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Innovation in surgery and surgical education

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Editorial: Innovation in surgery and surgical education

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KEYWORDS

innovation, education, training, surgery, sustainability, collaboration, robotic surgery, laparoscopic surgery

Editorial on the Research Topic
Innovation in surgery and surgical education

The face of surgery is changing at a phenomenally rapid rate. Shifts in societal perceptions, coupled with a better understanding of the benefits of global collaboration and the use of educational technology, are driving positive changes in our field.

In the current topic, the concept of clinical innovation is being explored. Binyu et al. described their novel method for closing the inner ring of a Gilbert type III indirect inguinal hernia. In this randomized controlled trial, patients were allocated to closed and non-closed groups. They concluded that closure reduces the incidence of postoperative seroma and postoperative pain without increasing the risk of postoperative infection and recurrence. Furthermore, Zou et al. created a validated questionnaire aiming to address the very important issue of prevention of intraoperative-acquired pressure injuries, a valuable tool for increasing intraoperative patient safety. Iyad et al. described three five millimeter ports, which reduced the number of reusable instruments and ports. The novel technique had equivalent in-patient outcomes to traditional laparoscopic cholecystectomy but was more cost effective. Although not highlighted by the authors, the technique may be more sustainable than the conventional one.

Sustainability was the topic in two of the original papers published in this issue, with Westwood et al. informing us about the application of the Royal College of Surgeons Green Theatre Checklist. Lathan et al. assessed the impact of telemedicine, a groundbreaking intervention popularized during the COVID-19 pandemic, on the reduction of carbon footprint. Telemedicine was found to be sustainable and safe in the diagnosis of post-operative surgical site infection (SSI). Moreover, the prevention of SSI was the topic of a future global collaborative study, announced by Heinz et al. in their protocol for a pan-specialty survey of SSI prevention practices.

Surgical education also featured in this issue, with Georgiou et al. using biomarkers to demonstrate the impact of simulation on reducing trainee stress levels. The reader also had the opportunity to find out about the progression, current status, and future of surgical training in the Caribbean Newnham et al.

The issue was complimented by two narrative reviews, one of which was by Walshaw et al. describing the evolution of minimally invasive surgery, including

a critical view of relevant landmark studies assessing its efficiency. Finally, Dexter et al. provided a comprehensive review of the pathophysiology, diagnosis, and treatment of fecal incontinence, describing traditional and cutting-edge treatments.

In summary, the current issue is inclusive of research from parts of the globe that at times are not proportionally represented in publications. It touched upon topical and very important issues, such as global collaboration and sustainability, whilst providing a condensed wealth of knowledge in other topics through comprehensive reviews. The diversity of the topics within this issue demonstrates that innovation can be achieved in every aspect of clinical and educational practice.

Author Contributions

MY: Writing – review & editing, Writing – original draft.

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The author declares 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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Cost-effective scarless cholecystectomy using a modified endoscopic minimally invasive reduced appliance technique (Emirate)

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Abstract: The current gold-standard surgical treatment for symptomatic gallstone disease is the conventional four-port laparoscopic cholecystectomy (CLC). In recent years, however, celebrities and social media have altered people's attitudes regarding surgery. Consequently, CLC has undergone several changes to reduce scarring and improve patient satisfaction. In this case-matched control study, the cost-effectiveness of a modified endoscopic minimally invasive reduced appliance technique (Emirate) that uses less equipment and three 5 mm reusable ports only at precisely specified anatomical sites was compared to CLC.

Methods: Single-center retrospective matched cohort analysis including 140 consecutive patients treated with Emirate laparoscopic cholecystectomy ("ELC-group"), matched 1:1 by sex, indications for surgery, surgeon expertise, and preop bile duct imaging, with 140 patients receiving CLC in the same period of time ("CLC group").

