) describe the network and identify the item pairs with the strongest adjusted associations, and (2) identify a reduced set of items with the strongest connectivity within the network. Given that network analysis is a data-driven approach, and that this is the first study to apply such techniques on the Back-PAQ, there were no priori hypotheses made about what item pairs would be the most correlated, or which items would have the greatest centrality measures.

2 Methods

2.1 Study design

Secondary data analysis using the methodology of network analysis.

2.2 Participants

This study used data from a previously published survey of the New Zealand population that used the Back-PAQ (6). One thousand people who were 18 years and older were randomly selected from the New Zealand Electoral Roll and invited by mail to complete the survey. The survey was completed by 602 participants (female = 331, male = 271). Participant characteristics are described in detail in the original publication (6), but briefly, 76 participants self-reported never having experienced a back pain history, 361 reported a past experience of a back pain history, 164 reported a current experience a back pain history, and one participant did not self-report.

2.3 Questionnaire

The Back-PAQ is a 34-item questionnaire (Table 1), scored on a a five-level ordinal scale [responses coded from "False" = 1 to "True" = 5 (Table 1)]. Eleven items (1, 2, 3, 15, 16, 17, 27, 28, 29, 30, 31) are reversed compared with the normal direction of the survey. Hence, for these 11 items, the answers were re-coded with the normal direction of the survey. The total score range from 34 to 170, with a higher score reflecting more unhelpful beliefs. The Back-PAQ has acceptable internal consistency ($\alpha = 0.70$) (12), excellent test-retest reliability (ICC = 0.84) (25), and moderate convergent validity relative to the Tampa Scale of Kinesiophobia ($r = -0.58$) (25) when used by a cohort of healthcare practitioners.

2.4 Approach to network analysis

2.4.1 Software and packages

The dataset was analyzed with R statistical software (version 4.2.2). Several packages were used to perform the analyzes, including *qgraph* (26) for network estimation and plotting, and *bootnet* (27) for stability analysis. Since the Back-PAQ items are ordinal, a nonparametric Spearman's rank correlation matrix was used as input

TABLE 1 Individual items and their questions of the Back-PAQ.

Items	Question
1	Your back is one of the strongest parts of your body
2	Your back is well designed for the way you use it in daily life
3	Bending your back is good for it
4	Sitting is bad for your back
5	Lifting without bending the knees is not safe for your back
6	It is easy to injure your back
7	It is important to have strong muscles to support your back
8	Good posture is important to protect your back
9	If you overuse your back, it will wear out
10	If an activity or movement causes back pain, you should avoid it in the future
11	You could injure your back if you are not careful
12	You can injure your back and only become aware of the injury sometime later
13	Back pain means that you have injured your back
14	A twinge in your back can be the first sign of a serious injury
15	Thoughts and feelings can influence the intensity of back pain
16	Stress in your life (financial, work, relationship) can make back pain worse
17	When you have back pain, you can do things which increase your pain without harming the back
18	Having back pain makes it difficult to enjoy life
19	It is worse to have pain in your back than your arms or legs
20	It is hard to understand what back pain is like if you have never had it yourself
21	If your back hurts, you should take it easy until the pain goes away
22	If you ignore back pain, you may cause damage to your back
23	It is important to see a health professional when you have back pain
24	To effectively treat back pain you need to know exactly what is wrong
25	If you have back pain you should avoid exercise
26	When you have back pain the risks of vigorous exercise outweigh the benefits
27	If you have back pain you should try to stay active
28	Most back pain settles quickly, at least enough to get on with normal activities
29	Worrying about your back can delay recovery from back pain
30	Focussing on things other than your back helps you to recover from back pain
31	Expecting your back pain to get better helps you to recover from back pain
32	Once you have had back pain there is always a weakness
33	There is a high chance that an episode of back pain will not resolve
34	Once you have a back problem, there is not a lot you can do about it

to the network analysis. We estimated an unregularised Graphical Gaussian model (GGM), using the *ggmModselect* algorithm with the following parameters (28): tuning = 0.25, stepwise = TRUE, consider PerStep = "subet," and missing = "pairwise." From a graphical lasso network model, edges were iteratively added and removed until the extended Bayesian information criterion (EBIC) did not improve (28). This is similar to performing stepwise selection in regression models using Akaike information criterion.

Presently, we assessed three measures of centrality: betweenness (how often one node lies on the shortest path between other nodes), closeness (shortest edges to other nodes), and Strength (magnitude of all the node's immediate edges) (29). Clinically, a node high in Strength can directly influence many adjacent nodes, without the influence of other nodes (29). A node high in Closeness can be interpreted as the speed of influence a change in one node has on all other nodes in the network (29). Lastly, if a node high on Betweenness were to be removed, the relationship between all other nodes become more indirect (29).

We assessed the variability of the edge weights using bootstrapping ($B = 1{,}000$) (27), to estimate the 95% confidence interval of the estimated edge weights (i.e., the partial correlations). To gain an estimate of the variability of the found centrality indices (CS-coefficient)—meaning if the order of centrality indices remains the same after re-estimating the network with fewer participants, we applied the participant-dropping subset bootstrap ($B = 1{,}000$) (27). This procedure drops a percentage of participants, re-estimates the network, and re-calculates the three centrality indices. The percentage of participants dropped ranged from 5% to 75%, across 10 sampling levels. The CS-coefficient reflects the maximum proportion of participants that can be dropped, such that with 95% probability the correlation (of the centrality value of the bootstrapped sample vs. that of the original) would reach a certain value (0.7 in the current study, $CS_{cor=0.7}$). It is suggested that the $CS_{cor=0.7}$ should be >0.25 and is better if it is >0.5 (27).

3 Results

The mean (standard deviation) score of each item of the Back-PAQ can be found in Figure 1. The five pairwise associations with the greatest magnitude of correlation were between Q30–Q31 [0.54 (95% CI 0.44 to 0.60)], Q15–Q16 [0.52 (95% CI 0.43 to 0.61)], Q1–Q2 [0.41 (95% CI 0.30 to 0.47)], Q13–Q14 [0.38 (95% CI 0.27 to 0.43)], and between Q32–Q33 [0.37 (95% CI 0.26 to 0.44)] (Figures 2, 3). These five relationships related to the association between items exploring the perceived influence of attentional focus and expectations (Q30–Q31), items exploring the perceived influence of feelings and stress (Q15–Q16), items exploring the strength and design of the back (Q1–Q2), items exploring interpretations of pain and injury (Q13–Q14), and items exploring persistent weakness and pain (Q32–Q33) (Table 1).

The three nodes with the greatest average centrality values across betweenness, closeness, and strength, were Q22 (betweenness = 1.00, closeness = 1.00, strength = 1.00), Q25 (betweenness = 0.88, closeness = 0.98, strength = 0.78), and Q10 (betweenness = 0.70, closeness = 0.95, strength = 0.64) (Figure 4). The three nodes with the lowest average centrality values across strength, betweenness, and closeness, were Q4 (betweenness = 0.00, closeness = 0.58, strength = 0.09), Q5 (betweenness = 0.00, closeness = 0.51, strength = 0.11), and Q17 (betweenness = 0.00, closeness = 0.60, strength = 0.20) (Figure 4). The stability of the centrality measures,

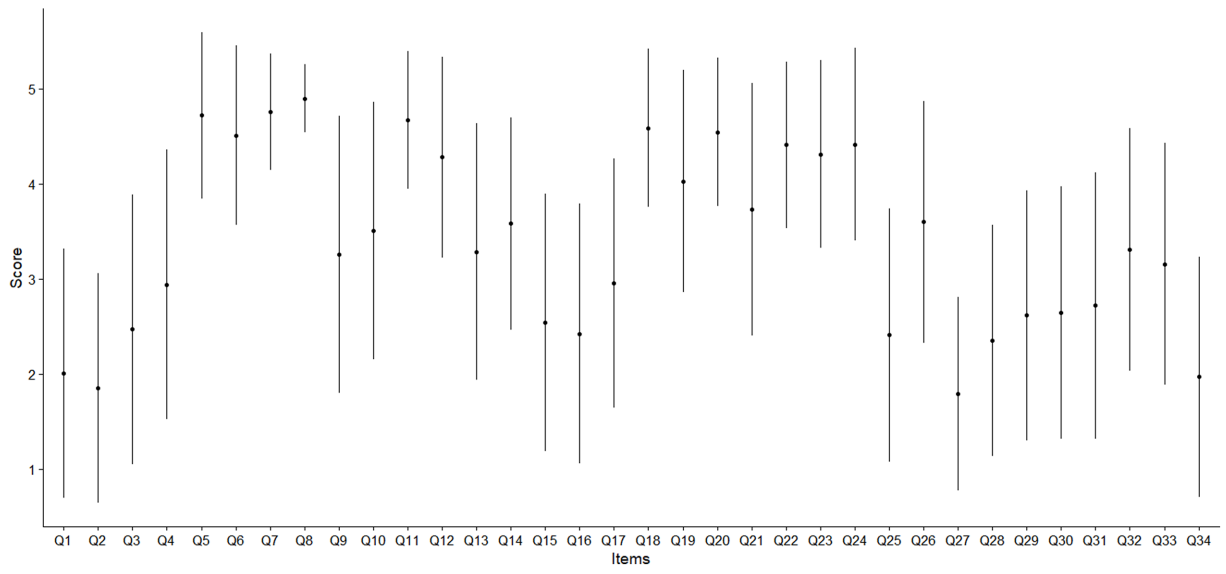

FIGURE 1
Mean and error bar as one standard deviation of the cohort's individual item score of the Back-PAQ.

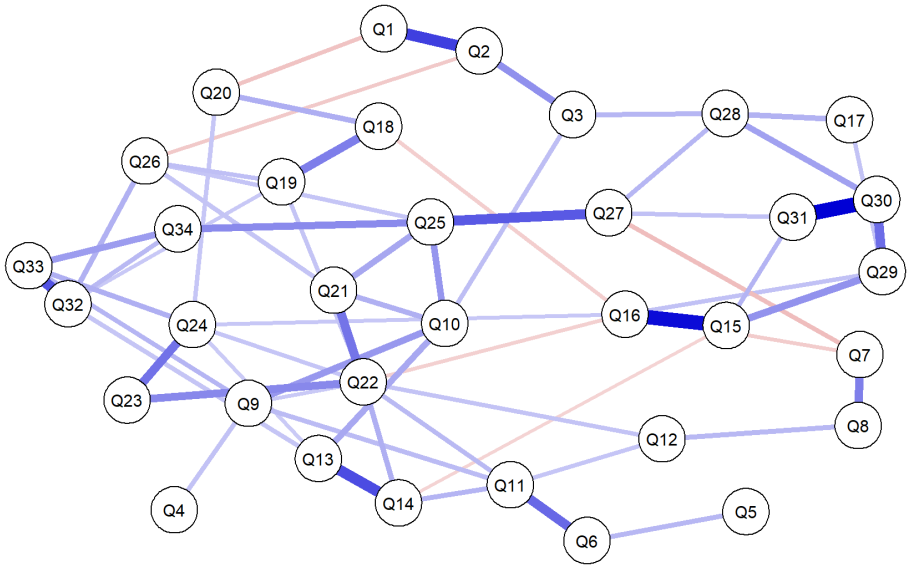

FIGURE 2
Network analysis of the association between the 34 items of the Back-PAQ. Each edge in the network represents either positive regularized adjusted associations (blue edges) or negative regularized adjusted associations (red edges). The thickness and color saturation of an edge denotes its weight (the strength of the association between two nodes).

$CS_{cor=0.7}$, of betweenness, closeness, and strength were 0.05, 0.00, and 0.60, respectively.

4 Discussion

Attitudes and beliefs are thought to be important contributors to the development, recovery, and management of LBP. The present study aimed to understand the complex relationship between the individual items of the Back-PAQ to better understand how different beliefs interact with each other. The top two most correlated edges were between focus and expectations (Q30–Q31), and feelings and stress (Q15–Q16). In addition, the three items with the greatest average centrality values across betweenness, closeness, and strength, were Q22, Q25 and Q10. These items reflect beliefs about damaging the back, exercise and activity avoidance, respectively.

A recent systematic review have reported that recovery expectations is a prognostic factor of return to work and recovery outcomes (20), and that expectation of symptom change modulates changes in pain and impairment (30, 31). From our network analysis, a more positive belief about recovery expectations was associated with more positive beliefs about the benefits of focusing on things other

than the back (Q30), staying active (Q27), and acknowledging the role of thoughts and feelings in LBP (Q15). These associations may represent candidate mechanisms by which recovery expectations influence LBP outcomes. From the literature, it is thought that recovery expectations might affect LBP outcomes by modifying coping, healthcare-seeking, and withdrawal behaviors (20). It may be that with a more positive belief about focusing on other things and staying active, patients have greater self-efficacy in pursuing activities, despite the presence of pain, which ultimately benefits the recovery of LBP.

Even though beliefs about good posture (Q8) were not most correlated with having strong muscles (Q7), our findings still support their direct association. The present finding supports prior research which reported that patients frequently viewed correct lifting techniques, posture, and having strong muscles as collective strategies for protecting the back (32). Interestingly, beliefs about bending (Q3), sitting (Q4), and lifting (Q5), were not directly associated with each other (Figure 1). Some of these beliefs have been thought to have their roots in communication with clinicians (32) and mass media campaigns (33). If beliefs about bending, sitting, and lifting had a common cause, it would be likely that they are directly associated with each other. Findings from the present study suggest that each of these three beliefs may not be as closely associated as previously thought (34), and may have different antecedent causes. Clinically, this suggests that if educational efforts were to be directed toward altering the beliefs of these activities, they will have to be done so individually, rather than with the expectation that changing the beliefs on one task will influence another.

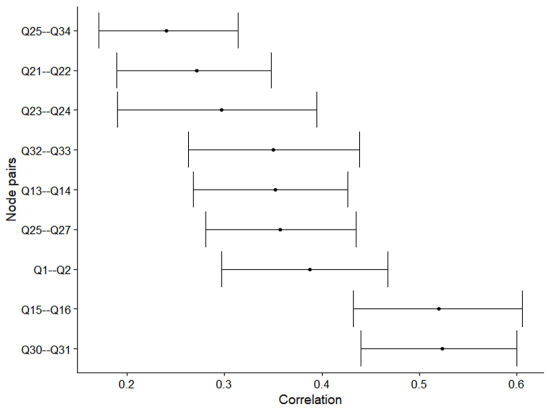

FIGURE 3
Bootstrapped 95% confidence interval of the estimated edge weights of the network. Only edges where 100% of the bootstrapped estimated correlation was non-zero retained for plotting.

Items on the Back-PAQ with the worse score may not always be the most connected items within the network. For example, items relating to posture (Q8), muscle strength (Q7), and lifting technique (Q5) were the most negatively scored (6), but represented some of the least central items (Figure 4). In other words, these aforementioned items are relatively isolated from all other items. The most central items relate to beliefs about causing back damage (Q22), the benefits of avoiding exercise (Q25), and activity avoidance (Q10). These three beliefs have close relations with prior reported perceived myths about LBP, particularly on the role of tissue damage in LBP, and the importance of stopping exercise and activity when LBP occurs (34). Not surprisingly, these unhelpful beliefs about exercise are also held by clinicians [e.g., Q9 in (35)], reinforcing the importance of the enduring influence of clinical opinions on the beliefs of LBP on lay people (32). Prior qualitative research has reported that negative beliefs about low back tissue damage results in high pain-related fear (36), while quantitative longitudinal research have reported that fear is a prognostic indicator of persistent LBP symptoms (9). Our findings also support prior research which identified that LBP individuals with high pain-related fear have two predominant beliefs—the potentially damaging effects of physical activity and that performing an activity with pain will increase suffering (37).

The network visualization is clinically very intuitive, enabling rapid and unique clinical insights which may be used to efficiently guide patient counseling. For example, our findings showed that the belief about the ease of injury (Q6) is directly associated with the belief about the safety of lifting (Q5), and not sitting (Q4). This means that for clinicians desiring to alter a patient's beliefs about sitting safety, educational efforts to modify the patient's beliefs about the vulnerability of the spine to injury may not be the most efficient

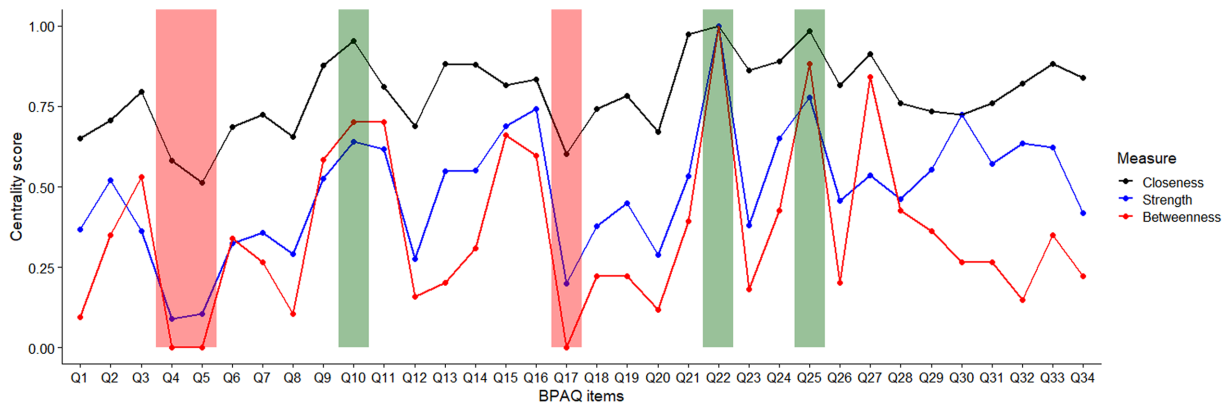

FIGURE 4
Standardized (0–1) centrality scores of the 34 items of Back-PAQ. Items shaded in green indicate the top three most central items and those in red indicate the least central items.

treatment approach. Second, in a busy clinical environment, findings from the present study suggest that educational efforts should focus on targeting beliefs related to back damage (Q22), exercise, and activity avoidance (Q25 and Q10). A recent editorial published the 10 common myths about LBP, calling on clinicians to incorporate these discussions with their patients (34). The present finding supplements prior clinical recommendation reports (34), providing evidence for the most efficient approach to navigating these beliefs with patients.

This study has several limitations. First, no attempt was made to distinguish the network dynamics of the Back-PAQ among people with and without LBP. Future investigations on understanding the differences in belief systems among different LBP subgroups may be useful for personalizing education efforts in managing and preventing LBP. Second, the longitudinal relationship between individual items of the Back-PAQ and clinical outcomes was not investigated. Including both the items of the Back-PAQ and measures related to clinical outcomes (e.g., pain intensity and impairment at follow-up) in a prospective study, may help to identify specific beliefs driving clinical outcomes. Third, the original study recruited participants with and without LBP randomly selected from an Electoral Roll. Information concerning the duration of current LBP and whether LBP had a specific cause (e.g., spondyloarthropathy), was not collected. A previous study reported that individuals with axial spondyloarthropathy reported lesser LBP intensity and better health related quality of life, than those with chronic non-specific LBP (38). Whether similar attitudes and beliefs are held in people with specific and non-specific LBP remains to be investigated.

5 Conclusion

Network analysis of the Back-PAQ revealed unique insights into the beliefs about LBP. Beliefs about back damage, exercise, and activity avoidance are factors most connected to all other beliefs within the network. This suggests that these three factors represent candidate targets that clinicians can focus their patient counseling efforts on.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by This study was approved by the University of Otago Ethics Committee (D12/255). The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

BL: Conceptualization, Formal analysis, Methodology, Software, Validation, Visualization, Writing – original draft, Writing – review & editing. BD: Conceptualization, Data curation, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Common differential diagnosis of low back pain in contemporary medical practice: a narrative review

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With a wide range of etiologies, low back pain (LBP) presents a true clinical challenge, finding its origins both in intrinsic spinal and systemic conditions, as well as referred ones. This review categorizes the LBP into these three groups and aims to offer a comprehensive look at the tools required to diagnose and differentiate them. The intrinsic etiologies are based on conditions that affect the musculoskeletal components of the lumbar spine, such as intervertebral disc disease, stenosis, muscular imbalance, and facet joint degeneration. The systemic causes usually extend beyond local structures. Such are the cases of neoplasia, infections, and chronic inflammation. The diagnosis is rendered even more complex by adding the referred pain, which only manifests in the lower back yet arises in more distant locations. By synthesizing the literature that encompasses the problem, this review aims to augment the understanding of the differential diagnoses of LBP by showcasing the subject's nuances. This categorization provides a structured approach to a patient-centered diagnosis, which could facilitate the medical practitioners' efforts to navigate this pathology more effectively.

KEYWORDS

low back pain, differential diagnosis, mechanical pain, non-mechanical pain, referred pain

Introduction

Low back pain (LBP) is one of the most frequently observed symptoms in the general population, with the most disability-adjusted life years, as well as an impact on the economy and social state of the affected patients (1). According to a systemic analysis of the global burden, at the beginning of the decade, about 619 million people were affected, with a projection of 843 million prevalent cases in the middle of the century (2). The intensity of the pain correlates with decreased overall productivity of the individual and a loss of the ability to function normally. The condition is defined by the identification or lack thereof of a nociceptive cause and is thus divided into specific and non-specific LBP. In the cases of directly related causes of LBP, an actual pathoanatomical substrate can be identified on imaging and is accompanied by a medical history, such as a presence of comorbidities (e.g., in the case of a metastasis) or a preceded trauma in the spinal fracture cases. In non-specific

LBP, the pain is not easily attributed to either category, and a certain conclusion for the actual reason for the pain is impeded (3).

The condition is further classified according to its source, which, when correctly identified, is most commonly the result of a disturbance of the structures of the particular spine. These might be the discs, the vertebra, or the associated ligamentous or joint tissues, in which case it is accepted as a mechanical or an intrinsic spinal condition (4). Additionally, pain that is strongly associated with the spine, however, is not directly caused by damage to either of the structures but rather by a process that secondarily involves them, such as an infection or metastatic neoplasia, is referred to as a non-mechanical or systemic condition (5, 6). Furthermore, the LBP experienced in certain patients could be from a completely different origin and not connected to the spinal cord or its structures. Such is the case in the so-called referred pain, which typically arises from a visceral organ or has a pelvic origin (7). In some instances, the diagnosis is still complicated, accounted for by the wide range of factors that could contribute to the symptomatology (1, 3).

We aim to present the entirety of the conditions associated with low-back pain and the methods used to diagnose them and differentiate them from the rest of the diagnoses. Some of them have well-known causes with a large number of reported studies and case series. Others are less frequently noted, mainly through singular case reports or limited studies. Having a more comprehensive look at all of the factors involved in LBP could help reduce the number of misdiagnoses and subsequently lower the socio-economic burden of the condition.

Materials and methods

This study conducted a comprehensive narrative review on the PubMed database, which offers extensive biomedical literature content. The strategy included a search for "low back pain causes," which gave us a more general look at the conditions associated with our aim. A total of 20 381 results were found. Later, a combination of the condition's name followed by the term "low back pain" was conducted for each identified condition to acquire a more comprehensive look into the cases and studies published regarding the individual conditions.

The inclusion criteria focused on human studies written in English, with neither clinical nor experimental studies being excluded, as long as they were relevant to understanding the etiology of low back pain. We were not interested on case reports and reviews. The studies were not limited by year of publication, with the idea of also examining more rare conditions that are not frequently published about. Nevertheless, we focused on the papers in the last 5°years, which were reduced to 4,977 for the period. At the end, a list was compiled of 257 publications.

The data was extracted to identify the key themes and contributors to the presence and exacerbation of low back pain. The anatomical substrate of the pain was also identified and commented on where possible. We designed flowcharts that allow for a coherent presentation of the diverse range of causes of low back pain.

Abbreviations: LBP, low back pain; MRI, magnetic resonance imaging; CT, computed tomography.

Mechanical or intrinsic spinal conditions

The mechanical conditions of the spine account for the predominant number of cases of low back pain (**Figure 1**). There are many anatomical components and pathological developments that could potentially account for LBP with mechanical genesis.

Discogenic and disc-related pain

The discogenic pain is usually attributed to intrinsic disc degeneration or an endplate fracture. The degeneration of the intervertebral disc is an event of a non-complete annular tear by the disc's nucleus, and it usually produces pain along the sinuvertebral nerves, innervating the disc (8). The pathology is experienced as a dull ache in symptomatic cases and is diagnosed through an MRI or a provocating discography. The latter of the methods relies on the replication of the pain with an increase in the intradiscal pressure. Additionally, an endplate fracture could cause LBP, seeing as patients with histologically verified micro-fractures of the endplate present with significantly higher pain and disability scores than normal (9).

On the other hand, disc-related pain results from conditions such as nucleus pulposus herniation, where the disc itself and its innervation are not the primary cause of the complaints. They provoke a radiating pain through the compression of a nerve root. The distribution of the pain is in three main patterns – low back, buttock, and leg radiating pain. The gold standard for diagnosing the condition is the MRI, showing T2-weighted signal changes confirming disc herniation (10).

Lumbar strain/sprain

The pain in this subgroup of patients originates from the muscles or fascia of the lower back. The term strain describes an excessively stretched or torn muscle, while a sprain is the process of ligament tearing (11). The conditions are usually associated with an acute injury or gradual wearing out of the related structure. The diagnosis is traditionally made with an MRI to examine soft tissues better. The CT is an important tool especially for initial work-up in traumatic cases. Yet, an X-ray could be used as a cheaper tool for the differential diagnosis of a vertebral fracture or a local infection but with lower sensitivity. A direct relationship was indicated between the elastic coefficient of the thoracolumbar fascia and the degree of LBP experienced by a group of people, with higher pain levels associated with lower elastic coefficients (12).

Vertebral pain, traumatic and compression fractures

The vertebral pain arises from the vertebral body or the posterior elements, such as pedicles and laminae. In the context of a mechanical condition, the cause is usually a traumatic or a compression fracture (13, 14). As for the vertebral body, a

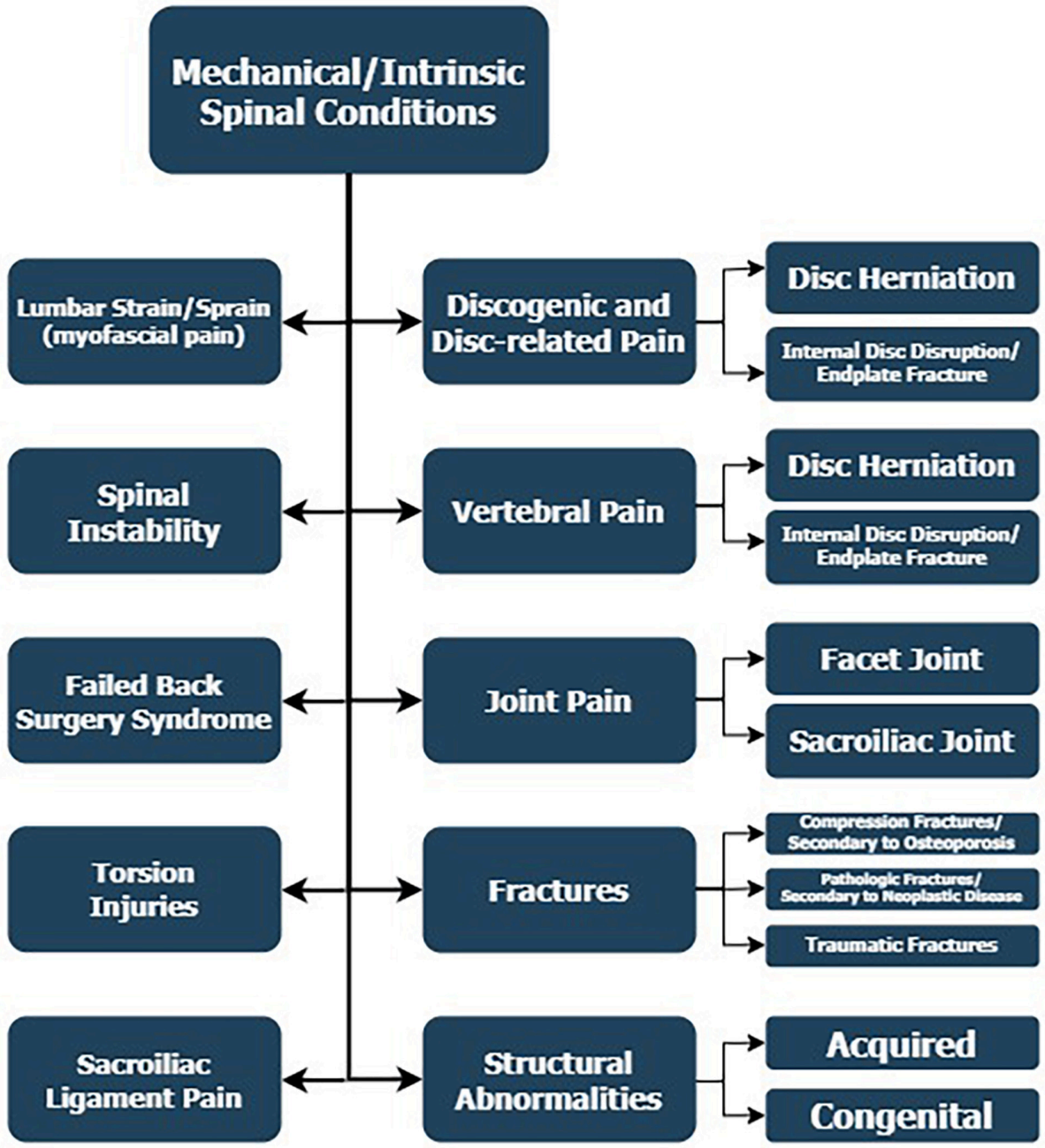

FIGURE 1
Mechanical or intrinsic spinal conditions from the anatomical components of the spine and pathological developments that could account for LBP.

compression fracture is the most common cause, typically resulting from a fall. Osteoporotic patients are especially endangered since the bone density is low and the axial force required to induce a fracture is minimal. The diagnosis is based primarily on the physical examination, involving a history of a fall or trauma, combined with risk factors, such as glucocorticoid use and osteoporosis, as well as LBP and loss of height (13). Even though the diagnosis is confirmed through a simple radiograph, a large number of cases remain undiagnosed. Nowadays, the employment of deep-learning algorithms in medicine has the potential to facilitate the process of detection and assessment of compression fractures using X-rays. Algorithms demonstrate results superior to those of trainee radiologists, on par with expert radiologists. Thus, the novel technology could potentially facilitate the diagnosis in primary medical centers (14).

Facet and sacroiliac joint pain

As for facet joint pain, the primary substrate is the medial branch of the posterior rami of the respective spinal nerve and the one just above the engaged zygapophyseal joint. The pain is most usually unilateral and limited in irradiation from the joint of origin until the buttocks, more rarely moving down the thigh

and mimicking radiculopathy. The cause is often an underlying degenerative process (15). Osteoarthritis, as a degenerative disease of the joints, has been linked with a higher incidence of LBP among patients operated on for disc herniation, as presented by Chen et al. (15). The authors noted that non-bacterial joint inflammation should be more meticulously examined pre-op since the condition could hinder the actual resolution of the lumbar pain (15).

Additionally, pain arising from the sacroiliac joint is often the result of a traumatic event, thus has a more sudden onset than facet joint or discogenic pain and is transmitted through the ventral rami of the L5-S2 for the anterior and the lateral branches of the dorsal rami of the S1-S4 nerve roots for the posterior part of the respective joint (16). A CT scan is usually preferred for sacroiliac pain with traumatic etiology. However, an MRI finds its usefulness when diagnosing inflammatory sacroiliac joint pain, such as in sacroiliitis resulting from spondyloarthritis. A study by Hangai et al. (17) has shown a correlation between the intensity of the signal on MRI and the symptoms of sacroiliac pain in patients experiencing the condition. In patients with non-inflammatory sacroiliac joint pain, readily available ultrasound evaluation of the long posterior sacroiliac ligament could reveal its thickening, soft tissue edema, and pathological transformations (18). The same authors showed in another clinical study that ultrasound changes in the attachment of the lumbar erector spinae muscles are associated with lumbosacral pain syndrome (19).

Failed back surgery syndrome

This condition has a multifactorial genesis, being the result of both patient psychosocial factors, such as psychiatric comorbidities and bad habits like smoking and alcohol consumption, as well as intraoperative factors. Such are surgery at the wrong segment, an insufficient number of levels, or an inadequate technique for the respective case. Postoperative factors might be pointed out, such as recurrence of the condition and adjacent segment disease (20, 21). The condition presents either with exacerbation of the current symptoms or with the apparition of new ones. In the latter case, "Post-surgical spine syndrome" is a suitable term. Patients >65 years are generally more susceptible and failed back surgery syndrome is present in close to 15% of patients (22). The condition comes with many limitations for the patients, such as difficulty in activities like traveling and social life, as well as everyday life activities. The diagnosis involves a thorough medical history and imaging diagnostics appropriate for the respective pathology (21).

Spinal instability

The diagnosis of spinal instability is impeded mainly by the ambiguous nature of the symptoms associated with the condition, which are not easily distinguished through common imaging diagnostics, such as CT scans, MRIs, and radiographs (23). Nevertheless, this pathology is one of the leading causes of LBP in younger patients and is caused by the instability of a vertebral segment reacting to applied loads. Microinstability, which describes the pure motion syndrome with no morphological changes and lack of defined structural abnormalities, has recently gained popularity. For a pathophysiological context, the lack of stabilization of the spine, usually applied by the segmental muscles generally inserted in it, provokes compensation by the trunk muscles. The range of motion of the spine is preserved. However, a painful arc is present, and erecting the body from a bent-over position is hindered. Single photon emission tomography could detect facet joint lesions. À diagnostic block in this situation could help differentiate the conditions (23).

Acquired and congenital structural abnormalities

Acquired structural changes, such as spondylolisthesis and spondylolysis, have been debated regarding LBP. We have identified two systematic reviews that evaluated the association between the conditions mentioned above and LBP, showing no statistically significant correlation between the presence of the conditions and symptomatic LBP (24, 25). According to some authors, a relation has been identified between lumbar spondylolisthesis and lumbar spinal stenosis, an actual cause of LBP. Yet, no exacerbation of symptoms was demonstrated with varying levels of disc slippage (25).

On the other hand, scoliosis patients often experience pain at the curve's apex and the inner side of the thigh – cruralgia. The lumbar and thoracolumbar curves are generally more painful than the thoracic curves, and the rotatory olisthesis – the lateral rotation of one over the other, has been identified as one of the major causes of said symptomatology (26). A study comparing the pain in left- and right-convex degenerative lumbar scoliosis in the context of the location of the pain areas found no significant difference between the two groups regarding location and pain severity. Nevertheless, a heat map was created with patients' data, indicating that LBP was centrally located for most patients, regardless of whether they were left or right (27). Non-specific LBP differed in patients with scoliosis and was more inclined toward either side than in a non-scoliotic control group, in which the patients showed a more centralized pain pattern. Scoliosis patients also had differences in mobility and back muscle strength (28). Additionally, one paper was identified, which measured the changes in experienced pain throughout several different periods preceding the moment of the study and the accompanying degrees of insomnia and depression. Patients with current back pain reported daytime sleepiness and insomnia at higher levels, and those with chronic back pain had moderate depression in addition to insomnia and daytime sleepiness (28).

Lumbosacral transitional vertebrae, otherwise known as Bertolotti's syndrome, is a highly prevalent anatomical variant in which a sacralization of the L5 or a lumbarization of the S1 is observed. In the former condition, the fifth lumbar vertebra adopts some characteristics of the sacral vertebrae. In the latter, the first sacral vertebra takes on the characteristics of the lumbar vertebrae (29). The literature is uncertain about the concrete connection between the condition and LBP. However, certain types of the condition were more strongly associated with LBP, such as type 2 – pseudoarticulation type with enlargement of the transverse

process with pseudoarthrosis, and type 4, in which the transverse processes on one side were pseudoarticulated and on the other were fused (29).

The congenital fusion of vertebrae is most commonly localized in the cervical, followed by the thoracic and lumbar spine, diagnosed through a CT or an MRI scan. Nevertheless, a case report was identified of a patient with fusion vertebrae experiencing chronic low back pain. The authors hypothesized that narrowing the intervertebral foramen could be the source of the symptoms that arise with certain specific postures (30).

A hemivertebra is a condition where a vertebra is not fully formed, which causes a deformation of the physiological structure of the spine. Depending on the part of the anatomical structure that lacks development, the condition can present with kyphosis, lordosis, or scoliosis. The primary symptom is usually a noticeable trunk deformation, causing a cosmetic defect, pain, and neurological symptoms, such as gait and urinary disturbances. The condition can be diagnosed with a plain X-ray, yet more advanced techniques, such as CT and MRI scans, are helpful for therapeutic clarification (31).

Non-mechanical or systemic conditions

The non-mechanical causes of LBP find their genesis in systemic conditions, whose development has not necessarily started in the spine's components (**Figure 2**). They are linked with this structure through dissemination or are systemic conditions that engage it. Additionally, the symptoms of engagement of the spine are usually accompanied by other manifestations of systemic diseases.

Infections

The vertebral osteomyelitis is most commonly caused by a hematogenous disseminated Staphylococcus aureus or coagulase-negative staphylococci in exogenous osteomyelitis in spinal surgery. Tuberculosis is rare but should always be under suspicion. About 5% of osteomyelitis cases involve the posterior vertebral structures. More than 90% engage the vertebral body with the possibility of dissemination to adjacent structures, such as nerve roots, the epidural and intradural spaces, ligaments through the rich arterial web surrounding the vertebral bodies and toward the spinal column through retrograde dissemination through the Batson venous plexus (32). Spinal instrumentation surgery is a common predisposing factor for vertebral osteomyelitis (33). All immunodeficiency disorders also increase the risk of developing vertebral infections. The typical symptoms include back pain, initially non-focal, which later localizes over the affected area, and fever, although not in every patient. The pathology is most commonly located in the lumbar spine, followed by the thoracic and cervical segments. Thus, the condition is essential in the differential diagnosis of low-back pain, as it can be life-threatening (32).

As for the diagnosis, the imaging and the laboratory findings are crucial, with the MRI being the imagery of choice with more than 90% accuracy. The deviations to look for are decreased T1- and increased T2-weighted signals at the area of the infection. As for the complete blood count, the erythrocyte sedimentation rate and C-reactive protein have a 94% sensitivity (32). The diagnosis of spondylodiscitis – an infection of the intervertebral disc as well as the adjacent vertebrae can also be conducted through the use of radionuclide testing in specific cases, such as in evaluating the treatment response or generally cases when MRI is inapplicable. Fluorodeoxyglucose-18F has shown promising results, as it allows differentiating between infectious and degenerative endplate disease with high sensitivity (34). It might be helpful when assessing inflammatory, neoplastic, and traumatic/osteoporotic diseases.

Spondylodiscitis can cause a paraspinal abscess in the spinal region when the infection spreads to nearby tissues such as muscles and connective tissues of the vertebral column (35). Of particular note are psoas abscesses with genesis from hematogenous dissemination or adjacent to spondylodiscitis and infections in the abdominal cavity. They directly involve the paraspinal muscles and the lumbosacral plexuses. The abovementioned conditions have to be differentiated from epidural abscess, which is located in the spinal epidural space and is typically the result of a hematogenous dissemination of a bacterial agent from a remote location (36). One of the significant presenting symptoms of both infection types is LBP. The differentiation is based on the medical history – spondylodiscitis in the case of a paraspinal abscess and a systemic condition (e.g., bacteremia, immunosuppressed state) in the case of an epidural abscess, combined with an MRI scan for the more exact localization of the pathology (35, 36).

Neoplasia

A lesion in the spinal column has the potential to produce LBP since it is usually the initial symptom in these cases, with 90% of spinal lesions being of a metastatic origin, most commonly from the breast, lung, and prostate (6). The complaint is usually at the level of the lesion. However, nerve involvement through compression could lead to a potential dermatomal distribution (37). Differentiating between causes through the correct imaging diagnostic, such as an MRI, is critical for treating the conditions since the patient could present with a more mainstream symptom of the spine, even when the primary tumor is yet to be found (38). Nevertheless, special attention should be placed on cases with known cancer that present with newly acquired back pain. A metastatic lesion is a common reason for a pathological fracture since the tumor cells are a source of osteoclastic and osteolytic activity, in which case the patient could present with excruciating axial and radicular pain (6, 37, 38).