Results: We performed a retrospective case-matched review of 140 patients who had Emirate laparoscopic cholecystectomy for gallstones between January 2019 and December 2022. The groups included 108 females and 32 males with an equal ratio of surgical expertise—115 procedures were performed by consultants and 25 by trainees. In each group, 18 patients had preoperative MRCP or ERCP and 20 had acute cholecystitis as indications for surgery. Preoperative characteristics such as age (39 years in the Emirates group and 38.6 years in the CLC group), BMI (29.3 years in the Emirates group and 30 years in the CLC group), stone size, or liver enzymes showed no statistical difference between the two groups. In both groups, the average hospital stay was 1.5 days, and there was no conversion to open surgery, nor was there any bleeding requiring blood transfusion, bile leakage, stone slippage, bile duct injury, or invasive intervention postoperatively. When compared to the CLC group, the ELC group had significantly faster surgery times (t-test, $p = 0.001$), lower levels of the bile duct enzyme ALP ($p = 0.003$), and much lower costs (t-test, $p = 0.0001$).

Conclusion: The Emirate laparoscopic cholecystectomy method is a safe alternative to the traditional four-port laparoscopic cholecystectomy that is also much faster and less expensive.

KEYWORDS

suprapubic approach, laparoscopic cholecystectomy, innovation & flexibility, case matching, cost-effectiveness, three port cholecyctectomy

1. Introduction

The frequency of gallstones is on the rise in Europe and North America, according to ultrasonography studies. Gallstone disease is the second most costly digestive condition in the United States, and about 700,000 cholecystectomies are performed in the US each year (1), while 190,000 patients with gallstones have surgery in Germany (2, 3). **Over the last two decades, the attitudes and expectations of patients have been significantly impacted by celebrities and social media. As a result, the drive for scar reduction and the growing acknowledgment of patient satisfaction have led to the advancement of traditional laparoscopic surgery. As surgeons have gained more experience, both the number of ports and the size of each port have decreased.** Numerous clinical studies have linked variables such as the number and size of ports, the site of the skin incision on the torso, the method of occluding the cystic duct and artery, the method of closing the fascia, the retrieval side of the specimen, and even the exact routing of ports in relation to anatomical landmarks like the falciform ligament to the safety of the treatment and the incidence of complications (4). However, the suprapubic laparoscopic cholecystectomy was initially reported in 1995 in Italy by Degano et al. (5). Today, only a few published articles can be found in the medical literature about this simple technique. This may be related to the widespread interest in alternative minimally invasive methods, such as natural orifice endoscopic translumenal surgery (NOTES) and single-incision laparoscopic cholecystectomy (SILC) (6–8). The mini laparoscopic cholecystectomy (MLC) is another method worth mentioning in this context. Even with the more recent generation of mini instruments, MLC does not offer any clear advantages over conventional laparoscopic cholecystectomy. This is especially true due to the hybrid use of 5 and 10 mm trocars for the camera and the removal of thick-walled gallbladders or large stones, making a pure MLC inapplicable and keeping the technique reserved for only a few selected cases (9). However, considering the global surgical community's strong interest in NOTES and SILC procedures, and significant concerns about the steep learning curve for MLC, safety and cost persist. These factors may help explain why there has been a recent global increase in demand for suprapubic cholecystectomy (10). Because of the low cost of this method without the need for any disposable or specific instruments, and the fact that it maintains the fundamental principles of laparoscopic cholecystectomy, this innovative version makes for a fascinating option that merits more investigation (11).

In this paper, we provide the findings of a retrospective case-matched analysis that evaluated the safety and cost-effectiveness of conventional laparoscopic cholecystectomy (CLC) vs. the endoscopic minimally invasive reduced appliance technique (Emirate).

2. Materials and methods

In this study we compared the outcomes of Emirate cholecystectomy ("E-group") and conventional laparoscopic cholecystectomy ("CLC") in a tertiary care private hospital in Abu Dhabi, United Arab Emirates, using a retrospective matched cohort analysis of 280 patients treated between January 2019 and December 2022. The patients were matched 1:1 by sex, rationale for surgery, surgeon expertise, and preoperative bile duct imaging. In order to eliminate any possibility of selection bias, the coordinator of the operating room used digital logbooks to conduct a random selection of patients for the control group. Informed consent was obtained from all the patients included in the study. Exclusion criteria were ASA > 3, pregnancy, or refusal to participate in the study. OR-cost, operative time, length of hospital stay, postoperative liver function laboratory test, and conversion to an open or four-port cholecystectomy were evaluated in both groups. A standard case record worksheet was used to gather data on demographic characteristics, pre-operative investigations, and intra- and postoperative parameters.

2.1. Equipment

Only the following instruments were required for Emirates laparoscopic cholecystectomy: (**Figure 1**) Veress needle, three 5 mm ports, one grasp instrument, electrocoagulation hook, bipolar Maryland forceps, endoclip applicator, and six polymer-clip cartridges. All the instruments are reusable (Karl Storz SE & Co. KG, Tuttlingen, Germany). A 10 mm trocar and suction device were on hand in case they were needed.

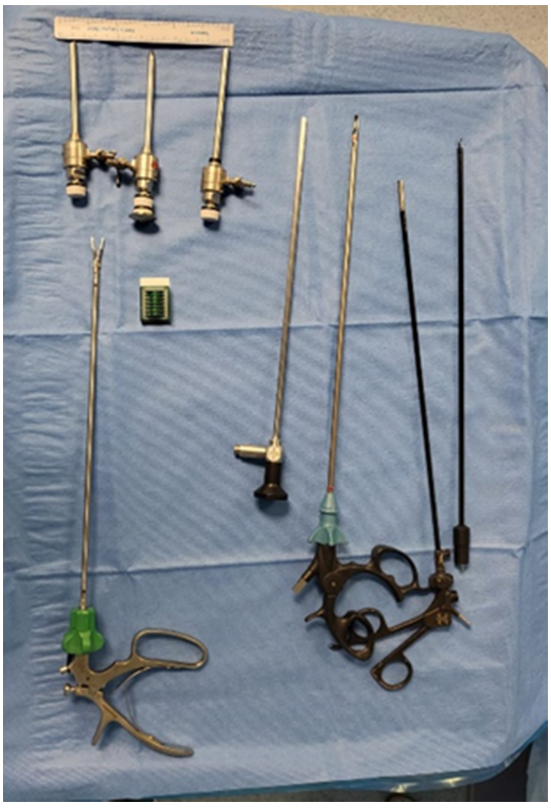

FIGURE 1
Reduced number of reusable instruments used to perform emirate cholecystectomy (karl storz SE & Co. KG, Tuttlingen, Germany).

2.2. Surgical technique for Emirate cholecystectomy

Following general anesthetic induction and endotracheal intubation, the patient's positioning and the sequence of the anesthesia provider, instrumenting nurse, and main surgeon are similar to the usual American position for laparoscopic cholecystectomy. The Emirate procedure begins with a 5 mm intraumbilical incision, through which a 5 mm blunt camera port (Karl Storz SE & Co. KG, Tuttlingen, Germany) is inserted. A 5 mm telescope (Karl Storz Image 1 three-chip system, Karl Storz SE & Co. KG, Tuttlingen, Germany) is inserted *via* the intraumbilical camera port, followed by abdominal cavity exploration. Another 5 mm trocar is inserted at the suprapubic hairline; if the pelvis is small, a Trendelenburg posture may be considered for safe trocar placement. Once the precise location and morphology of the gall bladder have been determined, a second 5 mm port is placed below the subcostal edge on the right hypochondrium. The operating surgeon and assistant stand on the patient's left side, while the staff nurse stands on the patient's right. Monitor, insufflation, and light source systems are kept on the foot side of the patient (Figure 2). The 5 mm camera is transferred to the suprapubic port. The bipolar Maryland forceps are inserted *via* the umbilical port and held with the surgeon's right hand to raise the gallbladder fundus above the liver to facilitate optimum grasping of the gallbladder infundibulum through the right subcostal 5 mm port. An alternate peeling approach with bipolar Maryland forceps can now be used to dissect the calot's triangle, forcipes, or monopolar hook from the intraumbilical working trocar. A critical perspective on safety can be seen after the posterior dissection. Bipolar forceps are used to occlude the cystic artery, saving precious time and effort by reducing the need for instrument interchange maneuvers and making the most of the available space for the application of a 5 mm Ham-O-Lock clip. Any bleeding caused by omental adhesion or fat in the gallbladder infundibulum should be stopped as soon as possible with the bipolar forceps. If required, an intraoperative cholangiogram (IOC) is conducted *via* the 5 mm subcostal port using a Fogarty catheter. After dissecting the gallbladder from the gallbladder fossa in the correct plane, the gallbladder specimen is retrieved from the 5 mm suprapubic port after the camera is switched to the umbilical port. The incision and fascia may be expanded by a huge stone larger than 2 cm. After attaining appropriate hemostasis, the suprapubic trocar is removed, and the peritoneum and posterior fasciae are grasped with bipolar forceps. Coagulation is performed to produce tighter and faster scarring of the incision side, as well as to reduce the chance of a trocar hernia. The trocars are then removed under supervision. Rapid Vicryl 4–0 cutting needle sutures are used to close the skin of the port sites (Figure 3).