The previous applies as well to multiple myeloma, which could progress asymptomatically until the occurrence of LBP due to a fracture. For the diagnosis of multiple myeloma, an MRI is not necessarily the optimal method, especially in cases where the bone marrow doesn't present with tangible enough differences. In these cases, the CT and especially the SPECT scans are preferred since they more accurately capture the osteolytic process of the affected bones, combined with a blood lab analysis of the cell count and the elevated levels of globulins (39, 40). Nowadays, the differential

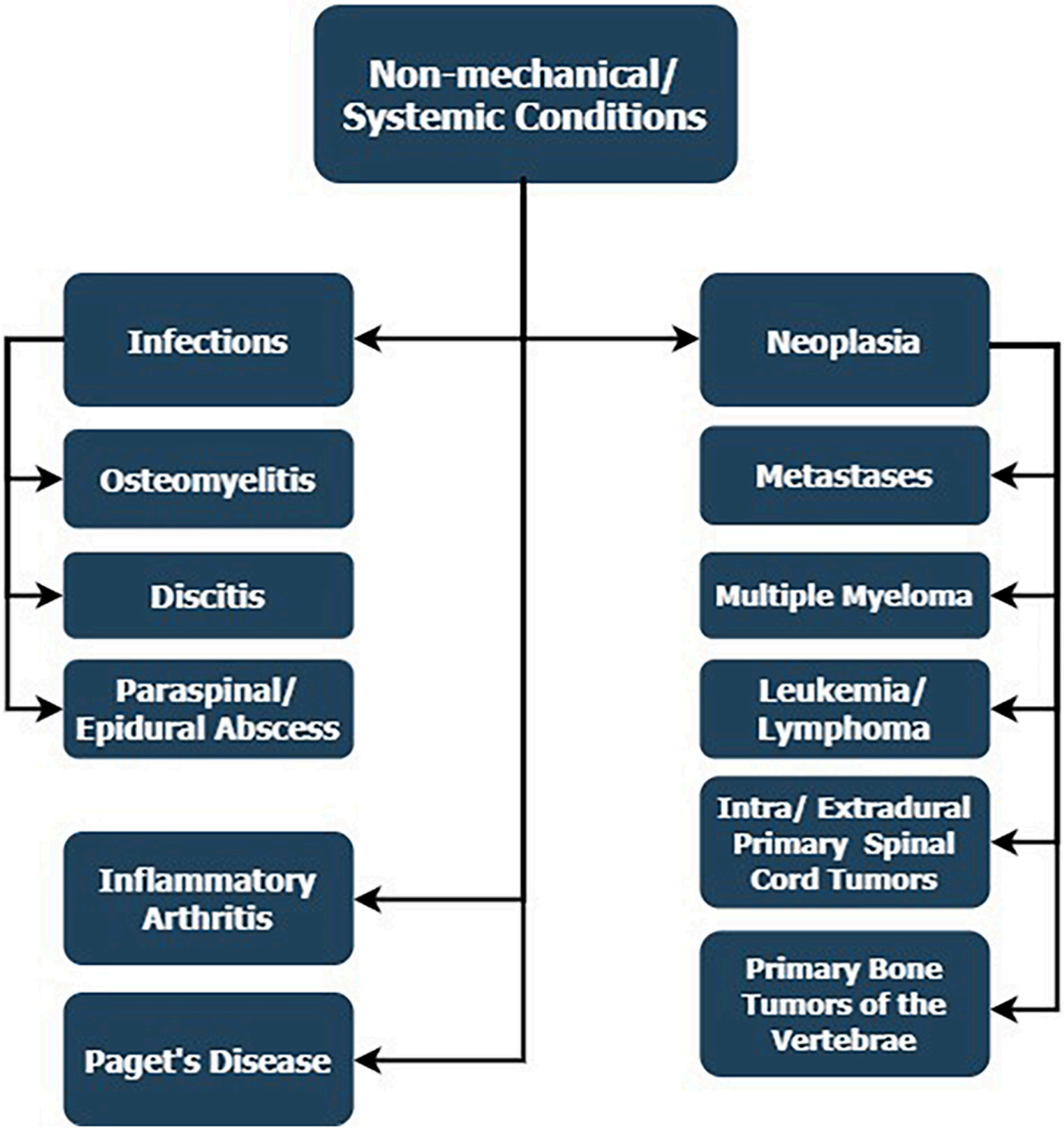

FIGURE 2
Non-mechanical reasons for LBP, whose development has not necessarily started in the spine's components but is linked with the spine through dissemination or systemic conditions that engage it.

diagnosis between a metastatic spine lesion and multiple myeloma is facilitated by machine learning algorithms that identify the features in an MRI to prioritize when examining (41).

As for differentiating between various types of malignancies affecting the spine, such as lymphoma and leukemia, for which a primary presentation in the axial skeleton is rare, the blood smear and complete blood count are of essential importance. The imaging diagnostic is a good addition for localizing the lesion and excluding other symptom causes. The presentation of leukemia primarily with LBP is more common in the pediatric population than in the adult population (42). The condition can cause pathological fractures with pain locally as well as compression of the nerve roots, which radiate toward the legs. The literature on the subject is scarce, consisting mainly of singular case reports (42, 43). One study showed 37 spinal lymphomas, where the lumbar region was the second most common localization with 10 cases, and pain was one of the significant presenting symptoms of the patients (44).

The intradural-extramedullary spine tumors are the second in frequency, following the extradural ones. The most common types are the schwannomas, followed by the meningiomas (45). The tumors can arise in each spine segment and are generally differentiated by their specific MRI findings (46, 47). Their initial symptom usually is axial or radicular pain, as well as sphincter and erectile dysfunction and paraparesis. The dumbbell appearance on

imaging studies is more typical for schwannomas. On the other hand, a typical finding in meningiomas is the vivid enhancement when contrast is applied in combination with the characteristic dural tail of the tumor. The specific filum terminale ependymoma is also classified in this category. On T2 weighted MRI, the lesion is hyperintense and is typically well enhanced by contrast medium.

Intramedullary tumors, mainly comprised of ependymomas and astrocytomas, might be found in every spinal cord segment (46). Among the two, the ependymomas are more common in the spinal cord's terminal parts, and the astrocytomas are more frequent at the thoracic level. Additionally, hemangioblastomas are the third entity on the list of intramedullary tumors, followed by metastases. On MRI, the astrocytomas tend to form syrinxes in the spinal cord and often span 5-6 segments, whereas the ependymomas present with a focal enlargement spanning around 3-4 segments and growing slowly and encapsulated. Angiography is a good examination for hemangioblastomas because it allows for assessing the feeding and draining vessels of the highly vascularized lesion. The most common symptom for these lesions is pain, which typically worsens during nighttime and could be radicular at the affected segment or distal with a neuropathic pattern. Furthermore, many neurological signs and symptoms can be present, caused by the tumor compressing and irritating motor or sensory nerves, such as gait disturbance, ataxia, paresthesias, as well as urinary disturbances.

Chronic inflammatory conditions

Axial spondyloarthritis, or ankylosing spondylitis and Bechterew's disease, causes inflammatory back pain, characterized by pain with an insidious onset before the age of 45 years, worse at night and during rest, with partial improvement during movement (48). The chronic inflammatory process causes ossification of the discs and ligaments and ultimately leads to fusion, which gives the spine the characteristic bamboo shape. To diagnose the condition early on, both an MRI and testing for HLA-B27 are performed. The prominent MRI feature is sacroiliitis, which may or may not be radiographically present, as well as the spine's inflammation and the ligament attachment sites. The X-rays and CT scans are typical in the advanced stages of the disease. The HLA-B27 is positive in a large part of the population. However, its presence or absence does not rule out or confirm the diagnosis with complete certainty (48).

Even though rheumatoid arthritis is strongly associated with peripheral joint involvement, a recent study found that poor control of the disease was associated with worsened LBP in the long run (49). Nevertheless, more research is needed to explain the connection between the two conditions more thoroughly.

Forestier disease, or diffuse idiopathic skeletal hyperostosis, is characterized by the ossification of spinal ligaments and entheses (50). The excessive osseous structures created by the condition render the patient more prone to compression of nerve structures and secondary injuries in minor trauma. A study in 1989 found through a survey that among 106 patients with the condition, low back pain was not more common than the presence in the general population (51). Thus, the disease is still debatable as a cause of complaints.

In Paget's disease, the spine is subject to abnormal bone growth caused by an upregulation of the osteoclastic activity, followed by excessive osteoblastic compensation, which leads to inadequacy in the size and shape of the affected bone. Regional pain is a typical presentation. The diagnosis is based on a CT scan of the bones or a radiograph, combined with alkaline phosphatase in the blood, hyperuricemia, and several other factors of the urine analysis (52).

Referred pain in visceral diseases

Referred pain is related to one that is felt in the lower back and has little or nothing to do with the spine itself (**Figure 3**). The primary cause of the symptomatology is usually a condition of a specific visceral organ or generally a process of the abdominal or pelvic cavities.

Renal causes

Acute pyelonephritis is a frequent cause of flank pain, which can be mistaken for LBP of spinal genesis (53). Etiologically, the condition is caused by bacteria, most frequently gram-negative E. coli, which adhere to the renal parenchyma and cause an inflammatory response. The diagnosis is based on urinalysis plus ultrasound when available. However, the negativity of the latter does not exclude the presence of the disease in its acute form. The condition is further characterized by unilateral costovertebral angle tenderness, typically over the affected kidney. High fever is one of the differentiating symptoms between acute pyelonephritis and acute renal colic, which also causes the characteristic flank pain. Yet, this time, the symptom radiates toward the groin and is pulsatile since the peristalsis of the urethral muscles remains active (7, 53, 54). Overall, the pain during renal colic is reported as more excruciating. Pathophysiologically, it results from the stretching of the renal capsule caused by the retention of urine before the level of obstruction. The diagnosis is based primarily on a CT scan, which is the method of choice, and ultrasound, which visualizes hydronephrosis. Radiography is still helpful since some stones are radiolucent (54).

Nevertheless, flank pain could also be the leading symptom in a perinephric abscess, radiating both to the groin and the leg imitating radicular genesis. The condition could result from a local infection or a hematogenous spread, affecting the renal capsule and Gerota's fascia. The standard for diagnosing the pathology is the contrast-enhanced CT scan, which gives additional information about the spread of the condition to adjacent structures (55).

Gastrointestinal causes

As for the gastrointestinal causes, acute cholecystitis and pancreatitis could produce pain. However, it radiates more toward the mid back and upper abdomen than the lower back (56, 57). The history of these patients usually includes the consumption of greasy foods in cholecystitis, which provokes gallbladder emptying and subsequent colic, whether in the presence of gallbladder stones or chronic alcohol consumption in the pancreatitis group. Nevertheless, gallstones could produce the discussed complications through obstruction of the common ducts. Both conditions are

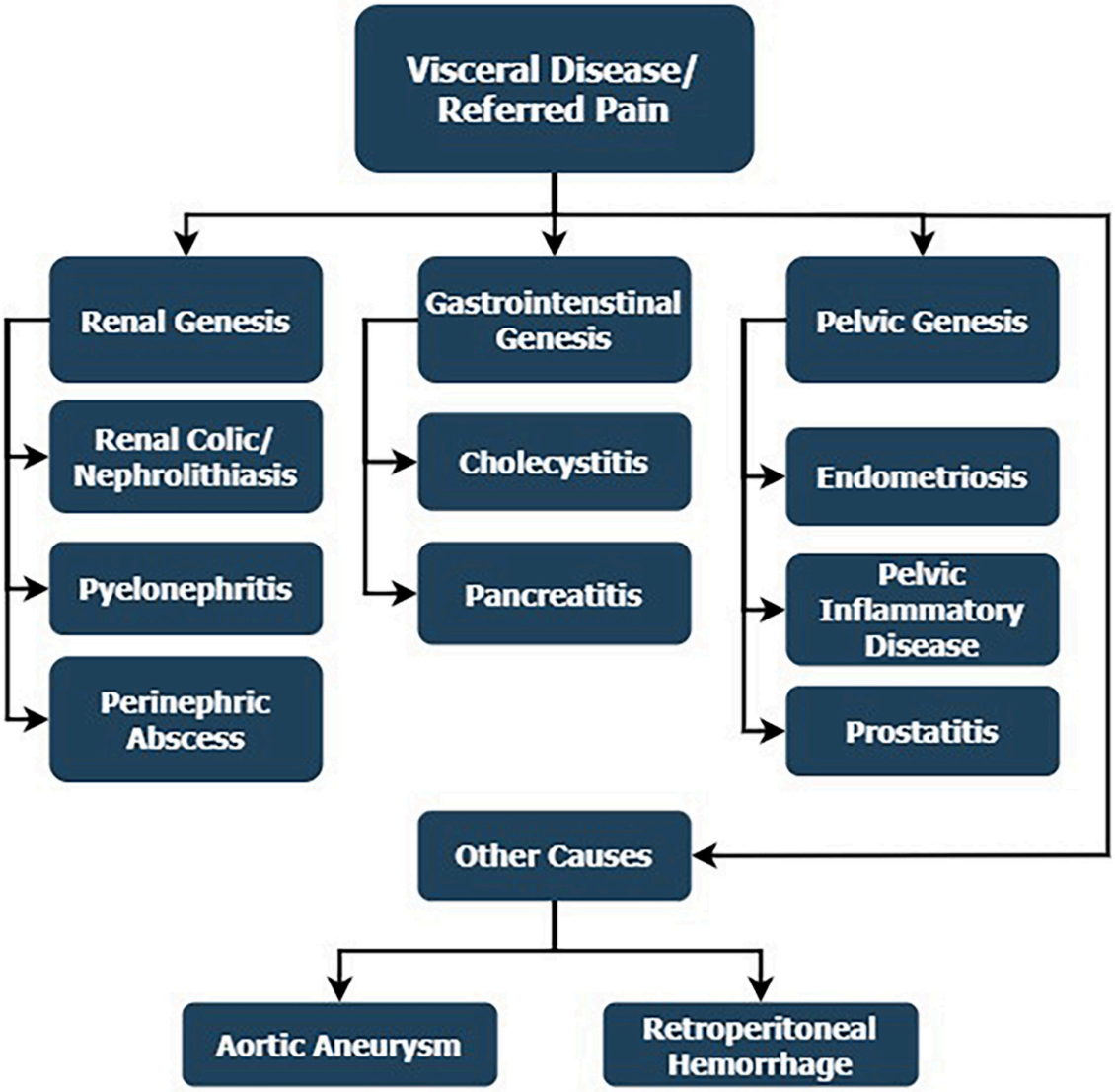

FIGURE 3
Referred low back pain in visceral diseases, which has little or nothing to do with the spine itself, and the primary cause of the symptomatology is usually a condition of a specific visceral organ or generally a process of the abdominal or pelvic cavities.

visualized through plain CT scans and ultrasound in the case of cholecystitis. The diagnosis is supported through a liver enzyme check-up (56, 57).

Pelvic disorders

Pain originating from the pelvic region is anatomically close to the lower spine. Endometriosis is one of the most common reasons for non-spinal LBP (7). The condition causes a painful inflammatory reaction, which could exacerbate the symptoms through the spread toward adjacent structures. It produces pain in the pelvic region that could be mistaken for LBP, as irradiation toward either of the legs does occur (58). Either ultrasound or an MRI is employed. The symptoms of dyspareunia and irregularities in the menstrual cycle support the diagnosis (59). Pelvic inflammatory disease in women is an ascending infection most typically caused by Neisseria gonorrhoeae or Chlamydia trachomatis, which, aside from pelvic and abdominal pain, presents with vaginal bleeding and dyspareunia (60). The bacteria can be identified through pelvic culture, and imaging diagnostics such as an MRI are reserved for evaluating any potential complications of the condition. As for the male population, prostatitis could be a cause of pelvic pain accompanied by some urinary as well as general symptoms of infection. Urinalysis is assessed for evaluation of the involved pathogen (61).

Other causes

Both abdominal and LBP are some of the most common symptoms of retroperitoneal hemorrhage, which could happen both as a result of a traumatic event or iatrogenic, following surgery or anticoagulation therapy (62). The symptoms are generally vaguer

when compared to the insidious nature of the condition with high mortality. The presence of a hypovolemic shock, which renders the patient hemodynamically unstable, combined with a thorough history of the patient and a CT scan, should be used for the differential diagnosis of the condition with other types of LBP. CT scans are beneficial for patients who have not undergone trauma since such an event usually facilitates the diagnosis (63).

Additionally, an abdominal aortic aneurysm could potentially cause LBP through compression of nearby structures as well as during a rupture (64). The aorta is adjacent to the spine, so enlargement of the wall could affect the surrounding structures and provoke complaints. Nevertheless, the typical symptoms associated with the condition are not always present. Therefore, the imaging diagnostic, mainly through ultrasound, is prioritized (65). Smoking and hypertension are the predisposing factors for the formation of the aneurysm. However, after that, the symptom could shift to hypotension, and both are potentially a part of the patient's presentation (65).

Other

Fibromyalgia is another condition that is associated with chronic LBP and cannot be classified in the previous categories. The diagnosis is often controversial and mainly made in rural areas, more commonly in women. The back pain associated with fibromyalgia does not differ noticeably from alternative types of chronic widespread pain. The etiology of the condition has been strongly linked with psychosocial factors. Usually the patient complains of additional disturbances, such as poor concentration, sleep, and memory, as well as irritability (66).

Conclusions

The diverse etiology of conditions contributing to the symptoms of LBP renders the diagnosis difficult to determine. The fact that not all of the conditions are attributable to the spinal structures themselves, and certain ones having been scarcely reported in the literature, further aggravates the confusion around the subject. In addition, many cases of LBP are that of non-specific pain, which cannot always be attributed to any apparent deviation from normal physiology. Having the correct imaging diagnostic conducted for the patient can positively impact the differentiation between the diverse types of pathology. Still, a certain number of conditions present with seemingly ambiguous findings. Thus, a sufficient combination of the proper blood tests, imaging studies, medical history, appropriate and meticulous clinical examination focused on the patient problem is imperative for the case. A good knowledge of the underlying causes and the differential diagnoses could facilitate this process.

Authors contributions

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Conflict of interest

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The efficacy of silver needle therapy for treating low back pain: a protocol for meta-analysis of randomized controlled trials

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Background: As population aging and unhealthy living habits may exacerbate the prevalence and burden of low back pain (LBP), effective treatment and improvement of patient quality of life are particularly critical. Silver needle therapy (SNT), having evolved from traditional acupuncture, involves placing silver needles into muscles, tendons, and fascia for treatment. However, it still lacks robust clinical evidence to substantiate its effectiveness. Therefore, it is necessary to conduct more emphasis on meta-analysis to evaluate the clinical efficacy of SNT for treating LBP.

Methods: We will search PubMed, Medline, Cochrane Library, Embase, China National Knowledge Infrastructure (CNKI), and Wanfang Databases up until December 2023 to identify randomized controlled trials of SNT treatment in adult patients with LBP. The primary outcome will be the intensity of pain after pain management. Secondary outcomes will include the Oswestry Disability Index, Japanese Orthopedic Association Back Pain Evaluation Questionnaire, requirement for analgesic drugs, and treatment-related adverse reactions. Two investigators conducted the literature search, selected studies that might meet the inclusion criteria based on the title and abstract, and extracted data from the eligible literature independently and will independently assess the risk of bias using the Revised Cochrane Risk-of-Bias (RoB2) tool. Multivariate analyses (including subgroup analysis, trial sequential analysis (TSA), sensitivity analysis, etc.) will be conducted to improve the quality of evidence.

Clinical trial registration: Registration: PROSPERO Registration Number: CRD42023466207, https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42023466207.

KEYWORDS

silver needle therapy, low back pain, meta-analysis, protocol, randomized controlled trials

1 Introduction

Low back pain (LBP) is characterized by pain, stiffness, or muscle tension, with pathological changes in muscles, fasciae, and ligaments being one of the significant causes. It typically occurs between the lower rib margin and the buttock crease, with or without associated leg pain and symptoms of the lower limb nervous system (1, 2). LBP is a prevalent condition worldwide, with 568.4 million cases globally, and the incidence increases with age

(3). A study assessing years lived with disability for 354 diseases across 195 countries/regions found that LBP is the leading cause of disability-adjusted life years and productivity loss globally, across 126 countries/regions (4). As population aging and unhealthy living habits may exacerbate the prevalence and burden of LBP, effective treatment and improvement of patient quality of life are particularly critical.

There are many methods for treating LBP clinically, including medication, exercise, manual therapy, physical therapy, dry needling, neural mobilization, cognitive functional therapy, education, etc. (5, 6). However, considering the side effects and adverse reactions of long-term drug use, guidelines suggest against the routine use of opioids for acute LBP and discourage their use for chronic LBP (7). Currently, the clinical practice guidelines of the American College of Physicians recommend non-pharmacological treatments such as superficial heat, massage, acupuncture, or spinal manipulation (8). Silver needle therapy (SNT) is derived from traditional acupuncture, where the silver needles are placed in muscles, tendons, and fascia rather than acupuncture points, and a specialized machine is used to heat the needles to eliminate aseptic inflammation and alleviate pain (9). SNT primarily alleviates pain through three mechanisms: eliminating aseptic inflammation, improving blood circulation, and relieving muscle spasms (10). The pain control mechanism of silver needle therapy is similar to moxibustion, but moxibustion involves burning a cotton ball to generate heat, which does not allow for temperature control. The silver needles are heated by a special device, with the temperature set according to patient feedback. Although SNT has been refined over a long period of development, it still lacks robust clinical evidence to prove its efficacy. Therefore, it is necessary to conduct meta-analysis to evaluate the clinical effectiveness of SNT for pain management in patients with LBP. The results of this meta-analysis will provide evidence for better clinical decision-making and future directions for further clinical trials.

We aim to conduct a meta-analysis and trial sequential analysis (TSA) of randomized clinical trials (RCTs) to assess the clinical efficacy and safety of SNT in the pain management of patients with LBP.

2 Materials and methods

2.1 Design and registration

This protocol is reported in accordance with the reporting guidelines provided in the Preferred Reporting Items for Systematic Reviews and Meta-analyses Protocols (PRISMA-P) statement. This meta-analysis will be conducted in accordance with the Cochrane Handbook for Systematic Reviews of Intervention, 2nd edition. This protocol has been registered in the PROSPERO database and the registered number is CRD42023466207.

2.2 Study selection

2.2.1 Study types

Only RCTs examining the clinical efficacy of SNT for pain management in patients with LBP will be included. There will be no language restrictions. Studies comparing SNT with SNT combined with other analgesic techniques will be excluded if data cannot be used for statistical analysis, if data is incomplete, if data cannot be extracted after contacting the original authors, or if the study is a duplicate publication, such as research published in the form of letters, editorials, conference proceedings, and review summaries.

2.2.2 Participations

Adult participants (age $\geq$ 18 years) with any LBP condition receiving SNT for pain treatment will be included. There are no restrictions on the participants' gender, race, body mass index, or the American Society of Anesthesiologists classification.

2.2.3 Interventions/controls

The intervention group will consist of participants who receive SNT alone or in conjunction with any other types of treatment techniques for managing LBP, while the control group will receive any type of treatment techniques other than SNT for managing LBP.

2.2.4 Outcomes

2.2.4.1 Primary outcome

The primary outcome will be the intensity of pain after management through SNT or other treatment techniques. Pain intensity, mainly post-treatment pain intensity, will include assessments using the Visual Analogue Scale (VAS) scores, Numerical Rating Scale (NRS) scores, or other scale scores. If possible, static and dynamic pain intensity after the treatment will also be included.

2.2.4.2 Secondary outcomes

The Oswestry Disability Index is the most commonly used outcome measure to gauge a patient's permanent functional disability and is considered the gold standard among tools measuring low back function (11). It is composed of 10 items evaluating the severity of a patient's LBP, self-care ability, and capacity to perform various day-to-day activities, with each question scored from 0 to 5, then summed to derive a total score. Higher scores generally indicate worse conditions (12).

The Japanese Orthopedic Association Back Pain Evaluation Questionnaire is a reliable and sensitive disability measurement method used to determine the functional status of LBP and to assess treatment efficacy. It consists of 25 questions evaluating LBP patients from five different perspectives: pain-related illness, lumbar spine dysfunction, gait disturbance, social life dysfunction, and mental disturbance (13).

Requirement for analgesic drugs, which encapsulates the cumulative use of opioid medication or other pain-relief drugs during and after treatment, including all modes of administration.

Treatment-related adverse reactions, which could occur during or after SNT treatment, such as local bruising, persistent soreness or numbness, fainting sensations, thermal burns, etc.

2.3 Electronic bibliographic databases

From the inception of databases until December 2023, published literature in both English and Chinese electronic databases will be searched. English databases will include PubMed, Medline, Cochrane Library, and Embase. Chinese databases will encompass China National Knowledge Infrastructure (CNKI) and Wanfang Databases. Trial registries (ClinicalTrials.gov and WHO International Clinical Trials Registry Platform) will also be reviewed to avoid

missing ongoing or unpublished clinical trials. Additionally, reference lists of each study will be scanned to identify studies that may have been missed.

2.4 Search strategy

Two reviewers will conduct the search independently, with any disagreements to be resolved through consultation with a third reviewer, if possible. The search strategy will use the following terms: silver needle, thermotherapy, LBP, and RCT. Relevant search terms will also be translated into Chinese for literature research and study identification in Chinese databases. The literature search results will be updated comprehensively before the final publication of the meta-analysis, to avoid missing studies published in the course of preparing the meta-analysis. The detailed search strategy is submitted in Supplementary Table S1.

2.5 Selection of studies

Two reviewers conducted the literature search independently. The search results were downloaded to Endnote 20 and duplication were excluded. Study screening was conducted in two steps. First, studies that might meet the inclusion criteria were selected based on the title and abstract section of the literature, and then the two authors would identify randomized controlled trials that met the inclusion criteria based on the full text of the studies. If the two reviewer disagree on the selection, the third reviewer will solve disagreements. The study selection process is shown in the PRISMA flowchart Figure 1.

2.6 Data extraction

The data extraction form includes demographic data of participants, the degree and location of LBP, the etiology of LBP, inclusion and exclusion criteria, detailed information about the treatment protocol, and any outcomes, including primary, secondary, and exploratory outcomes. Characteristics of the study design will also be recorded, including randomization methods, allocation concealment, blinding (patients, treatment providers, outcome assessors), collection of incomplete outcome data, and statistical analysis and reporting of results. Continuous and dichotomous data will be recorded as $x \pm S$ deviation and percentages or proportions. If any data is unknown or missing, we will contact the original author to clarify the data. If necessary, numerical data from figures will be extracted using Adobe Photoshop (14).

2.7 Risk of bias

Two reviewers will independently assess the risk of bias by the Revised Cochrane Risk-of-Bias (RoB2) tool. We will evaluate randomization, deviation from the intervention's original plan, outcome data missing, measurement of the outcome, and selection of the reported result. We will judge each study as high-risk of bias, some concerns of bias or low-risk of bias. Any disagreements regarding the assessment of risk of bias will be resolved by discussion.

2.8 Data synthesis

This review will analyze the data by using Review Manager version 5.4 (Revman 5.4). Because of the potential heterogeneity of the intervention thresholds and intervention methods used, a random effects model will be used. Since both the primary and secondary outcomes are continuous variables and have the same units, we will calculate their mean differences and 95% confidence intervals. If the mean and variance are not reported in a trial, we will estimate the sample mean and standard deviation from the sample size, median, range and/or interquartile range. Meta-analyses will be performed only when two or more included studies reported the same outcome.

Statistical heterogeneity will be measured by the Cochran's Q and I^2 statistics, $p < 0.1$ was considered statistically significant for Cochran's Q, and $I^2 > 75\%$ taken to indicate considerable heterogeneity. If the heterogeneity is significant, we will investigate the source of it and find ways to reduce the heterogeneity.

The results of the meta-analysis will be interpreted according to clinical and statistical significance. A statistically significant reduction in any outcome indicator has some clinical significance. No additional analysis will be conducted in this study. If a quantitative synthesis is not appropriate, this study will only describe and analyze the study results in textual terms

2.9 Trial sequential analysis

The required information size (RIS) will be calculated to correct the risks of random errors by TSA using the TSA program V.0.9.5.10 Beta (Copenhagen Trial Unit, Copenhagen, Denmark) (15). TSA program version is available at http://www.ctu.dk/tsa (16). Every outcome will be monitored through RIS, the cumulative Z-curve, and the TSA monitoring boundary to prevent the risk of false-positive (type I error) and false-negative (type II error) results. We will keep a two-sided type I error rate at 5% (alpha boundary), and calculate the required RIS with 80% power, assuming a clinically significant difference of 20% (17).

2.10 Subgroup analysis

Subgroup analysis will be conducted to comprehensively interpret the results through analysis of subgroups or subsets wherever possible. If there are enough trials, data from different age groups of subjects, different types of LBP or different locations of LBP, different treatment regimens, and different treatments in control groups will be analyzed independently.

2.11 Quality of evidence

Two reviewers will evaluated strength of evidence related to all outcomes using the Grades of Recommendation Assessment, Development and Evaluation (GRADE) method, The quality of effect estimates will be classified as high, moderate, low or very low depending on the risk of bias, consistency, directness, precision and publication bias (18). Data from RCTs are generally considered

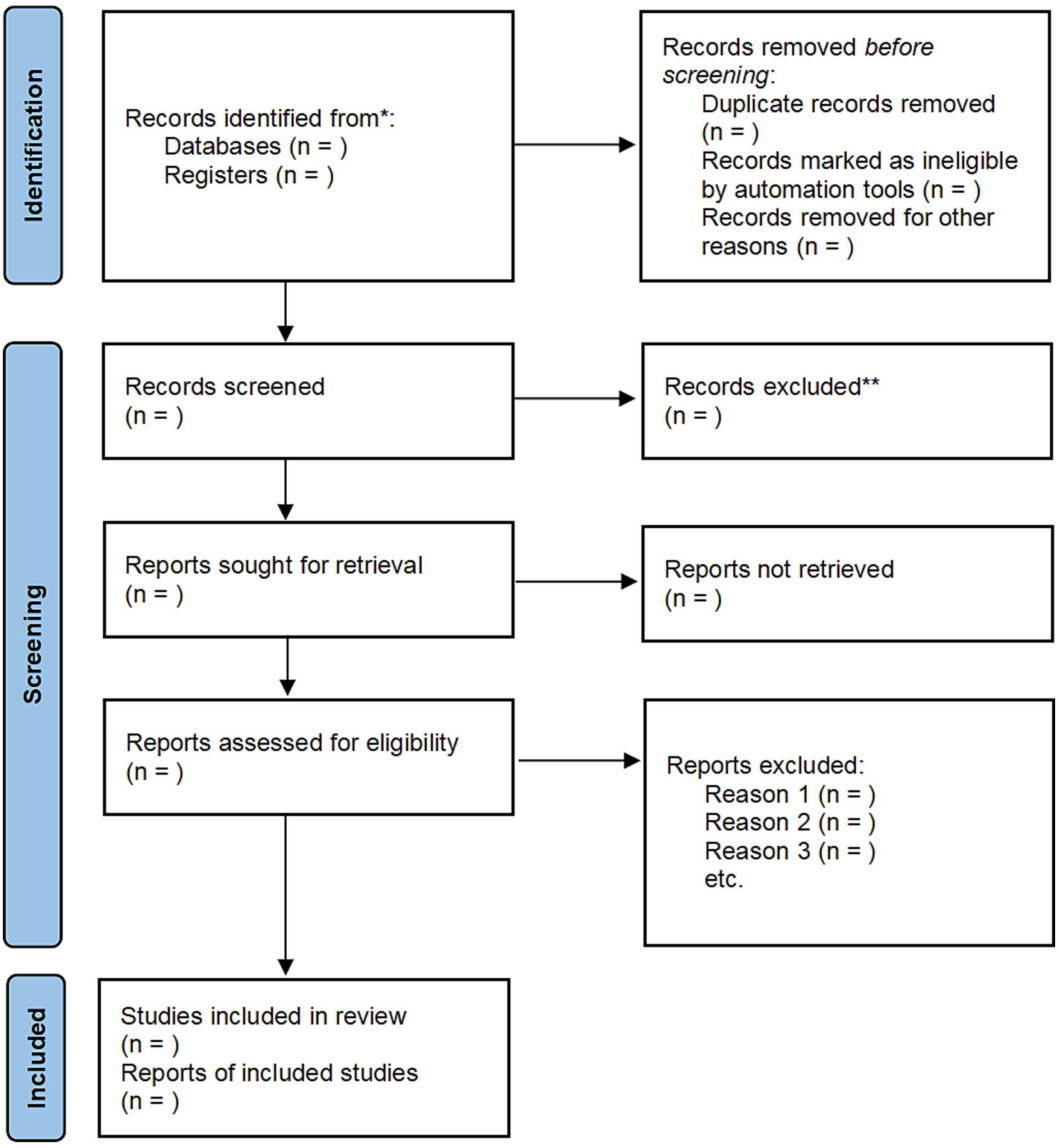

FIGURE 1
PRISMA 2020 flow diagram.

to be of high quality, but it can be downgraded due to the risk of bias, imprecision, inconsistency, indirectness, or publication bias in the experimental design or implementation.

3 Discussion

For many years, LBP has remained a significant public health burden, leading to a substantial amount of work-related disability and healthcare costs (19). It is estimated that between 70 and 85% of the general population will experience at least one episode of LBP at some point in their lives (20). LBP can be categorized into three types based on the duration of the symptoms following an episode. Acute LBP is defined as pain that persists for less than 4 weeks, subacute LBP lasts for 4 to 8 weeks and chronic LBP is characterized by symptoms that persist for more than 8 weeks since onset. There are many treatment methods for LBP, however, the optimal treatment plan has not yet been determined (21). In China, SNT is commonly considered an effective treatment for chronic LBP, a study utilizing SNT to treat chronic nonspecific LBP found that SNT was superior to physical therapy in improving patients' pain scores, and the therapeutic effect lasted for more than 6 months (22). Furthermore, recent studies have investigated the effects of SNT in treating acute LBP caused by lumbosacral disc degeneration, and have found that SNT can effectively alleviate disability and pain in patients, both in the short and long term (23).

SNT have been developed in China for over 60 years, and are widely used in the treatment of myofascial pain, while fascia plays an important role in LBP (24). Research has found that SNT can reduce the levels of IL-6, IL-8, and TNF-α (25), decrease the expression of neuronal nitric oxide synthase and substance P (26). Earlier numerous scholars have begun to explore 5-HT receptors' contribution to the

regulation of pain. Research has indicated that the ability of these receptors to either amplify or dampen pain signals is tightly linked to the specific receptor types and their action locations (27, 28). Recently scientific inquiries have brought to light 5-HT3 receptors role in the spinal cord's descending facilitation, a process that may potentially escalate to central sensitization. Lv et al. (29) showed an elevated expression of 5-HT3 receptors in the spinal cords of rats with myofascial pain, pointing to a probable connection between 5-HT3 receptors and myofascial pain related central sensitization. Furthermore, our studies have discovered that administering silver needle thermal therapy can notably reduce spinal 5-HT3 receptors expression in myofascial pain rat models, consequently alleviate pain feeling.

This meta-analysis will summarize the current evidence on the clinical efficacy and safety of SNT in treating patients with LBP. We will examine the analgesic effects, the benefits in reducing disability rates, and the incidence of treatment-related adverse events. The results of this systematic evaluation will aid in clinical decision-making to better treat LBP. The protocol for this meta-analysis was rigorously implemented in accordance with the PRISMA-P guidelines. The strengths of this meta-analysis include: First, a comprehensive literature search of both Chinese and English databases. Secondly, we will conduct multivariate analysis (including subgroup analysis, TSA, sensitivity analysis, etc.) to enhance the quality of evidence. Thirdly, the literature search, data extraction, and assessment of study quality will be independently conducted by at least two review authors according to the guidelines. Any disagreements will be resolved through discussion or consultation with other review authors wherever possible.

Limitations are as follows: First, studies involving LBP of varying locations, etiologies, and durations will be included, leading to potential heterogeneity. Secondly, there is a scarcity of clinical research on silver needle therapy for LBP, hence, the sample size of each included study may be limited and the number of studies with data available for subgroup analysis may be small. Thirdly, studies with high-level evidence, such as well-designed double-blind randomized controlled trials might be limited due to the difficulty in blinding patients.

Ethics statement

Ethical approval was not required for the study involving humans in accordance with the local legislation and institutional requirements. Written informed consent to participate in this study was not required from the participants or the participants' legal guardians/next of kin in accordance with the national legislation and the institutional requirements.

Author contributions

WL: Writing – review & editing, Writing – original draft. XX: Writing – review & editing. RL: Writing – review & editing, Writing – original draft.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

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Clinical efficacy of acupuncture therapy combined with core muscle exercises in treating patients with chronic nonspecific low back pain: a systematic review and meta-analysis of randomized controlled trials

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Introduction: This meta-analysis aimed to determine the clinical efficacy of acupuncture combined with core muscle exercises on pain and functional status in patients with chronic nonspecific low back pain.

Methods: This study followed the Preferred Reporting Items for Systematic Reviews and meta-analysis criteria for systematic reviews and meta-analyses. Randomized controlled trials published till November 2023 were searched in PubMed, Web of Science, Cochrane, Embase, China National Knowledge Infrastructure, Chinese Biomedical Literature, and Wanfang databases. The search strategy was related to disease type, intervention, and control measures and was structured around the search terms "low back pain," "acupuncture therapy," and "exercise." Two reviewers applied inclusion and exclusion criteria. Sensitivity and fixed effects analyses were performed to determine the primary outcomes.

Results: We included 11 randomized controlled trials ($n = 727$) on acupuncture combined with core muscle exercises in patients with chronic nonspecific low back pain. Compared with controls, clinical efficacy was significant, with improvements in pain scores (visual analog pain scale and numerical rating scale) and Oswestry Disability Index in the intervention group.

Discussion: Acupuncture therapy combined with core muscle exercises improved pain and functional status in patients with chronic nonspecific low back pain, with favorable clinical outcomes compared with single-core muscle training. Multicenter large-sample trials are required to obtain more reliable conclusions.

KEYWORDS

acupuncture therapy, core muscle exercises, chronic nonspecific low back pain, pain, clinical efficacy, dysfunction

1 Introduction

Low back pain (LBP) and acute and chronic pain in the posterior of the lumbar gluteal region between the 12th rib margin and the subgluteal fold are common clinical conditions classified into two major categories: idiosyncratic (caused by a specific etiology of spinal or non-spinal origin) and non-idiosyncratic (1). Nonspecific low back pain (NLBP) accounts for over 85% of LBP, and its diagnosis requires excluding specific pathological causes. The disease progresses to chronicity over 3 months of illness, primarily manifesting as pain and disability (2–4). In the Chinese context, "disability" refers to conditions that can cause short- or long-term health losses (5). According to epidemiological surveys, the number of people with chronic nonspecific low back pain (CNLBP) worldwide is approximately 568.4 million, with an average prevalence of approximately 18.3% and a lifetime prevalence reaching 47%. LBP has become the primary cause of years lived with disability worldwide, causing extensive medical expenditure, social burden, and productivity loss to families, communities, and countries (2, 6, 7).

Non-pharmacological interventions dominate the first-line treatment for CNLBP (8, 9). Regular exercise programs can significantly improve pain, function, posture, health status, and quality of life (8, 10, 11). The guidelines recommend exercises that activate the multifidus and transversus abdominis muscles, the primary core muscles of the lumbar spine that maintain lumbar spine stability, to improve pain and disability in patients with CNLBP (12, 13). Acupuncture is one of the most important means of traditional disease prevention and treatment in China. A large number of fundamental and clinical studies have confirmed that acupuncture has the therapeutic effects of correcting endocrine metabolism disorders, relieving pain, regulating mental health, and improving the quality of life, and that it plays an important role in neurology, connective tissue pathology, mental health, and other related fields (14).

High-quality evidence strongly recommends that patients with CNLBP should engage in physical exercise whenever possible; however, the quality of the evidence recommending acupuncture therapy is inconsistent (2–4, 9, 15). A systematic review published in 2022 addressed core stability exercises versus conventional exercise for chronic LBP, using meta-analysis to include 14 relevant studies, concluding that core stability exercises were superior to conventional exercise regarding short-term pain relief and improvement in functional disability (16). Another 2023 systematic review (comprising meta-analyses) reported acupuncture as an alternative or complementary treatment to conventional treatment for CNLBP and had six subgroups where acupuncture alone or combined with conventional treatment acupuncture were compared with conventional treatments (pharmacological, non-pharmacological, and combined pharmacological and non-pharmacological). Combined acupuncture and non-drug treatments reportedly further improve pain and disability; however, the quality of evidence is low, and only one randomized controlled trial (RCT) with exercise control was included (17). No relevant systematic review has demonstrated the therapeutic effects of acupuncture combined with core exercise programs. In the light of the above, this systematic review and meta-analysis aimed to assess the effectiveness of acupuncture combined with core muscle exercises in treating CNLBP, especially in improving patients' pain and disability.

Abbreviations: LBP, low back pain; NLBP, nonspecific low back pain; CNLBP, chronic nonspecific low back pain; RCT, randomized controlled trial; VAS, visual analog pain scale; NRS, Numerical Rating Scale; ODI, Oswestry Disability Index; CNKI, China national knowledge infrastructure.

2 Information sources and search strategies

Reference data were searched using the following electronic databases: PubMed, web of science, Cochrane, Embase, China national knowledge infrastructure (CNKI), Chinese biomedical literature, and Wanfang. We systematically searched the above databases for articles published till November 23, 2023, without language restrictions.

The search criteria were based on participants, intervention, comparison, outcome, time, and study design (PICOTS), and the search strategy was correlated with disease types, intervention, and control measures and was structured around the search terms "low back pain," "acupuncture therapy," and "exercise." Subject terms, their synonymous free words, and qualifiers were used to improve search sensitivity: ("Low Back Pain" OR "Back Pain, Low" OR "Back Pains, Low" OR "Low Back Pains" OR "Pain, Low Back" OR "Pains, Low Back" OR "Lumbago" OR "Lower Back Pain" OR "Back Pain, Lower" OR "Back Pains, Lower" OR "Lower Back Pains" OR "Pain, Lower Back" OR "Pains, Lower Back" OR "Low Back Ache" OR "Ache, Low Back" OR "Aches, Low Back" OR "Back Ache, Low" OR "Back Aches, Low" OR "Low Back Aches" OR "Low Backache" OR "Backache, Low" OR "Backaches, Low" OR "Low Backaches" OR "Low Back Pain, Postural" OR "Postural Low Back Pain" OR "Low Back Pain, Posterior Compartment" OR "Low Back Pain, Recurrent" OR "Recurrent Low Back Pain" OR "Low Back Pain, Mechanical" OR "Mechanical Low Back Pain") AND ("Acupuncture Therapy" OR "Acupuncture Treatment" OR "Acupuncture Treatments" OR "Treatment, Acupuncture" OR "Therapy, Acupuncture" OR "Pharmacoacupuncture Treatment" OR "Treatment, Pharmacoacupuncture" OR "Pharmacoacupuncture Therapy" OR "Therapy, Pharmacoacupuncture" OR "Acupotomies" OR "Acupotomy") AND ("Exercise" OR "Exercises" OR "Physical Activity" OR "Activities, Physical" OR "Activity, Physical" OR "Physical Activities" OR "Exercise, Physical" OR "Exercises, Physical" OR "Physical Exercise" OR "Physical Exercises" OR "Acute Exercise" OR "Acute Exercises" OR "Exercise, Acute" OR "Exercises, Acute" OR "Exercise, Isometric" OR "Exercises, Isometric" OR "Isometric Exercises" OR "Isometric Exercise" OR "Exercise, Aerobic" OR "Aerobic Exercise" OR "Aerobic Exercises" OR "Exercises, Aerobic" OR "Exercise Training" OR "Exercise Trainings" OR "Training, Exercise" OR "Trainings, Exercise") AND ("randomized controlled trial" OR "randomized" OR "placebo"). In PubMed, search results were limited to "randomized controlled trials." The Supplementary File contains further search strategies. The first author (XL) screened the studies by title and abstract according to the inclusion and exclusion criteria. In addition, a manual search of the references and abstracts of all the included articles and previous relevant systematic reviews and meta-analyses was conducted. The Preferred Reporting Items for Systematic Reviews and meta-analyses guided this systematic review and meta-analysis (18).