2.3. Conventional laparoscopic cholecystectomy (CLC)

The CLC procedure was carried out as follows. Disposable trocars were used; subcostal and lateral ports of 5 mm, an epigastric port of 10 mm, and an umbilical port of 10 mm (Ethicon Endo-Surgery, Cincinnati, OH, USA) for a 30 ° laparoscope were employed (Figure 2). Furthermore, 5 mm graspers and an electro hook were used (Karl Storz SE & Co. KG, Tuttlingen, Germany).

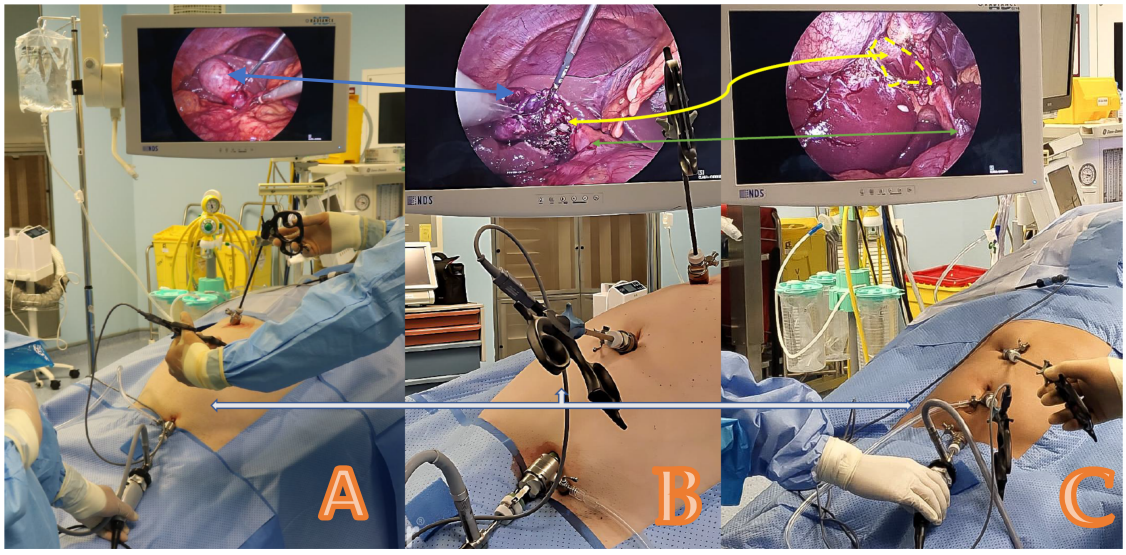

FIGURE 2
Emirate cholecystectomy showing the standard laparoscopic setup and trocar position (karl storz SE & Co. KG, Tuttlingen, Germany). A case of acute cholecystitis is shown in (**A**,**B**). Blue arrows indicate the hydropic gallbladder (**A**) and the status after bile aspiration (**B**). Another case of typical stone disorder is shown in (**C**). The green arrow points to the common bile ducts. The white arrow represents the 5 mm trocars with the optic in the suprapubic trocar and the intra-umbilical main working trocar; in (**B**), bipolar forceps are used in that trocar to dissect the calot triangles. The yellow arrow indicates the critical view of safety in both cases of acute and chronic cholecystitis performed *via* the Emirate technique.

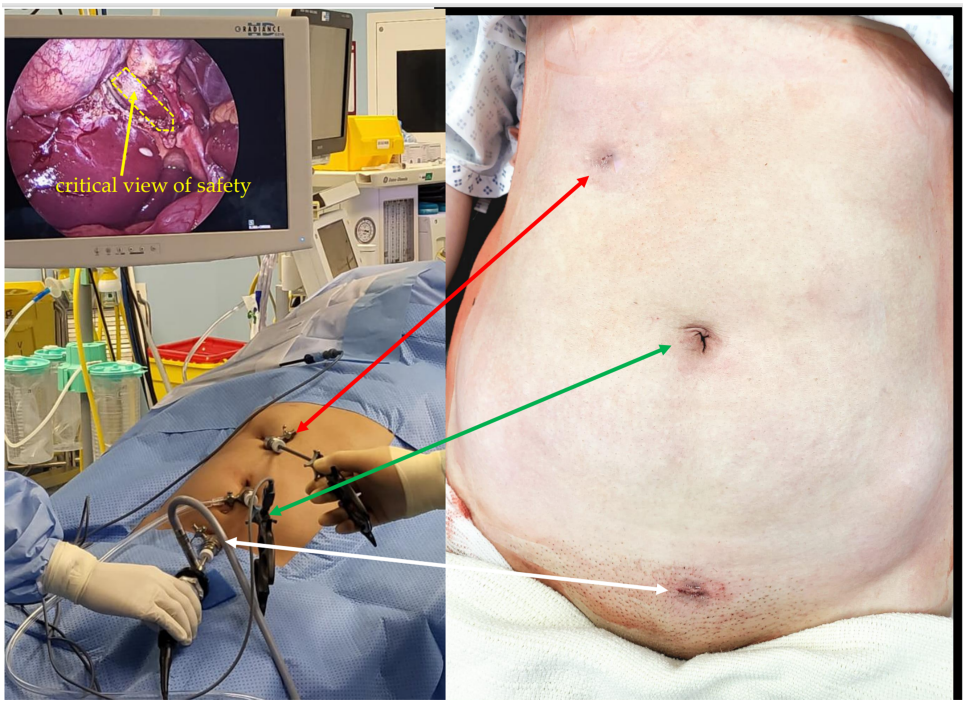

FIGURE 3
Emirate laparoscopic cholecystectomy showing all 5 mm port positions and final non-visible scars.

The cystic artery and duct were clipped with a 10 mm applier (Ethicon Endo-Surgery, Cincinnati, OH, USA), and a 10 mm, 30° laparoscope was repositioned into the patient's epigastric port to track the specimen's extraction. The facia was closed with a Vicryl-J-needle strength 1 (Ethicon Endo-suture, Cincinnati, OH, USA).

2.4. Statistical analysis

IBM SPSS version 22 was used to carry out the statistical analysis (SPSS Inc., Chicago, IL, USA). The parametric data are reported as a mean with a standard deviation, whereas the non-parametric data are expressed as a median rank with an interquartile range. Student's *t*-tests and Mann–Whitney *U*-tests were used for continuous variables in the univariate analysis, whereas Fischer's exact test was used for categorical variables. A statistically significant *p*-value was defined as one that was less than 0.05.