2.1 Inclusion criteria

The inclusion criteria of the articles is RCTS published in the above seven authoritative electronic databases. RCTS need to cover the following research components: (1) participants' inclusion criteria were limited to patients with CNLBP, defined as disease duration beyond 3 months; (2) The control groups underwent exercises targeting the core muscles; (3) the intervention groups involved the addition of acupuncture therapy to the control group that contained general acupuncture (manual acupuncture), electroacupuncture, needle-knife, and fire-needle; (4) the outcomes were pain, disability, and clinical outcomes of the patients. using measures including the visual analog pain scale (VAS), numerical rating scale (NRS), oswestry disability index (ODI), and clinical effectiveness.

2.2 Exclusion criteria

We excluded studies with the following characteristics: (1) Unavailability of full text and/or incomplete data; (2) LBP attributable to a specific pathology (including pelvic or urinary tract infections, tumors, renal disease, osteoporosis, lumbar spine lesions, inflammatory disorders, and neurogenic syndromes); (3) Studies where acupuncture was applied to a specific "microsystem" (e.g., scalp, ear, eye, or buccal needling); (4) Forms of acupuncture combined with moxibustion or medication, such as warm needling, acupoint injections, or hydroentanglement; (5) The inclusion of two or more acupuncture therapies in the observational group; (6) Exercise that does not target the core musculature; (7) The use of pharmacological treatments in the study.

2.3 Study selection and data extraction

Two researchers (GZ and HZ) independently assessed the potentially relevant articles after reading the full text for final inclusion. Disagreements were discussed with other authors, and a third researcher (ZT) resolved differences. The information collected included the first author's name, publication year, subject characteristics (mean age, sex, and disease duration), sample size, intervention (specific acupuncture therapy, exercise method, and duration of intervention), risk assessment, and outcome indicators.

2.4 Outcome measurement

In this systematic review and meta-analysis, the primary outcome was the pain score. The secondary outcomes were effectiveness and ODI scores.

2.5 Evaluation of research quality

Two researchers (XL and MW) independently assessed the methodological quality of each RCT using the Cochrane risk-of-bias assessment tool. Disagreements were resolved through discussions with a third investigator (ZH). The risk-of-bias assessment included random sequence generation, allocation concealment, blinding of participants and investigators, blinding of outcome assessment, completeness of outcome data, selective reporting, and other biases. All criteria were assessed equally at "low," "unclear," and "high" risk levels.

2.6 Data synthesis

All data analyses were performed using Review Manager version 5.3. Dichotomous outcomes were analyzed by calculating the relative risk for each trial, with the uncertainty of each outcome expressed as a 95% confidence interval (CI). When studies were assessed using the same scale, continuous outcomes were analyzed by calculating the mean difference of the 95% CI. When instruments were different, we used the standardized mean difference of the 95% CI. The statistical heterogeneity of the results of each study was evaluated using the Cochrane Q-test, and I^2 values were quantified using the Q-test significance threshold $p = 0.1$ and I^2 value (50%). The fixed-effects model was used when I^2 was <50%, and heterogeneity was explored when I^2 was >50%. The final results were presented as traditional meta-analytic forest plots.

2.7 Heterogeneity exploration and analysis

When there was statistical heterogeneity in the studies, we identified its potential causes through sensitivity analyses and used a random-effects model if it could not be eliminated and was <70%. Similarly, we prioritized sensitivity analyses, followed by subgroup analyses: classification of specific acupuncture therapies, patient age (less than or greater than 40 years), and disease duration (less than or greater than 12 months). However, we did not perform subgroup analyses because the final included studies were not significantly heterogeneous after sensitivity analyses to exclude some studies. We assessed possible publication bias by visually inspecting funnel plots (plots of effect estimates for each study versus sample size or standard error of the effect).

3 Results

3.1 Research options

We identified 247 studies from the selected databases, with 53 duplicate entries removed by document management software and manual searches. The remaining 194 studies were screened using titles and abstracts to exclude 179. The remaining 15 studies were assessed based on the inclusion and exclusion criteria described above. We selected 11 RCTs for meta-analysis (19–29). A flowchart is shown in Figure 1.

3.2 Study characteristics and interventions

The number of participants in the 11 RCTs was 727 (observation group, $n = 364$; control group, $n = 363$), with sample sizes in individual studies ranging from 26 (20) to 50 (19). The 11 trials included both sexes, with a predominantly young adult age profile and mean age fluctuations ranging from 26 years (23) to 55 years (20), and all included patients had NCLBP. In the 11 RCTs, the control group performed core muscle exercises, including suspension exercise

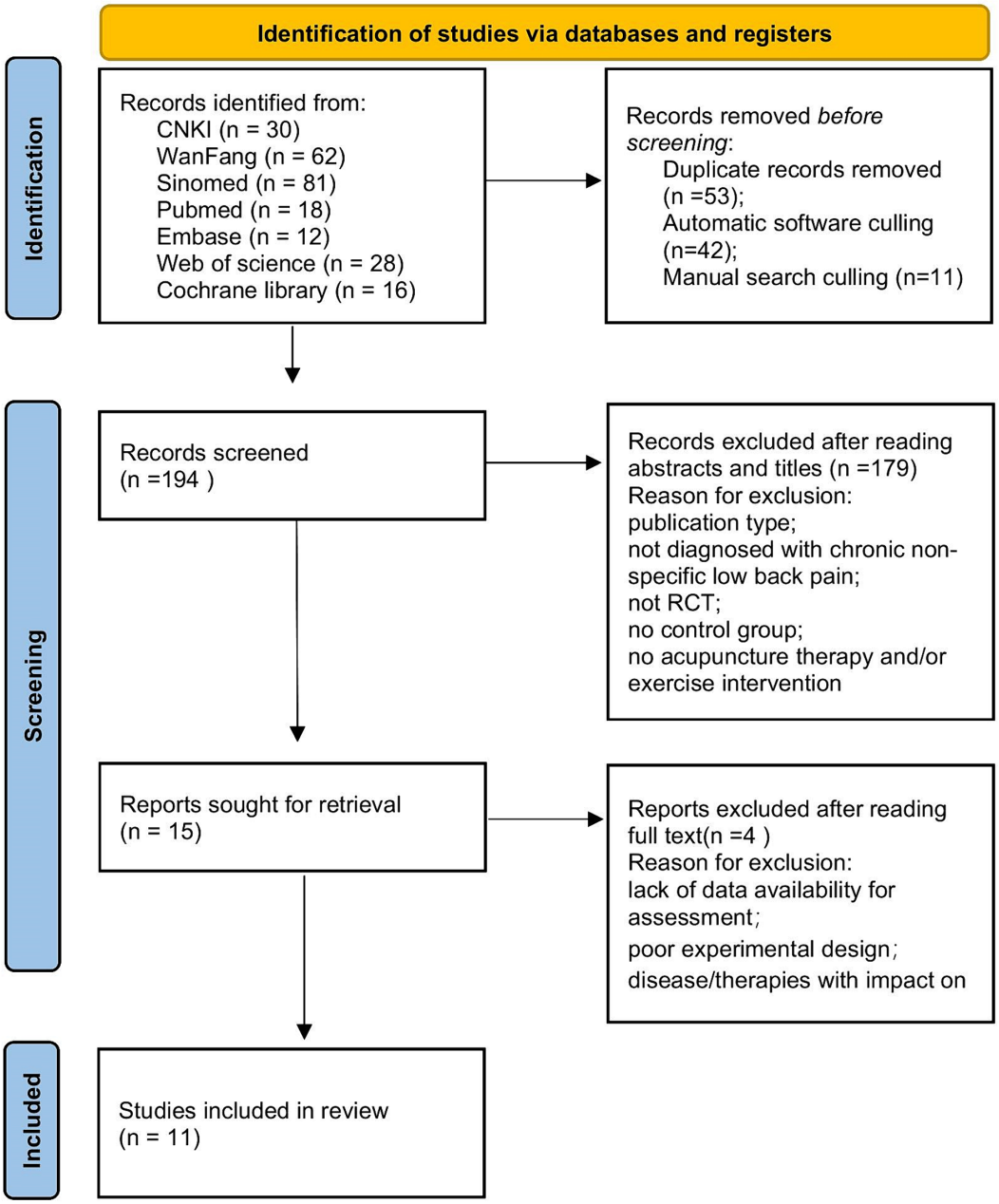

FIGURE 1
Preferred reporting items for systematic reviews and meta-analysis flow diagram.

training modalities; three were core muscle exercises performed by the treatment staff through the suspension training system (20, 23, 28), and the rest were self-exercised core muscle exercises guided by the treatment staff. The observation group received acupuncture therapy, while the control group received no specific treatment type. The intervention time and frequency of acupuncture therapy varied according to the specific type, ranging from 2 weeks (19, 22, 29) to 8 weeks (25), and the frequency of intervention from once weekly (25, 27, 29) to once daily (23, 26). For exercise therapy interventions, the duration ranged from 2 weeks (22) to 3 months (29), and the frequency of exercise ranged from once daily (20, 22, 23, 26–28) to once weekly (25). One RCT (23) specified only the number of interventions without frequency, and one RCT (28) did not explicitly explain the frequency of acupuncture therapy interventions. The details of the study characteristics and interventions are presented in Table 1.

The 11 RCTs involved assessing pain, low-back dysfunction, and treatment effects. 10 RCTs (19, 21–29) involved using VAS to assess overall pain, and one (20) involved using NRS to assess peak versus mean pain. Six RCTs (21, 22, 24, 25, 27, 29) involved using ODI to assess lumbar dysfunction, and the rest were conducted using The Aberdeen LBP scale (20), The Roland Morris disability questionnaire (26), and the Japanese Orthopedic Association Assessment Treatment score (23, 28). Three RCTs (23, 28, 29) were conducted using the Japanese Orthopedic Association Assessment Treatment score, and another (29) converted the Japanese Orthopedic Association Assessment Treatment score results to a percentage to evaluate the

TABLE 1 Characteristics of the included RCT studies.

First author, year	Sample size		Gender (M:F)		Mean age		Disease duration		Intervention duration		Exercise intervention	Control intervention	Outcome
	Exercisers	Controls	Exercisers	Controls	Exercisers	Controls	Exercisers	Controls	acupuncture therapy	Exercise therapy			
Li et al., 2020 (29)	30	30	1:1	17:13	48.1 ± 8.6	47.6 ± 7.2	8.67 ± 3.44	9.20 ± 4.10	1 session weekly, 2 weeks	4 sessions weekly, 3 months	Acupotomy + core stability training	core stability training	A;B;C
Liao, 2019 (24)	30	30	7:8	17:13	41.6 ± 5.01	42.13 ± 4.78	35.07 ± 1.59	37.47 ± 8.96	3 sessions weekly, 4 weeks	3 sessions weekly, 4 weeks	Traditional acupuncture + core muscle group training	core muscle group training	A;B;C
Han, 2017 (23)	30	30	13:17	2:3	26.71 ± 7.12	27.14 ± 6.65	10.22 ± 4.28	9.16 ± 3.52	1 session daily, 10 sessions	1 session dayly, 10 sessions	electroacupuncture + core strength training	core muscle group training	A
Liu et al., 2020 (22)	40	38	21:19	17:21	49.70 ± 7.13	47.05 ± 8.35	29.93 ± 13.94	26.89 ± 16.07	1 every other day, 2 weeks	1 session weekly, 2 weeks	floating needle therapy + core muscle group training	core muscle group training	A;C
Liu et al., 2021 (21)	42	42	10:11	3:4	36.64 ± 7.59	36.59 ± 7.82	30.27 ± 11.09	21.46 ± 2.49	5 sessions weekly, 4 weeks	5 sessions weekly, 4 weeks	electroacupuncture + core strength training	core strength training	A;B;C
Liu, 2012 (28)	20	20	1:1	4:3	43.28 ± 10.34	46.73 ± 11.58	66.78 ± 14.57	67.43 ± 13.55	/, 4 weeks	1 session weekly, 4 weeks	acupuncture + suspension core muscle training	suspension core muscle training	A
Jiang, 2021 (27)	40	40	23:17	11:9	49.50 ± 3.27	49.00 ± 3.28	8.00 ± 1.30	8.50 ± 1.28	1 session weekly, 3 weeks	1 session dayly, 20 days	bladed needle + core muscle group training	core muscle group training	A;B;C
Li et al., 2018 (26)	26	27	19:11	16:13	36.29 ± 4.61	36.95 ± 4.4	15.94 ± 5.08	14.98 ± 5.17	1 session dayly, 20 days	1 session dayly, 20 days	Tendon acupuncture + core stability training	core stability training	A;B
Huang, 2019 (25)	30	30	3:2	19:11	27.23 ± 4.13	27.44 ± 4.29	10.92 ± 3.29	10.36 ± 3.43	1 session weekly, 8 weeks	1 session weekly, 8 weeks	fire acupuncture + core muscle group training	core muscle group training	A;B;C
Wang and Zhu, 2020 (19)	50	50	14:11	27:23	36 ± 6	36 ± 6	8.7 ± 4.3	8.6 ± 4.1	6 sessions weekly, 2 weeks	3 sessions weekly, 4 weeks	Cangguitanxue acupuncture + suspension core muscle therapy	suspension core muscle training	A;B
Yeung et al., 2003 (20)	26	26	2:11	5:21	50.4 ± 16.3	55.6 ± 10.4	/	/	3 sessions weekly, 4 weeks	1 session weekly, 4 weeks	electroacupuncture + back muscles exercises	back muscles exercises	D

A, VAS scores; B, Efficiency; C, ODI scores; D, NRS scores.

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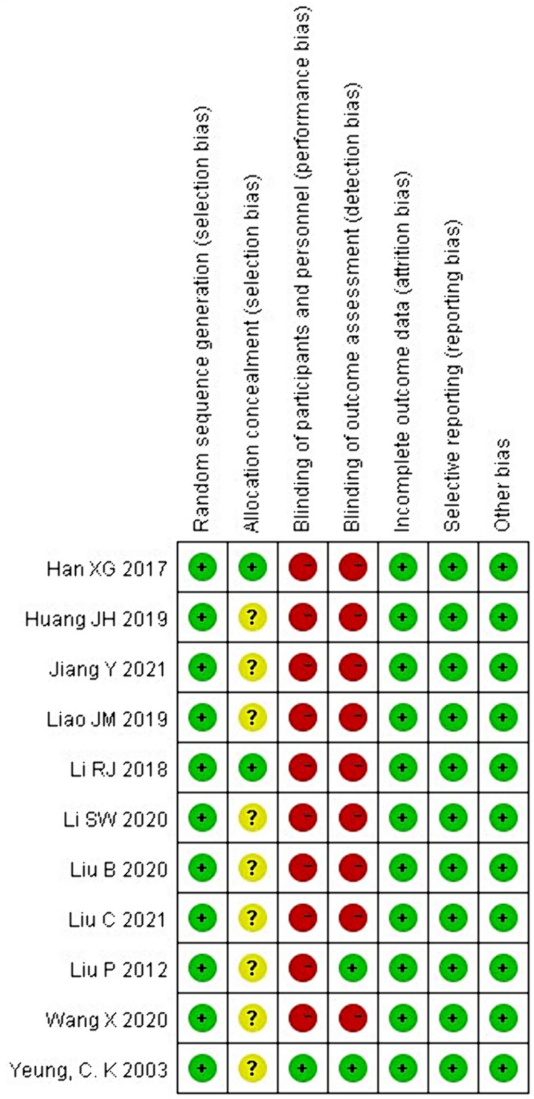

FIGURE 2
Risk of bias assessment summary of randomized control trials (RCTs).

treatment effect. Seven RCTs (19, 21, 24–27, 29) involved using the efficiency rate to evaluate the clinical treatment, and the details of the remaining outcome indicators are presented in Table 1.

3.3 Methodological quality

The Cochrane Collaboration tool was used to assess the risk of bias in RCTs for systematic review and meta-analysis. The methodological quality assessment is shown in Figures 2, 3. All studies were judged to be at low risk of bias in randomized sequence generation, completeness of results, and selective reporting. Nine studies were at uncertain risk of bias in the allocation scheme (allocation concealment) owing to the risk of bias not being specified in the article (19–22, 25, 27–29). 10 studies were judged to be at high risk of bias in the blinding of participants and personnel (19, 21–29). Nine studies at high risk of bias were judged similarly in the blinding of the outcome assessment (19, 21–27, 29). The risk of bias assessment is shown in Figures 2, 3.

3.4 Outcome measures

3.4.1 Effect of acupuncture therapy combined with core muscle exercises on pain scores (VAS and NRS) in patients with CNLBP

Eleven RCTs ($n = 727$) involved assessing the effects of acupuncture combined with core muscle exercises on pain score outcomes (19–29). Because the NRS used by Yeung et al. (20) has the same unit of measurement as the VAS pain score, and the final post-treatment effect sizes were all mean difference values, we included them in the assessment.

Eleven RCTs showed large heterogeneity ($I^2 = 95\% > 50\%$, $p < 0.1$); therefore, we conducted a heterogeneity analysis. Sensitivity analysis was performed on the 11 RCTs in this study and revealed that Jiang Yi, Li Ruijie, Liu Chang, and Li Shuwen studies had significant heterogeneity (21, 26, 27, 29). After removing these four studies, the heterogeneity test was repeated, and the results showed that the remaining seven studies did not have heterogeneity ($I^2 = 36\% < 50\%$, $p = 0.15 > 0.1$). Subsequently, the fixed effects were used to combine effect sizes, and the results showed that the difference between the two groups was statistically significant. The effect size of the remaining seven studies reached −0.88 with a 95 CI of −1.07 to −0.68 and was statistically significant ($Z = 8.80$, $p < 0.00001$). Therefore, according to the results of the fixed effects analysis, pain scores were significantly reduced in the acupuncture therapy combined with the core exercise group compared with those in the control group (Figure 4).

3.4.2 Effect of acupuncture therapy combined with core muscle exercises on the clinical outcomes of patients with CNLBP

The clinical efficacy of acupuncture therapy combined with core muscle exercises for pain reduction, functional improvement, and quality of life was assessed in seven (19, 21, 24–27, 29) of the current 11 RCTs. After the heterogeneity test, $I^2 = 0\% < 50$, $p = 0.67 > 0.1$, suggesting that the heterogeneity between the selected studies was not statistically significant and that fixed effects should be selected for meta-analysis. The pooled relative risk value of the seven studies was 1.14, with a 95% CI of 1.07 to 1.22, and was statistically significant ($Z = 3.83$, $p = 0.0001 < 0.05$). Therefore, according to the fixed-effects analysis, the clinical efficacy of acupuncture combined with core exercises was more evident than that of the control group (Figure 5).

3.4.3 Effect of acupuncture therapy combined with core muscle exercises on ODI in patients with CNLBP

The ODI was used to assess lumbar dysfunction, and six of the 11 RCTs in this study (21, 22, 24, 25, 27, 29) involved using the ODI scores. We deleted one study with a different calculation method (24) where heterogeneity extensively persisted ($I^2 = 96\% > 50$, $p < 0.1$), prompting a search for heterogeneity. Sensitivity analysis was performed on the current six studies, and two RCTs (27, 29) largely affected heterogeneity. After deleting these two studies, the heterogeneity test was repeated and revealed no heterogeneity in the remaining three studies ($I^2 = 21\% < 50\%$; $p = 0.28 > 0.1$). The fixed effects were used to combine the effect sizes, and the results showed that the difference between the two groups was statistically significant. The remaining three study effect size reached −2.80 with a 95% CI of −3.25 to −2.35 and was statistically significant ($Z = 12.21$, $p < 0.00001$), suggesting that acupuncture therapy combined

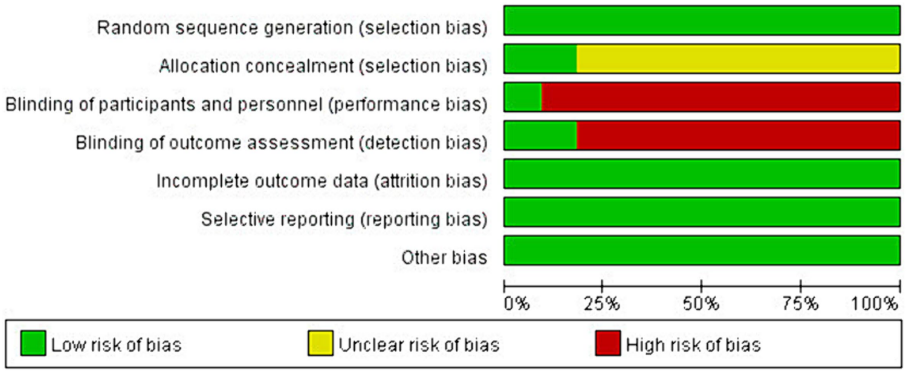

FIGURE 3
Risk of bias items as percentages across all included studies.

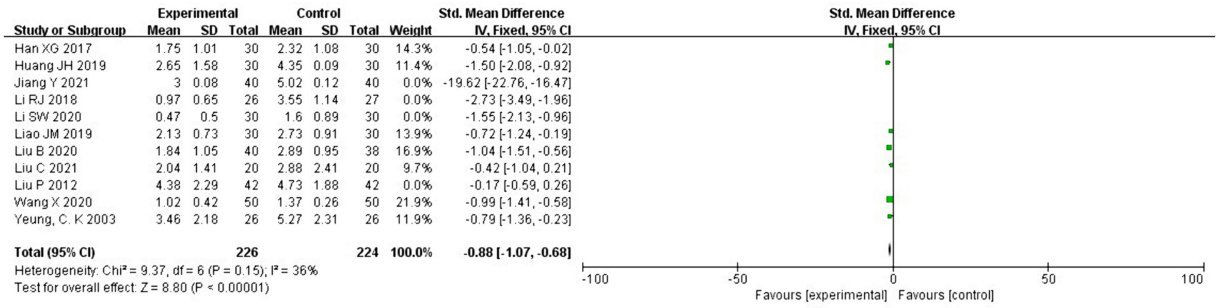

FIGURE 4
Forest plot for pain scores.

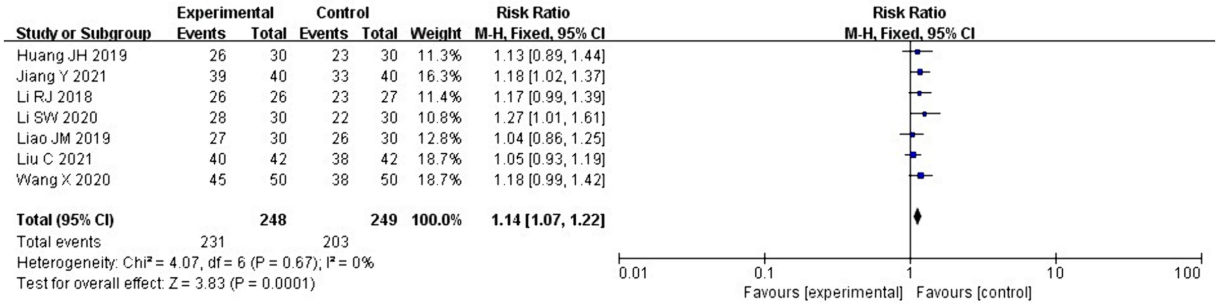

FIGURE 5
Forest plot for clinical effectiveness.

with core exercises is superior to exercise therapy alone in improving dysfunction (Figure 6).

3.5 Publication bias

We planned to use funnel plots to evaluate publication bias; however, the number of included trials ($n = 11$) and that of patients per trial were small (25–49). Therefore, we could not assess publication bias.

4 Discussion

This study primarily aimed to assess the effect of acupuncture combined with core exercise on pain and functional disability in patients with CNLBP through a systematic review and meta-analysis of RCTs. According to the results of meta-analysis, acupuncture therapy combined with core exercises can improve the pain and functional status of patients with CNLBP, and the therapeutic efficiency is significantly better than that of core

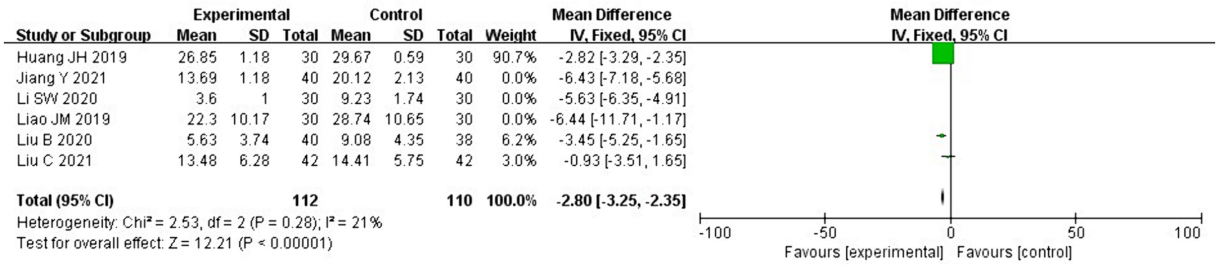

FIGURE 6
Forest plot for ODI scores.

exercises alone; therefore, we recommend acupuncture therapy combined with core exercises as a treatment option.

According to the results of basic and clinical studies related to the treatment of CNLBP, core stability training can activate the function of deep lumbar and abdominal muscle groups to improve lumbar spine stability (30), as well as improve pain thresholds and reduce pain intensity (31). Acupuncture therapy can inhibit inflammatory pain through peripheral, spinal and supraspinal mechanisms that activate a range of bioactive molecules containing opioid receptors, 5-hydroxytryptamine, norepinephrine and cytokines (32). Similarly, clinical trials have shown that acupuncture combined with baclofen has better clinical efficacy than baclofen alone in the treatment of CNLBP (33), and that acupuncture alone can still produce positive clinical results (34). Therefore, we believe that the combination of the two treatments may lead to better clinical outcomes.

Pain is the fifth most important vital sign in human beings (35), and the main clinical symptom of CNLBP patients is pain, and the improvement of pain is the main assessment index after acupuncture therpy combined with core muscle exercises treatment, so we used VAS score as the primary outcome index in this study. The VAS and NRS scores are pain intensity assessment scales. The NRS involves asking participants to select a number from 0 to 10 to rate their average pain intensity over the past 7 days. The VAS involves asking participants to select a point on a 0–10 cm line to represent their average pain intensity over the past 7 days, which is converted to a number. The two scores are rarely influenced by non-pain intensity in assessing a patient's pain factors (pain or distress beliefs) and have high accuracy as pain assessment criteria (36). Yeung et al. used NRS to assess the mean pain intensity of patients with CNLBP, which is consistent with the range of VAS scores used in other studies. Moreover, according to the study, the NRS and VAS (36, 37) showed no significant differences in assessing LBP severity, and the VAS is a pain intensity measure similar to the NRS. The final post-treatment effect sizes were all mean differences, and there was no heterogeneity in the sensitivity analyses; therefore, we included the Yeung study in analyzing pain scores.

CNLBP patients also have low-back dysfunction, and the ODI is one of the most commonly used scales to assess low-back dysfunction, so we used the ODI as a secondary outcome indicator. The ODI is a research scale for assessing the functional status of patients with LBP based on the subjective evaluation of their CLBP symptoms and function. In the sensitivity analyses of the included studies, we excluded two studies with greater heterogeneity (27, 29), which involved using bladed needles and needle knives with a loosening effect. Needle knives and bladed needles originated from the ancient "nine-needle" therapy, which differs from the round needle with a pointed tip of traditional acupuncture, with a thicker diameter and a flattened and bladed tip, except for the effect of regulating qi and blood of the traditional acupuncture, which can peel off and loosen the adhesion, contracture of the tendons, and relieve the nerve and blood vessel from the pressing stimulation (38–41). The study revealed that the needle knife with loosening effect and blade needle have a better effect on improving the functional status of patients' waist; however, we included fewer studies with smaller sample sizes, and the research data to argue the possibility of the cause of this heterogeneity are insufficient. In terms of disability assessment, a total of four scales were used as observational indicators, including ODI scores, which was involved in the meta-analysis, and The Aberdeen LBP scale (42), The Roland Morris disability questionnaire (43), and the Japanese Orthopedic Association Assessment Treatment score (23, 28). For this meta-analysis of acupuncture combined with core muscle exercise for CNLBP, the ODI scale was the most commonly used scale in the included clinical studies, and the Roland Morris disability questionnaire was less frequently used, with only one clinical study using this scale, which was insufficient to develop reliable data results and did not allow for conversion of data between scales; therefore, we did not perform a meta-analysis of the Roland Morris disability questionnaire.

In our initial statistical results, we included studies with large heterogeneity. After sensitivity analyses to exclude studies with large heterogeneity, we attempted to analyze the reasons for the statistical heterogeneity caused by the excluded studies. We considered acupuncture therapy as a treatment that involves using needles to penetrate the body to prevent and treat diseases. Therefore, we included in this retrospective analysis, different acupuncture studies that involved conventional acupuncture, electroacupuncture, needle knife (bladed needle), and fire acupuncture, with differences in the corresponding theories of these treatments, the application site, the choice of needles, and the treatment means. Therefore, the variability of the specific acupuncture therapies in the included studies may be the primary cause for statistical heterogeneity.

Our systematic review analyses were derived from comprehensive bibliographic searches of multiple databases without time constraints, followed Cochrane standards, and involved using a rigorous process and methodology. However, there are some limitations to our review. As international studies on acupuncture therapy have primarily focused on the clinical effects and mechanisms explored in

acupuncture and most of the RCTs were on acupuncture versus sham acupuncture (44–51), we could not include enough relevant international studies.

We removed two English-language articles from the final studies included in the assessment. Minakawa et al. excluded people with LBP who exercised for 30 min or more at least twice a week for at least 1 year (52). The researchers of this study concluded that patients' fear of LBP causes them to avoid physical activity. Therefore, using patient education to eliminate fear and encourage exercise can yield good results; however, older adults with exercise habits do not have associated challenges. We believe that this study improved patients' psychological state and behavior through the provided patient education and that psychoeducational and behavioral change techniques are good facilitators for maintaining symptom improvement after LBP treatment (53). Hence, we excluded this study. Martín-Corrales et al. control group was treated with a combination of sham-dry needling based on exercise, that is, without penetrating the skin, using Park sham needles (Park Sham Device, AcuPrime, UK) on the skin to induce a tingling sensation (54). However, exploring the therapeutic mechanism of acupuncture based on meridian research theories suggests that acupuncture points are rich in sensory nerve receptors and that stimulation of acupuncture points, manually or using low currents and frequencies, reportedly works through the connection of the central nervous system to the effector organs and the integrative function of neurons in the brain (55). The research method of pseudo acupuncture, which separates the biological and psychological effects of acupuncture, does not conform with the traditional therapeutic concept of Chinese medicine, which is "unity of mind and body," and also violates today's "biopsychosocial" medical model; therefore, it should not be treated as a placebo in a drug trial. Sham acupuncture cannot be compared with placebo in a drug trial in a double-blind RCT; therefore, we also excluded this study.

We attempted to validate the specific effects of the duration of the exercise program and the different types of acupuncture therapies on pain, functional status, and clinical outcomes in patients with CNLBP; however, the small sample size hindered this. Thus, multi-center, large-sample trials are needed to obtain more reliable conclusions.

CLBP covers two categories, specific and non-specific, and non-specific low back pain is more common in clinical practice, accounting for about 85% (1), so this systematic review and meta-analysis only included acupuncture therapy combined with core exercise for CNLBP for relevant analysis, but specific low back pain should also attract the attention of clinicians, and we will conduct a relevant research for specific low back pain in the next study.

We concluded that acupuncture therapy combined with core exercise improved pain and function in patients with CNLBP compared with core exercise therapy alone and had good clinical efficacy. However, multicentre, large-sample trials are required to obtain more definitive conclusions.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

XiL: Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. GZ: Writing – review & editing, Data curation, Conceptualization. HZ: Writing – review & editing, Data curation. XuL: Writing – review & editing, Data curation, Conceptualization. MW: Writing – review & editing, Data curation. SZ: Writing – review & editing, Data curation. JC: Writing – review & editing, Investigation. ZT: Writing – review & editing, Writing – original draft, Visualization, Supervision, Methodology, Funding acquisition, Formal analysis, Data curation, Conceptualization. ZH: Writing – review & editing, Data curation.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fmed.2024.1372748/full#supplementary-material

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Thoracic spinal anesthesia with intrathecal sedation for lower back surgery: a retrospective cohort study

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Background: Spinal anesthesia (SA) is a good alternative to general anesthesia (GA) for spine surgery. Despite that, a few case series concern the use of thoracic spinal anesthesia for short-duration surgical interventions. In search of an alternative approach to GA and a better opioid-free modality, we aimed to investigate the safety, feasibility, and patient satisfaction of thoracic SA for spine surgery.

Materials and methods: We analyzed retrospectively a cohort of 24 patients operated on for a degenerative and osteoporotic pathology of the lower thoracic and lumbar spine. Data was collected from medical records, including clinical notes, operative and anesthesia records, and patient questionnaires.

Results: Twenty-one surgeries for herniated discs, two for degenerative spinal stenosis, and one for multi-level osteoporotic vertebral body fractures were performed under spinal anesthesia with intrathecal sedation. In all cases, we applied 0.5% isobaric bupivacaine and the following adjuvants: midazolam, clonidine or dexmedetomidine, and dexamethasone. We boosted the anesthesia with local ropivacaine due to inefficient sensory block in two patients. Nobody in the cohort received intravenous opioids, non-steroidal anti-inflammatory drugs, or additional sedation intraoperatively. Postoperative painkillers were upon the patient's request. No significant complications were detected.

Conclusion: Thoracic spinal anesthesia incorporating adjuvants such as midazolam, clonidine or dexmedetomidine, and dexamethasone demonstrates not only efficient conditions for spine surgery, a favorable safety profile, high patient satisfaction, and intrathecal sedation but also effective opioid-free pain management.

KEYWORDS

thoracic spinal anesthesia, intrathecal midazolam, intrathecal clonidine, intrathecal dexmedetomidine, intrathecal sedation, spine surgery

Introduction

Numerous studies have confirmed that spinal anesthesia (SA) is a good alternative to general (GA) for lower spine surgeries. It demonstrates a low level of intra- and postoperative complications, including cognitive impact in at-risk patients, and better postoperative pain management with reduced anti-inflammatory drugs and opioid utilization. Additionally, the SA is associated with decreased operative duration, time to ambulation, length of hospitalization, and costs compared to GA (1–5).

Anesthetic procedures at the thoracic and upper lumbar segment are far less common but are expected to offer similar advantages. The literature concerning the use of thoracic spinal anesthesia with intrathecal sedation for lumbar spine surgery is scarce. Only a few case reports and series with limited subjects have recently been published, and a widely accepted protocol is missing (6–8). Some clinicians have voiced concern about an increased risk of neurological deficits from injuring the spinal cord and difficulty in getting intrathecal access to perform spinal anesthesia in patients with degenerative vertebral pathology, especially with segmental vertebral deformities. However, some authors present results without an increased rate of complications (8, 9).

The aim of this study is to evaluate the feasibility, safety, patient satisfaction, and opioid-sparing potential of thoracic spinal anesthesia with intrathecal sedation for spine surgery.

Materials and methods

All procedures discussed in this retrospective cohort study were conducted between March 2022 and December 2023 in the Clinic of Neurosurgery at St. Ivan Rilski University Hospital, Sofia, Bulgaria, a tertiary care facility for spinal and neurosurgical intervention. This work fulfills the STROBE checklist for reporting cohort observational studies. We analyzed a cohort of 24 patients operated on for a degenerative and osteoporotic pathology of the lower thoracic and lumbar spine.

Briefly, all patients received spinal anesthesia through a routine single-shot technique with a 22G Quincke needle in a sitting position. After identifying the intervertebral space by anatomical landmarks, 2 cm of the spinal needle was inserted by a paramedian approach. Any further insertion was performed with caution until bony contact with vertebral lamina. The spinal needle was then redirected and further advanced by 2–3 mm increments. After each advancement a check for cerebral spinal fluid backflow was performed. Once the needle was in the intrathecal space, 0.5% isobaric bupivacaine solution was applied in the range of 10–15 mg. Adjuvants, including an α-2 agonist (clonidine 10–20 mcg or dexmedetomidine 10–15 mcg), midazolam (2–3 mg), and dexamethasone (4 mg), were administered. Patients were then placed supine till the sensory block fixation and then in lateral decubitus or prone position for surgery. The level of puncture was verified by C-arm. No urethral catheters were inserted.

Postoperative pain management consisted of non-steroidal anti-inflammatory drugs (NSAID) on demand, including 1 g of paracetamol or 50 mg of dexketoprofen. Opioids were given if sufficient analgesia wasn't achieved with the previous.

We used the Ramsay Sedation Scale (RSS) as a tool to evaluate the intraoperative level of consciousness, Table 1 (10). Pain intensity was assessed by the Visual Analogue Scale (VAS) presented by a straight line with points ranging from 0 ("no pain at all") to 10 ("the worst possible pain"). It was measured at the 6th and 24th hour after the puncture for SA. Information about the level of patient satisfaction was retrieved from specific questionnaires designed by our group and given to all patients who underwent surgery under loco- regional anesthesia on the day of hospital discharge. The questionnaires included 3 questions, each with three possible answers, Table 2. Every patient with a sum of fewer than 7 points was considered satisfied, whereas we accepted a result of 7 as borderline.

Procedural time, puncture level, drug amounts, sensory blockade and sedation levels, patient and surgeon satisfaction, and postoperative usage of painkillers were analyzed for each case. Data was collected from medical records, including clinical notes, operative and anesthesia records and questionnaires.

TABLE 1 Ramsay sedation scale to assess patient's consciousness level.

Clinical score	Patient characteristics
1	Awake, agitated or restless or both
2	Awake, cooperative, oriented, and tranquil
3	Awake, responds to commands only
4	Asleep, brisk response to light glabellar tap or loud auditory stimulus
5	Asleep, sluggish response to light glabellar tap or loud auditory stimulus
6	Asleep, no response to glabellar tap or loud auditory stimulus

TABLE 2 Patient satisfaction questionnaire, designed by our group, consists of 3 questions with three answers each.

Question to patients	Patient's responses	Points
How did you feel during the anesthesia administration?	Totally relaxed	1
	Uneasy, concerned	3
	Anxious, stressed, scared	6
How would you rate your experience during the surgery?	Very pleasant	1
	Neither pleasant nor unpleasant	3
	Totally unpleasant	6
Would you choose the same anesthetic modality for a supposed surgery in the future (if applicable)?	I would surely choose it	1
	I cannot decide	3
	Most definitely not	6

Results

The study cohort included 24 patients (11 females and 13 males) with a mean age of 49.6 years (range 21–88 years). All patients were grade I or II according to the physical status classification system of the American Society of Anesthesiologists (ASA). They suffered from disc herniations at the lumbar level, except two with degenerative spinal stenosis and one with multi-level osteoporotic compression vertebral fractures at the thoracolumbar junction. Patients' data and details regarding the surgical intervention, spinal anesthesia, and early clinical outcome are extensively presented in Table 3.

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TABLE 3 Patients' data and details regarding the surgical intervention, spinal anesthesia, and early clinical outcome are.