3. Results

3.1. Preoperative characteristics

A total of 140 patients underwent laparoscopic cholecystectomy using the novel modified Emirate technique (ELC) between January 2019 and December 2022. These patients were case-matched to 140 patients who underwent laparoscopic cholecystectomy using the standard four-port technique (CLC) over the same time period in our institution. These patients were randomly selected by the Operative Theater Clerk from the operating room logbooks to eliminate selection bias. Both groups were comparable with respect to baseline characteristics such as age, sex composition, BMI, surgeon competence, operative indication, and liver function (Table 1).

3.2. Perioperative outcomes

When compared to the CLC group, the ELC group had a significantly shorter median length of operation. This difference was statistically significant (34 min in the ELC cohort and 43 min in the CLC; *t*-test, $p = 0.0001$). In addition, the overall cost of the OR was considerably lower in the ELC group ($528 in the ELC cohort as opposed to $793 in the CLC group test, $p = 0.0001$) (Figure 4). In the ELC group, the alkaline phosphatase level in serum was generally lower on the first postoperative day compared to the CLC cohort *t*-test, $p = 0.003$. This difference was statistically significant. The median length of stay in the hospital was 1.5 days across both groups (Table 2). In none of the study groups was it necessary to convert to open surgery or perform any other kind of intervention due to complications such as bile leakage, bleeding, or biliary obstruction.

4 . Discussion

In the last two decades, scarless, non-invasive cosmetic treatments have become more popular worldwide. Social media may indeed be driving the public's increased interest by offering a variety of information, from online teaching tools and physician-

TABLE 1 Demographic and pre-operative data for each study group.

Variable	ELC-group ($n = 140$)	CLC-group ($n = 140$)	*p*-value
Age in years	39.05 (11.8)	38.66 (11.5)	0.783*
Female/male	32/108	32/108	1†
Body mass index	29.2 (4.9)	30.1 (5.9)	0.24*
Consultant/trainee	25/115	25/115	1†
Acute/chronic cholecystitis	19/121	19/121	1†
Preop bile duct imaging	18/122	18/122	1†
Previous abdominal surgery	34/106	32/108	0.778†
Preop serum aspartate aminotransferase	48.85 (91.6)	46.99 (111.2)	0.885*
Preop serum alanine transaminase	66.61 (127.1)	57.95 (100.2)	0.559*
Preop serum alkaline phosphatase	88.83 (52.2)	100.51 (70.7)	0.141*

ELC-group = Emirate cholecystectomy; CLC-group = conventional four-port laparoscopic cholecystectomy. Values are presented as the mean with standard deviation in brackets.
†*p*-value of Fisher's exact test.
**p*-value of $_{independent}$ *t*-test.

TABLE 2 Post-operative data for each study group.

Variable	ELC-group ($n = 140$)	CLC-group ($n = 140$)	*p*-value
Surgery duration in minutes	34.36 (13.95)	43.36 (26.33)	**0.0001**
Length of hospital stay	1.58 (1.399)	1.54 (1.210)	0.806
OR cost per case	528.64 (139.564)	793.57 (263.39)	**0.0001**
Postop serum aspartate aminotransferase	46.15 (31.46)	43.1 (68.65)	0.806
Postop serum alanine transaminase	65.35 (71)	56.47 (114)	0.513
Postop serum alkaline phosphatase	74.98 (32.9)	94.5 (52.36)	**0.003**

ELC-group = Emirate cholecystectomy; CLC-group = conventional four-port laparoscopic cholecystectomy. Values are presented as the mean with standard deviation in brackets.
p values less than 0.05 was deemed statistically significant are highlighted in bold.
p-value of Fisher's exact test.
p-value of $_{independent}$ i-test.

managed accounts to patient experiences and marketing. Promotions from celebrity accounts have been proven to have an impact on general interest. Surgeons could enhance their expertise and add innovative services by understanding more about their patients' particular interests. This is the situation with cholecystectomy, which has gradually evolved to be safer and less invasive. Furthermore, several novel laparoscopic techniques aim to improve aesthetic results while maintaining or improving therapeutic effects. Within this context, MLC, SSS, and NOTES are among the most popular and innovative minimally invasive techniques (12–14).