ID	Age, sex	Diagnosis	Operative procedure	Surgical position	OR time	Surgery duration	Puncture level	Anesthesia level	Medication	VAS 24 h
1.	71 m	Degenerative spinal stenosis L4-L5 with polyradiculopathy	Hemilaminectomy L4 (left), foraminotomy L4-L5 (left) and over-the-top decompression	prone	115	50	L2-L3	T12	BUPI 15 mg, MDZ 3 mg, DEX 10 mcg	3
2.	64 m	HD L5-S1 with radiculopathy L5 (left)	Interlaminar approach L5-S1 (right), sequestrectomy and discectomy	prone	85	60	L1-L2	T2-T3	BUPI 15 mg, MDZ 2 mg	4
3.	45f	HD L5-S1 with radiculopathy S1 (right)	Interlaminar approach L5-S1 (right), sequestrectomy and discectomy	lateral decubitus	80	35	T12-L1	T7-T8	BUPI 15 mg, MDZ 2.5 mg, CLON 10 mcg	2
4.	36 m	HD L5-S1 with radiculopathy S1 (right) - recidive	Interlaminar approach L5-S1 (right), sequestrectomy and discectomy	prone	110	60	L2-L3	T10	BUPI 15 mg, MDZ 2 mg, CLON 15 mcg	5
5.	36f	HD L4-L5 with radiculopathy L4 and L5 (left)	Interlaminar approach L4-L5 (left), sequestrectomy and discectomy	prone	140	70	L3-L4	T12	BUPI 15 mg, ROPI 7.5 mg, MDZ 3 mg, CLON 20 mcg	3
6.	39f	HD L5-S1 with radiculopathy S1 (right)	Interlaminar approach L5-S1 (right), sequestrectomy and discectomy	prone	90	60	T12-L1	T1-T2	BUPI 15 mg, MDZ 3 mg, CLON 20 mcg	4
7.	72f	Osteoporotic compression fractures of T11, T12 and L1	Percutaneous transpedicular vertebroplasty T11, T12 and L1	prone	65	30	L1-L2	T11	BUPI 12.5 mg, MDZ 2.5 mg, CLON 20 mcg	4
8.	48 m	HD L5-S1 with radiculopathy S1 (right)	Interlaminar approach L5-S1 (right), sequestrectomy and discectomy	prone	65	30	T12-L1	T5	BUPI 15 mg, MDZ 2.5 mg, CLON 15 mcg	4
9.	35 m	HD L5-S1 with radiculopathy S1 (right)	Interlaminar approach L5-S1 (right), sequestrectomy and discectomy	prone	70	45	T12-L1	T2	BUPI 12.5 mg, MDZ 3 mg, CLON 20 mcg	3
10.	38 m	HD L5-S1 with radiculopathy S1 (right) - recidive	Interlaminar approach L5-S1 (right), sequestrectomy and discectomy	lateral decubitus	100	70	T12-L1	T8	BUPI 12.5 mg, MDZ 3 mg, CLON 20 mcg	1

(Continued)

TABLE 3 (Continued)

ID	Age, sex	Diagnosis	Operative procedure	Surgical position	OR time	Surgery duration	Puncture level	Anesthesia level	Medication	VAS 24 h
11.	52f	HD L5-S1 with radiculopathy S1 (right)	Interlaminar approach L5-S1 (right), sequestrectomy and discectomy	prone	70	30	T12-L1	T7	BUPI 10 mg, MDZ 3 mg, CLON 20 mcg	2
12.	69f	HD L3-L4 with radiculopathy L4 (right) / Intradural sequester	Interlaminar approach L3-L4 (right), sequestrectomy, discectomy and dural repair	prone	165	120	T12-L1	T4	BUPI 12.5 mg, MDZ 3 mg, CLON 20 mcg	1
13.	44f	HD L4-L5 with radiculopathy L4 and L5 (left)	Hemilaminectomy L4 (left), foraminotomy L4-L5 (left), sequestrectomy and discectomy	prone	100	55	T12-L1	T5	BUPI 12.5 mg, MDZ 3 mg, CLON 20 mcg	2
14.	48 m	HD L5-S1 with radiculopathy S1 (left)	Interlaminar approach L5-S1 (left), sequestrectomy and discectomy	prone	90	40	T12-L1	T5	BUPI 12.5 mg, MDZ 3 mg, CLON 20 mcg	2
15.	88 m	Degenerative spinal stenosis L3-L4 with polyradiculopathy	Laminectomy L3 and partial laminectomy L4	prone	95	60	T12-L1	T5	BUPI 15 mg, MDZ 3 mg, DEX 15 mcg	4
16.	42 m	HD L5-S1 with radiculopathy S1 (left)	Interlaminar approach L5-S1 (left), sequestrectomy and discectomy	prone	60	30	T12-L1	T5	BUPI 12.5 mg, MDZ 3 mg, CLON 20 mcg	4
17.	38f	HD L5-S1 with radiculopathy S1 (right) - recidive	Interlaminar approach L5-S1 (right), sequestrectomy and discectomy	prone	75	40	T12-L1	T3	BUPI 10 mg, MDZ 3 mg, CLON 20 mcg	2
18.	60 m	HD L4-L5 with radiculopathy L5 (left)	Interlaminar approach L4-L5 (left), sequestrectomy and discectomy	prone	75	45	T11-T12	T5	BUPI 10 mg, MDZ 3 mg, CLON 20 mcg	5
19.	44 m	HD L2-L3 with radiculopathy L2 (left)	Interlaminar approach L2-L3 (left), foraminotomy and sequestrectomy	prone	100	80	T12-L1	T5	BUPI 12.5 mg, MDZ 3 mg, CLON 20 mcg	1
20.	48f	HD L4-L5 with radiculopathy L5 (left) and synovial cyst	Interlaminar approach L4-L5 (left), cystectomy, sequestrectomy and discectomy	prone	120	90	T12-L1	T5	BUPI 12.5 mg, MDZ 3 mg, CLON 20 mcg	3

(Continued)

TABLE 3 (Continued)

ID	Age, sex	Diagnosis	Operative procedure	Surgical position	OR time	Surgery duration	Puncture level	Anesthesia level	Medication	VAS 24 h
21.	45f	HD L5-S1 with radiculopathy S1 (right) - recidive	Interlaminar approach L5-S1 (right), sequestrectomy and discectomy	prone	110	85	L1-L2	T10	BUPI 10 mg, MDZ 3 mg, CLON 20 mcg	3
22.	39 m	HD L3-L4 with radiculopathy L3 (left)	Translaminar approach L3-L4 (left) and sequestrectomy	prone	90	50	T11-T12	L1	BUPI 10 mg, ROPI 7.5 mg, MDZ 3 mg, CLON 20 mcg	3
23.	21 m	HD L4-L5 with radiculopathy L5 (right)	Interlaminar approach L4-L5 (right) and sequestrectomy	prone	75	60	T12-L1	T2-T3	BUPI 12.5 mg, MDZ 3 mg, CLON 20 mcg	3
24.	54f	HD L4-L5 with radiculopathy L5 (right)	Interlaminar approach L4-L5 (right), sequestrectomy and discectomy	lateral decubitus	65	45	T11-T12	T5	BUPI 12.5 mg, MDZ 3 mg, CLON 20 mcg	2

BUPI, isobaric bupivacaine 0.5%; ROPI, isobaric ropivacaine 0.5%; MDZ, midazolam; CLON, clonidine; DEX, dexmedetomidine; m, male; f, female. Dexamethasone 4 mg is applied in all cases.

The mean time spent by the patient in the operating room was 92 min (range 60–165 min, SD ± 26 min), and the surgical duration was 56 min (range 30–120 min, SD ± 22 min). In six cases, the point of access was at or below the L1-L2 level, whereas all the remaining dural punctures were in the T11-L1 segment, with the T12-L1 level being the most common in 15 procedures. The drug amounts were adjusted individually based on the puncture level, patient demographics, and comorbidities. We applied up to 12.5 mg of bupivacaine above L1-L2 with a single-shot technique and 15 mg at lower access points. Two patients (ID No 5 and 22) required an additional local application of 7.5 mg of ropivacaine due to an inefficient sensory block. In all cases, the spinal anesthesia was successful. Sedation, lasting approximately 45 min, was achieved at levels between 2 and 3 according to the Ramsay Sedation Scale in all cases. Nobody in the cohort received opioids, NSAIDs, or additional intravenous sedation intraoperatively.

Hemodynamic stability was maintained throughout the whole period of anesthesia, with a mean drop of the systolic blood pressure of 28 mmHg (range 10–50 mmHg, SD ± 19 mmHg). The mean drop of mean arterial pressure (MAP) was 15 mmHg (range 0–43 mmHg, SD ± 14 mmHg), corresponding to 18.1% (range 0–38.2%, SD ± 18.3%). One patient (ID No: 15, 88 year-old, degenerative spinal stenosis with laminectomy) developed a drop of MAP of 38.2% which required the use of a vasopressor (10 mg ephedrine intravenously).

Four patients had 6, fifteen had 5, five had 3, and two had 7 points on patient satisfaction scores assessed by our proprietary questionnaire. Thus, the satisfaction rate was 91.7%. The rest were borderline. Twenty patients reported that they would choose the same anesthetic modality in the future, whereas four could not decide. All patients reported an overall positive experience in the operating room.

The median reported VAS score both at 6th post-puncture hour was 2 (range 1–3) and 24th hour was 3 (range 1–5). Twenty-one out of 24 patients reported the need for postoperative analgesia with an NSAID. In all of them it occurred in the morning of surgery and during movement. In none of the cases opioids were required. All patients were ambulated on the same day and were discharged on postoperative days between 1 and 3.

The surgical conditions evaluated by the operator were optimal in all performed interventions, further supporting the feasibility of this technique. No intraoperative liquorrhea related to the spinal anesthesia was evident. No transient or permanent neurologic deficit was registered after dissipation of the sensory blockade. One patient developed transient urinary retention and a globus vesicalis, which was resolved after the insertion of a urinary catheter. No major complications related to the anesthesia or surgery were observed.

Discussion

It is believed that spinal anesthesia is unsuitable and even contraindicated for patients with pathology of the spine mainly because of the normal anatomy compromise and the unpredictability of the local anesthetic spread. In this article, we present a cohort of 24 patients who underwent spine surgery for degenerative disorders and osteoporotic fractures under SA. The anesthesia was successful in all cases without major surgical or procedural complications.

Nevertheless, spinal anesthesia has been used for vertebral surgery, and large numbers of patients were treated, but dural punctures were typically performed at the lumbar spine (4, 5, 11–13). On the one hand, as Saifuddin et al. noted, the location of conus medullaris in a large adult population was shown to range from the middle third of T12 to the upper third of L3, mean at the lower third of L1 (14), which is a zone of risk for any interventions. On the other hand, Duniec et al. reported that the concordance rate between clinical examination and using assessment of level identification for the lumbar puncture is 64% among patients undergoing spinal anesthesia for lower limb surgery (15). Because of the uncertain and insufficient coverage of the sensory blockade in the cranial direction for interventions at the lumbar spine, we adopted the lower thoracic

dural puncture technique. Our data shows that the difference in only one level of puncture (L1-L2 compared to T12-L1) provides a significant increase (5 dermatome levels) of local anesthetic spread without increasing the risk of conus medullaris injury. Using our protocol as described, the somatosensory block consistently reached a level between T2 and T7 (mean at T5 dermatome) for access points at T12-L1 and above. The lower puncture sites achieved a level up to T10, which was insufficient for completely anesthetizing the skin in the upper border of the surgical incision. Thus, it mandates the need for supplemental local anesthetic skin infiltration by the surgeon. The observed sensory block patterns suggest that the spread of the anesthesia correlates with the level of puncture rather than the concentration and volume of the local anesthetic used.

The use of intrathecal sedation with midazolam and an α-2 agonist (either clonidine or dexmedetomidine) not only mitigated their hemodynamic and respiratory drive suppression effects, compared to when applied intravenously but also provided patient comfort during the procedure (7). This approach offers better hemodynamic stability than traditional SA without adjuvants with a lesser mean drop of MAP. The last provides an opportunity for its use in the elderly or comorbid patients. Vital signs are more stable than when emerging from GA and during the immediate postoperative period, which may be beneficial for patients with severe cardiac illness (16, 17). We confirm these findings with only one case at the age of 88 with a temporary and not clinically significant drop of MAP.

Importantly, none of the patients in our cohort required any additional sedation different from the described. Furthermore, no intra-procedural opioids were administered for pain management, indicating adequate analgesia without the need for traditional opioid-based approaches and even the use of NSAIDs. In our study, a good level of sedation lasted approximately 45 min. All patients reported an overall positive experience during surgery and an excellent satisfaction rate. This observation is supported by other authors using both benzodiazepines and dexmedetomidine (17).

Few articles present patient and surgeon satisfaction when comparing SA to GA (18, 19). We carefully prepared our patient satisfaction questionnaire to provide insight into the overall patient experience with the modality and compare pre- and postoperative patient comfort. The procedures were explained in great detail, and directions were given to all the patients. They were instructed to signal the anesthetist or the surgeon if any discomfort occurred because of stress, fear, pain, body position, etc. None of the patients had any of the mentioned complaints. To note, despite being lightly sedated, they responded well to commands and were cooperative overall. No involuntary movements were observed, which can create difficulties for the surgeon working under magnification.

In our study, all surgeries were performed by the same team. The operators were asked to evaluate the surgical conditions in terms of ease of obtaining the surgical field, patient positioning, operative room stay, and the feasibility of the intervention. In contrast with Sadrolsadat et al. (20) study, which showed SA had no advantages over GA, our surgical team evaluated the conditions as optimal. This confers with the findings of McLain et al. (21) with a focus on easier patient positioning, shorter operative room stay, and better facility management than with GA to further support the spinal anesthesia feasibility.

As many authors advocate, we also support the opioid-free options for anesthesia in spine surgery (22). No intrathecal or intravenous opioids were used in our cohort, and the postoperative painkillers were on demand. Patients were instructed to demand medications if pain level rises above VAS score 4 or discomfort is high. The staff was instructed to be vigilant about subjects requiring additional analgesia and/or complaining of insufficiency of analgesia by NSAIDs and the need for opioids. Out of the protocol, the patients were also asked at discharge to describe when and how the highest level of pain occurred, with the majority reporting pain at the surgical skin incision, only when moving, and in the following morning after the procedure, not exceeding VAS score 5. Adequate analgesia was achieved in all cases only with NSAIDs, while four patients did not need any painkillers.

Early ambulation was achieved in all 24 patients without any complications or neurologic deficits, which again highlights the safety and efficacy of thoracic spinal anesthesia with intrathecal sedation. We could not find any other study investigating these circumstances. In none of the patients, a urinary catheter was inserted before surgery, and fluid administration was cautious. Nevertheless, one patient (female, 34 years) developed a globus vesicalis, which was treated successfully, and no micturition disturbances were reported.

While our study provides valuable insights, certain limitations should be acknowledged. The relatively small sample size and the absence of a control group warrant caution in generalizing the results to broader patient populations. All patients being ASA I-II limits the findings to patients without severe comorbidities. However, it would be specifically appropriate for the high-risk groups. Therefore, further research is needed to explore the applicability and safety of thoracic spinal anesthesia in patients with more significant health challenges. Building on the positive outcomes observed in this study, future research should consider prospective trials with larger sample sizes to validate further the safety, efficacy, and cost-effectiveness of thoracic spinal anesthesia. Exploring the long-term effects, particularly concerning postoperative recovery and complications, would contribute to a more comprehensive understanding of its applicability in diverse clinical scenarios.

Conclusion

Thoracic spinal anesthesia incorporating adjuvants such as midazolam, clonidine or dexmedetomidine, and dexamethasone demonstrates not only efficient conditions for spine surgery, a favorable safety profile, high patient satisfaction, and intrathecal sedation but also effective opioid-free pain management. Thus, our findings imply that this is an appropriate alternative to the general anesthesia for spine surgery. Future research should further investigate and validate the potential of the technique, including its cost-effectiveness, and explore the optimal surgical and pain management strategies.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

Ethical approval was not required for the study involving humans in accordance with the local legislation and institutional requirements. Written informed consent to participate in this study was not required from the participants or the participants' legal guardians/next of kin in accordance with the national legislation and the institutional requirements.

Author contributions

NB: Data curation, Formal analysis, Investigation, Methodology, Writing – original draft. DF: Formal analysis, Project administration, Resources, Supervision, Visualization, Writing – review & editing. PV: Investigation, Project administration, Resources, Writing – original draft. DY: Formal analysis, Resources, Supervision, Writing – review & editing. SB: Investigation, Resources, Validation, Writing – original draft. RT: Conceptualization, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Factors affecting functional disability in patients with non-specific chronic low back pain: a cross-sectional study

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Background: Knowledge about factors affecting functional disability in patients with non-specific chronic low back pain (NSCLBP) is helpful in guiding treatment, but there has been little systematic research on this topic. This study aimed to identify independent factors contributing to functional disability in NSCLBP patients especially the impact of sagittal parameters and body postures in work, learning, and daily life.

Methods: Sociodemographic data, sagittal parameters, Oswestry Disability Index (ODI), Numeric Rating Scale (NRS), and 36-item Short Form Health Survey (SF-36) of NSCLBP patients were collected. Patients were divided into a low-functional disability group (ODI $\leq$ 20) and a high-functional disability group (ODI $>$ 20), and the ODI was converted to ranked ODI (RODI) accordingly. Sociodemographic data, sagittal parameters, NRS, and SF-36 were compared by univariate analysis between both groups. A correlation analysis of the aforementioned factors with the RODI was conducted. The sociodemographic data and sagittal parameters related to the RODI were analyzed by logistic regression to select potential RODI-associated factors. The level of significance was set at $P < 0.05$.

Results: Age, educational background, daily main posture while working or learning (DMPWL), daily standing time while working or learning (DSTTWL), daily sitting time while resting (DSITR), sacral slope–pelvic tilt (SS-PT), spinosacral angle (SSA), NRS, and SF-36 (except mental health, MH) were different between the two groups ($P < 0.05$). Correlation analysis showed that they were related to the RODI ($P < 0.05$). The logistic regression analysis indicated that the regression coefficients of a college degree, postgraduate diploma, DSITR, and SSA were ($B = -0.197$; $P = 0.003$), ($B = -0.211$; $P = 0.006$), ($B = -0.139$; $P = 0.039$), and ($B = -0.207$; $P = 0.001$), respectively, and the odds ratio (OR) and 95% confidence interval (CI) were 0.489 (0.308; 0.778), 0.299 (0.125; 0.711), 0.875 (0.772; 0.993), and 0.953 (0.925; 0.981), respectively.

Conclusion: Educational background, DSITR, and SSA are independent factors affecting functional disability in NSCLBP patients. NSCLBP patients with a lower educational background, shorter DSITR, or smaller SSA should be taken into account in clinical practice and therapeutic choices. Extending sitting time for rest and the avoidance of a forward-leaning standing position are beneficial for reducing functional disability in NSCLBP.

KEYWORDS

non-specific chronic low back pain, functional disability, patient self-reported outcome, health-related quality of life, sagittal parameters, cross-sectional study

Introduction

Non-specific chronic low back pain (NSCLBP) is a musculoskeletal disease with a high incidence among the general population and has a lifetime prevalence in individuals worldwide. The incidence of NSCLBP varies with age, gender, and occupation in individual patients, as well as in different countries and regions. The overall prevalence of NSCLBP among workers in the United States of America is 25.7%, including 24.5% in men, 27.1% in women, 23.8% in younger workers aged 18–40 years, and 27.7% in older workers aged 41–64 years (1). The prevalence in the general population of Sub-Saharan Africa ranges from 18.1 to 28.2% (2) and is 23.4% in Brazilian adults over the age of 20 years (3). However, among primary school teachers in Mekele, Ethiopia, it is as high as 74.8% (4). With undetermined etiology, a high disability rate, and a low cure rate, NSCLBP often results in the work absenteeism of patients, low production efficiency, and a huge economic burden to the patients' families and social healthcare systems (5, 6).

A study of the causes of NSCLBP is helpful for its correct diagnosis, prevention, and treatment. However, multiple factors and the inherent complexity of the pathogenic factors of NSCLBP, coupled with the inconsistent research standards, lead to an uneven level of evidence-based medicine in many research conclusions, and hence the guiding significance for prevention of NSCLBP is limited. As a musculoskeletal disorder associated with disability, the treatment of NSCLBP focuses on reducing pain, disability, and other consequences caused by pain (7). It is suggested that the study on pathogenic factors of NSCLBP is of limited value (8). A scientific classification system has been proposed to classify NSCLBP patients into homogeneous subtypes and provide appropriate treatment strategies (9). The subdivision of the NSCLBP patients reveals that differences in sitting postures are associated with functional disability, which also illustrates the importance of classifying NSCLBP patients (10). The criteria of the US National Institutes of Health (NIH) for NSCLBP research proposes that given the current knowledge, NSCLBP classification based on its impacts is more feasible (7).

At present, research on NSCLBP mainly focuses on risk prediction and evaluation of treatment protocols (11, 12). The common risk factors for NSCLBP include female gender (13), educational background (14), smoking and obesity (15), sedentariness or excessively vigorous physical activity (16, 17), and sitting or standing for more than 2 h (18). Lumbar lordosis (LL) is the pathogenesis of NSCLBP (19, 20). However, whether they are related to functional disability in NSCLBP is undetermined, especially sagittal parameters. Sagittal parameters are associated with the postoperative quality of life in patients with degenerative lumbar scoliosis and adolescent idiopathic scoliosis (21, 22). It was found in our recent previous study that age and spinosacral angle (SSA) were associated with functional disability in NSCLBP patients (23). However, knowing that NSCLBP is a biopsychosocial problem with complex factors affecting its pain and functional disability, it is to be expected that there cannot be a simple relationship between spinal posture in standing and functional disability. We also assumed that functional disability in NSCLBP patients has a certain relationship with body postures in work, learning, and daily life in the modern world. In conclusion, adjusting sociodemographic data and sagittal parameters concurrently is potentially valuable to comprehensively understand the factors affecting functional disability in NSCLBP patients. The combination of sociodemographic data and sagittal parameters may contribute to the new findings. Therefore, this study used sociodemographic data collected at the same time as the previous study (23) to analyze factors affecting functional disability in NSCLBP patients, and factors closely related to working, learning, and lifestyle such as daily main posture while working or learning (DMPWL), daily sitting time while working or learning (DSITWL), daily standing time while working or learning (DSTTWL), daily sitting time while resting (DSITR), and daily standing time while resting (DSTTR) were highlighted and quantified. This is the first study that combined sociodemographic data with sagittal parameters to screen factors affecting functional disability in NSCLBP patients by including as many sagittal parameters as possible while quantifying modern lifestyles.

Abbreviations: B, regression coefficient; BMI, body mass index; BP, bodily pain; CI, confidence interval; DMPWL, daily main posture while working or learning; DSITR, daily sitting time while resting; DSITWL, daily sitting time while working or learning; DSTTR, daily standing time while resting; DSTTWL, daily standing time while working or learning; GH, general health; HRQoL, health-related quality of life; IQR, interquartile range; LL, lumbar lordosis; MH, mental health; NICE, National institute for Health and Care Excellence; NIH, National Institutes of Health; NRS, numerical rating scale; NSCLBP, non-specific chronic low back pain; ODI, Oswestry Disability Index; OR, odds ratio; PF, physical function; PI, pelvic incidence; PI-LL, pelvic incidence–lumbar lordosis; PROs, patient self-reported outcomes; PT, pelvic tilt; RE, role emotional; RODI, ranked Oswestry Disability Index; ROM, range of motion; RP, role physical; SD, standard deviation; SE, standard error; SF, social function; SF-36, Short Form 36 Health Survey; SFD, sacrofemoral distance; SPSS, Statistic Package for Social Science; SS, sacral slope; SS-PT, sacral slope–pelvic tilt; SS/PT, sacral slope/pelvic tilt; SSA, spinosacral angle; STROBE, Strengthening Reporting of Observational Studies in Epidemiology; SVA, sagittal vertical axis; TK, thoracic kyphosis; TK-LL, thoracic kyphosis–lumbar lordosis; TK/LL, thoracic kyphosis/lumbar lordosis; TPA, T1 pelvic angle; T1SPi, T1 spinopelvic inclination; T9SPi, T9 spinopelvic inclination; VT, vitality.

Methods

Participants

The participants of the study were NSCLBP patients who visited the Spine Surgery Outpatient Service of the First Affiliated Hospital of the Naval Military Medical University from February 2021 to August 2021. The study was approved by the Institutional Review Board and Ethics Committee of the said university, and all patients provided informed consent. For each patient, full spine anteroposterior and lateral X-ray radiography was performed by using a vertical 30 × 90 cm film with a constant distance between the subject and the radiographic source. All patients were in a naturally relaxed and comfortable standing posture, with the knee fully extended, the fingers on the clavicle, and the shoulder flexed 45° forward (24). The inclusion and exclusion

criteria of the NSCLBP patients are the same as described in our previous article (23). The study was a cross-sectional study reported according to the Strengthening Reporting of Observational Studies in Epidemiology (STROBE) guidelines (25).

Data collection

The number of participants, patients not eligible for the study and the specific reasons, and the screening process can be referred to in our previous article (23). The final sample size for inclusion was 435 NSCLBP patients. The flow chart of the participants is shown in Figure 1 in our previous study (23). Sociodemographic data, Oswestry Disability Index (ODI), 36-item Short Form Health Survey (SF-36), and Numeric Rating Scale (NRS) were collected by an online questionnaire, in which the sociodemographic data included age, gender, body mass index (BMI), educational background, marriage status, income, smoking, drinking, main nature of work, years of employment, workload, exposure to vibration sources while working, family history of low back pain, DMPWL, DSITWL, DSTTWL, DSITR, and DSTTR. Among the other parameters, DMPWL was derived from the patients' choice of answers to "What is your main posture (standing or sitting) while you are working or learning every day?" DSITWL from the patients' choice of answers to "What is your sitting time while you are working or learning every day?" DSTTWL from the patients' choice of answers to "What is your standing time while you are working or learning every day?" DSITR from the patients' choice of answers to "What is your sitting time while you are resting every day?" and DSTTR from the patients' choice of answers to "What is your standing time while you are resting every day?" The time frame for the answers to the questions ranges from 1 to 10 h.

The ODI was used to assess the functional disability in NSCLBP, the NRS was used to assess pain intensity, and SF-36 was used to assess health-related quality of life (HRQoL). The reliability and validity of simplified Chinese version 2.1 of the ODI make it applicable to Chinese patients (26). SF-36 v2 has also been verified in Chinese patients (27). ODI is the most commonly used indicator to assess acute and chronic low back pain (28, 29). Functional disability was classified into the following five classes: minimal disability (0–20); moderate disability (21–40); severe disability (1–60); crippled (61–80); and being bed-bound (81–100) (28).

The included sagittal parameters were thoracic kyphosis (TK), LL, sacral slope (SS), pelvic incidence (PI), pelvic tilt (PT), sagittal vertical axis (SVA), T1 pelvic angle (TPA), T1 spinopelvic inclination (T1SPi), T9 spinopelvic inclination (T9SPi), spinosacral angle (SSA), sacrofemoral distance (SFD), Barrey ratio, TK/LL, TK-LL, PI-LL, SS/PT, and SS-PT. The measurement methods and measured values of sagittal parameters can be referred to in our previous article (23).

Statistical analysis

All NSCLBP patients were divided into a low-functional disability group (ODI $\leq$ 20) and a high-functional disability group (ODI $>$ 20), and the ODI was converted to ranked ODI (RODI) accordingly. The normal distribution was tested by the Shapiro–Wilk test, and the Levene test was used for assessing the homogeneity of variance. Quantitative variables were presented with means and standard deviation (SD) or medians and interquartile (IQR; as appropriate), and qualitative variables were presented with absolute numbers and frequencies (%). The quantitative variables were compared between the two groups by the *t*-test or the rank-sum test. A comparison between the two groups of the unordered qualitative variables was carried out by using the chi-square test or the corrected chi-square test or Fisher's exact test. The Cochran–Mantel–Haenszel test was used to compare the ordered qualitative variables between the two groups. The correlation was analyzed by Spearman's correlation or the chi-square test (the coefficient of contingency was calculated; as appropriate). A logistic regression was conducted to assess the variables associated with the RODI, and the test level for variable inclusion in the equation is 0.05, and the test level for variable exclusion in the equation is 0.1. All statistical analyses were performed using Statistic Package for Social Science 22.0 (SPSS Inc., Chicago, IL). The p-value of < 0.05 was considered statistically significant. The evaluation of sample size is mainly based on empirical rules. Multivariate regression analysis generally requires that the number of samples for event outcomes be 5–10 times the number of independent variables (30).

Results

A total of 435 NSCLBP patients (262,60% were female patients) with a median (IQR) age of 34 (16) years, a median (IQR) BMI of 22.9 (4.4) kg/m^2, and a median (IQR) ODI of 14 (14) were included in the study (Supplementary Table 1). The frequency distribution of the ODI is shown in Figure 1. According to the five classes of functional disability, 320 (74%) patients had mild disability, 97 (22%) patients had moderate disability, 13 (3%) patients had severe disability, five (1%) patients were crippled, and no patient was bed-bound. Of them, 320 (74%) patients were included in the low-disability group, and 115 (26%) patients were included in the high-disability group (Figure 2). Other characteristics of the 435 NSCLBP patients, their subgroups, and the comparison of all variables between the two subgroups are summarized in Supplementary Table 1.

Age, educational background, DMPWL, DSTTWL, DSITR, SS-PT, SSA, NRS, and SF-36 (except mental health, MH) with statistical differences between the two groups are summarized in Table 1, and the RODI was found to be associated with them (except MH; $P < 0.05$; Table 2). The number of independent variables that can finally be included in the regression equation ranged from 11 to 23. There were seven variables used in this study, which was in line with the empirical rules. The logistic regression analysis indicated that the regression coefficients of a college degree, postgraduate diploma, DSITR, and SSA were ($B = -0.197$; $P = 0.003$), ($B = -0.211$; $P = 0.006$), ($B = -0.139$; $P = 0.039$), and ($B = -0.207$; $P = 0.001$), respectively, and the odds ratio (OR) and 95% confidence interval (CI) were 0.489 (0.308; 0.778), 0.299 (0.125; 0.711), 0.875 (0.772; 0.993), and 0.953 (0.925;0.981), respectively (Table 3).

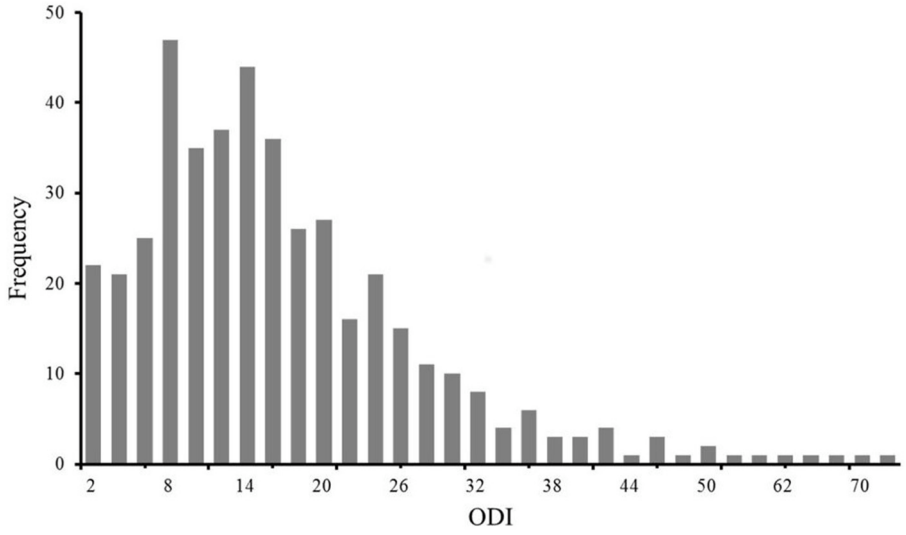

FIGURE 1
Frequency distribution of the ODI.

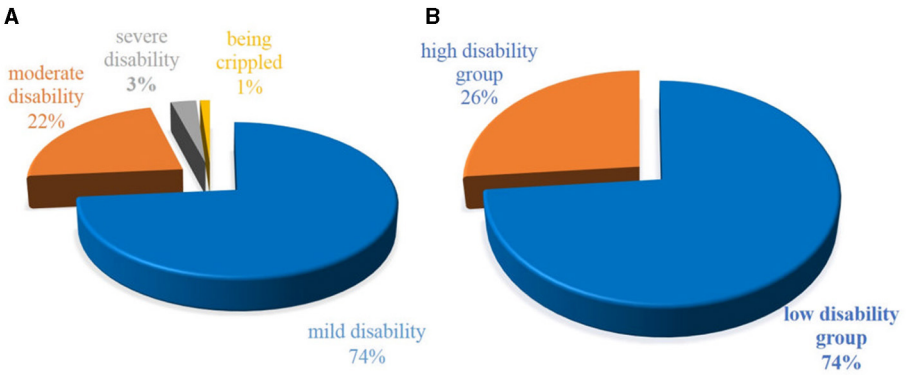

FIGURE 2
(A) The proportion of five classes of functional disability in 435 NSCLBP patients. **(B)** The proportion of the low-functional disability group (ODI $\leq$ 20) and the high-functional disability group (ODI $>$ 20) in 435 NSCLBP patients.

Discussion

Unlike the chronic pain symptoms that are usually accompanied with other diseases, NSCLBP is a condition that requires specific treatment and care (31). Conservative therapy is the first-line option for NSCLBP to alleviate pain and improve functional disability, and researching factors affecting functional disability can help medical staff identify patients with severe functional disability and guide the treatment. In our series, 97 (22.30%) patients had moderate disability, 13 (2.99%) patients had severe disability, 5 (1.15%) patients were crippled, and no patient was bed-bound. To satisfy the sample size of statistical analysis, we converted the ODI to RODI. Univariate correlation analysis showed that the RODI was positively correlated with the NRS and negatively correlated with seven dimensions in SF-36 (except MH), indicating that the greater the pain, the more severe the disability, and the worse the quality of life, and the grouping of cases with low and high disability has clinical significance. It has also been shown that age, educational background, DMPWL, DSTTWL, DSITR, SS-PT, and SSA were related to functional disability in NSCLBP, indicating that functional disability was more severe in patients with older age or lower educational background or those with a standing posture as the main daily posture while working or learning, and the disability increased with longer DSTTWL or shorter DSITR. After adjusting for confounding factors in logistic regression analysis, educational background, DSITR, and SSA were found to be independent factors affecting functional disability in NSCLBP patients. Compared with the patients with a high-school or below educational background, the OR for increased disability in NSCLBP patients with a college degree and postgraduate diploma was 0.30-fold and 0.49-fold higher, respectively. The OR was 0.88-fold higher for every 1 h increase in the DSITR and 0.95-fold higher for every 1 degree increase (reduced kyphosis). Educational background, DSITR, and SSA were independent

TABLE 1 Variables with statistical differences between the two subgroups.

Variables	All patients (n = 435)	ODI ≤ 20 (*n* = 320)	ODI > 20 (*n* = 115)	*P*-value
Age (years); median (*IQR*)	34 (16)	33 (13)	37 (20)	0.002
Educational background, *n* (%)				0.000
High school or below	179 (41)	116 (36)	63 (55)	
College degree	207 (48)	162 (51)	45 (39)	
Postgraduate diploma	49 (11)	42 (13)	7 (6)	
DMPWL, *n* (%)				0.037
Standing posture	119 (27)	79 (25)	40 (35)	
Sitting posture	316 (73)	241 (75)	75 (65)	
DSTTWL (hours), median (*IQR*)	0 (2)	0 (0)	0 (4)	0.049
DSITR (hours), median (*IQR*)	3 (2)	3 (2)	3 (2)	0.034
SS-PT (°), mean (*SD*)	19.7 (11.9)	20.5 (12.0)	17.2 (11.4)	0.011
SSA (°), mean (SD)	124.5 (7.8)	125.1 (7.7)	122.7 (7.6)	0.004
NRS, median (*IQR*)	3 (3)	3 (2)	4(3)	0.000
SF-36				
PF, median (*IQR*)	80 (30)	85 (20)	65 (25)	0.000
RP, median (*IQR*)	100 (50)	100 (25)	50(100)	0.000
BP, median (*IQR*)	69 (24)	80 (18)	58 (35)	0.000
GH, median (*IQR*)	50 (25)	53 (28)	45 (23)	0.000
VT, median (*IQR*)	65 (30)	70 (25)	60 (25)	0.009
SF, median (*IQR*)	88 (25)	88 (25)	75 (25)	0.000
RE, median (*IQR*)	100 (67)	100 (67)	66 (100)	0.002

BP, bodily pain; DMPWL, daily main posture while working or learning; DSITR, daily sitting time while resting; DSTTWL, daily standing time while working or learning; GH, general health; IQR, interquartile range; NRS, numerical rating scale; ODI, Oswestry Disability Index; PF, physical function; RE, role emotional; RP, role physical; SD, standard deviation; SF, social function; SF-36, Short Form 36 Health Survey; SS-PT, sacral slope–pelvic tilt; SSA, spinosacral angle; VT, vitality.

protective factors affecting functional disability in NSCLBP; the higher the educational background, the longer the DSITR, or the greater the SSA (reduced kyphosis), the lower the risk of increased disability. Thus, the findings of the present study may serve as a reminder for clinicians to pay more attention to patients with lower educational backgrounds, shorter DSITR, or smaller SSA in clinical practice and therapeutic choices.

It was found in our study that educational background was negatively correlated with the RODI ($r = -0.174$, $P < 0.01$). This may be related to the low socioeconomic status in patients with a low educational background, and there is a higher proportion of NSCLBP patients with disability in people with a low socioeconomic status (15). At the same time, patients with a high educational background have strong self-care awareness, such as performing regular physical exercise, which reduces the impact of NSCLBP on physiological function (PF), and the RODI had the highest correlation with PF ($r = -0.470$; $P < 0.01$). The guidelines of the National Institute for Health and Care Excellence (NICE) recommend education and self-care for the early treatment of NSCLBP, including advising and educating patients about the nature of pain, not necessary for bed rest during treatment, and encouraging them to remain active and continue their daily activities, including work (32). As expected, a longer DSITR is beneficial for NSCLBP patients. This may be related to the relatively free sitting posture at rest, and the waist muscles are in a relaxed state. A long, flat, or stiff waist increases the risk of severe NSCLBP, which is difficult to explain by other mechanical factors such as muscle strength and lumbar mobility (8). Therefore, extending the sitting time for rest is beneficial for reducing functional disability in NSCLBP patients and may be an important and simple treatment.

Biological factors (such as old age, overweight or obesity, female gender, current smoking, and co-existing chronic diseases), social conditions (such as low educational background, low per capita household income, singlehood, and living in rural areas), and psychological health conditions (such as the presence of depressive symptoms) are associated with a higher prevalence of NSCLBP (3). However, this study found that age, gender, BMI, smoking, DMPWL, DSITWL, and DSTTWL were unexpectedly unrelated to NSCLBP disability. In our recent previous study (23), age was found to be associated with NSCLBP disability, and this may be related to the fact that fewer variables were included, compared to this study. Sedentariness combined with an incorrect posture has been shown to increase the risk of NSCLBP (18). This could be attributed to the relationship between the factors of the onset of

NSCLBP and their association with disability is unclear; in other words, it may have to do with the different purpose of this study, and we suggested that the two overlap but may not be identical. Furthermore, previous studies on low back pain have produced a number of controversial results. An epidemiological study reported an association between reduced disc space found on x-rays of people with sedentary occupations and acute low back pain (33, 34); for instance, motor vehicle driving and sedentary occupations were considered to have a relatively higher risk of disc space reduction and acute low back pain, but the authors emphasized that further research was needed to confirm or refute the association of the sitting posture with disc degeneration and acute low back pain (33). However, there was also a study on 45 male monozygotic twin pairs that refuted this association, one in each twin pair spent more than five times as much time driving a motor vehicle during his lifetime as the other, yet there was no difference in lumbar disc degeneration on magnetic resonance imaging (35). Based on the lumbar flexion commonly involved in sitting relative to standing posture (36) and related epidemiological study (35), it was found that lumbar flexion associated with the sitting posture had no more a serious impact on the disc health or the onset of NSCLBP than did a relatively extended standing posture. It may also be related to the small sample size of this study and the uneven proportion of patients with different degrees of disability. Moreover, the sitting posture is not described specifically, such as whether there is rotation or not. However, lumbar rotation in a sitting posture is an important part of daily life and activities of different occupations (such as dentists, cashiers, and laboratory workers).

Sociodemographic data such as educational background and DSITR were not included in our previous study (23), but SSA remained an independent factor after they were included in this study, indicating that SSA is an important factor associated with functional disability in NSCLBP. The cutoff point of SSA was 127.35, which would be important for clinical applicability (23). For its definition, SSA is the combined reflection of the reduction in LL and SS, which is a cumulative gain, and enhances the ability of SSA to distinguish NSCLBP disability (23). SSA can comprehensively reflect the compensatory state of sagittal balance in NSCLBP patients and poor sagittal balance represented by decreased SSA is a risk factor for increased disability in NSCLBP patients (23). The avoidance of body forward leaning in a standing position is beneficial for reducing functional disability in NSCLBP. NSCLBP is a biopsychosocial problem in which the patient's anatomical injury interacts with psychosocial conditions (37). Central pain regulation mechanisms and pain cognition play an important role in the development of persistently disabling NSCLBP (15). Hashmi et al. found that brain activity in patients with acute or subacute low back pain is limited to areas of acute pain, while brain activity in NSCLBP patients is limited to emotional circuits (38). Patients with chronic pain have changes in the regions involved in the emotional and cognitive regulation of pain in the brain (39), which may explain why patients with persistent pain are prone to developing depression and anxiety (40). One research has highlighted emotional distress as a factor that potentially increases the risk of sustained disability in NSCLBP (15). Emotional distress is an important issue in the management of NSCLBP. However, little is known about how emotional distress occurs and develops in NSCLBP patients. Previous studies showed that factors affecting the onset of NSCLBP included the degree of pain, mental factors, sleep, and quality of life (41, 42). These factors as characteristics of NSCLBP contribute to its diagnosis, but some of these factors interact with NSCLBP (39, 40), and some result from pain and ineffective treatment of NSCLBP (8). Furthermore, the sensitivity of factors with low influence may be reduced by factors with high influence (such as mental factors and physical function), thus it is not scientific and reasonable to study them as pathogenic factors. Therefore, mental and sleep factors as well as related patient self-reported outcomes (PROs) such as physical function, role physical,

TABLE 2 Correlations of sociodemographic characteristics, sagittal parameters, NRS, SF-36, and RODI of 435 NSCLBP patients.

Age	0.126**	PF	−0.470**
Educational background	−0.174**	RP	−0.334**
DMPWL	0.488**	BP	−0.276**
DSTTWL	0.094*	GH	−0.191**
DSITR	−0.102*	VT	−0.125**
SS-PT	−0.115*	SF	−0.241**
SSA	−0.116*	RE	−0.148**
NRS	0.266**	MH	−0.064

BP, bodily pain; DMPWL, daily main posture while working or learning; DSITR, daily sitting time while resting; DSTTWL, daily standing time while working or learning; GH, general health; IQR, interquartile range; MH, mental health; NRS, Numerical Rating Scale; ODI, Oswestry Disability Index; PF, physical function; RE, role emotional; RODI, ranked Oswestry Disability Index; RP, role physical; SD, standard deviation; SF, social function; SF-36, Short Form 36 Health Survey; SS-PT, sacral slope-pelvic tilt; SSA, spinosacral angle; VT, vitality.
*$P < 0.05$; **$P < 0.01$.

TABLE 3 Binary logistic regression analysis of independent factors affecting functional disability in NSCLBP patients.

Variables	B	SE	Wald	*P*-value	OR	95% CI of OR
Constant	5.829	1.886	9.550	0.002		
Educational background*						
College degree	−0.715	0.237	9.122	0.003	0.489	(0.308, 0.778)
postgraduate diploma	−1.208	0.443	7.450	0.006	0.299	(0.125, 0.711)
DSITR	−0.133	0.064	4.256	0.039	0.875	(0.772, 0.993)
SSA	−0.048	0.015	10.461	0.001	0.953	(0.925, 0.981)

B, regression coefficient; CI, confidence interval; DSITR, daily sitting time while resting; NSCLBP, non-specific chronic low back pain; SE, standard error; OR, odds ratio; SSA, spinosacral angle.
*Control group was patients with high school education or below.

and mental health were not included as factors affecting functional disability in NSCLBP. In addition, a comprehensive assessment of functional disability in NSCLBP patients should include objective biomechanical and kinematic data such as muscle endurance and strength (43) in addition to PROs.

Strengths and limitations

To the best of our knowledge, the present study is the first to identify independent factors affecting NSCLBP functional disability by combining sociodemographic data and sagittal parameters. Nevertheless, this study presents several limitations. The first limitation is that the subjects in this study are NSCLBP patients from the hospital, and an uneven proportion of patients with different degrees of disability may not have been fully representative of the general NSCLBP patients. The second limitation is that all variables were collected from PROs, which may lead to subjective results, and the inclusion of objective measurement would have been desirable. The third limitation is that relying on smartphone electronic questionnaires may also lead to selection bias; for instance, patients who were able to complete questionnaires using smartphones may be more educated than those who were unable to complete questionnaires using smartphones, especially older people. However, the questionnaire survey for this study was conducted by a spine surgeon who specifically assisted patients who could not use smartphones to complete the questionnaire to reduce the bias caused by survey methods. Finally, the cross-sectional study did not allow us to establish causality between independent factors and functional disability in NSCLBP patients.

Conclusion

Educational background, DSITR, and SSA are independent factors affecting functional disability in NSCLBP patients. Functional disability is severer in patients with a lower educational background, shorter DSITR, or smaller SSA. NSCLBP patients with a lower educational background, shorter DSITR, or smaller SSA should be taken into account in clinical practice and therapeutic choices. Extending sitting time while resting and avoidance of the body forward leaning while standing are beneficial for reducing functional disability in NSCLBP.

Author's note

It was found in our recent previous study that age and spinosacral angle (SSA) were associated with functional disability in NSCLBP patients (23).

Data availability statement

The original contributions presented in the study are included in the article/Supplementary material, further inquiries can be directed to the corresponding authors.

Ethics statement

The studies involving humans were approved by the Ethics Committee of The First Affiliated Hospital, Naval Medical University. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Author contributions

SZ: Writing—original draft, Writing—review & editing. HY: Data curation, Formal analysis, Investigation, Writing—review & editing. BL: Data curation, Formal analysis, Investigation, Writing—review & editing. YC: Data curation, Formal analysis, Investigation, Writing—review & editing. SN: Project administration, Supervision, Validation, Visualization, Writing—review & editing. CY: Conceptualization, Writing—review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

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Focused extracorporeal shockwave therapy for the treatment of low back pain: a systematic review

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Introduction: Low back pain (LBP) is a common condition affecting up to 84% of people in their lifetime, with a prevalence of 11.9% and a high recurrence rate within the first year. Furthermore, chronic low back pain syndrome has been described in up to 7%, making it a significant health and socioeconomic problem. Among nonoperative treatment options, the recently used focused extracorporeal shockwave therapy (ESWT) devices generate waves that converge at a precise depth in the body, thereby revealing the potential to affect pathology remotely from the contact surface. The article aims to present a systematic literature review with a critical discussion on treating low back pain using this modality.

Methods: A search for randomized controlled trials (RCT) of focused ESWT for low back pain published before April 1, 2024, in PubMed, Web of Science, Scopus, Google Scholar, and trial registries (WHO International Clinical Trials Registry Platform and ClinicaTrials.gov) was performed.

Results: Only three studies against conservative treatment comprising 94 patients met the selection criteria and were further analyzed. Comparative clinical studies regarding the effectiveness of radial and focused ESWT for low back pain were missing. The results revealed that all treated patients had significantly reduced pain and improved functional impairment immediately after the procedures and 1month later. At the third month time point, the pain levels remained better in the experimental than in the control group without achieving statistical significance. None of the studies had a long-term follow-up.

Conclusion: Focused ESWT is a modern physiotherapeutic method that can potentially treat a broad spectrum of conditions responsible for low back pain. Despite the small number of low-evidence studies, there is sufficient data on the effectiveness and safety of this therapeutic modality. With future well-designed trials, the bias risks would be diminished, the indications for its use would expand, and the treatment protocols would be clarified.

KEYWORDS

low back pain, treatment, focused shockwave therapy, randomized controlled trial, systematic review

Introduction

Low back pain (LBP) is a common condition that affects up to 84% of people in their lifetime and has a prevalence of 11.9% (1). In most cases, the acute episode will resolve in 6 weeks, but between 25 and 78% of patients will have recurrence within the first year (2–4). Chronic low back pain syndrome has been described in up to 7% and is defined as symptoms

lasting more than 12 weeks, making it a significant health and socioeconomic problem (5).

LBP treatment requires an interdisciplinary approach that includes modalities ranging from bed rest, manual and kinesiotherapy, pharmacological treatment, physical methods, and a broad spectrum of minimally invasive interventions before open surgery (6, 7). However, only 31–47% of patients with chronic LBP will have relief within 1 year, which raises the need for new approaches (8).

Among nonoperative treatment modalities, extracorporeal shock wave therapy (ESWT) is a noninvasive procedure using acoustic waves generated outside the body and targeted in depth on the pathology. This type of energy has a described biological effect at the cellular, tissue, and organ levels. Still, the exact mechanisms of impact on the structures of the musculoskeletal system and the adjacent neural elements remain unclear. Low energy levels have mechanical stimuli and positive effects, leading to cell migration, proliferation, and differentiation. Reduced swelling and infiltration of inflammatory cells in the tissues were also found (9). High energy levels are believed to have shear stress and are destructive (10). Pain relief is thought to result from hyperstimulation of nerve endings (11). In addition to the above, given the importance of paravertebral muscle spasm in degenerative spine pathologies, ESWT has been found to reduce spasticity, decrease connective tissue stiffness, and stimulate nitric oxide synthesis, leading to improvement in neuromuscular transmission and vasodilation (12).

From a therapeutic point of view, radial and focused extracorporeal shock wave therapy (ESWT) is considered. The radial one produces pressure waves that diverge deep into the tissues, with low velocity and peak pressure, depleting away from the applicator (9). Thus, the effects are primarily superficial. The FDA approved the use of radial ESWT devices for the treatment of plantar fasciitis in 2000 and lateral epicondylitis in 2003 (13). The indications, therapeutic protocols, and results regarding musculoskeletal disorders are clear to date. In contrast, the newer focused ESWT generates waves that converge at a precise depth in the body, thereby revealing the potential to affect pathology that is remote from the contact surface (10). The main power generators used are piezoelectric, electromagnetic, and electrohydraulic (13). The physical effects of focused ESWT are related to the energy delivered to a specific cross-section, defined as energy flux density (EFD, mJ/mm^2).

To date, many clinical studies have compared the effectiveness of the two types of ESWT for diverse indications. The results show the effectiveness of both therapies despite the different mechanisms on the tissues (14–17) Few studies have addressed the treatment of low back pain using focused ESWT. This work aims to present a systematic literature review with a critical discussion.

Materials and methods

A search for randomized controlled trials (RCT) of focused ESWT for low back pain published before April 1, 2024, in PubMed, Web of Science, Scopus, Google Scholar, and trial registries (WHO International Clinical Trials Registry Platform and ClinicaTrials.gov) was performed. The following keywords and phrases were used: focused extracorporeal shockwave therapy, ESWT, low back pain, lumbosacral pain, lumbar spine, sacroiliac joint, and facet joint syndrome. Relevant references from the identified articles were further retrieved and analyzed. The PRISMA guidelines were used in preparing this systematic review, and a corresponding diagram is presented here (Figure 1). No restrictions regarding the year of publication, country of origin, or language were applied.

Results

Following the search strategy, 55 articles were initially identified. By refining the results, 19 clinical studies were extracted. Table 1 presents a list of randomized controlled trials for the treatment of low back pain (LBP) with extracorporeal shockwave therapy (ESWT), which were excluded from further analysis after a detailed review. All these studies report results with radial shockwave or vibrotherapy devices. Only 3 met the criteria for a randomized controlled trial of focused extracorporeal shockwave to treat low back pain. Comparative clinical studies regarding the effectiveness of radial against focused ESWT for low back pain are missing. Table 2 summarizes the basic demographic characteristics, symptoms' duration, clinical outcome assessment tools, and follow-up periods. Table 3 presents the treatment protocols of the selected studies. Tables 4, 5 summarize the results of the analyzed randomized clinical studies.

Moon et al. (18) published a prospective randomized, sham-controlled, single-center trial on 25 patients with sacroiliac joint pain. The inclusion criteria are clearly defined with symptoms duration of more than 6 months, at least 19 years of age, pain >4 on a 10-cm numeric rating scale localized in the SIJ region, and at least three of five provocation SIJ tests from Patrick's sign, Gaenslen test, compression test, thigh trust test, and distraction test (19). Among the author's exclusion criteria were: ESWT administered to any other body lesion; a positive straight leg-raising test; radiologically confirmed lumbar or hip joint pathology; pregnancy; acute pelvic inflammation; and previous SIJ intervention (i.e., corticosteroid injection within the previous 12 months). Participants were instructed to refrain from any other conservative treatments, including medications for pain or physical therapy. Randomization was in blocks of six by a blinded physician using a computerized random number generator. The study protocol included a focused ESWT in a single treatment session comprising 2000 shocks at 3 Hz, though perpendicular to the area probe and energy level 0.09–0.25 mJ/mm^2. The control group received a single session of sham intervention with a parallel-oriented probe and a noise at every sock, which was delivered with a minimal energy of 0.03 mJ/mm^2. All patients were blindfolded. A 10-cm VAS type and the ODI were used for evaluations before and 1 and 4 weeks after treatment by a physician blinded to the other procedures. The authors found a significant improvement in the pain score in the fESWT group at week 4 post-treatment compared to the baseline, which was not observed in the control group. Although there was a trend toward improvement from baseline in the ODI regarding the intervened patients, statistical significance was not reached for both groups. Side effects of fESWT were not evident.

Taheri et al. (20) presented the results from a randomized controlled trial on 32 patients with chronic low back pain with a duration of more than 3 months who had never undergone surgery or

Abbreviations: LBP, Low back pain; SIJ, Sacroiliac joint; ODI, Oswestry Disability Index; LPS, Laitinen Pain Scale; fESWT, Focused extracorporeal shock wave therapy; MRI, Magnetic resonance imaging; EFD, Energy flux density; BMI, Body mass index; FUP, Follow-up.

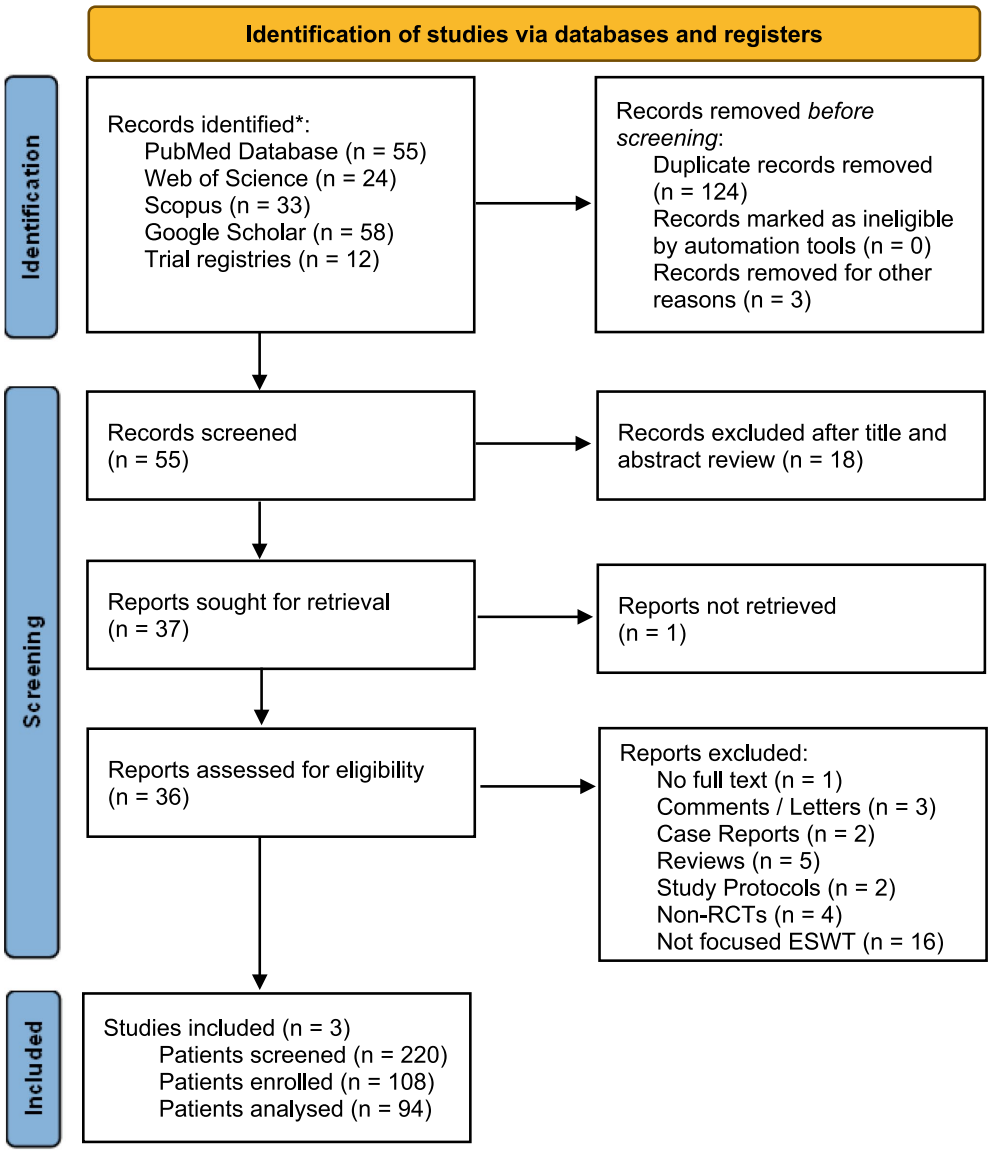

FIGURE 1
PRISMA diagram presenting the search for randomized controlled trials (RCT) of focused ESWT for low back pain published before April 1, 2024. *No restrictions regarding the year of publication, country of origin, or language were applied.

any other treatment for the last month associated with their disease. Pregnant women and patients with mental or cognitive problems were not included. Among the exclusion criteria were cancer, fractures, infections, disc degeneration resulting from aging or trauma, an unstable medical condition, or uncontrolled systematic diseases. Thirty-eight patients were enrolled and randomly allocated equally to the focused ESWT or control group, nine were not eligible, and three refused. Six subjects were lost during the follow-up due to unwillingness to continue, and 32 study completers were analyzed—17 and 15 from the abovementioned groups, respectively. The protocol included focused ESWT or sham procedure, as well as oral medications and an exercise program for all. The pressure pulses were targeted on the surface trigger points through a contact lubricant, and 1,500 of them were delivered at 0.15 mJ/mm^2 energy density and 4 Hz frequency. The sessions were once weekly for 4 weeks. Patients in the control group had sham procedures with the same treatment regimen, which had the same sound but without energy applied. All subjects received oral medications (meloxicam 15 mg/daily for 2 weeks and tizanidine 2 mg/daily for 10 days) and fulfilled an exercise program. ODI questionnaire was used to evaluate the degree of functional disability, and the visual analog scale was used to assess the pain at baseline and after 1 and 3 months. Appropriate statistical analysis was performed. The groups were comparable in terms of sex, age, body mass index, duration, and severity of complaints. The pain score decreased during the study period in both groups without statistically significant differences between them. ODI is observed to be the same but with a significantly lower score at 1 month in favor of the interventional arm and not at 3 months.

Rajfur et al. (21) conducted a prospective randomized, single-blind study with a 3-month follow-up regarding the efficacy of focused ESWT in patients with chronic low back pain. Subjects were assigned to real or sham treatments using a computer random

TABLE 1 List of randomized controlled trials for the treatment of low back pain (LBP) with extracorporeal shockwave therapy (ESWT), which were excluded from further analysis after a detailed review.

Author	Year	Study	Reason for exclusion
Zheng et al. (26)	2013	ESWT vs. Thermomagnetic therapy in chronic LBP	Radial ESWT device—ShockMaster 500, Gymna, Belgium
Lee et al. (27)	2014	ESWT vs. Conservative physical therapy in chronic LBP	Radial ESWT device—JEST-2000, Joeun Medical, Korea
Han et al. (28)	2015	ESWT vs. Conservative physical therapy in chronic LBP	Radial ESWT device—VITERA, Comed, Korea
Hong et al. (29)	2017	EWST vs. Trigger point injection for the treatment of the quadratus lumborum myofascial pain syndrome	Dornier AR2 with smart focus technology (MedTech, Munchen, Germany)
Nahas et al. (30)	2018	ESWT and exercises vs. Exercises in postpartum LBP	Radial ESWT device—Unknown model, Storz Medical, Switzerland
Schneider et al. (24)	2018	ESWT and myofascial trigger therapy vs. myofascial trigger therapy in chronic LBP	Vibrotherapy—Cellconnect Impulse
Walewicz et al. (31)	2019	ESWT and stabilization training vs. Sham ESWT and stabilization training in chronic LBP	Radial ESWT device—Pro-Shock Waves Pneumatic, Cosmogamma, Indonesia
Çelik et al. (32)	2020	ESWT vs. Sham ESWT in chronic LBP	Electrohydraulic lithotripter—EMD, E1000, C-ARMOR, Turkey
Eftekharsadat et al. (23)	2020	ESWT and stretching exercises vs. Corticosteroid injections and stretching exercises in LBP	Radial ESWT device—enPulsPro, Zimmer MedizinSysteme, Germany
Notarnicola et al. (33)	2020	ESWT vs. Exercises in sacroiliac joint pain	Lithotripter—Minilith SL1, Storz Medical, Switzerland
Guo et al. (34)	2021	ESWT vs. ESWT and medication therapy vs. Medication therapy in chronic LBP	Radial ESWT device—Swiss DolorClast® EVO BLUE, Switzerland
Lange et al. (35)	2021	ESWT vs. Sham ESWT and medication therapy in acute LBP	Radial ESWT device—Swiss DolorClast® EVO BLUE, Switzerland
Elgendy et al. (36)	2022	ESWT and standard exercise program vs. standard exercise program in chronic LBP	Radial ESWT device—HC Shock Wave, Elettronica Paganis, Italy
Kong et al. (37)	2022	ESWT vs. Laser therapy in chronic LBP	Radial ESWT device—HK.ESWO-AJ, Shenzhen Huikang Medical Apparatus, China
Sun et al. (38)	2022	ESWT comparing different treatment protocols in chronic LBP	Radial ESWT device—enPuls, Zimmer MedizinSysteme, Germany
Wu et al. (39)	2023	ESWT vs. Thermomagnetic therapy in LBP	Radial ESWT device—BHSW Ballistic, Weihai Bohua Medical Equipment Co., China

All these studies report results with radial shockwave or vibrotherapy devices.

TABLE 2 Summary of the randomized controlled trials regarding the basic demographic characteristics, duration of symptoms, assessment tools for the clinical outcome, and follow-up periods.

Author	Year	Study design	Group	Subjects enrolled	Subjects analyzed	Mean age, years	BMI	Symptoms duration, months	Assessment tools	FUP, months
Moon (18)	2017	Prospective, randomized, controller, single-center	ESWT	15	14	54.42 ± 19.05	NS	20.42 ± 11.81	VAS, ODI	1 and 4 weeks
			Sham	15	11	59.18 ± 15.30		17.70 ± 6.81		
Taheri (20)	2021	Prospective, randomized, controlled, single-center	ESWT	19	17	42.5 ± 10.1	27.1 ± 5.5	4.6 ± 1.2	VAS, ODI	1 and 3 months
			Sham	19	15	37.1 ± 11.8	26.8 ± 2.1	5.0 ± 1.2		
Rajfur (21)	2022	Prospective, randomized, controlled, single-blinded, single-center	ESWT	20	19	42.3 ± 13.1	24.3 ± 3.9	57.5 ± 50.9	VAS, LPS, ODI	After the end, 1 and 3 months
			Sham	20	18	45.4 ± 14.0	26.5 ± 3.0	61.8 ± 53.1		

ESWT, focused extracorporeal shockwave group (experimental arm); Sham, sham-intervened group (control arm); VAS, Visual Analogue Scale; ODI, Oswestry Disability Index; LPS, Laitinen Pain Scale; FUP, follow-up period.

TABLE 3 Treatment protocols of the randomized controlled trials.

Author	Year	ESWT	Control	Treatment regimen	Additional treatment	Device
Moon (18)	2017	2000 shocks, 3 Hz frequency, 0.09–0.25 mJ/mm²*	Sham procedure (0.03 mJ/mm² with parallel probe orientation)	Single session	Refrain from anti-inflammatory medication and other physical modalities	Aries, Dornier MedTech, Germany
Taheri (20)	2021	1,500 shocks, 4 Hz frequency, 0.15 mJ/mm²**	Sham procedure (sound without energy)	Once weekly for 4 weeks (4 sessions)	Exercise program with muscle stretching and strengthening; oral medications (meloxicam 15 mg/d for 2 weeks; tizanidine 2 mg/d for 10 days)	Aries2, Dornier MedTech, Germany
Rajfur (21)	2022	1,000 shocks, 4 Hz frequency, 0.15 mJ/mm²**	Sham procedure (absorbing insert)	Twice weekly for 5 weeks (10 sessions)	Stabilization training (45 min, once a day, 5 days a week) with myofascial relaxation, dynamic postural exercises	Duolith SD1, Storz Medical, Switzerland

The additional treatments are described in detail. ESWT, focused extracorporeal shockwave group (experimental arm); Control, sham-intervened group (control arm).
*Energy flux density (EFD) was set to the maximum tolerated by the patient.
**EFD was fixed.

TABLE 4 Baseline characteristics and clinical results for pain (VAS).

Author	Year		Baseline	After treatment	Month 1	Month 3
Moon (18)	2017	ESWT	6.42 (5.19–7.66)	not given	3.64 (2.29–4.99)*,#	
		Sham	Not given	Not given	6.18 (5.34–7.02)#	
Taheri (20)	2021	ESWT	6.6 ± 1.8		3.0 ± 2.3*	1.8 ± 2.8**
		Sham	6.8 ± 1.9		4.6 ± 1.8*	1.1 ± 1.5**
Rajfur (21)	2022	ESWT	7.2 ± 1.9	1.5 ± 0.6*,#	1.7 ± 1.1*,#	2.0 ± 1.2*
		Sham	7.3 ± 1.7	2.9 ± 1.3*,#	3.1 ± 1.7*,#	3.3 ± 1.9*

Data is expressed as mean ± SD except for the study of Moon et al., where the 95% confidence interval is presented in brackets.
*Statistically significant difference within groups at the corresponding follow-up time points compared to baseline.
**Statistically significant difference within groups at month 3 compared to month 1.
#Statistically significant difference between groups at each time point.

TABLE 5 Baseline characteristics and clinical results regarding the quality of life because of pain (ODI).

Author	Year	Group	Baseline	After treatment	Month 1	Month 3
Moon (18)	2017	ESWT	17.80 (13.08–22.63)	12.92 (9.19–16.67)	11.28 (7.30–15.28)	
		Sham	Not given	Not given	Not given	
Taheri (20)	2021	ESWT	41.1 ± 21.2		11.9 ± 6.6*,#	7.1 ± 5.7**
		Sham	40.5 ± 19.1		22.9 ± 9.4*,#	8.9 ± 5.7**
Rajfur (21)	2022	ESWT	33.4 ± 6.3	18.3 ± 7.5*	17.3 ± 7.1*	18.3 ± 6.8*
		Sham	32.5 ± 8.6	19.5 ± 6.5*	18.7 ± 6.6*	19.9 ± 7.4*

Data is expressed as mean ± SD except for the study of Moon et al., where the 95% confidence interval is presented in brackets.
*Statistically significant difference within groups at the corresponding follow-up time points compared to baseline.
**Statistically significant difference within groups at month 3 compared to month 1.
#Statistically significant difference between groups at each time point.

number generator. Both groups performed basic exercises to stabilize the spine. The same therapist performed all tests and surveys, and the same physiotherapist performed all treatments and exercises. Patients with MRI-confirmed L5-S1 discopathy (Modic type 3 changes), chronic pain lasting at least 12 weeks, and no spinal surgical interventions were enrolled. Among the exclusion criteria were discopathy beyond the L5-S1 level (Modic type 1 and 2), reduced segmental mobility, other spinal conditions, neurologic deficit, blood coagulation disorders, metal implants at the treatment site, sensory disturbances, mental disorders, cancer, local skin lesions, and infections. The study involved 40 subjects equally allocated in the two homogenous and comparable groups. Three patients were excluded from the statistical analysis—one was lost in the follow-up period from the treatment group and two from the sham procedure group because of taking painkillers. According to the authors, each procedure was performed using the contact method at the lower back, where the most severe pain is localized.

The energy flux density was 0.15 mJ/mm^2 in 1000 pulses with a frequency of 4 Hz. Treatments were performed twice a week for 5 weeks under ultrasound guidance. Patients from the control group received a sham procedure using a polyethylene-absorbing insert on the top of the applicator with the same audible signals and technical parameters. Identical stabilization training with myofascial relaxation and dynamic postural exercises were performed in both groups 5 days a week. The assessment was done using a visual analog scale (VAS), Laitinen Pain Scale (LPS), and Oswestry Disability Index (ODI) before and after treatment and during follow-up at 1 and 3 months. Appropriate statistical analysis was performed. The groups were comparable in terms of demographic and clinical characteristics. The authors found a significantly greater improvement for the focused ESWT compared to the sham group immediately after treatment and 1 month later but not in the 3-month follow-up in VAS and LPS. This was not evident regarding the ODI scores. Still, the patients in the experimental group had greater improvement.

Discussion

Considering the available clinical studies, several problems in future designs should be addressed. First of all, the differences in the inclusion and exclusion criteria for subjects in the known series are significant. Many of them are controversial and prone to selection bias. At the same time, if we strictly adhere to them, major patient populations are not covered. Second, uniform treatment parameters have not been established to date. The applied therapeutic protocols are not based on theoretical statements, experimental findings, and practical experience. Lastly, there is a need for objective assessment and reproducible tools regarding the clinical outcome. Thus, even the few low-quality studies are not comparable.

Notably, in the study of Moon et al. (18), 98 patients were assessed for eligibility, of which 39 did not meet the inclusion criteria, and 27 declined participation. From the allocated 30 subjects, 15 in the focused ESWT and 15 in the sham-intervened group, there was one loss for follow-up from each one. Another three patients from the controls were drop-outs due to pain medication intake. Thus, only 25 patients, 14 from the experimental and 11 from the sham-stimulation groups, achieved analysis. The abovementioned poses a significant risk of selection bias. Several points of this study also remain disputable. For example, focused ESWT in another body part is irrelevant to the local procedure in the current area of interest, and such patients might not be excluded. Furthermore, cases with facet joint syndrome encompass a large proportion of the low back pain population. This is an important group, where it is sometimes difficult to differentiate from the pain of sacroiliac joint origin, even with negative imaging findings, and it contributes further to the selection bias.

The study of Taheri et al. (20) has several limitations, including the small number of subjects, as noted by the authors. Out of 50 patients, 12 were excluded, and another six were lost during the follow-up, which implies observational bias. Disc degeneration is stated to be an exclusion criterion, but this is the anatomical substrate of low back pain in most cases. Thus, this point is disputable and unclear. In addition, it is difficult to differentiate the effect of the focused EWST because of the routinely administered drug therapy in all patients.

The randomized controlled trial of Rajfur et al. (21) also has several drawbacks and limitations that have not been discussed by the authors. Some exclusion criteria remain disputable, like implanted cardiac pacemakers. For the study examiners, it is difficult to control the intake of painkillers and anti-inflammatory drugs in patients with pain syndrome. Reduced mobility in the lumbosacral segment is nonsense as an exclusion criterion. In the same context, a discopathy beyond the L5-S1 Modic type 1 and 2 changes remains unclear. Furthermore, ovulation in healthy women included in this study is expected to occur every 4 weeks, which confronts the protocol, and this population of patients should not be included.

Evaluation of the treatment effect in patients with pain syndrome is difficult and, in many cases, subjective. To address this problem, Elgendy et al. (22) published a randomized controlled trial of radial ESWT in chronic low back patients. Therefore, this study is not part of the current analysis. However, the authors evaluated the electromyographic (EMG) activity of trunk muscles (lumbar multifidus and lumbar erector spinae) in the form of root mean square. After electrode placement, the protocol included the application of an appropriate resistance at the scapular region to maintain the maximum isometric muscular contraction three times. Then, the patient was asked to gradually increase the force to reach an absolute maximum and to hold it for 8–10 s. Three maximal isometric extension efforts were performed. Approximately 30 s of rest were given between contractions. EMG sampling frequency in their protocol was 1,000 HZ, and the sensitivity was 500 µs. The total root mean square of the recorded signals was obtained. The authors found that their increase correlates with lower VAS scores for pain. This approach needs to be replicated in further studies.

In a single-blind randomized clinical trial, Eftekharsadat et al. (23) investigated the effect of radial ESWT on patients with low back pain, which is also not included in this analysis. However, the authors present a pressure-pain threshold assessment using a commercially available digital algometer for the myofascial trigger points on quadratus lumborum muscles. Larger values indicate higher pain thresholds. The device has a 1.0 cm^2 circular flat tip, which was slowly pushed upright to the skin over the trigger points. The exerted pressure was increased gradually until the pain was perceived. The measurements were implemented thrice with 40 s intervals, and the mean value was considered.

Addressing the primary end-point, which is the pain intensity, all future studies for LBP treatment should rely not only on the widely accepted visual analog type of scales. A more detailed assessment could be achieved with the Oswestry Disability Index and the Short Form 36 health survey for quality of life. However, both require active patient participation and, in some cases, the need for assistance from a third party, which may contribute to bias. For example, Schneider et al. used a very simple pain measurement instrument, the 7-point-Likert-Scale, with anchors: no pain, very low, low, moderate, strong, very strong, and unbearable (24). However, the use of uncommon evaluation tools makes it difficult to compare results between studies.

Notably, in all analyzed studies, pain decreased over time in treatment and control groups (18, 20, 21). Complaints in degenerative diseases of the spine generally have a chronically relapsing course with periods of exacerbation, then improvement. The latter can be accelerated with the help of medication, physiotherapy, manual therapy, and exercises. Similarly, focused ESWT significantly reduced pain and improved functional impairment immediately after the procedures and 1 month later. At the 3-month follow-up, the results remained better in the experimental compared to the control groups, despite minimal pain levels in both. None of the studies followed the

TABLE 6 Systematic review with meta-analyses of randomized controlled trials of ESWT.

Author	Year	Study	Limitations
Yue et al. (40)	2021	Systematic review and meta-analysis of RCTs	8 radial ESWT/1 focused ESWT/1 vibrotherapy
Li et al. (41)	2022	Systematic review and meta-analysis of RCTs	11 radial ESWT/2 focused ESWT/1 vibrotherapy
Ma et al. (42)	2022	Systematic review and meta-analysis of RCTs	12 radial ESWT/1 focused ESWT/1 vibrotherapy
Wu et al. (43)	2023	Systematic review and meta-analysis of non-RCT and RCTs	18 radial ESWT/3 focused ESWT/1 vibrotherapy
Liu et al. (44)	2023	Systematic review and meta-analysis of RCTs	9 radial ESWT/2 focused ESWT/1 vibrotherapy

treated patients long-term, and this is precisely where the focused shockwave has the potential for a significantly better outcome.

Patients who are not indicated for surgery but are still unresponsive to conservative treatment may benefit from focused ESWT to relieve pain. As an alternative to corticosteroid infiltrations, this approach dismisses the possibility of complications such as infection, hematoma, vessel injury, intravascular drug administration, hypertension, glucose intolerance, and osteoporosis development (25). The focused ESWT could also be combined with medical therapy and exercises (20). Despite the differences between these few studies, the findings show a significant reduction in low back pain and disability. However, none have a high level of evidence, treatment protocols are still not established, and sample sizes are small.

Several systematic reviews with meta-analyses of randomized controlled trials for ESWT of low back pain have been published (Table 6). None of them reliably confirm the effectiveness of the therapeutic approach despite the good results evident in each clinical trial. It is important to note that these reviews do not analyze separately or compare the radial against focused modality. Contrary to the results with radial ESWT, the focused devices are more promising in the context of the precise targeting and dosing of energy deep within the human body to the pathological process. However, only a few studies with a small number of patients and varying treatment protocols exist to make an unambiguous conclusion about the effectiveness of the therapy and the risk of complications. All future trials necessitate approving objective methods for assessment and establishing uniform treatment parameters.

Conclusion

Focused ESWT is a modern physiotherapeutic method that can potentially treat a broad spectrum of conditions responsible for low back pain. Despite the small number of low-evidence studies, there is sufficient data on the effectiveness and safety of this therapeutic modality. With future well-designed trials, the bias risks would be diminished, the indications for its use would expand, and the treatment protocols would be clarified.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

DF: Conceptualization, Formal analysis, Investigation, Methodology, Visualization, Writing – original draft, Writing – review & editing.

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Sleeping <6.55 h per day was associated with a higher risk of low back pain in adults aged over 50 years: a Korean nationwide cross-sectional study

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Background: Patients with low back pain (LBP) often suffer from sleep disorder, and insufficient sleep duration was recognized as a potential risk factor for LBP. Our aim was to explore the exact effect of sleep duration on LBP and the optimal sleep duration to reduce the risk of LBP.

Methods: Analyzing data from the Korean National Health and Nutrition Examination Survey (KNHANES), we investigated the association between sleep duration and LBP in individuals aged 50 years and older. We used logistic regression models, interaction stratification analysis, and threshold effect assessment to analyze the relationship between sleep duration and LBP.

Results: A total of 6,285 participants, comprising 3,056 males and 3,229 females with a median age of 63.1 years, were enrolled in the study. The association between sleep duration and LBP risk exhibited an L-shaped curve ($p < 0.015$) in RCS analysis. In the threshold analysis, the OR of developing risk of LBP was 0.864 (95% CI:0.78–0.957, $p = 0.005$) in participants with sleep duration <6.55 h. Each additional hour of sleep was associated with a 13.6% decrease in the risk of LBP. No significant association was observed between sleep duration ≥6.55 h and the risk of LBP. The risk of LBP did not decrease further with increasing sleep duration. Results remain robust across subgroups.

Conclusion: Our findings indicate that shorter sleep duration is a risk factor for LBP in adults aged over 50 years. We revealed an L-shaped association between sleep duration and LBP, with an inflection point at approximately 6.55 h per day. These results underscore the significance of sleep duration as a factor in the risk assessment for LBP.

KEYWORDS

low back pain, sleep duration, cross-sectional analysis, KNHANES, Korean older adult

1 Introduction

Low back pain (LBP) is a significant contributor to the global burden of disability (1). Based on data from the most recent Global Burden of Diseases, Injuries, and Risk Factors Study (GBD), the estimated global prevalence of individuals with LBP in 2020 was 619 million people (2). It is projected that by 2050, the number of affected individuals will increase to 843 million. Meanwhile the GBD data has revealed a marked rise in the

occurrence of LBP within the Asian population. It is to be expected that both the burden of disability and the costs associated with LBP will increase further (3).

Previous research on LBP has largely focused on exploring the pathophysiological causes at the biomedical level, such as herniated discs, degenerative spinal deformity, sprain, and spinal stenosis (4, 5). However, the etiology of LBP involves multidimensional factors including biological, sociological, and psychological aspects (6, 7). Evidence suggests that gender, type of strength training, body mass index (BMI), affective states of depression, and the presence of social support are hidden risk factors for LBP (8, 9). To optimize the management and prevention of LBP, a detailed comprehension of the relationship between key factors and LBP is necessary (10).

Sleep is essential for survival (11). While asleep, the body orchestrates a multitude of vital functions, including the regulation of blood pressure and heart rate, hormonal secretion, immune system efficacy, cellular repair, thermoregulatory balance, the recovery of memory capabilities, and the enhancement of cognitive processes (12). However, sleep can also be marred by a variety of sleep disorders or abnormal behaviors, including insomnia, obstructive sleep apnea, circadian rhythm sleep-wake disorders, and sleep bruxism, which can significantly impact overall health and wellbeing (13, 14). Previous studies revealed a significant correlation between sleep and pain (15). Sleep disorders can lead to increased perception of pain severity and may negatively influence the patient's return to functional capabilities (16). Epidemiological studies have revealed a high prevalence of sleep disorders among LBP patients, with more than 50% affected, and have demonstrated a substantial negative correlation between sleep disorders and LBP (17, 18). The incidence of LBP is significantly associated with decreased sleep duration, deterioration in sleep quality, intensified difficulty initiating sleep, decline in daytime functionality, and an increase in sleep dissatisfaction and distress (19). The predominant focus in LBP management is on pain intensity and disability (20). However, the latest review indicates that the evaluation of sleep conditions has been neglected in many clinical research studies of LBP, an oversight that limits our understanding of the interplay between sleep-related factors and the occurrence of LBP (21).

Considering the relevant background, our study utilizes a nationally representative sample of Korean adults to achieve the following aims: (1) determine whether sleep duration is an independently associated risk factor for LBP; (2) investigate the dose-response relationship between sleep duration and LBP. The findings may help to clarify the role of sleep duration as a risk factor for LBP and provide information for future LBP management strategies in the general population.

2 Materials and methods

2.1 Study design and participants

This is a population-based cross-sectional study conducted using nationally representative survey data, all of which were publicly obtained from The Korea National Health and Nutrition Examination Survey (KNHANES) website (https://knhanes.kdca.go.kr/knhanes/eng/index.do). The KNHANES is an annual nationwide survey organized and executed by the Korea Centers for Disease Control and Prevention (KCDC) since 1998. With the assistance of experienced interviewers, healthcare personnel, and laboratory professionals, the KNHANES systematically collects a comprehensive array of health-related data through the administration of health interviews, health examinations, and nutritional assessments on participants. This approach allows for the evaluation of health and nutritional conditions and trends among South Korean residents. In the survey, participants were selected utilizing probability-sampling techniques, employing a multistage clustering approach that considered age group, region, and gender extracted from household registries (22).

The study sample consisted of 48,652 participants from the KNHANES-V and VI surveys conducted from 2010 to 2015. The study focused on individuals aged 50 years and older, as participants below the age of 50 were not examined for LBP in the survey. Furthermore, individuals with missing data on LBP, sleep duration, and relevant covariates were excluded from this study. In total, 6,285 participants with complete data were enrolled in this study. The participant inclusion and exclusion process was illustrated in Figure 1.

2.2 Exposed variables and outcome variables

Participants were considered to experience LBP if they responded affirmatively to the following query during survey: "Have you reported experiencing LBP persisting for a duration of 30 days or longer within the most recent 3-month period (22)."

In the KNHANES, the evaluation of habitual total sleep duration, which includes daytime napping, was obtained through the following inquiry: "How many hours do you typically sleep per day?" Participants' responses were recorded using an integer scale. The International Classification of Sleep Disorders classifies a "short sleeper" as an individual who experiences a sleep duration of under 5 h, and a "long sleeper" as an individual who experiences a sleep duration exceeding 9 h (13). Consequently, study participants were divided into five categories: $\leq$ 5, 6, 7, 8, and $\geq$9 h.

2.3 Description of related variables

The covariates utilized in this study for analysis were gathered through health interview and examination. We focused on variables that had been previously correlated with LBP and sleep duration in the existing literature (2, 23–28). These variables included demographic characteristics (age, sex, height, weight, and BMI), socioeconomic status (household income, educational level, and occupation), health-related behaviors (smoking and alcohol consumption, time spent on walking, resistance training, and flexibility exercises), psychological aspects (psychological stress and depression), and comorbidities (seven other diseases, such as hypertension).

Detailed descriptions of these specific variables are provided below. The household income level was quartile-categorized as: low, low-moderate, moderate-high, and high. Educational

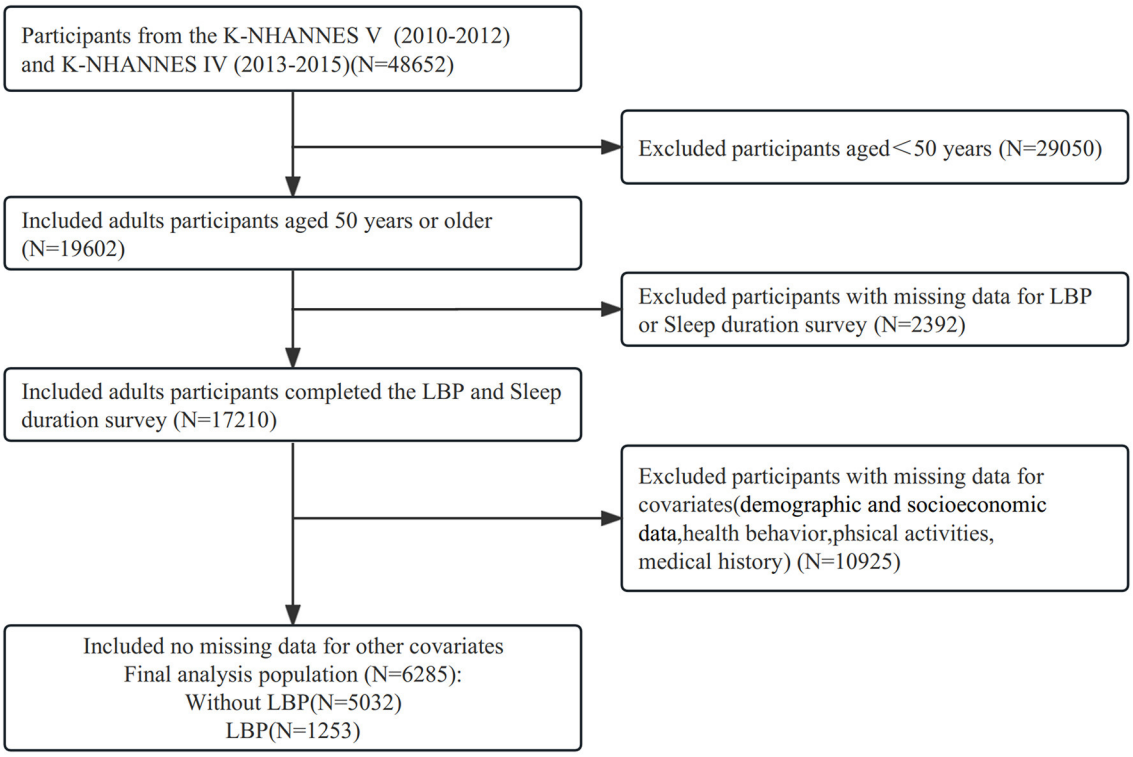

FIGURE 1
Flow diagram of study participants. The figure represents the information of excluded participants based on 4,8652 participants. A total of 6,285 participants with complete information at baseline were eligible for the cross-sectional analysis. K-NHANES, Korea National Health and Nutrition Examination Survey; LBP, Low Back Pain.

attainment was stratified into four categories based on the highest degree achieved: elementary school, middle school, high school, and university or college. Participants' current occupational status was classified into five distinct groups: office workers (e.g., professionals, office workers, and managers), sales and services, agriculture, forestry and fishery, machine fitting and simple labor (e.g., technicians, low-level laborers, and device and machine operators), unemployed (e.g., housewives and students) (29, 30). Within the domain of health behaviors, three variables associated with physical activity, including weekly time allocation for walking, resistance training, and flexibility exercises, were utilized. These variables were uniformly categorized into four groups: none, 1–2 days per week, 3–4 days per week, and ≥5 days per week (26, 28). The classification of smoking habits among participants was simplified into two categories: current and non-/ex-smoker. Additionally, drinking habits were classified based on the frequency of alcohol intake over the past year: none, ≤1 drink/month, 2 drinks/month to 3 drinks/week, and ≥4 drinks/week. Psychological health status primarily encompasses subjective stress level and depressive conditions. The former evaluates participants' self-reported psychological stress intensity in their daily lives, categorized as severe, moderate, mild, or none (27). The latter assesses whether participants have been diagnosed with depression by a medical professional (24). Comorbid conditions, including hypertension, diabetes, dyslipidemia, stroke, myocardial infarction, angina, and arthritis, were also determined through medical diagnosis.

2.4 Statistical analysis

A logistic regression of a binary response variable (LBP) on a continuous, normally distributed variable (sleep duration) with a sample size of 6,285 observations achieves 85% power at a 0.05000 significance level to detect a change in the Probability of LBP being positive from a value of 0.199 at the mean of sleep duration to 0.183 when sleep duration is increased to one standard deviation above the mean. This change corresponds to an odds ratio of 0.900. An adjustment was made since a multiple regression of the independent variable of interest on the other independent variables in the logistic regression obtained an R-Squared of 0.200. The statistical analyses in this study utilized the R statistical software package (http://www.R-project.org, R Foundation) along with Free Statistics Software versions 1.8. Categorical variables were represented as numbers (percentages), whereas continuous variables were expressed as mean ± standard deviation. Statistically significant results were defined as two-tailed p-values < 0.05.

Undertaking a comprehensive descriptive analysis to meticulously assess the characteristics of the included participants. This multifaceted analysis compared the basic characteristics of subjects grouped by different sleep durations, as well as those of participants with and without LBP. The specific analytical techniques employed encompass the utilization of chi-square tests for assessing categorical variables and the application of one-way analysis of variance or Student's t-test for the evaluation of continuous variables.

Utilizing logistic regression analysis, we assessed the relationship between sleep duration and LBP, subsequently calculating the corresponding odds ratios (ORs) and their associated 95% confidence intervals (CIs). In order to eliminate the possibility of differences attributed to sleep duration from being confounded by potential variables, we systematically adjusted for covariates through the utilization of three distinct logistic regression models. Model 1 was adjusted to account for essential demographic variables, including age and gender. This adjustment was justified by the findings of studies conducted by Jennifer and colleagues, which indicated a correlation between age, sex, and an elevated risk of LBP (31). In Model 2, we performed adjustments for covariates whose effect estimates were altered by more than 10% upon their inclusion in the model. These covariates included age, sex, household income level, educational level, height, weight, self-perceived stress level, and a history of osteoarthritis diagnosis. Beyond the variables adjusted in Model 2, Model 3 executed a comprehensive adjustment, encompassing supplementary variables like occupation, smoking status, alcohol consumption, depressive symptoms, different categories of physical exercise (walking, resistance training, and flexibility exercises) duration, and additional comorbidities. In the process of stepwise adjustments, sleep duration was categorized and sensitivity analyses were performed to evaluate the stability of the findings.

A trend test was subsequently applied to Model 3 to evaluate the presence of a linear trend in the relationship between sleep duration, considered as a continuous variable, and LBP. Dose-response curve between sleep duration and LBP were analyzed using restricted cubic spline (RCS) regression on the 5^{th}, 35^{th}, 65^{th}, and 95^{th} percentiles of sleep duration. Upon detection of a non-linear relationship, a two-piecewise linear logistic regression model was applied to investigate the association threshold between sleep duration and LBP after adjusting the potential confounders in Model 3. Additionally, a recurrence method was utilized to define the threshold value for sleep duration, including the selection of turning points along a predefined interval and the choice of the turning point resulting in the maximum likelihood model.

Lastly, within discrete strata defined by age, gender, household income, educational attainment, and occupation, stratified logistic regression models were employed for the purpose of conducting subgroup analyses. To test interactions across these subgroups, the likelihood ratio test was applied.

3 Results

3.1 Characteristics of the study population according to low back pain

In this study, 48,652 potential participants were selected from KNHANES (2010–2015), of which 19,602 adults (≥50 years) completed health interviews for inclusion in our study. Participants with missing LBP and sleep duration (n = 2,392) were excluded. After further excluding those with missing covariate information (n = 10,925), the final analytical sample comprised 6,285 participants (48.6% male and 51.8% female). The average age and sleep duration of the participants are 63.1 ± 8.7 years and 6.6 ± 1.5 h. The baseline characters of the population included and excluded are presented in Supplementary Table S1.

Table 1 presents a comparative analysis between 1,253 LBP patients and 5,032 subjects without LBP. Compared to the group without LBP, LBP patients are obviously older (65.9 ± 8.9 years old vs. 62.5 ± 8.5 years old; $p < 0.001$) and have shorter sleep duration (6.4 ± 1.7 h vs. 6.7 ± 1.4 h; $p < 0.001$). Besides, females, a lower household income, and a lower education level were combined with an increased risk of LBP. The Supplementary Table S2 describes in detail the baseline characteristics of the subjects stratified by distinct sleep duration categories.

3.2 Association between sleep duration and low back pain

Table 2 summarizes the results of the multivariate logistical regression analysis for the relationship between sleep duration and LBP. The crude model suggested that sleep duration negatively correlated to the occurrence of LBP (OR = 0.87, 95% CI: 0.84–0.91). This means that a 1-h sleep duration increase was linked to a 13% lower risk of LBP. Moreover, we considered sleep duration as a categorical variable (≤5,6,7,8, ≥9 h) and found that participants who had 6, 7, 8, ≥9 h of sleep duration had a reduced risk of LBP compared with "short sleepers" who had sleep duration ≤5 h. Comparable results were noted upon adjustment for age and sex within model 1 (OR = 0.92; 95% CI: 0.88–0.95). After progressive adjustment for potential confounding factors, the odds ratios from model 3 still indicated a significant inverse relationship between sleep duration and the incidence of LBP. In the fully adjusted Model 3, subjects who slept 7 to 8 h per night had a reduced risk of LBP compared to those who slept 5 h or less, referred to as "short sleepers."

Figure 2 shows the restricted cubic curve spline analysis for fully adjusted model 3, we observed a non-linear relationship between the sleep duration and LBP (p for non-linearity = 0.015). The solid line in the figure indicates the predicted risk for the occurrence of LBP, and the dashed line indicates the point-wise 95% confidence interval after adjusting for potential confounding variables, which reveals an L-shaped relationship between sleep duration and the risk of LBP.

The results of further threshold analyses are shown in Table 3, where the risk of LBP was negatively associated with sleep duration when the sleep duration was <6.55 h, and the risk of LBP was reduced by 13.6% for every 1-h increase in sleep duration (OR = 0.864, 95% CI: 0.78–0.96). Nonetheless, no significant association was observed between sleep duration and the risk of LBP when the duration was at least 6.55 h (OR = 1.054, 95% CI: 0.953–1.167).

3.3 Subgroup analyses

The results of the stratified analysis are shown in Figure 3, which reveals that the relationship between sleep duration and LBP remained stable among different subgroups. We can find that none of the variables of age (50–59, 60–69, 70–79, and ≥80 years), sex (female and male), household income (low, low-mid,

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TABLE 1 KNHANES 2010–2015 participant characteristics stratified by LBP status.

Variables	Total ($n = 6,285$)	Without LBP ($n = 5,032$)	With LBP ($n = 1,253$)	p
Sleep duration (hour), Mean ± SD	6.6 ± 1.5	6.7 ± 1.4	6.4 ± 1.7	< 0.001
Age (year), Mean ± SD	63.1 ± 8.7	62.5 ± 8.5	65.9 ± 8.9	< 0.001
Height (cm), Mean ± SD	160.4 ± 8.7	161.2 ± 8.5	156.9 ± 8.5	< 0.001
Weight (kg), Mean ± SD	61.9 ± 10.2	62.6 ± 10.2	59.5 ± 9.6	< 0.001
Body mass index (kg/m^2), Mean ± SD	24.0 ± 3.1	24.0 ± 3.1	24.1 ± 3.1	0.288
Sex, *n* (%)				< 0.001
Male	3,056 (48.6)	2,659 (52.8)	397 (31.7)	
Female	3,229 (51.4)	2,373 (47.2)	856 (68.3)	
Household income, *n* (%)				< 0.001
Low	1,693 (26.9)	1,141 (22.7)	552 (44.1)	
Low-mid	1,704 (27.1)	1,392 (27.7)	312 (24.9)	
Mid-high	1,423 (22.6)	1,231 (24.5)	192 (15.3)	
High	1,465 (23.3)	1,268 (25.2)	197 (15.7)	
Education level, *n* (%)				< 0.001
Elementary school	2,504 (39.8)	1,780 (35.4)	724 (57.8)	
Middle school	1,151 (18.3)	936 (18.6)	215 (17.2)	
High school	1,677 (26.7)	1,459 (29)	218 (17.4)	
College or university	953 (15.2)	857 (17)	96 (7.7)	
Occupation, *n* (%)				< 0.001
Office work	638 (10.2)	579 (11.5)	59 (4.7)	
Sales and services	655 (10.4)	557 (11.1)	98 (7.8)	
Agriculture, forestry and fishery	495 (7.9)	405 (8)	90 (7.2)	
Machine fitting and simple labor/manual labor	1,460 (23.2)	1,259 (25)	201 (16)	
Unemployed (student, housewife, etc.)	3,037 (48.3)	2,232 (44.4)	805 (64.2)	
Walking, *n* (%)				< 0.001
None	1,293 (20.6)	978 (19.4)	315 (25.1)	
1–2 day/week	939 (14.9)	754 (15)	185 (14.8)	
3–4 day/week	1,257 (20.0)	1,010 (20.1)	247 (19.7)	
≥5 day/week	2,796 (44.5)	2,290 (45.5)	506 (40.4)	
Resistance training, *n* (%)				< 0.001
None	4,749 (75.6)	3,705 (73.6)	1,044 (83.3)	
1–2 day/week	497 (7.9)	418 (8.3)	79 (6.3)	
3–4 day/week	444 (7.1)	372 (7.4)	72 (5.7)	
≥5 day/week	595 (9.5)	537 (10.7)	58 (4.6)	
Flexibility exercises, *n* (%)				< 0.001
None	2,849 (45.3)	2,213 (44)	636 (50.8)	
1–2 day/week	907 (14.4)	743 (14.8)	164 (13.1)	
3–4 day/week	986 (15.7)	780 (15.5)	206 (16.4)	
≥5 day/week	1,543 (24.6)	1,296 (25.8)	247 (19.7)	
Smoking status, *n* (%)				0.095
Non/ex-smoker	5,181 (82.4)	4,128 (82)	1,053 (84)	

(Continued)

TABLE 1 (Continued)

Variables	Total ($n = 6,285$)	Without LBP ($n = 5,032$)	With LBP ($n = 1,253$)	p
Current smoker	1,104 (17.6)	904 (18)	200 (16)	
Alcohol consumption, *n* (%)				< 0.001
None	1,611 (25.6)	1,221 (24.3)	390 (31.1)	
≤1 drink/month	1,982 (31.5)	1,545 (30.7)	437 (34.9)	
2 drinks/month to 3 drinks/week	2,056 (32.7)	1,741 (34.6)	315 (25.1)	
≥4 drinks/week	636 (10.1)	525 (10.4)	111 (8.9)	
Degree of Stress, *n* (%)				< 0.001
None	1,539 (24.5)	1,303 (25.9)	236 (18.8)	
Mild	3,590 (57.1)	2,930 (58.2)	660 (52.7)	
Moderate	927 (14.7)	643 (12.8)	284 (22.7)	
Severe	229 (3.6)	156 (3.1)	73 (5.8)	
Depression, *n* (%)				< 0.001
No	5,897 (93.8)	4,799 (95.4)	1,098 (87.6)	
Yes	388 (6.2)	233 (4.6)	155 (12.4)	
Hypertension, *n* (%)				< 0.001
No	3,983 (63.4)	3,267 (64.9)	716 (57.1)	
Yes	2,302 (36.6)	1,765 (35.1)	537 (42.9)	
Diabetes, *n* (%)				< 0.001
No	5,349 (85.1)	4,340 (86.2)	1,009 (80.5)	
Yes	936 (14.9)	692 (13.8)	244 (19.5)	
Dyslipidemia, *n* (%)				< 0.001
No	4,874 (77.5)	3,978 (79.1)	896 (71.5)	
Yes	1,411 (22.5)	1,054 (20.9)	357 (28.5)	
Stroke, *n* (%)				< 0.001
No	6,005 (95.5)	4,849 (96.4)	1,156 (92.3)	
Yes	280 (4.5)	183 (3.6)	97 (7.7)	
Myocardial infarction, *n* (%)				0.316
No	6,180 (98.3)	4,952 (98.4)	1,228 (98)	
Yes	105 (1.7)	80 (1.6)	25 (2)	
Angina, *n* (%)				< 0.001
No	6,100 (97.1)	4,905 (97.5)	1,195 (95.4)	
Yes	185 (2.9)	127 (2.5)	58 (4.6)	
Arthritis, *n* (%)				< 0.001
No	5,104 (81.2)	4,293 (85.3)	811 (64.7)	
Yes	1,181 (18.8)	739 (14.7)	442 (35.3)	

SD, standard deviation.

mid-high, and high), education (elementary school, middle school, high school, college, or university), and occupation (office work, sales and service, agriculture, forestry and fishery, machine fitting, and simple labor/manual labor, unemployed such as student or housewife) significantly interacted with the relationship between sleep duration and LBP (all p for interaction > 0.05).

4 Discussion

We used the data from KNHANES to conduct the nationally representative cross-sectional study. After adjusting for covariates, our results showed a significant and independent association between sleep duration and the risk of LBP among adults in Korea

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TABLE 2 Logistic regression to assess the relationship between sleep duration and LBP.

Variable	n. total	n. LBP_%	OR (95% CI)							
			Non-adjusted	*p*-value	Model 1	*p*-value	Model 2.	*p*-value	Model 3.	*p*-value
Sleep duration (hour)	6,285	1,253 (19.9)	0.87 (0.84~0.91)	<0.001	0.92 (0.88~0.95)	<0.001	0.95 (0.91~0.99)	0.011	0.94 (0.9~0.98)	0.004
Q1 (≤5h)	1,336	374 (28)	1(Ref)		1(Ref)		1(Ref)		1(Ref)	
Q2 (6h)	1,635	304 (18.6)	0.59 (0.49~0.7)	<0.001	0.73 (0.61~0.88)	0.001	0.83 (0.69~1)	0.045	0.84 (0.69~1.01)	0.069
Q3 (7h)	1,592	257 (16.1)	0.5 (0.41~0.59)	<0.001	0.62 (0.51~0.75)	<0.001	0.76 (0.62~0.92)	0.005	0.77 (0.63~0.94)	0.01
Q4 (8h)	1,286	217 (16.9)	0.52 (0.43~0.63)	<0.001	0.66 (0.55~0.81)	<0.001	0.78 (0.64~0.96)	0.019	0.8 (0.65~0.99)	0.036
Q5 (≥9h)	436	101 (23.2)	0.78 (0.6~1)	0.048	0.84 (0.65~1.09)	0.191	0.88 (0.67~1.15)	0.349	0.8 (0.6~1.05)	0.109
Trend. test	6,285	1,253 (19.9)		<0.001		0.001		0.043		0.023

Model 1: Adjusted for age, sex. Model 2: Adjusted for the variables in Model 1 plus household income, education level, height, weight, self-reported stress level, Arthritis. Model 3: Adjusted for the variables in Model 2 plus occupation, body mass index, smoking, alcohol consumption, time spent on walking, resistance training, and flexibility exercises, depression, comorbidities (such as hypertension, diabetes, dyslipidemia, stroke, myocardial infarction, angina).

aged fifty and above. To our knowledge, our study first revealed that there is an L-curve relationship between sleep duration and risk of LBP. When the sleep duration is <6.55 h, the risk of LBP decreases by 13.6% for each additional hour of sleep. However, when the sleep duration is 6.55 h or longer, further increments in sleep duration do not result in a reduced risk of experiencing LBP. This result was consistent across subgroups defined by age, sex, income level, education level, and occupation.

Previous studies have concentrated on examining the relationship between sleep disorders and LBP (32, 33). The specific dose-response relationship between sleep duration and risk of LBP has been less explored. The findings of this study revealed that individuals suffering from LBP exhibited a markedly reduced sleep duration compared to those without LBP, which may indicate a potential prevalence of sleep deprivation among the LBP patients. After we adjusted for multiple covariates from the biological, sociological, and psychological domains, in-depth analyses using multivariate logistic regression models consistently demonstrated a strong correlation between longer sleep duration and a reduced risk of LBP, thus revealing that adequate sleep may be an independent protective factor against LBP. Recent research findings have unveiled a potential bidirectional mechanism between LBP and sleep disorder (34). On one hand, symptoms of LBP may precipitate sleep disorders; on the other hand, the persistent presence of sleep disorder may exacerbate the pain experience of individuals suffering from LBP (35, 36). In view of this, there remains a meaningful imperative to conduct in-depth research into the interplay between sleep duration and the risk of LBP occurrence.

Sufficient sleep is beneficial in the prevention and treatment of diseases such as stroke, diabetes, and depression (37, 38). However, this study found that the risk of LBP does not appear to be consistently reduced by longer sleep duration. Specifically, the risk of LBP declined with increasing sleep duration only when sleep duration was <6.55 h. The National Institutes of Health (NIH) recommends that adults need 7–8 h of sleep per day10. The natural aging process is often accompanied by a decline in the total sleep duration, which may adversely affect the musculoskeletal system's ability to recuperate, thereby increasing the propensity for LBP to manifest (36, 39, 40). The results of this research suggest that to minimize the risk of LBP in Korea adults aged 50 years and older, it is recommended to secure no <6.55 h of daily sleep. This finding provided a scientific rationale for employing sleep intervention strategies to prevent and manage LBP issues.

Exploration of subgroup analysis data within clinical research is crucial for a more nuanced comprehension of the intricate relationship between exposure variables and outcome variables, which enhances the interpretability of study findings (41). This study revealed that among individuals aged 50 and above, across various age brackets, genders, income levels, educational backgrounds, and occupational categories, there exists a consistent inverse correlation between sleep duration and the risk of LBP. This discovery validated the extensive generalizability of the outcomes across diverse populations. Given the limited attention to the Korean demographic in previous research, the current study analyzed data from KNHANES with the goal of achieving a nationally representative assessment. Consequently, the findings

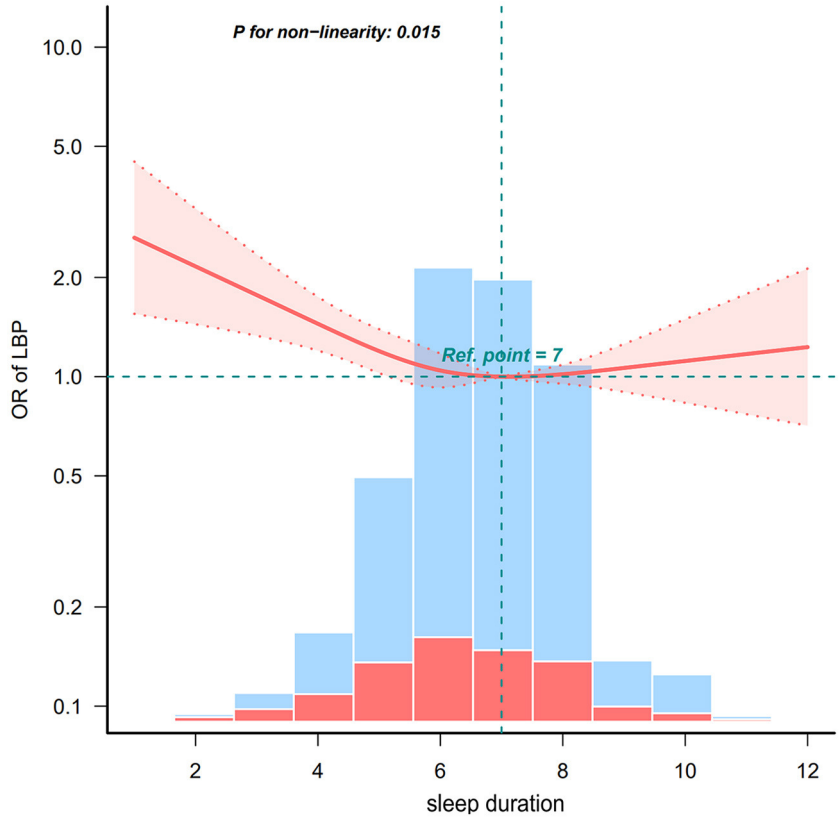

FIGURE 2
Non-linear relationship between sleep duration and LBP. LBP, low back pain. Solid and dashed lines represent the predicted value and 95% confidence intervals. Adjusted for age, sex, education level, household income, occupation, height, weight, body mass index, smoking status, alcohol consumption, walking day, resistance training day, flexibility exercises day, degree of stress, depression, hypertension, diabetes, stroke, myocardial infarction, angina, and arthritis. Only 99% of the data is presented.

TABLE 3 Threshold analysis of the relationship of sleep duration with risk of LBP.

Sleep duration, hour	Adjusted Model, OR	*P*-value
One-line linear regression model	0.94 (0.9∼0.98)	0.004
Two-piecewise linear regression model		
Sleep duration < 6.55 hours	0.864 (0.78∼0.957)	0.005
Sleep duration ≥ 6.55 hours	1.054 (0.953∼1.167)	0.307
Likelihood Ratio test		0.006

OR, odds ratio; CI, confidence interval. Adjusted for sociodemographic (age, sex, education level, household income, and occupation), height, weight, body mass index, smoking status, alcohol consumption, walking day, resistance training day, flexibility exercises day, degree of stress, depression, hypertension, diabetes, stroke, myocardial infarction, angina, arthritis. Only 99.9% of the data is shown.

of our study are projected to be broadly relevant and extend to the older adult in Korean, specifically those aged 50 and above. To accurately determine the causal association between sleep duration and LBP, there is a necessity for an increased focus on conducting more prospective longitudinal studies in future research.

Although the specific mechanism between sleep duration and the risk of LBP have yet to be fully elucidated through additional research, current evidence amassed is sufficient to partially explain the findings of this study. Firstly, some studies indicated that insufficient sleep may contribute to the onset and chronicity of LBP through alterations in brain activity, which reduced the pain threshold and impaired cognitive pain processing capabilities (42). Moreover, Krause's study revealed that sleep deprivation intensifies the pain responsiveness in the primary sensory areas of the cerebral cortex, while concurrently reducing the functional activity within other regions involved in pain modulation, such as the striatum and insula (43). Further findings validated that sleep deprivation expands the range for categorizing stimuli as pain, specifically by lowering pain thresholds. Besides, multiple studies have revealed that inflammatory processes may play a significant role in the cycles of pain and sleep disorder. Heffner et al. (44) observed a correlation between reduced sleep quality and elevated IL-6 levels in adults afflicted with LBP. Additionally, the study implicated both diminished sleep quality and increased IL-6 as determinants significantly associated with the severity of pain as reported by the participants (44). The finding indicated that the inflammatory response within individuals with LBP and comorbid sleep disorders may indirectly influence the progression and persistence of pain. A previous systematic review and meta-analysis found that sleep disorder was associated with elevated levels of C-reactive protein (CRP) and IL-6 (45). Proinflammatory cytokines promote disc degeneration by augmenting matrix breakdown and recruiting

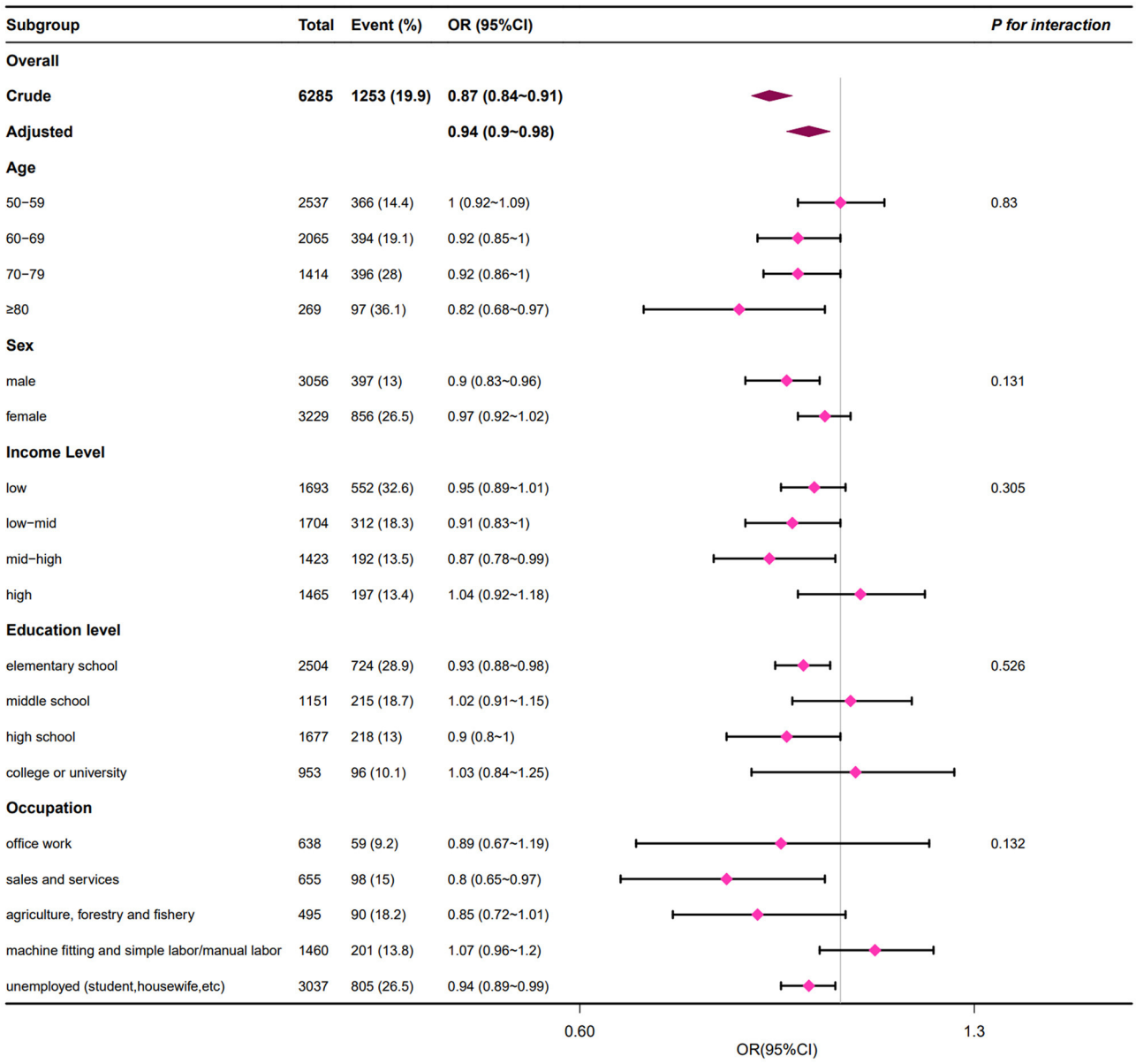

FIGURE 3
Subgroup analyses of associations of sleep duration with LBP. LBP, low back pain. Adjusted for age, sex, education level, household income, occupation, height, weight, body mass index, smoking status, alcohol consumption, walking day, resistance training day, flexibility exercises day, degree of stress, depression, hypertension, diabetes, stroke, myocardial infarction, angina, and arthritis.

immune cells to discal tissues (46). Accelerated disc degeneration may trigger LBP. Proinflammatory mediators can exert influences on neurotransmitter systems and neural circuits responsible for mood regulation, arousal, and motor activity, thereby potentially precipitating sleep disturbances (47). However, in the same meta-analysis it was also noted that the shorter sleep duration, but not the extreme of short sleep, was associated with higher levels of CRP but not IL-6 (45). The potential impact of systemic inflammatory markers on the association between sleep duration and LBP requires further researches.

The clinical implications of our study are centered on the significant association between sleep duration and the risk of LBP, particularly for the older adult. By identifying an optimal sleep duration threshold of approximately 6.55 h per day, our findings provide a clear target for clinical recommendations, advocating for sleep hygiene as a preventive measure in LBP management. The non-linear relationship between sleep and LBP risk suggests a focus on achieving adequate sleep without exceeding the threshold, where additional sleep offers no further protective effect. This insight has direct applications in clinical practice, where healthcare providers can assess and improve patients' sleep as part of routine LBP evaluations and treatment plans. Furthermore, our results highlight the necessity for integrated care approaches that consider sleep management as an integral component of LBP therapy, potentially involving a multidisciplinary team. Lastly, our findings call for additional research into the mechanisms

connecting sleep and LBP, which could lead to more targeted interventions and improved patient outcomes. Collectively, these implications contribute to a more comprehensive understanding of LBP management, emphasizing the role of sleep as a modifiable risk factor and the need for further investigation into its underlying pathways.

This study exhibits several distinct advantages: Firstly, the study is underpinned by KNHANES, a large-scale, nationally representative population study. Consequently, the substantial sample size ensures the reliability and robustness of the findings. Subsequently, threshold analyses were conducted to further elucidate the L-shaped relationship between sleep duration and the incidence of LBP. Ultimately, stratified subgroup analyses were conducted, revealing no significant interactions with other factors.

Certainly, the current study is not without its inherent limitations. Firstly, sleep duration was defined through patients' self-reported outcomes, which may be subject to recall bias. Similarly, the accuracy of diagnoses for LBP could introduce bias into the study findings. What's more, the cross-sectional nature of our study precludes the inference of causality between short sleep duration and LBP. Additionally, this study faced limitations inherent to the data available in public databases, with a shortfall in adjusting for critical confounders, including a history of lumbar disc herniation, recurrence rates, and pain severity. Furthermore, our study focused on the duration of sleep but did not provide an in-depth assessment of sleep disorders such as insomnia. Future studies that incorporate a more nuanced examination of sleep disorders in relation to LBP could significantly enhance our understanding of their interplay, potentially leading to more targeted and effective clinical interventions for managing sleep disturbances in patients with LBP.

5 Conclusion

In conclusion, our study showed that an increase in sleep duration was inversely associated with a decreased risk of LBP when sleep duration was <6.55 h range in various categories of people over 50 years old in Korea. Therefore, adequate sleep duration may be an important factor in the prevention of LBP in older adults.

Data availability statement

Publicly available datasets were analyzed in this study. This data can be found here: https://knhanes.kdca.go.kr/knhanes/sub03/sub03_02_05.do.

Ethics statement

Ethical review and approval was not required for the study on human participants in accordance with the local legislation and institutional requirements. Written informed consent from the patients/participants or the patients'/participants' legal guardian/next of kin was not required to participate in this study in accordance with the national legislation and the institutional requirements.

Author contributions

DH: Conceptualization, Data curation, Investigation, Software, Visualization, Writing – original draft, Writing – review & editing. YZ: Data curation, Investigation, Visualization, Writing – review & editing, Writing – original draft. XL: Methodology, Software, Writing – review & editing. XY: Data curation, Visualization, Writing – review & editing. XL: Writing – review & editing, Funding acquisition, Supervision. XH: Supervision, Writing – review & editing, Methodology. HY: Formal analysis, Funding acquisition, Project administration, Resources, Supervision, Validation, Writing – review & editing, Conceptualization. CZ: Funding acquisition, Resources, Supervision, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2024.1429495/full#supplementary-material

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Prevalence of musculoskeletal pain among undergraduate students

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Introduction: Musculoskeletal disorders (MSDs) are rapidly rising in Saudi Arabia, reaching levels similar to those in the Western world. Hence, we aimed to assess the prevalence of neck, shoulder, and lower back pains (musculoskeletal pain, MSP) among students at King Khalid University in Abha, Saudi Arabia.

Methods: This cross-sectional study was conducted at King Khalid University in Abha, Saudi Arabia, from March 2023 to August 2023. Inclusion criteria were: university students aged 18 years and older of both sexes who agreed to participate in the study. The modified Nordic questionnaire was used, which comprised three parts.

Results: Out of 536 respondents, 337 were women and 199 were men. The average body mass index (BMI) of the study population was 25.3 $\pm$ 4.01. In total, 223 (41.60%) had a history of MSDs. Only 232 (43.28%) of the population did regular exercise. According to multiple logistic regression analysis, factors associated with MSDs are mobile device use (with both hands) with a large neck tilt below the horizon line position (OR = 2.276, CI 1.178–4.397, $p = 0.014$), family history of trauma (OR = 5.450, 95% CI 3.371–8.811, $p = 0.000$), family history of MSDs (OR = 4.241, 95% CI 2.296–7.835, $p = 0.000$), coffee consumption (OR = 1.967, CI 1.281–3.020, $p = 0.002$), and time spent on electronic devices: 1–3 h (OR = 0.252, 95% CI 0.124–0.511, $p = 0.0001$), 4–6 h (OR = 0.455, 95% CI 0.237–0.873, $p = 0.018$), and 6–9 h (OR = 0.348, 95% CI 0.184–0.660, $p = 0.001$).

Conclusion: The present study concludes that MSP among university students is high. A history of trauma, a family history of MSDs, the hand and neck position when using electronic devices, the amount of time spent using them, and regular exercise are risk factors that are strongly associated with MSP. There is strong evidence to suggest that increasing physical activity plays a significant role in enhancing the functionality of the musculoskeletal (MSK) system and alleviating pain. It is recommended that universities implement educational programs to raise awareness and health screenings about the impact of device usage on MSK health and the benefits of regular exercise.

KEYWORDS
low-back pain, shoulder pain, musculoskeletal disorders, neck pain, students

1 Introduction

A growing number of people are experiencing neck pain (NP), which has a significant socioeconomic impact on people, their families, and communities. NP is a significant contributor to illness, lower educational achievement, and missing university classes, all of which have an impact on students' future jobs. Musculoskeletal disorders (MSDs) are characterized as injuries to the musculoskeletal (MSK) system that can result from repeated or isolated trauma and that negatively impact a person's day-to-day activities (1). In Saudi Arabia, rates of musculoskeletal pain (MSP) are developing quickly and are now comparable to those in the West: MSP accounts for 38% of visits to family practice and is the third most common reason for hospital visits (2). Neck discomfort is regarded as the fourth most common cause of disability because it has an annual prevalence rate of >30%. Although acute NP often resolves with or without therapy, approximately 50% of individuals will experience pain recurrence to some extent (3).

In the past 30 years, there has been an increase in the prevalence of neck–shoulder pain (NSP) and low back pain (LBP) among teenagers. The use of computers and mobile phones for extended periods of time is one aspect that has contributed to this rise. The lower back is the third most typical area of non-traumatic pain in adolescents of both sexes, with the neck and shoulder being the most frequently affected musculoskeletal regions (4). According to several studies, the most frequent risk factors for LBP include female sex, advanced age, hyperactivity, competitive sports, decreased life quality, and emotional symptoms (5). LBP is as common as neck discomfort, with a prevalence of 7.6%. Although many individuals have acute self-limited LBP that does not require medical attention, people who experience LBP earlier in adolescence are more likely to experience it later in life (6). Psychological elements, such as depression and psychosomatic symptoms, have also been proposed as risk factors for MSP and are related to a lower quality of life (7). The spread of NSP is further accelerated by psychological issues and poor self-reported health (8). The development of mobile technology in the 21st century has connected an increasing number of people daily via their phones. They spend more time on social media, cell phones, tablets, text reading, and other electronic devices, which causes their necks to flex for an extended period of time and results in text neck syndrome (9). This is due to repeated, intense tension on the flexed neck. It causes headaches (10) as well as pain in the neck, shoulders, and head. It is a growing health concern, and the youth may be more affected than older generations.

Uncomfortable postures, non-stop smartphone and computer use, and frequent or prolonged laptop use have all been identified as risk factors for musculoskeletal problems (11). For instance, a systemic evaluation of studies of the working population in Europe from 2010 found that 25% of people suffer from NSP (12). A Canadian study on users of mobile devices found that 68% of participants had neck complaints and 46–52% of individuals experienced shoulder symptoms (13). A total of 40% of participants in a Chinese study on young phone users reported having NSP (14).

The relationship between texting on mobile devices and NSP has been the subject of numerous studies. Prolonged neck flexion is also associated with pain in the neck, shoulder, and upper extremities during other activities (15). This can be explained by the static muscle load brought on by extended neck flexion, the lack of arm support, and the repetitive motion of the fingers, especially when just one hand is being used (16). The user's position when using a mobile phone is another factor taken into account. Everyone agrees that sitting with a straight neck and supporting forearms is ideal. This position should only be held for a brief period of time, along with holding the cell phone with both hands and utilizing both thumbs. The primary determinants of NSP and its intensity are the frequency of cell phone usage, the reason for using a cell phone, the degree of neck flexion while using a cell phone, and body position (17).

However, further research is required to determine how these and other factors affect university students. Hence, the purpose of our study is to assess the prevalence of neck, shoulder, and lower back MSP among students at King Khalid University in Abha, Saudi Arabia.

2 Methods

2.1 Study design and sample size

This cross-sectional study was conducted at King Khalid University in Abha, Saudi Arabia, between 2 March and 30 August 2023. The sample size was calculated using the Raosoft (18) sample size calculator (Cochran's formula). The sample size was based on the total number of students in the university (1,500) with a 95% confidence level, a 50% response rate, and a 5% margin of error, according to Raosoft's online sample size calculator. The target sample size was set at $n = 385$ to reduce the error in the results and improve the reliability of the study. A total of 588 students responded with a completed questionnaire. Of these 588 questionnaires, 52 were excluded due to insufficient data. The effect size was found to be 0.3 when the df (degrees of freedom) was as high as 5 (between two variables of interest) and the power of the study was 0.80.

2.2 Inclusion criteria

University students of both sexes who were at least 18 years old and willing to participate in the study met the inclusion criteria. Exclusion criteria were participants younger than 18 years and non-university students. Incomplete questionnaires were also excluded.

2.3 Questionnaire

The Standardized Nordic Questionnaire (19), which was translated into Arabic for use in this study, was modified into an

online self-administered questionnaire that was delivered via Google Forms. The modified Nordic questionnaire was used according to the method outlined by Smith et al. (20). The internal consistency of the questionnaire items was measured using Cronbach's alpha to evaluate reliability. The Cronbach's alpha coefficient was 0.70.

The questionnaire comprised three parts. Part A consisted of questions on sociodemographic information: sex, age, weight, height, BMI, and study year. BMI was calculated by the following formula: weight (kg)/height $(m)^2$. Overweight and obesity were defined by BMI values of 25 and 30 kg/m^2, respectively (21).

Part B consisted of questions related to risk factors, namely smoking habits, exercise habits, coffee consumption, history of trauma, and family history of musculoskeletal diseases; type of device, purpose, and length of use; hours spent using a computer or studying each day; position of the neck and hands when using a smartphone; severity of neck or shoulder pain experienced while using an electronic device; use of painkillers; performing neck and shoulder exercises after using an electronic device for an extended period of time; and relationship between pain and prior injury and how it affects daily activities.

In Part C, questions were asked about neck, shoulder, and lower back pain in the previous 7 days and 12 months.

2.4 Data collection

The web link to the questionnaire was distributed to the students of all academic years using Google Forms, through social media such as WhatsApp groups, Twitter, Facebook, and email. Written informed consent was obtained by explaining the purpose of the study to the participants and assuring them of anonymity and confidentiality.

Participants were told that they had the right to decline the survey questionnaire at any time. Incomplete responses were excluded from the data analysis. The Institutional Review Board of King Khalid University ECM 2023-706 gave the study its approval, and the study was carried out in accordance with the Declaration of Helsinki.

2.5 Statistical analysis

The Statistical Package of Social Sciences (SPSS) program, version 17, was used for the analysis. The frequencies, percentages, means, and SDs were obtained using descriptive analysis. A chi-squared test at $p < 0.05$ was used to evaluate the association between the dependent variables and the independent variables. The odds ratio was calculated with a 95% confidence interval in order to assess the strength of the association. Multivariable logistic regression analysis was used to examine the relationship between the independent variables and the dependent variables (MSDs in the previous 7 days in at least one location and MSDs in the previous 12 months in at least one location). The effect size was found to be 0.3 when the df (degrees of freedom) was as high as 5 (between two variables of interest) and the power of the study was 0.80.

3 Results

A total of 588 people took part in this survey, with 52 surveys not complete and therefore excluded. Out of $n = 536$ participants, 337 (62.87%) were women, and 199 (37.13%) were men. The average age of the participants was 23.72 ± 2.86 years. The average BMI of the study population was 25.3 ± 4.01 kg/m^2. The male participants were more likely to smoke than their female counterparts, with male smokers ($n = 150$) accounting for 27.98% of the total population and female smokers ($n = 37$) accounting for 6.90%. The academic years of the participants were as follows: 33 first years (6.2%), 47 s years (8.8%), 92 third years (17.2%), 186 fourth years (34.7%), and 178 fifth years (33.2%). The time spent on devices was distributed as follows: 114 (21.27%) used devices between 1 and 3 h per day, 158 (29.28%) between 4 and 6 h, 172 (32.09%) between 6 and 9 h, and 92 (17.16%) over 9 h per day. A total of 295 people (55.04%) reported using their electronic devices for studying, whereas 241 (44.96%) reported using them for entertainment and social media. A total of 223 (41.60%) had a history of neck, shoulder, or lower back injuries, while 313 (58.40%) had no such history. A total of 112 people (20.90%) had a family history of MSDs, compared to 424 (79.10%) who did not. Only 232 (43.28%) of the population did regular exercise, whereas 304 (56.72%) did not. At least three cups of coffee per day were consumed by 332 (61.94%) of the population, more than half, compared to 204 (38.06%), who consumed less than three cups per day. In total, 147 (27.43%) of the population used iPads or tablets and smartphones, followed by 103 (19.22%) who used smartphones, 84 (15.67%) who used iPads or tablets, smartphones, and computers, 71 (13.25%) who used iPads or tablets, 62 (11.57%) who used iPads or tablets and computers, 41 (7.65%) who used smartphones and computers, and 28 (5.22%) who used computers. A total of 75 (14%) used their device with both hands with a slight tilt of the neck below the horizon line, 159 (29.7%) used their device with both hands with a large neck tilt below the horizon line, 144 (26.9%) used their device with one hand with a large neck tilt below the horizon line, and 158 (29.5%) used their device with one hand with a slight tilt of the neck below the horizon line (Table 1).

Prevalence of MSD body sites: 354 students (66.04%) reported having NP in the previous 7 days compared to 308 (57.46%) who did not. In the previous 12 months, 228 students (42.54%) reported NP, compared to 229 (42.72%) who did not. A total of 327 people (61.01%) reported having lower back discomfort in the past week, compared to 297 (55.41%) who did not. A total of 239 people (44.59%) reported having lower back pain in the previous 12 months, compared to 297 (55.41%) who did not. A total of 307 people (57.28%) reported having shoulder pain in the previous 7 days, compared to 288 (53.73%) who did not. A total of 248 people (46.27%) reported having shoulder pain in the previous 12 months, compared to 209 (38.99%) who did not.

Using chi-squared tests, a significant association was found for those with MSDs during the previous 7 days among those who had a history of trauma (neck/shoulder/lower back pain) compared to those who had no trauma (OR = 3.46, 95% CI 2.08–5.73, $p = 0.0001$), among those who reported a significant family history of MSDs in comparison to those who did not (OR = 2.72, 95% CI 1.40–5.28, $p = 0.0030$), among those who did regular exercise in comparison to those who did not (OR = 0.56, CI 0.36–0.86, $p = 0.0082$), and among those with certain positions of their neck and hands when using their device ($p = 0.0003$).

For those who had MSDs during the previous 12 months, there was a significant association among those who had a history of trauma (neck/shoulder/lower back pain) compared to those who had no trauma (OR = 3.89, 95% CI 2.59–5.86, $p = 0.0001$) and among those who reported a significant family history of MSDs in comparison to those who did not (OR = 3.93, 95% CI 2.24–6.92, $p = 0.0001$). The

TABLE 1 Sociodemographic characteristics of the study population.

Variables	Category	*N* (536) %
Sex	Male	199 (37.13)
	Female	337 (62.87)
Academic Year	1	33 (6.2)
	2	47 (8.8)
	3	92 (17.2)
	4	186 (34.7)
	5	178 (33.2)
BMI (kg/m^2)	25.3 ± 4.01	
History of trauma (neck/shoulder/low back):	Yes	223 (41.60)
	No	313 (58.40)
Family history of MSDs:	Yes	112 (20.90)
	No	424 (79.10)
Regular exercise	Yes	232 (43.28)
	No	304 (56.72)
Coffee	Coffee ≥3 cups consumed per day	332 (61.94)
	Coffee ≤3 cups consumed per day	204 (38.06)
Position of neck and hands when using the device	Mobile use (with both hands) with a slight tilt of the neck below the horizon line	75 (14)
	Mobile use (with both hands) with a large neck tilt below the horizon line	159 (29.7)
	Mobile use (with one hand) with a large neck tilt below the horizon line	144 (26.9)
	Mobile use (with one hand) with a slight tilt of the neck below the horizon line	158 (29.5)
Time spent using the device	1–3 h	114 (21.27)
	4–6 h	158 (29.28)
	6–9 h	172 (32.09)
	9 h and more	92 (17.16)

prevalence of MSDs in the past year showed a strong association in the regular exercise group compared to those who were not in the group (OR = 1.48, CI 1.03–2.14, $p = 0.03$). The prevalence of MSDs in the past year was higher among the students in the coffee consumption group compared to those who were not in the group (OR = 3.29, CI 2.28–4.74, $p = 0.0001$). In the past year, the prevalence of MSDs showed an association among the students with the time spent on the used device ($p = 0.04$) (Table 2).

With multiple logistic regression analysis, factors associated with MSP during the past week were being fourth-year students (OR = 2.122, 95% CI 1.160–3.879, $p = 0.015$), having a family history of MSDs (OR = 4.273, 95% CI 2.413–7.567, $p = 0.000$), doing regular exercise (OR = 0.56, CI 0.36–0.86, $p = 0.001$), being in the coffee consumption group (OR = 1.687, CI 1.020–2.791, $p = 0.042$), and using a mobile device with both hands with a large neck tilt below the horizon line position (OR = 2.276, CI 1.178–4.397, $p = 0.014$). Factors associated with MSP during the past year were being male (OR = 0.520, 95% CI 0.325–0.832, $p = 0.006$), being a fourth-year student (OR = 1.711, 95% CI 1.025–2.856, $p = 0.040$), having a family history of trauma (OR = 5.450, 95% CI 3.371–8.811, $p = 0.000$), having a family history of MSDs (OR = 4.241, 95% CI 2.296–7.835, $p = 0.000$), being in the coffee consumption group (OR = 1.967, CI 1.281–3.020, $p = 0.002$), and spending the following time on devices: 1–3 h (OR = 0.252, 95% CI 0.124–0.511, $p = 0.000$), 4–6 h (OR = 0.455, 95% CI 0.237–0.873, $p = 0.018$), and 6–9 h (OR = 0.348, 95% CI 0.184–0.660, $p = 0.001$) (Table 3).

4 Discussion

A BMI of 25.3 kg/m^2 indicates overweight in the study population. According to the authors of one prior study, the general adult population is more likely to experience chronic pain in the lower back, neck, and shoulders as a result of physical inactivity and high BMI (22). Another study found that overweight and obese young individuals are in the risk category for mechanical NP and different cervical diseases, and it is crucial to raise awareness of preventive measures such as posture correction exercises and weight management techniques (23). Yogasana relieves tense and exhausted limbs by restoring retracted and stiff muscles. The practice of specific asanas is

TABLE 2 Factors associated with MSDs in the previous week and previous 12 months among students using the chi-squared test.

Variables	Category	MSDs during the previous 7 days				MSDs during the previous 12 months			
		Yes	No	OR (95% CI)	*p*-Value	Yes	No	OR (95% CI)	*p*-Value
Sex	Male	167	32	1.51 (0.96–2.39)	0.07	131	68	1.01 (0.69–1.46)	0.95
	Female	261	76			221	116		
Academic year	First Year	27	6		0.06	19	14		0.79
	Second Year	40	7			32	15		
	Third Year	69	23			63	29		
	Fourth Year	159	27			124	62		
	Fifth Year	133	45			114	64		
Body mass index (kg/m^2)		428 (Mean, IQR) 24.90, 2.30	108 (Mean, IQR) 24.60, 2.23			352 (Mean, IQR) 25.30, 2.00	184 (Mean, IQR) 24.60, 2.00		
History of trauma (neck/shoulder/low back):	Yes	201	22	3.46 (2.08–5.73)	*0.0001	183	40	3.89 (2.59–5.86)	*0.0001
	No	227	86			169	144		
Family history of MSDs	Yes	101	11	2.72 (1.40–5.28)	*0.0030	96	16	3.93 (2.24–6.92)	*0.0001
	No	327	97			256	168		
Regular exercise	Yes	173	59	0.56 (0.36–0.86)	*0.0082	164	68	1.48 (1.03–2.14)	*0.03
	No	255	49			188	116		
Coffee	Coffee ≥3 cups consumed per day	266	66	1.04 (0.67–1.61)	0.84	233	99	3.29 (2.28–4.74)	*0.0001
	Coffee ≤3 cups consumed per day	162	42			85	119		
Position of neck and hands when using the device	Mobile use (with both hands) with a slight tilt of the neck below the horizon line	49	26		*0.0003	50	25		0.88
	Mobile use (with both hands) with a large neck tilt below the horizon line	140	19			102	57		
	Mobile use (with one hand) with a large neck tilt below the horizon line	119	25			98	46		
	Mobile use (with one hand) with a slight tilt of the neck below the horizon line	120	38			102	56		
Time spent using the device	1–3 h	90	24		0.09	68	46		*0.04
	4–6 h	124	34			106	52		
	6–9 h	147	25			107	65		
	9 h and more	67	25			71	21		

*$p < 0.05$ considered significant.

TABLE 3 Multiple logistic regression analysis of factors associated with MSDs in the previous 7 days and previous 12 months.

Variables	Category	MSDs during the previous week						MSDs during the previous 12 months					
		Yes	No	B value	*p*-Value	OR	(95% CI)	Yes	No	B value	*p*-Value	OR	(95% CI)
Sex	Male	167	32	0.191	0.491	1.210	(0.703–2.083)	131	68	−0.654	*0.006	0.520	0.325–0.832
	Female	261	76					221	116				
Academic year	First Year	27	6	0.372	0.497	1.450	0.496–4.240	19	14	−0.304	0.498	0.738	0.306–1.779
	Second Year	40	7	−0.166	0.736	0.847	0.322–2.225	32	15	−0.211	0.610	0.810	0.360–1.821
	Third Year	69	23	−0.163	0.631	0.850	0.438–1.649	63	29	0.523	0.110	1.687	0.889–3.204
	Fourth Year	159	27	0.752	*0.015	2.122	1.160–3.879	124	62	0.537	*0.040	1.711	1.025–2.856
	Fifth Year	133	45					114	64				
Body mass index (kg/m^2)				0.016	0.598	1.016	0.957–1.079			0.051	0.063	1.052	0.997–1.110
History of trauma (neck/shoulder/low back):	Yes	201	22	1.452	*0.000	4.273	2.413–7.567	183	40		*0.000	5.450	3.371–8.811
	No	227	86					169	144				
Family history of MSDs	Yes	101	11	0.688	0.057	1.990	0.980–4.041	96	16	1.445	*0.000	4.241	2.296–7.835
	No	327	97					256	168				
Exercise	Yes	173	59	−0.844	*0.001	0.430	0.265–0.698	164	68	0.238	0.268	1.269	0.833–1.934
	No	255	49					188	116				
Coffee	Coffee ≥3 cups consumed per day	266	66	0.523	*0.042	1.687	1.020–2.791	233	99	0.677	*0.002	1.967	1.281–3.020
	Coffee ≤3 cups consumed per day	162	42					85	119				
Position of neck and hands when using the device	Mobile use (with both hands) with a slight tilt of the neck below the horizon line	49	26	−0.401	0.243	0.669	0.341–1.313	50	25	0.376	0.271	1.456	0.746–2.842
	Mobile use (with both hands) with a large neck tilt below the horizon line	140	19	0.823	*0.014	2.276	1.178–4.397	102	57	0.152	0.577	1.165	0.681–1.991
	Mobile use (with one hand) with a large neck tilt below the horizon line	119	25	0.314	0.316	1.369	0.741–2.529	98	46	−0.059	0.833	0.943	0.546–1.629
	Mobile use (with one hand) with a slight tilt of the neck below the horizon line	120	38					102	56				
Time spent on using the device	1–3 h	90	24	−0.060	0.872	0.942	0.454–1.953	68	46	−1.380	*0.000	0.252	0.124–0.511
	4–6 h	124	34	−0.127	0.709	0.881	0.452–1.715	106	52	−0.787	*0.018	0.455	0.237–0.873
	6–9 h	147	25	0.577	0.095	1.780	0.904–3.507	107	65	−1.056	*0.001	0.348	0.184–0.660
	9 h and more	67	25					71	21				

B, Beta value; OR, odds ratio; CI, confidence interval, *$p < 0.05$ considered significant.

a potent tool for the prevention or treatment of MSDs, including postural problems, forward head posture, chronic neck tension, depressed chest, carpal tunnel syndrome, impingement syndromes, outlet syndrome, subacromial pain syndrome, and spinal disk pathologies (24).

In this study, the time that participants spent on their devices was distributed as follows: 114 (21.27%) spent between 1 and 3 h per day, 158 (29.28%) spent between 4 and 6 h, 172 (32.09%) spent between 6 and 9 h, and 92 (17.16%) spent more than 9 h. More than half the study population, 55.04%, said they used their electronic devices for learning, while 44.96% said they used them for social media and entertainment.

Another study found that approximately 39% of participants watched cartoons or movies on their devices, 27% used social media, and 17% played video games. Due to the COVID-19 epidemic at the time of the study, 24.48% of participants also used these devices to take online courses. Only a small percentage of participants (8.74%) used mobile devices for routine communication (25). An Asian study that supports this idea showed that social influences from various online activities, such as social media, online classes, and gaming, have a significant impact on developing a preference for technology use or internet addiction and displaying disinterest in outdoor activities (26).

According to another previous study, 87.5% of participants use digital devices regularly. They all have cell phones and 89.2% of them have tablets. A total of 70.0% of participants said they used digital devices while lying in bed, and 60% said they used computers for less than 6 h per day, phones for less than 10 h per day, and other digital devices for less than 3 h per day (27).

We discovered that the majority of students frequently use apps on mobile devices. Utilizing digital devices for longer periods of time increases the chance of health problems. The various levels of education rely on online learning using computers, smartphones, tablets, iPads, and other devices, especially in the wake of the COVID-19 pandemic. Students have many concerns about using these digital devices since they may cause physical discomfort, particularly neck and back pain. According to a study by Cheung et al. (28), 46.3% of students used computers less than an hour a day in 2022.

The majority of the individuals in our study reported regular use of mobile digital devices, which raises their risk of neck and back pain. A total of 41.60% had a history of neck, shoulder, or lower back injuries, while 58.40% of the population had no such history. Only 20.90% had a family history of MSDs. Alshagga et al. (29) concluded that those who had a family history of MSDs with trauma to the shoulder, neck, or lower back, were at a high risk of developing MSP, supporting the finding in our study that there is a substantial correlation between MSP and a history of trauma (30). Our study reported that only 43.28% of the population had a regular exercise habit. A previous study concluded that pericervical strength and range of motion in young adults were improved by a 6-week pericervical muscle stretching and strengthening program. The majority of subjects experienced reduced cervical pain (31). According to the meta-analysis, there is a statistically significant difference favoring strengthening training over no exercise for pain relief (32).

In our study, 61.94% ($n = 332$), or more than half the population, consumed more than three cups of coffee per day. Caffeine, a component of coffee, helps fight stress, tiredness, and pain. McPartland and Mitchell (33) noted significant caffeine consumption among patients with lower back pain and emphasized the need to limit coffee drinking in this population since caffeine raises urine calcium levels and may have long-term negative effects on bones. Interestingly, prolonged excessive coffee consumption produced a vicious cycle between shoulder and NP and short sleep cycles. The findings suggest that people who get less than 6 h of sleep each night or who experience shoulder and NP should limit their intake of coffee to two cups per day (34).

In the present study, 27.43% of students reported using iPads or tablets and smartphones, and 19.22% reported using smartphones. A previous study found that 45% of students used smartphones, followed by smartphones and computers (19.2%) (35). In a previous study, 71.2% of respondents reported cervical pain as their most frequent symptom. The use of a cell phone can lead to improper body mechanics and posture, which can result in pain in the neck, shoulders, upper back, arms, and throughout the entire body. The uncomfortable and repetitive stress injury caused by extensive and prolonged use of cell phones is referred to in medicine as text neck syndrome. The majority of cell phone users are known to be impacted by this condition, which is also perceived as an increasingly widespread worldwide burden affecting individuals of all ages and genders who are a part of every community. This syndrome is the result of repeated stress to the body from using handheld electronic devices over an extended period of time, specifically repeated forward head flexion while looking at cell phone screens for an extended period (36). A study was done to look into the stresses experienced by the spine when the head is bowed forward into a worsening position. The results of the investigation demonstrated that there is a significant increase in weight on the spine with different degrees of head flexion. Significantly additional stress is placed on the cervical spine as a result of the loss of the spine's natural curve (37).

In the current study, 195 (36.38%) of participants used a mobile device while holding it in one hand and tilting their necks below the horizon line. Our findings are consistent with other research: 40.5% of users had their necks slightly tilted downward while using a mobile device (35). MSP in the neck and shoulders has been linked to the position of the head and neck when using electronic devices (9). In the current study, more participants used their cell phones with one hand while bending their necks well below the horizon line than did so in any other way. The prevalence of MSDs among medical students was shown to be significant in another study; 85.3% of the students had MSDs in at least one site at any given moment (30). There is a considerable risk of developing new health issues when using equipment for a long period in the same position. The amount of time spent utilizing electronics and musculoskeletal discomfort are significantly correlated. Raising the amount of time spent using electronics would result in more musculoskeletal injuries. Past research found that young, healthy college students who use their smartphones excessively experience NP (38). According to previous research, neck discomfort complaints increased in direct proportion to the amount of time spent using electronic devices, with a close correlation between the two (39).

In the current study, in terms of MSD site, 354 students (66.04%) reported having NP in the previous week, 327 (61.01%) reported having lower back pain, and 307 (57.28%) reported having shoulder pain. In another study, the prevalence over the previous 7 days was 60.64%, with the upper and lower back (31.91%) neck (21.28%), and shoulders (15.96%) being the most prevalent regions (40). According to Smith et al. (41), 67.6% of Chinese medical students experienced

pain in the previous 7 days, with lower back pain accounting for the majority of cases (20.8%), followed by knee and NP (12.1%). The neck (55.8%) was reported as the body part experiencing the most pain from smartphone use in a second Korean survey of smartphone users by Kim et al. (42). Similarly, Namwongsa et al. (43) found that the most common musculoskeletal condition among smartphone users in Thailand was NP. Furthermore, the cross-sectional investigations found that mobile touchscreen device users had the highest prevalence rates of neck and/or shoulder problems, ranging from 26.3 to 60%. According to earlier research, uncomfortable postures are a physical risk factor for neck MSK disease in employees. Many musculoskeletal issues can result from prolonged smartphone use (44). Particularly when using a smartphone, uncomfortable postures may be encouraged.

In the previous 12 months, 42.54% ($n = 228$) of students reported NP, 44.59% ($n = 239$) reported having LBP, and 46.27% ($n = 248$) reported having shoulder pain. Another study found that the prevalence of NSP and LBP among adolescents is 69.4 and 62.2%, respectively (4). Self-reported LBP and NSP were already very common among teenagers, according to a previous study. Girls are more likely to report LBP and NSP. Yue et al. discovered that there is a significant association between the risk of LBP and each of the following: daily computer use (OR = 1.32, 1.05–1.60), daily mobile use (OR = 1.32, 1.00–1.64), and daily TV watching (OR = 1.07, 1.04–1.09). We reported a linear correlation between LBP and daily computer use, with an 8.2% increase in LBP for each hour of use (45). A previous study revealed that a large percentage of medical students have MSP. Depressive and psychosomatic symptoms, in addition to a history of trauma, are factors that raise the risk of MSP (46). This study has limitations. Because it is a single-institution study, non-probability sampling reduces the representativeness of the sample by not guaranteeing that each person has an equal chance of being chosen. Thus, generalizing the study's findings is not possible.

5 Conclusion

The present study concludes that MSP among university students is high. A history of trauma, family history of MSDs, hand and neck position when using a device, amount of time spent using it, and regular exercise are risk factors that are strongly associated with MSP. There was a strong correlation between NSP and LBP and certain individual, ergonomic, and occupational variables. To provide a successful preventive strategy for these extremely common and undetected conditions, research on other interventional strategies is also necessary. There is strong evidence to suggest that increasing physical activity plays a significant role in enhancing the functionality of the musculoskeletal system and alleviating pain. It is recommended that universities implement educational programs to raise awareness and health screenings on the impact of device usage on MSK health and the benefits of regular exercise.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by the King Khalid University (2023-706) Ethical Committee. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

GK: Conceptualization, Methodology, Visualization, Writing – original draft, Writing – review & editing. MoA: Data curation, Project administration, Writing – original draft, Writing – review & editing. TA: Data curation, Methodology, Project administration, Resources, Writing – original draft. KO: Formal analysis, Investigation, Methodology, Visualization, Writing – review & editing. ES: Conceptualization, Methodology, Project administration, Writing – original draft. AMA: Conceptualization, Data curation, Formal analysis, Writing – review & editing. KP: Data curation, Investigation, Project administration, Writing – review & editing. VV: Conceptualization, Data curation, Formal analysis, Writing – review & editing. PA: Conceptualization, Methodology, Project administration, Writing – original draft. SA: Conceptualization, Methodology, Visualization, Writing – original draft. FayA: Formal analysis, Investigation, Resources, Writing – review & editing. MuA: Project administration, Software, Validation, Writing – review & editing. FaiA: Formal analysis, Investigation, Supervision, Validation, Writing – review & editing. AA: Formal analysis, Investigation, Project administration, Validation, Writing – review & editing. FahA: Data curation, Formal analysis, Investigation, Resources, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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CT-guided joint cavity release for postpartum sacroiliac joint pain management: an evaluation of its efficacy, safety, and clinical outcomes

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Objective: The central aim of this study was to evaluate the safety and effectiveness of Computed Tomography (CT)-guided joint cavity release in treating patients suffering from postpartum sacroiliac joint pain.

Methods: A retrospective analysis was conducted on a sample of 37 patients who presented with postpartum sacroiliac joint pain and underwent CT-guided sacroiliac joint release treatment at The Affiliated Hospital of North Sichuan Medical College. General clinical attributes of the patients were recorded, and the intensity of their pain before and after the operation was compared using the Numeric Pain Rating Scale (NRS). The effectiveness of the surgical treatment was assessed using the Modified MacNab criteria. The functional status of the sacroiliac joint at 3-and 6-month intervals post-operation was examined, and any complications related to surgery were documented.

Results: The follow-up period was completed by all patients, with the successful implementation of CT-guided unilateral/bilateral sacroiliac joint release undertaken in 37 patients. Patient reported pain, as measured by the Numeric Pain Rating Scale (NRS), was considerably reduced postoperatively with scores showing significant decrement from 7.14 ± 1.23 preoperatively to 1.26 ± 0.53 at 1 week, 1.86 ± 0.62 at 1 month, 1.92 ± 0.48 at 3 months, and 1.97 ± 0.61 at 6 months postoperatively, respectively ($p < 0.05$). The comprehensive record of treatment response rates, interpreted as excellent and good, were consistent, standing at 100% (37/37), followed by 97.30% (35/37) and concluding with 91.89% (33/37). The Oswestry Disability Index (ODI) scores reflecting the patient's perceived level of disability prior to the surgery, and at 3 and 6 month intervals post-surgery were 45.12 ± 6.01, 18.14 ± 2.23, and 14.25 ± 2.15, respectively, demonstrating a significant improvement in postoperative scores when compared with preoperative scores ($p < 0.05$). The surgeries conducted were devoid of any complications such as bleeding, infection, cardiovascular or cerebrovascular incidents, or decline in joint functionality in any of the patients.

Conclusion: Evidently, CT-guided joint cavity release presents as an effective therapeutic approach for the management of postpartum sacroiliac joint pain, enhancing quality of life and preserving patient safety.

KEYWORDS

sacroiliac joint, postpartum, imaging-guided, release, intervention

1 Background

Dysfunction of the sacroiliac joint during pregnancy or in the postpartum period can arise from a multitude of biomechanical changes, such as weight gain, postural adjustments, augmented abdominal and intrauterine pressures, and the loosening of ligaments in spinal and pelvic areas, as documented in the literature (1–3). It is estimated that approximately 50% of women experience sacroiliac joint discomfort during these stages, and although the majority recover within 4 months postpartum, about 20% endure ongoing pain (4, 5). Notably, the incidence of sacroiliac joint pain reported in everyday settings by postpartum women may be underrepresented, as many seek medical intervention only when the pain substantially interferes with their daily activities. This suggests that the actual prevalence of sacroiliac joint pain among postpartum women could be higher than previously estimated, thus necessitating further attention to this condition (6, 7).

Historically, treatment modalities for sacroiliac joint pain have encompassed a range of interventions including physical therapy, pharmacological treatments, nerve blockades, intra-articular injections, radiofrequency ablation, and surgical fixation of the sacroiliac joint, each with variable outcomes (8–10). In the current study, we utilized CT-guided sacroiliac joint release surgery as a treatment for 37 patients experiencing postpartum sacroiliac joint pain, aiming to assess its effectiveness and safety profile. The results are detailed in the subsequent sections.

2 Materials and methods

2.1 General information

A retrospective study was conducted on a cohort of 37 patients diagnosed with postpartum sacroiliac joint pain, who were treated at the Affiliated Hospital of North Sichuan Medical University over a period extending from February 2018 to May 2022. The study meticulously gathered and statistically scrutinized demographic data and clinical symptoms of these patients (refer to Table 1). The research methodology was rigorously designed to be in strict compliance with the ethical standards outlined in the Declaration of Helsinki, in addition to adhering to the procedural guidelines set forth by the Affiliated Hospital of North Sichuan Medical University. Prior to their inclusion in the study, each patient was thoroughly briefed on the study protocol and treatment procedures, post which informed consent was obtained.

The criteria for inclusion in the study were meticulously defined to ensure a homogeneous patient profile. These criteria encompassed: (1) A clinical confirmation of postpartum sacroiliac joint pain, substantiated by symptomatology and corroborated by imaging studies; (2) A history of insufficient symptom relief following conservative treatment approaches, such as oral medication administration and engagement in pelvic floor exercises; (3) A Numeric Rating Scale (NRS) pain intensity score equal to or exceeding 4; (4) Voluntary agreement to undergo the treatment protocol as proposed in the study.

Conversely, potential participants were excluded from the study based on the following criteria: (1) Current breastfeeding status; (2) The presence of lumbar or pelvic masses, as evidenced by MRI or CT scans; (3) The presence of abnormal coagulation function or active anticoagulant therapy, which could predispose to bleeding complications; (4) The existence of an infection at the site designated for surgical intervention. These exclusion criteria were established to mitigate potential confounding factors and ensure patient safety throughout the study.

2.2 Methods

2.2.1 Preoperative preparation

Upon their admission, patients were subjected to computed tomography (CT) and magnetic resonance imaging (MRI) of the lumbar spine and pelvis. This imaging was essential to accurately identify lesions within the sacroiliac joint, as depicted in Figure 1. Additionally, routine preoperative assessments were diligently performed to exclude any contraindications to the surgical procedure.

2.2.2 Surgical procedures

Prior to the surgery, patients were required to fast for a duration of 4 h. The procedure was carried out in the MR/CT intervention

TABLE 1 Demographics characteristics of patients ($n = 37$).

Variables	
Age (year)	32.2 ± 3.4 (21 ~ 44)
Height (cm)	158.4 ± 4.6 (148 ~ 172)
Weight (Kg)	51.4 ± 2.4 (41 ~ 68)
BMI index	
<18.5	2 (5.4%)
18.5–24.9	16 (43.3%)
25–30	17 (45.9%)
>30	2 (5.4%)
Course of disease (month)	13.2 ± 3.4 (24 ~ 56)
Delivery method, n (%)	
Natural childbirth	28 (75.6%)
Cesarean section	9 (24.4%)
Pain frequency, n (%)	
Paroxysmal	32 (86.5%)
Persistence	5 (13.5%)
Pain orientation, n (%)	
Left	14 (37.8%)
Right	16 (43.3%)
Bilateral	7 (18.9%)
Combined symptoms, n (%)	
Lumbar pain	31 (83.8%)
Sacrococcygeal pain	14 (37.8%)
Hip pain	26 (70.2%)
Groin pain	11 (29.7%)
Thigh pain	18 (48.6%)
Calf pain	6 (16.2%)
Restricted activities	22 (59.5%)

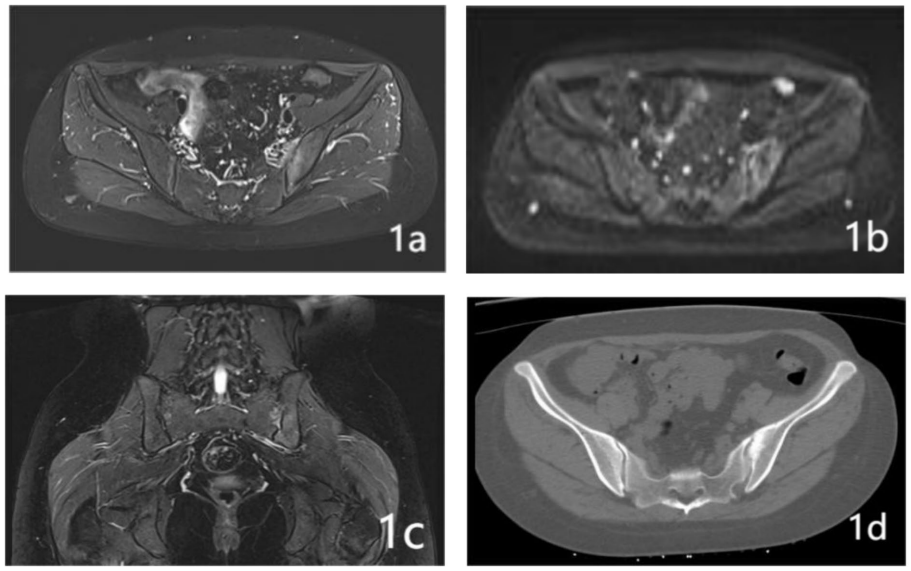

FIGURE 1
A 32-year-old woman who presented with persistent pain in her left sacroiliac joint, which had been on going for 6 months following childbirth. Pre-operative MRI and CT examination revealed the following: **(A)** The fs-MRI (fat-suppressed MRI) of the left sacroiliac joint displayed an increased signal intensity beneath the joint surface. **(B)** Diffusion-Weighted Imaging (DWI): The DWI scan revealed restricted diffusion in the left iliac bone and the surface of the sacroiliac joint. **(C)** Coronal plane fs-MRI illustrating increased signal beneath the left sacroiliac joint. **(D)** CT cross-sectional analysis: The CT scan of the left iliac bone showed increased bone density.

center of our hospital. Using Philips 64 slice spiral CT with a slice thickness of 1 mm and continuous scanning, each patient is scanned 5–6 times during the operation, with a total radiation dose of approximately 50–60 mGy. During the surgery, patients were placed in a prone position, and their vital signs, including heart rate, blood pressure, pulse rate, and blood oxygen saturation, were continuously monitored. In order to precisely target the sacroiliac joint space and its posterior border, a custom-designed metal fence marker was securely placed on the affected gluteal region. The surgical approach adopted was a posteromedial one, accessed through the gluteal region, and local infiltration anesthesia was administered using 1% Lidocaine. For the purpose of puncturing, a 22G, 14 cm coaxial trocar was utilized. The needle's advancement was carefully guided by a pre-determined angle and pathway, as illustrated in Figures 2A,B. The correct positioning of the puncture needle was verified through CT scanning. Subsequent to this verification, a combination of 5 mL of ozone and 5 mL of anti-inflammatory fluid (comprising 0.25% Lidocaine, 1 mg of compound Betamethasone, and 1.5 mg of cobalamine adenosine) was injected. A follow-up CT scan was conducted to confirm the effective distribution of ozone within the sacroiliac joint cavity, as shown in Figure 2C. Post-procedure, the puncture needle was removed, and patients were advised to remain in a supine position for 6 h in the ward. To ensure consistency and reduce variability in the surgical procedure, all interventions were performed by the same senior associate chief physician and an attending physician.

2.3 Evaluation of treatment efficacy

2.3.1 Pain assessment

The severity of pain both preoperatively and postoperatively was quantitatively assessed using the Numeric Rating Scale (NRS), which spans from 0 (indicating no pain) to 10 (representing the most severe pain). The effectiveness of the treatment was further evaluated through the application of the Modified MacNab Scoring Scale, which classifies outcomes into four distinct categories: excellent, good, fair, or poor. The combined rate of excellent and good outcomes was calculated using the formula: [{Number of Excellent Outcomes + Number of Good Outcomes}/{Total Number of Patients}] × 100%. The criteria for the Modified MacNab Scale are delineated as follows: Excellent: The patient experiences complete alleviation of pain symptoms, facilitating a return to normal work and daily activities. Good: There is a significant reduction in pain levels, allowing for a near-normal resumption of work and everyday life. Fair: The patient experiences a partial reduction in pain, which continues to impact normal work and daily activities. Poor: There is either no improvement in pain levels or an exacerbation of symptoms.

2.3.2 Functional evaluation

The postoperative functionality of the sacroiliac joint was assessed using the Oswestry Disability Index (ODI). This index comprises 10 questions that evaluate various aspects: pain intensity, self-care, social life, lifting, walking, sitting, standing, sleeping, sexual function, and engagement in recreational activities. Each question is assigned a score ranging from 0 to 5, with the cumulative score potentially reaching a maximum of 50 points. A higher total score is indicative of more severe functional impairment. All participants completed this questionnaire postoperatively to facilitate a comprehensive assessment of functional outcomes.

2.3.3 Surgical complications

In our study, we meticulously documented any surgical complications that occurred. These included but were not limited to hemorrhagic events (bleeding), infectious complications,

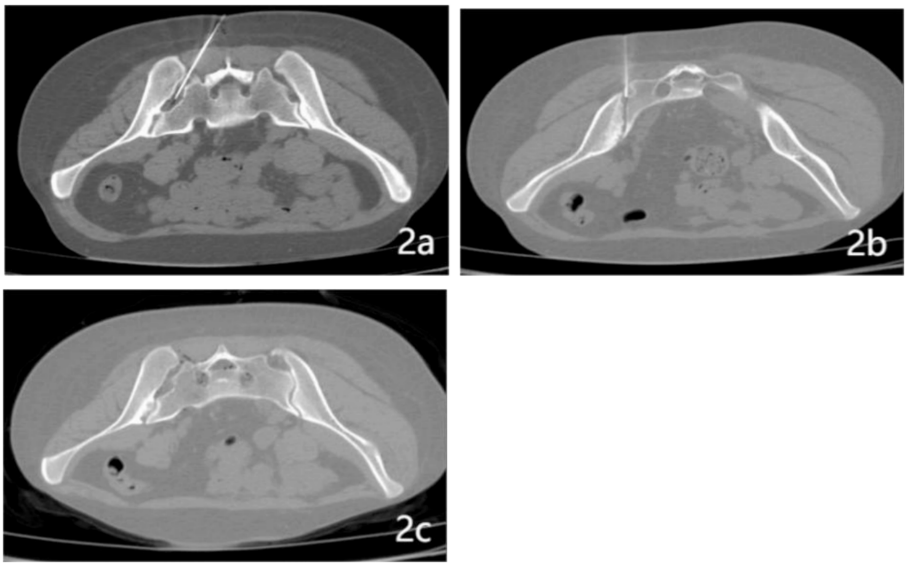

FIGURE 2
CT-guided joint cavity release surgery. **(A)** Puncture of the left sacroiliac joint cavity utilizing a specialized puncture needle. **(B)** Engagement of the posterior ramus of the sacroiliac joint via puncture needle insertion. **(C)** Detailed visualization of gas distribution both within the sacroiliac joint cavity and its adjacent regions.

cardiovascular and cerebrovascular incidents, and any observed deterioration in pelvic function.

2.4 Statistical methods

For the analysis of our data, we utilized SPSS statistical software, IBM SPSS 25.0 (SPSS Inc., Chicago, IL, United States). Our approach to data presentation involved the use of descriptive statistics. Specifically, categorical data were expressed as percentages, while continuous variables were articulated as means accompanied by standard deviations [denoted as (x \pm s)]. To scrutinize the changes in Numeric Rating Scale (NRS) and Oswestry Disability Index (ODI) scores across various time points within the group, we employed repeated measures analysis of variance. Furthermore, the Least Significant Difference (LSD) test was applied for *post hoc* analysis. A *p*-value threshold of less than 0.05 ($p < 0.05$) was established to determine statistical significance.

3 Results

3.1 Patient demographics

This study encompassed a cohort of 37 patients. The age distribution among these patients ranged from 21 to 44 years, with the mean age being 32.2 years, accompanied by a standard deviation of ±3.4 years. The duration of symptoms reported by these individuals varied considerably, extending from a minimum of 6 months to a maximum of 4 years, with the average duration calculated at 1.7 years (±0.3 years).

In terms of symptomatology, all patients in the study presented with persistent and recurrent pain, which was localized to the lumbosacral region, gluteal areas, pelvic girdle, or lower limbs. A significant proportion of the cohort, accounting for 31 cases (83.8%), reported experiencing concurrent lumbar and back discomfort. Furthermore, hip pain was a common complaint, noted in 26 cases (70.2%). Additionally, 22 patients (59.5%) exhibited varying degrees of restricted mobility, as detailed in Table 1. To ensure the comprehensiveness of our study, all patients were diligently followed up for a period of 6 months. This follow-up was conducted either through telephonic conversations or during outpatient services. Notably, there were no instances of patients being lost to follow-up during this period.

3.2 Evaluation of patient postoperative outcomes

An analysis of preoperative and postoperative Numeric Rating Scale (NRS) scores revealed substantial reductions at intervals of 1 week, 1 month, 3 months, and 6 months following the surgical procedure. These reductions are indicative of a significant alleviation of postoperative pain, as evidenced by the observed statistically significant differences. Moreover, an examination of the Oswestry Disability Index (ODI) scores in the preoperative and postoperative phases disclosed marked improvements at both 3 and 6 months post-surgery when compared to preoperative values. These improvements were statistically significant ($p < 0.05$). However, it is noteworthy that the analysis did not reveal any statistically significant difference in the ODI scores between the 3-month and 6-month postoperative periods ($p > 0.05$), as detailed in Table 2.

3.3 Evaluation of clinical efficacy

The assessment of clinical outcomes post-surgery demonstrated that the percentages of "excellent" and "good" results at subsequent

intervals of 1 week, 1 month, 3 months, and 6 months were uniformly high, with initial rates being 100% (37 out of 37 patients) at both 1 week and 1 month. These rates slightly decreased to 97.30% (35 out of 37 patients) at the 3-month mark and further to 91.89% (34 out of 37 patients) by 6 months post-operation. Notably, after the 6-month evaluation period, three patients experienced a recurrence of pain, highlighting a decline in the success rate of the surgical outcomes, as detailed in Table 3.

3.4 Surgical complications

None of the patients experienced bleeding, subcutaneous hematoma, infection, or deterioration of sacroiliac joint function.

4 Discussion

The sacroiliac joint (SIJ), forming a union between the sacrum and the bilateral iliac bones, stands as the largest true synovial joint in the human body. Characterized by its uniquely fitting joint surface and an encompassing joint capsule, the SIJ is further stabilized by robust ligaments. These anatomical features collectively confer upon the joint a significant weight-bearing capacity, enabling it to effectively transmit gravitational forces (11). Functionally, the SIJ plays a pivotal role in the biomechanical process of force transference between the spine and the lower limbs. It acts as a critical intermediary in distributing gravitational forces and muscular-generated forces from the surrounding structures to either the lower limbs or the trunk. This distribution is essential for maintaining the overall equilibrium of the body (12). Several key ligaments, including the iliolumbar, sacrospinal, sacral tuberosity, and interosseous sacroiliac ligaments, are integral to the maintenance of the SIJ's stability. These ligaments not only safeguard the joint's stability but also permit a degree of micro-motion within the joint, which is crucial for its function (13). In the context of pregnancy, hormonal shifts, particularly the increase in Relaxin and estrogen levels, play a significant role in modulating the SIJ. These hormonal changes induce the relaxation of ligaments surrounding the SIJ, facilitating the expansion of the pelvic band and the stretching of tissues during childbirth. However, these physiological adaptations may lead to potential complications such as separation of the joint surfaces, ligament tears, or even dislocation of the SIJ, culminating in sacroiliac joint pain (14–18).

Contrasting with discogenic lower back pain, patients suffering from postpartum sacroiliac joint pain predominantly exhibit unilateral discomfort inferior to the L5 spinal nerve level. The locus of pain is typically pinpointed at the distal and medial aspects of the posterior superior iliac spine and extends into the medial region of the gluteus. These symptoms, manifesting as tingling, a persistent dull ache, or a burning sensation, are frequently misinterpreted as radicular pain due to their propensity to radiate down to the posterior thigh. This extension notably coincides with the innervation territory of the S1 nerve ganglia, thereby complicating the differential diagnosis (19).

A significant clinical observation in patients with sacroiliac joint pain postpartum is the widespread incidence of pelvic girdle instability. This condition detrimentally affects spinal integrity by compromising the stability of the lumbar region. In our comprehensive study, we examined a cohort of 30 subjects (81.1%) who presented with unilateral symptom onset, 31 individuals (83.8%) who reported lower back discomfort, 18 participants (48.6%) who experienced thigh pain, and 6 patients (16.2%) who described pain extending to the lower leg. Crucially, lumbar magnetic resonance imaging (MRI) assessments, conducted as part of our investigation, revealed lumbar disc herniation and nerve root edema in three cases. These findings highlight the complex and varied nature of postpartum sacroiliac joint pain manifestations.

The initial management of postpartum sacroiliac joint pain predominantly involves conservative methods, including physical therapy, pelvic massage, and pharmacological interventions. However, when these conservative strategies prove insufficient, more invasive treatments may be necessary. Intra-articular and peri-articular corticosteroid injections, as well as radiofrequency ablation, are often employed as secondary interventions (20, 21). Corticosteroid injections aim to alleviate inflammation in the sacroiliac joint and adjacent tissues. Conversely, radiofrequency ablation utilizes thermal energy to disrupt pain transmission by damaging peripheral nerves (22). In cases where these approaches are ineffective, sacroiliac joint fusion surgery becomes a viable option. Although previous research has suggested that sacroiliac joint fusion surgery may be helpful for joint pain, there is a potential risk of postoperative joint stiffness, which may affect daily activities. In addition, it also includes the impact on adjacent joints: stabilizing one joint may increase the pressure on adjacent joints, leading to new problems (23).

TABLE 2 Comparison of NRS and ODI scores during the follow-up period.

Time	NRS	ODI
Preoperative	7.14 ± 1.23	45.12 ± 6.01
1w post-surgery	1.26 ± 0.53*	
1 m post-surgery	1.86 ± 0.62*	
3 m post-surgery	1.92 ± 0.48*	18.14 ± 2.23*
6 m post-surgery	1.97 ± 0.61*	14.25 ± 2.15*#
F	6.14	9.51
P	0.000	0.000

*Compared with preoperative, $P < 0.05$; #Compared with postoperative 3 months, $p > 0.05$.

TABLE 3 Excellent and good rates according to modified MacNab clinical evaluation criteria.

Time	Excellent	Good	Medium	Poor	Excellent and good rate (%)
1w post-surgery	35(94.59%)	2(5.41%)	0(0.00%)	0(0.00%)	100%
1 m post-surgery	33(89.19%)	4(10.81%)	0(0.00%)	0(0.00%)	100%
3 m post-surgery	28(75.68%)	7(18.92%)	2(5.41%)	0(0.00%)	97.30%
6 m post-surgery	27(72.97%)	7(18.92%)	3(8.11%)	0(0.00%)	91.89%

In our investigation, we utilized intra-articular and sacroiliac joint posterior branch techniques for ozone nerve release surgery. The underlying mechanism of action encompasses several critical components: Rapid Nerve Conduction Blockade: This is achieved through the application of local anesthetics, facilitating immediate relief from pain. Betamethasone's Prolonged Effects (24–28): As a glucocorticoid, Betamethasone exerts long-term anti-inflammatory and analgesic impacts. Multifaceted Benefits of Ozone: Ozone therapy offers anti-inflammatory, antioxidant, and analgesic advantages through a variety of mechanisms. These include: (a) Peripheral Nerve Adhesion Release: Ozone acts as a metabolizable gas that promptly alleviates peripheral nerve adhesion. (b) Regulation of Pain Mediators: It modulates the release of nociceptive substances such as 5-hydroxytryptamine, dopamine, and hydrogen dissociation from damaged free nerve endings. (c) Inhibition of Inflammatory Processes: Ozone effectively suppresses the synthesis and activity of protein hydrolases and inflammatory cytokines, facilitating the expression of antioxidant enzymes, neutralizing oxygen free radicals, and thereby safeguarding cellular integrity and fostering the repair of demyelinated nerve fiber bundles. (d) Environmental Optimization within Joint Cavities: By adjusting the pH and osmotic pressure, ozone improves the joint cavity's internal milieu, thereby promoting cartilage repair. Moreover, ozone therapy has been shown to activate inhibitory interneurons, prompting them to release enkephalin and other pain-relieving substances. Our findings revealed a significant decrease in the Numeric Rating Scale (NRS) and Oswestry Disability Index (ODI) scores during the follow-up period. Notably, we observed excellent and good therapeutic success rates of 97.30 and 91.89%, respectively, at 3 and 6 months following the procedure. These outcomes underscore the substantial therapeutic efficacy of this treatment approach.

Given the intricate nature of accessing deep and confined joint spaces, the role of image-guided interventional therapy has become paramount. CT-guided minimally invasive interventional therapy, in particular, offers considerable benefits in terms of safety, accuracy, efficiency, and effectiveness, establishing it as the preferred modality for pain management (29). In our study, CT-guided sacroiliac joint injections were performed without any incidents of complications, such as bleeding, subcutaneous hematomas, or infections. This success is attributed to thorough preoperative assessments, including magnetic resonance imaging (MRI) and high-resolution computed tomography (CT) scans, which facilitated the early identification of anomalous blood vessels, thereby preemptively mitigating the risk of bleeding. Furthermore, the practice of minimizing repeated needle insertions during the procedure played a crucial role in reducing the likelihood of hematoma formation. Optimal puncture technique, recommending needle insertion parallel to the sacroiliac joint surface to the greatest extent possible, significantly increased the puncture success rate and minimized tissue trauma. This meticulous approach underscores the importance of precision in enhancing treatment outcomes and patient safety in minimally invasive pain management procedures.

4.1 Limitations of this study and recommendations for future research

This study has some limitations. Firstly, it includes a relatively small sample of patients. Another reason is that the follow-up time is relatively short. The patient was only followed up for 6 months after injection. In addition, due to the lack of a control group, we cannot rule out bias in patient selection, which may affect the generalizability and reliability of the results. We hope to conduct further research with more patient samples and longer observation periods in the future.

5 Conclusion

The conclusion drawn from the study highlights the efficacy and safety of CT-guided sacroiliac joint cavity release surgery as a treatment for postpartum sacroiliac joint pain. This technique has been demonstrated to significantly improve symptoms and enhance the functional status of patients, all while maintaining a high safety profile with no significant complications reported. The use of CT guidance in this context ensures precise targeting and minimally invasive intervention, which are key factors in the successful management of postpartum sacroiliac joint pain. This finding supports the adoption of image-guided surgical interventions as a viable and beneficial option for patients experiencing this specific type of postpartum pain, offering them a path to recovery with minimal risk and maximized therapeutic outcomes.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by the Ethics Committee of the Affiliated Hospital of North Sichuan Medical College. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Author contributions

YM-j: Data curation, Formal analysis, Methodology, Project administration, Writing – original draft, Writing – review & editing. QX: Conceptualization, Data curation, Methodology, Writing – original draft, Writing – review & editing. AB: Writing – original draft, Writing – review & editing. LB: Conceptualization, Formal analysis, Project administration, Writing – original draft, Writing – review & editing. XX-x: Funding acquisition, Resources, Supervision, Validation, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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Lower back pain amongst medical trainees in clinical rotations: implications for choosing future career regarding medical practice

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Background: Low back pain (LBP) is an increasing concern amongst medical students. There is a dearth of publications regarding how the occurrence of LBP impact medical trainees' career decisions.

Objective: To determine: (i) the point and annual prevalence of LBP amongst Ugandan medical students, (ii) its associated factors, and (iii) whether the experience of LBP during clinical rotations influence medical students' career choices regarding medical practice.

Methods: A multi-center cross-sectional study of 387 randomly selected clinical-phase students was conducted in three Ugandan medical schools, during 17th January to 10th March 2023. Proportions of participants with current and 12-months history of LBP were computed as well as odds for career prospects. We performed binary logistic regression models to determine factors associated with LBP at 95% confidence interval regarding $p<0.05$ as statistically significant.

Results: The response rate was 100%. Participants' mean age was 24.7 ± 3.2 years of which 66.2% (256/387) were males. The point and annual prevalence of LBP was 52.5% (203/387) and 66.1% (256/387) respectively. Age [OR 1.23, 95% CI (1.03–1.47), $p = 0.02$], time spent sitting per day [OR 1.08, 95% CI (1.06–1.3), $p < 0.01$], perceived influence of LBP on future medical career [OR 4.75, 95% CI (1.87–12.06), $p < 0.01$] were the significant predictors of LBP. LBP interrupted the students' learning for at least 6.8 ± 12.8 h in 42.4% of participants. Nearly half of participants affirmed that their LBP experience would influence their career prospects. Based on their LBP experiences, trainees ruled out surgery 51.5% (172/334), obstetrics/gynecology 29.6% (99/334), paediatrics 18.3% (61/334), and internal medicine 17.7% (59/334) as their future career specialties. The proportion of trainees that would not consider surgical as opposed to medical disciplines were 81.1% vs. 36.0%, respectively, ($p < 0.001$).

Conclusion: The high prevalence of low back pain among medical students impacts their choices of future medical career with an aversion towards specialization in surgical disciplines. This has far-reaching implications on the disparities in specialist physician health workforce in Low-middle-income countries.

KEYWORDS

occupational safety, backache, pain, medical career, job exit, occupational health, Africa

Introduction

Low back pain (LBP) is the single most contributor to musculoskeletal disability, reduced productive working hours and work absence (1). Ultimately, LBP results in 8.1% of all-cause years lived with disability (2). For instance, LBP affected 619 million (one in every 13) people in 2020 and is projected to affect 843 million people globally by 2050 (2). The global point and annual prevalence of LBP ranges from 12–33% to 22–65%, respectively, (3) affecting both low-middle-income (LMICs) and high income countries (HICs) (4). However, the projected increase in LBP burden is expected to be highest in LMICs as a result of evolving population aging and use of inefficacious costly treatments (1). In HICs, including those in Americas, Europe and Western Pacific; a recent systematic review estimated the pooled annual rate of hospitalization due to LBP at 0.6–5.7%; which imply a pooled annual direct and indirect total cost of US$10144 per patient (4).

On the other hand, in LMICs, including those in Asia, South America and Africa; the annual pooled rate of hospitalization due to LBP ranged between 13.4–18.7% resulting in an annual total cost of US$1226 per patient (3). In a recent prevalence-based cost of analysis study in South Africa, the total annual average direct cost due to acute and chronic LBP were US$99 and 1516, respectively, (5). It has been difficult for researchers to compare the burden of LBP based on pooled global prevalence of hospitalizations due to heterogeneity of studies (6) but the limited human resources for health, constrained health care budgets and inadequate prioritization of LBP research aggravates the morbidity of LBP in LMICs compared to HICs (7). According to the critical evaluation of 22-years trend in LPB-related publications, there was compelling evidence to suggest disparities, where HICs preceded LMICs yet the latter is home to 85% of the world's population (8).

LMICs such those in Africa have the least developed ergonomic technologies to prevent work-related LBP thus should be at the forefront of high quality population-level research aimed at risk detection, early diagnosis, and treatment of LBP but there is a lack funding (7). According to a systematic review and meta-analysis by Moris et al. (9), the pooled point and annual prevalence of LBP in Africa were 39 and 57%, which are higher than the global point (18.3%) and annual (38.5%) prevalence of LBP, respectively, (10). Synthesized evidence suggest that 80–90% of the African population's work is physically demanding; entailing heavy lifting; which together with socioeconomic constraints, coexisting malnutrition and tuberculosis of the spine underpin the high burden of LBP in Africa (11). Moreover there is a growing burden of LBP in the young African population with a point prevalence of up to 58% amongst African adolescents (9), which counteracts the United Nations' mission of healthy aging (2).

Recent studies have demonstrated that other than pathological causes, non-specific LBP ascribed to lifestyle factors and work environments contribute to 90% of cases (12). Systematic reviews demonstrate that working in healthcare settings is considered one of the top 10 risky occupations for developing LBP (13). In Africa, the burden of LBP amongst health workers is aggravated by the lack of assistive devices to move patients with disabilities; largely attributable to: limited production, low quality, and prohibitive costs of such devices (14). As such, standard ergonomic work practices are embryonic which contributes to higher burden of LBP amongst health practitioners in Africa (12, 15). For instance, in a recent systematic review by Kasa et al. (15), the pooled point prevalence of LBP amongst African nurses was 64.1% (95% CI 58.7–69.5). Prolonged standing, lifting and transfer of patients, repeated bending or twisting and working in awkward postures are the main risks for LBP amongst African health workers (16). These factors have been previously identified as proxy for occupational ergonomic exposure to LBP (2). Indeed a previous cross-sectional study in Nigeria showed that nurses who self-reported the above factors at their work environment also had intentions to change their workplaces or quit the nursing profession (16).

Uganda is one of the African countries in the low-income category where researchers have documented LBP as an occupational hazard amongst its qualified health workers, with a point prevalence of 39.6% (12). For qualified Ugandan health care providers, working conditions and occupational hazards are closely monitored by the Ministry of Health as mandated by the Labour laws. However, medical students largely rely on their training institutions to address issues related to work organization, management, and working conditions despite their limited knowledge of occupational hazards. While manual patient handling, repetitive bending or twisting, and extended working hours are known contributors to LBP among licensed Ugandan health workers (12), the extent of ergonomic risks related to these activities has not been thoroughly examined among Ugandan medical trainees who form 75% of Uganda's health workforce (17), despite emerging global evidence which demonstrate considerably high prevalence of LBP amongst students (18–20). In a systematic review of 16 studies which evaluated 7072 students, the annual prevalence of LBP amongst nursing and medical students was 44% (95% CI 27–61) and 53% (95% CI 44–62) respectively, whereas the incidence rate of LBP amongst nursing students ranged from 29 to 67% but studies never reported the incidence rate amongst medical students (21). Being in a final study year (psychosocial stress and anxiety), female sex (21), long study hours and sedentary lifestyle are some of the documented factors contributing to LBP amongst medical trainees (19).

Evidence show that LBP has influence on the employees' decision to exit paid employment especially amongst lower grade employees (22). Globally, medical trainees and interns rank the lowest in seniority withing their work environment, thus early detection of those potentially at risk of developing LBP and their intent to exit or change their career paths are critical to prevention policy aimed at retaining the employee pool in the labor market. The aim of this study was to determine: (i) the point and annual of LBP among Ugandan medical students, (ii) the factors associated with it, and (iii) whether the experience of LBP during clinical rotations influenced medical students' career choices regarding medical practice.

Materials and methods

Study design

A multi-institutional cross-sectional online self-administered survey questionnaire was sent to 387 randomly selected clinical year medical students who endorsed an electronic consent form to participate in the research during 17th January to 10th March 2023. The cross-sectional design was suitable due to the lack of robust electronic medical records in Uganda which prohibited the use of retrospective cohorts. We defined LBP as pain in the posterior aspect of the body that lasted at least a day or more in the area between the lower margin of 12th rib and the lower gluteal folds with or without limb involvement in accordance with previous studies (2). We used the current and 12-months recall periods to minimize recall bias in accordance with previous studies (12).

Study population and settings

The survey was conducted in three medical schools and their respective teaching hospitals in Uganda (two public and one private), including: Mbarara University of Science and Technology located in the city of Mbarara; Kabale University located in Kabale city, and Kampala International University with campuses located in Kampala capital city and Ishaka. In total, these medical schools have 10 affiliated teaching hospitals where students undertake clinical rotations. In the academic year that preceded the survey, these medical schools in total boosted 4,000 medical students both from various parts of the country and from abroad. The participants were undergraduate students enrolled in Bachelor of Medicine and Bachelor of Surgery Degree (MBChB) hereafter being referred to as medical students. To obtain the MBChB degree in Uganda, candidates who have completed two preparatory college years, and have succeeded in biological sciences are enrolled to study for at least 5 years plus one additional year of pre-licensure supervised internship. The first 2 years of medical training are preclinical whereas years three, four, and five are clinical. The clinical year students attend lectures, seminars, bed-side teaching ward rounds, and assist in surgical operations and dispensing medication under supervision. Further, the students perform clinical clerkships, case writeups, and are paired with intern doctors to attend medical and surgical emergencies which contributes to their logbooks.

Eligibility criteria

The university medical schools were purposively selected to represent a mixture of public and private institutions. All medical students in their third, fourth and fifth (final) year of study who were undertaking their clinical rotations at the respective medical schools and affiliated teaching hospitals had a chance to participate in the study. These clinical-phase students were selected on the basis that previous studies identified patient manual handling amongst healthcare providers as a risk for LBP (12) of which trainees in clinical rotations perform such tasks. We excluded students who were designated as non-attending for the academic semester during which the study was conducted; as well as those with documented history of physical injuries resulting from falls, traffic crash and congenital spine deformities that could lead to LBP (23).

Sample size determination

At the time of the study, the total population of medical students in the three medical schools was 4,000, considering all academic years. The sample size was determined using a hypergeometric formula for known small populations,

$$(n) = \frac{NZ^2PQ}{\left\{E^2(N-1) + Z^2PQ\right\}}$$

Where (n) = required sample size; N = population size (4,000); E = value setting accuracy of sample proportions (0.05); Z = value for the level of confidence (1.96) at 95% confidence interval; P = proportion of medical students that suffered LBP, Q = (1-P). Since these proportions were unknown, P and Q were assumed to be 50%, which by substitution, yielded 351 participants. We added 10% to cater for non-response and obtained a total sample size of 387 students. In this exploratory study that did not aim at establishing causal inference, it was deemed unnecessary to compute a sample size as way of demonstrating a valid association between each covariate with LBP.

Sampling procedure

Following administrative and ethical clearance, a random sample of 387 participants was drawn without replacement from a pool of 1100 medical trainees who were registered as attending in the clinical disciplines (third, fourth, and fifth year students), using XLSTAT software for windows (XLSTAT add-on statistical software, 2023. Lumivero, Denver, USA). For equal representation, the number of sampled participants were proportional to the total number of medical students in clinical years at each university. The proportion (P) depending on the population of students in clinical years (Nc), was calculates as:

$$P = Sample\ size(n) \times \frac{100}{N_c} = 387 \times \frac{100}{1100} = 35.2\%$$

Thus 35.2% of each medical school's clinical-year students were studied, which meant 209 participants from Kampala International University, 89 from Kabale University and 88 from Mbarara University of Science and Technology.

Study procedure

Participants were sent weekly email reminders to complete the online google form survey though their class representatives and university secretaries. Each participant completed an electronic consent form followed by a pre-tested authors' questionnaire modified from Aleku et al. (12), which demonstrated a tests-re-test reliability coefficient of 0.9. The questionnaire (Supplementary material S1) captured demographic variables (age, sex, year of study); personal (alcohol consumption and cigarette smoking); and work-related factors (current and most recent clinical disciplines, ergonomics of work environment such as time spent standing, sitting, lifting, bending, or transferring patients as well as career pursuits). These

variables had been documented to influence LBP amongst medical students in previous studies (18–21).

Ethical considerations

This study followed the Uganda National Council for Science and Technology (2014) guidelines on research involving humans as research subjects. Ethical clearance was obtained from the Research and Ethics Committee of Kampala International University, Faculty of Clinical Medicine, and Dentistry (Ref: BMS/11775/173/DU). All participants signed a predesignated electronic informed consent form prior to participation.

Data analysis

Descriptive analysis of the sample characteristics were presented as means, standard deviation, percentages and frequencies. Other descriptive statistics were performed according to each objective.

A predefined assessment of LBP was included in the instrument used for data collection. We computed the percentage of participants with LBP by dividing the number of people with LBP by the total number of participants and multiplying by one hundred.

Factors contributing to LBP

Participants rated a range of factors affecting LBP in their work environment on a scale from 0 to 5. These factors included work schedule, posture, and fatigue, among others as identified in previous studies (12). In addition, there were open ended options to detail other factors which participants regarded as important. We ranked the overall impact of these factors based on their average scores. Factors that were signficant at the bivariate level of analysis were further examined in a binary logistics regression.

Impact on career choices

The study assessed whether LBP affected trainees' future career decisions. It looked at how many trainees said their LBP experience influenced their specialty choices and compared the proportions of those considering surgical versus medical fields using Chi-square test of independence. All analyses were performed in R statistical environment (V4.3.1 R Core Team 2023). All tests were two tailed and considered significant at 95% confidence interval, when $p < 0.05$.

Results

All the 387 returned the questionnaire (response rate 100%). The mean age of participants was 24.7 years (SD = 3.2). Majority were males 66.2% ($n = 257$) and had completed their fourth year of medical training (38.5%, $n = 149$). Only 1.6% ($n = 6$) of participants reported that they were currently smoking cigarettes. Almost a third of participants indicated that they were currently consuming alcohol (28.4%, $n = 110$). More than half of the participants were in a private medical training institution (Kampala International University). At the time of the survey, most participants were undertaking clinical rotations in surgery 25.1% ($n = 97$), and internal medicine 22.7% ($n = 88$) (Table 1).

Prevalence of low back pain

Of the 387 participants, 52.5% ($n = 203$) suffered LBP at the time of the survey whereas 66.1% ($n = 256$) had suffered LBP within the past 12-months. Moreover 42.4% (164/387) reported that LBP ever interfered with their class work or ward session for an average duration of 6.8 h (12.8 SD). Most participants were rotating in surgery 35.5% (106/296), obstetrics and gynecology 34.8% (103/296) at the onset of their LBP. The majority 65.3% (196/300) of respondents attributed prolonged standing or sitting as the main activity when they noticed their first episode of LBP (Figure 1) whereas 77.1% (252/327) identified prolonged standing or sitting as the trigger for recurrence of their LBP (Figure 2). The highest ranked perceived exposure to LBP at the participants' work environment was working without designated shifts (Figure 3).

Factors associated with low back pain

The one sample students t-test revealed that the mean difference of those with and without current LBP significantly differed across participants' age $t(387) = 153$, $p < 0.001$, duration spent in clinical rotation $t(387) = 20.6$, $p < 0.001$, time spent while: standing $t(387) = 20.6$, $p < 0.001$, sitting $t(387) = 20.6$, $p < 0.001$, bending $t(387) = 20.6$, $p < 0.001$, lifting $t(387) = 20.6$, $p < 0.001$ and transferring patients $t(387) = 20.6$, $p < 0.001$ per day during the clinical rotation. There were no statistically significant differences with respect to current experience of LBP across sex [X^2 (1, $N = 387$) = 0.67, $p = 0.41$], and participants' current clinical rotation LBP [X^2 (7, $N = 387$) = 10.2, $p = 0.178$]. Current LBP was associated with history of "ever" smoking of cigarette [X^2 (1, $N = 387$) = 4.357, $p = 0.037$] but not with history of "current" cigarette smoking [X^2 (1, $N = 387$) = 1.029, $p = 0.310$] or history of alcohol consumption [X^2 (1, $N = 387$) = 0.005, $p = 0.946$].

Binary logistic regression analysis of factors associated with LBP showed that age [OR 1.23, 95% CI (1.03–1.47), $p = 0.02$], time spent sitting per day during the current clinical rotation [OR 1.08, 95% CI (1.06–1.3), $p < 0.01$], and perceived influence of LBP on future medical career [OR 4.75, 95% CI (1.87–12.06), $p < 0.01$] significantly predicted LBP. The best fit model demonstrated that predictors were associated with 49.7% of occurrence of LBP (adjusted $R^2 = 49.7$) as shown in (Table 2).

When asked whether experiencing LBP during clinical rotations would influence their intent to specialize in a particular discipline for a medical career, 49.6% (192/387) of participants indicated "yes." The odds of disagreeing were lower amongst those who were currently suffering from LBP compared to those were not, i.e., [OR 0.474, 95% CI (0.382–0.589)] vs. [OR 2.309, 95% CI (1.808–2.950)], $p < 0.001$. The odds of disagreeing were also lower amongst those who had experienced LBP in the past 12 months compared to those who had not, i.e., [OR 2.598, 95% CI (1.872–3.606)] vs. [OR 0.631, 95% CI (0.542–0.735)], $p < 0.001$.

Based on their perceptions and LBP experiences, medical students indicated they had no intent to pursue surgery (including orthopedics, physical therapy, and trauma rehabilitation) 51.5% (172/334), obstetrics and gynecology 29.6% (99/334), paediatrics 18.3% (61/334), internal medicine 17.7% (59/334). The proportion of trainees that would not consider surgical as opposed to medical discipline were

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TABLE 1 Sociodemographic and behavioral characteristics of study participants.

Variable	Category	Frequency (n)	Percentage (%)
Sex assigned at birth	Male	257	66.2
	Female	130	35.5
Age	Median (SD)	24.7 (3.2)	
Institution	KIU	209	54.1
	MUST	88	22.8
	Kabale University	89	23.1
History of ever smoking cigarette	No	361	93.0
	Yes	27	7.0
History of current cigarette smoking	No	382	98.5
	Yes	6	1.5
History of alcohol consumption	No	71.6	28.4
	Yes	278	71.6
Year of study	Year three	106	27.3
	Year four	150	38.7
	Year five	132	34.0
Current clinical rotation	Surgery	97	25.1
	Internal medicine	88	22.7
	Pediatrics	69	17.8
	Obstetrics and gynecology	60	15.5
	Dermatology	36	9.3
	Psychiatry	26	6.7
	Anesthesia	13	3.4
	Ear Nose Throat	7	3.4
	Ophthalmology	7	3.4
Are you currently experiencing low back pain lasting at least one day?	No	184	47.5
	Yes	203	52.5
Have you ever experienced low back pain as a medical student in the past 12 months?	No	131	33.9
	Yes	256	66.1
Which clinical rotation were you at the first onset of low back pain? (N = 296)	Surgery	106	35.8
	Obstetrics and gynecology	103	34.8
	Internal medicine	89	30.1
	Pediatrics	56	18.9
	Anesthesia	6	2.0
	Psychiatry	4	1.4
	Ophthalmology	3	1.0
	Dermatology	3	1.0
Years of clinical exposure	Mean (SD)	2.2 (2.0)	
Duration spent in current clinical rotation in months	Mean (SD)	1.9 (3.8)	
Duration spent other clinical rotations in months	Mean (SD)	2.0 (1.3)	
Time spent lifting per day in current clinical rotation (Hrs.)	Mean (SD)	1.4 (5.3)	
Time spend bending per day in current clinical rotation (Hrs.)	Mean (SD)	1.6 (1.7)	
Time spent transferring dependent patients per day in current clinical rotation (Hrs.)	Mean (SD)	1.1 (1.4)	
Time spent sitting per day in current clinical rotation	Mean (SD)	4.8 (6.0)	
Time spent standing per day in current clinical rotation	Mean (SD)	4.8 (2.5)	

KIU, Kampala International University, MUST, Mbara University of Science and Technology.

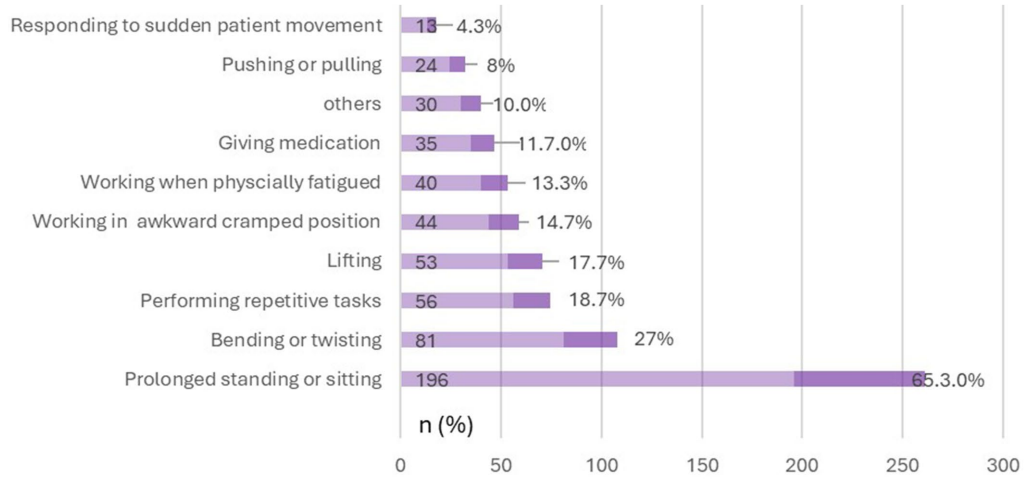

FIGURE 1
Detailing participants' activity at the onset of their low back pain ($N = 300$).

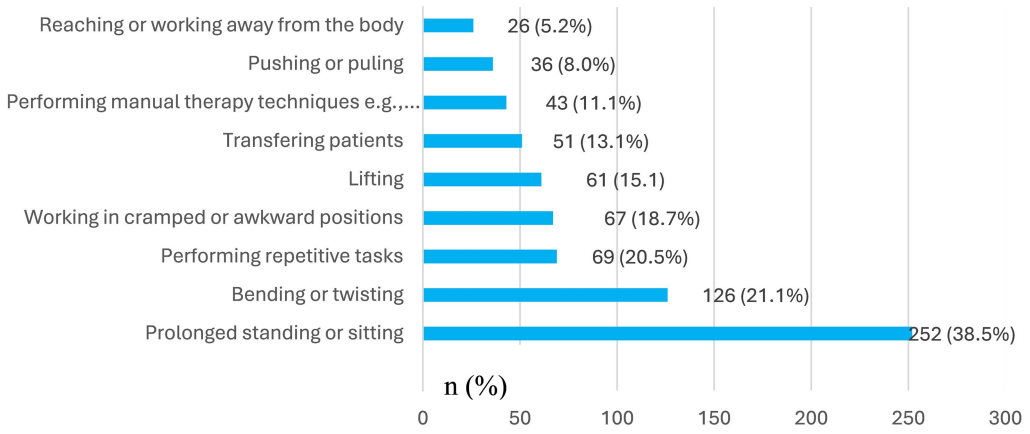

FIGURE 2
Participants' view of activities that triggered recurrence of their low back pain ($N = 327$).

81.1% vs. 36.0%, respectively, and the difference in proportions was statistically significant [X^2 (1, $N = 334$) = 140.6, $p < 0.001$].

Discussion

This study aimed at determining the point and annual prevalence of LBP amongst Ugandan clinical-year medical trainees, its associated factors, and whether the experience of LBP during clinical rotations influenced the learners' career choices regarding medical practice. The point and annual prevalence of LBP was found to be 52.5 and 66.1%, respectively. Previous studies have reported the point and annual prevalence of LBP amongst medical students as: 37.8 and 80.4% in Tunisia (19); 25.6 and 63.3% in Bangladesh (18); 14.4 and 66.8 in Brazil (24); 17.2 and 59.5% in Serbia (25); 10.1 and 44.9% in Saudi Arabia (26); 42.1 and 72.1% in France (20) respectively. Thus, although the 12-month prevalence was comparable, the point prevalence in the present study was slightly higher than reported in previous studies. The difference could result from variation in inclusion criteria, having limited the present study to trainees in clinical years.

Regarding the predictors of LBP, we found that age ($p = 0.02$) played a role in contrast to previous studies (26). Researchers in Tunisia (19) and France (20) have argued that age itself might not be a predictor of LBP amongst medical students but rather the year of study, which changes with increasing psychosocial stress as one approaches the terminal clinical years (21, 27). However, our study did not support this notion as neither the year of study ($p = 0.09$) nor the time spent in the clinical rotation ($p = 0.3$) as a biomarker for duration of exposure were associated with LBP. Although some scholars documented 1.8 times frequence of LBP amongst female medical students (21), we did not observe this relationship in congruity with other studies (26).

Further, we found that time spent sitting per day during clinical rotations was associated with LBP ($p < 0.01$). Moreover, most participants (77.1%) identified prolonged sitting during classes and prolonged standing during ward rounds as the key triggers for

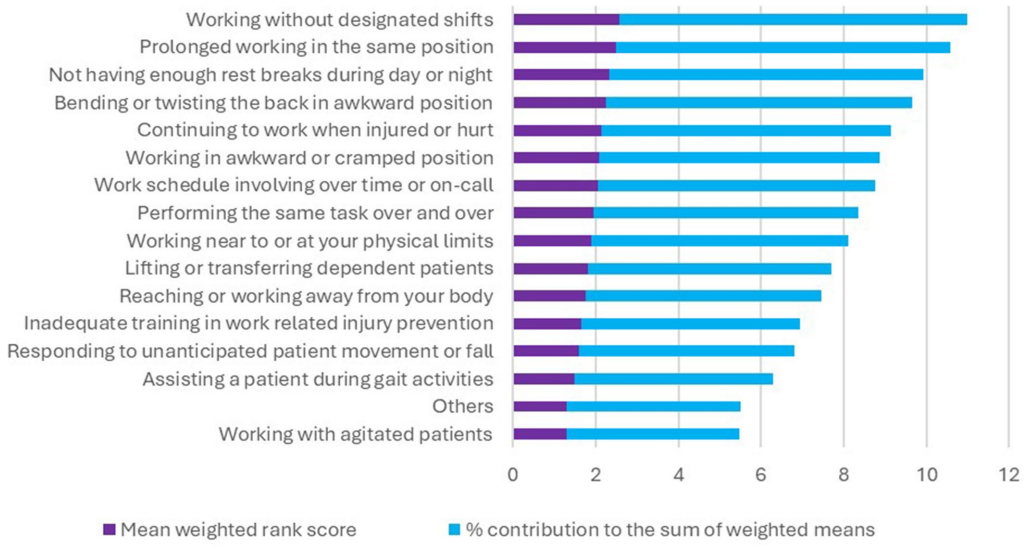

FIGURE 3
Weighted mean rank scores for exposure to low back pain during clinical clerkship.

TABLE 2 Binary logistic regression analysis for predictors of LBP.

Variables	Estimate	Standard error	*p*-value	OR	95% CI	
Age	0.43	5.51	0.02*	1.23	1.03	1.47
Time spent in current clinical rotation (months)	−0.36	0.18	0.3	0.95	0.85	1.05
Time spent lifting per day in current clinical rotation (hours)	−0.41	0.42	0.32	0.71	0.43	1.16
Time spent bending per day in current clinical rotation (hours)	0.24	0.24	0.30	1.07	0.80	1.44
Time spent transferring patients per day in current clinical rotation (hours)	0.21	0.39	0.58	0.95	0.62	1.45
Time spent standing per day in current clinical rotation(hours)	0.21	0.15	0.15	0.82	0.72	0.92
Time spent sitting per day in current clinical rotation (hours)	−0.22	0.10	<0.01*	1.08	1.06	1.3
Perceived influence of LBP on future medical career	0.10	0.50	<0.01*	4.75	1.87	12.06

OR, Odds Ratio; CI, Confidence Interval; *Statistically significant at $P < 0.05$.

recurrence of their LBP, with average sitting and standing time of 4.8 ± 6.0 h and 4.8 ± 2.5 h, respectively. Other scholars have identified sedentary lifestyle as a contributing factor to LBP amongst medical trainees. In a cross-sectional study of 207 medical students in Bangladesh, it was established that sitting more than 6 h per day was a predictor of LBP (18). In another study of 300 medical trainees in Saudi Arabia (26), researchers found that those who did not do physical exercises were three times more likely to report LBP whereas those who spent more than 8 h sited had 5.6 times increased risk of LBP. According to a French study of 1243 medical students, it was found that trainees who walked at least 30 min per day and performed weekly vigorous exercise were less likely to report LBP (20). Moreover LBP had a negative impact on students' day work performance, and on their quality of sleep which created a vicious cycle of LBP in their personal lives (20).

To minimize this undesirable effect of sedentary lifestyle during medical training, experts in USA advised on the inclusion of medical trainees as longitudinal exercise co-instructors for patients with or at risk of LBP, with room to incorporate the students' suggestions for the physiotherapy and medical programme improvement (28). Moreover, an inclusion of moderate levels of physical activity within the trainees' work environment had been suggested in a previous systematic review that evaluated the association between physical activity and LBP (29), in accordance with the World Health Organization's holistic non-invasive approach to LBP which contextualizes individuals' unique workloads (30).

However, the busy schedule of medical students often precludes them from exercise. In a cross-sectional survey of 377 Saud Arabian medical students, 45.4% did not engage in any physical activity other than walking due to time constraints (31), which imply the necessity for innovative physical activity plans that accommodate the unique busy demands of medical trainees. Moreso, research has shown that even physiotherapy students do not practice what they preach; often fail to fulfil their daily exercise demands and self-back care, leading to LBP. For instance, a Brazilian study found that physiotherapy students were 2.5 times more likely to report LBP compared to medical students (24), whereas in the present study, 13.1% of our participants attributed their LBP to performing manual techniques such as massage and assisting patients to ambulate during their assignment to the physiotherapy unit. To mitigate the possibility of future back health practitioners becoming patients themselves, Australia's clinical care standards guidelines advocates for

introduction quality indicators to enable care providers measure how well they implement prevention and early treatment strategies for both patients and health providers (32). This approach should be used for medical students who report their first episode of LBP since a mushrooming epidemic of poor care has been identified in the Lancet series as the most critical aggravating factor for LBP burden (2).

Finally, we found that perceived influence of LBP experience on future medical career choices ($p < 0.01$) was a predictor of LBP. Moreover, our findings showed that the experience of LBP during clinical rotations would influence the career choices of nearly 50% of medical trainees and consequently more than 50% ruled out surgical disciplines as potential choices to consider for specialization. This aversion is likely due to the prolonged standing associated with surgical disciplines as undergraduate clinical students scrub-in to observe and or assist during major theatre operations. Each of such operations in surgical disciplines such as general, orthopaedics and neurosurgery could last as long as 2 h or more, and while this might the case for medical trainees globally, the situation is worse in LMICs as from the authors' experience; a typical theatre list could have up to four to six patients due to the overwhelming surgical patient backlogs in lieu of the low doctor-patient ratio in LMICs (33). Also, it is the case that for medical students who are not scrubbed-in to actively assist in surgical operations due to limited theatre space and infection control protocols would have to sit and watch the real-time broadcast or recorded videos for advanced operations which contributes to their sedentary screen time. Indeed, prolonged siting and standing were the most cited triggers of onset and recurrence of LBP amongst medical students in the present study.

Overall, the results of the present study have threefold policy implications. First of all, although LBP is principally a non-surgical disease (2), referral for interventional procedures and surgical approaches form an integral part of progressive LBP treatment that is nonresponsive to other therapy (32, 34). Moreover the authors' experience in Africa and Europe is that patients with LBP would typically visit a general practitioner or occupational physical therapist followed by a neurosurgeon or orthopaedic spine surgeon in that order which corroborates with evidence from the USA that demonstrates LBP as the third leading cause of surgical specialty consultations (35). However, compelling evidence suggest that LMICs already have an unmet need for 143 million surgical procedures per year to adequately prevent disability including that due LBP as the current surgery case volume in these countries is far below 5000 procedures per 100,000 population per year recommended by the Lancet Commission on Global Surgery (33). Thus the intent not to consider surgical specialties for career choices amongst medical students is worrisome in Uganda which boosts of only one surgeon per 100,000 persons (17). Moreover, how this will affect future human resource capacity for LBP care within the context of specific causes such as due to neural compression and degenerative lumbar spine diseases should be an emerging area of research interest as the country already suffers reduced numbers of surgical professionals, low-operative volumes and poor access to surgical, obstetrics, and anesthesia care (36).

More specifically to put our results into local context, an earlier study of 418 medical students in seven Ugandan medical schools established that the majority (52.6%) would consider a career in internal medicine due to the donor funding bias towards infectious diseases and an opportunity to get "time-off clinical work" for research (37). Moreover in another survey of 251 final year Ugandan medical students which assessed their career intentions after graduation, it was found that due to their presumed safer ergonomic working conditions abroad, 44.6% planned to emigrate from Uganda to USA, UK or South Africa whereas 11.2% intended to abandon the health sector to join business, agriculture or politics due to the overwhelming workload and risky working environment amidst low wages (37). Thus, our findings have policy implications for sustainability in production and maintaining a pool of future LPB care givers through medical training locally and globally. Accordingly, software developers, occupational health engineers, and health educators should devise low-cost simulations as adjunct to traditional clinical rotations in LMICs to minimize the situations that predispose medical trainees to LBP in their physical work environments. Evidence show that 11–30% of clinical training time could be replaced with simulated placements without endangering patients and learners (38, 39).

Secondly, our study revealed that LBP had interrupted the learning process during class work or ward sessions for at least 6.8 h (12.8 SD) in 42.4% of participants. LBP is a known cause of sickness absence from work, with an estimated prevalence of annual absence from work ranging from 12.5% in the UK, 9% in New Zealand to 32% in Ireland (40). In a recent global burden of disease study, it was established that LBP had led to an average absence from work of 100 days in Brazil and 10 days in the USA per person per year (2). Moreover, according to a systematic review by Wynne-Jones et al. (40), up to 32% of individuals who suffer an episode of LBP are not able to return to work within a period of 1 month and 6.7% may not return within 6 months from the time of onset. For the case of LMICs, absence from work implies a double loss as learners miss from their studies while at the same time, this strains the skeleton health workforce as medical trainees form an integral part of human resource for health in rural African settings (17). For instance, as demonstrated in this Ugandan study, a portion of medical students are routinely assigned to the physiotherapy unit as part of their surgery rotation to assist with physical therapy techniques not only to beef up the skeleton staffing but also to address the inequalities in access to back health practitioners.

Lastly, the fact that most of our participants cited prolonged sitting, standing, and working without designated breaks during shifts as triggers for their LBP recurrence during clinical rotations deserves attention. In a systematic review by Wong et al. (21), it was found that students who had prior history of LBP were 3.5 times more likely to develop recurrence within 1 year compared to those with no prior history, emphasizing the need to holistically address potential barriers to full recovery. Medical trainees are the future generation frontline health workers for LBP care. The current ergonomic clinical working conditions of medical trainees in LMICs such as lifting and transferring patients manually have potential to predispose them to LBP, with profound consequences on their retention in clinical practice after graduation. According to a 28-year follow-up of 8665 British Whitehall II cohort study (22), it was found that employees who experienced recurrence of LBP were 1.5 times more likely to exit from their paid employment due to health related conditions compared to those who did not report LBP, having controlled for other socioeconomic modifiers. Moreover it's the lower grade and middle grade workers who were more likely to exit the workforce (22). In medical profession, often medical

students and interns have the lowest rank amongst the LBP care frontline workers. At the time of the study, there were only 500 physiotherapists serving Uganda's 50 million population, as medical trainees including interns and residents contribute to 75% of the country's health workforce (17). Thus, it is imperative to address the events that trigger LBP to reoccur to prevent early retirement or change of career amongst medical trainees. A mixed methods study of 57 medical trainees in England found that LBP emerged from all work cycles of "the students' life" such as lectures, seminars and clinical ward rounds which demanded various body postures including sitting, standing, bending (41) but inadequate breaks between tasks has been singled out as an important contributor to LBP in the students' population (18).

Study strengths and limitations

In terms of strengths, this one of the few multi-institutional studies in Africa which have probed trainee medical professionals' career intentions based on their LBP experience during clinical rotations and have explored their own voices regarding the perceived exposure to LBP in clinical settings. In addition, the high response rate and random sampling improved reliability and generalizability of our findings to train health professionals. On the contrary, there were limitations that are worth acknowledgement. First, we collected the data from self-reports both regarding the occurrence of LBP, its perceived triggers and effects on intended career choices which could raise concerns about recall and social desirability bias. However, self-reports, point prevalence and 12-months recall periods have been used in previous studies (12), and there no particular reasons to think that students would not correctly report whether they intend not to specialize in particular disciplines; besides, why would the career choices differ by LBP experiences during varying clinical rotations. After all, the experience of LBP is subjective as the absence or presence of pain is better expressed by the individual experiencing it, although the threshold could differ between individuals (29). Furthermore, this study focused mostly on the physical working conditions but to a lesser extent, psychosocial working conditions also play a role in LBP as evidenced from pooled analysis of studies in US, Japan and Norway (42). Lastly, uncertainly remains when using LPB experience to predict career choices in a cross-sectional study design as the trainees' experiences could change over time, although based on a Danish study (43), and on a systematic review of LBP amongst medical students (21), its known that occurrence of LBP early in life due to strenuous work predicts its continuity or recurrence later in life.

Conclusion

The point prevalence of LBP was 52.5% and was higher than reported in existing literature although the annual prevalence was comparable at 66.1%. The time spent sitting was the key modifiable factor associated with LBP. LBP interrupted the students' learning for at least 6.8h in nearly half of the participants. Previous studies have primarily focused on determining the prevalence of LBP and its associated factors among medical students. In contrast, the present study further elucidates that experiencing LBP during clinical rotations significantly influences medical trainees' career choices regarding medical practice. Notably, more than half of the trainees expressed no intention to specialize in surgical disciplines. Our findings have implications for future specialized human resource pool derived from medical trainees regarding LBP care and could worsen the existing specialty health care disparities in LMICs. Ergonomic restructuring, structured exercise programs blended with clinical simulations could minimize the situations that predispose medical trainees to LBP. Future studies should be long-term prospective cohorts that evaluate LBP at multiple time points to ascertain how this impacts the medical trainees' career choices after graduation.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by Research and Ethics Committee, Faculty of Clinical Medicine and Dentistry, Kampala International University. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

SH: Conceptualization, Data curation, Investigation, Project administration, Resources, Software, Writing – review & editing. FK: Formal analysis, Methodology, Software, Validation, Visualization, Writing – original draft, Writing – review & editing. DA: Project administration, Resources, Supervision, Writing – review & editing. JP: Funding acquisition, Investigation, Resources, Validation, Visualization, Writing – review & editing. HL: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2024.1412010/full#supplementary-material

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