These techniques initially showed great promise; however, there are still some drawbacks. For example, Ma et al. (15) found that SILC had no effect on overall patient satisfaction. In addition, it has been shown that surgeons with CLC competence need additional training to perform SLIC surgery safely owing to the higher collision of surgical tools due to a lack of triangulation and the restricted number of devices that may be employed (16).

Hoyuela et al. found that SILC is linked with a statistically substantially greater long-term incisional hernia rate at the umbilical port site than CLC. According to their statistics, there

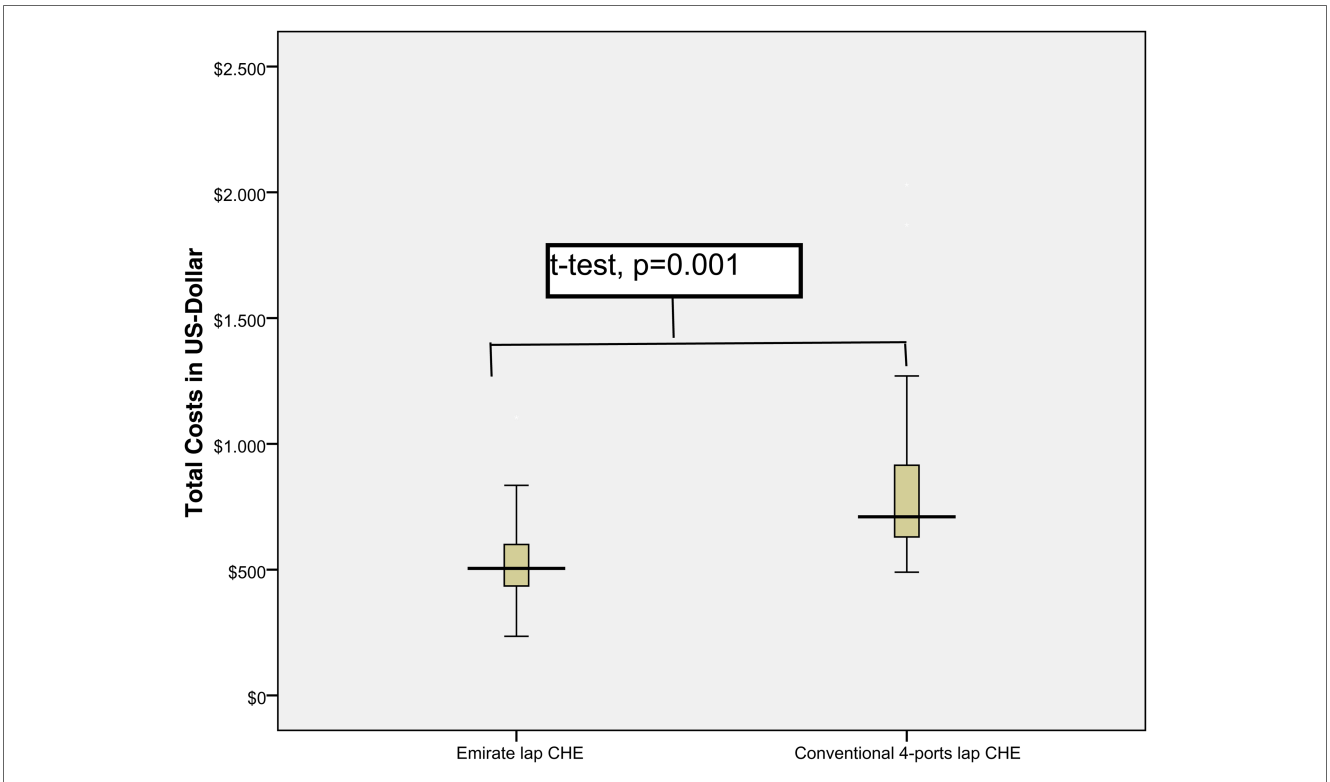

FIGURE 4
Comparison of total consumable costs and operating room utilization per minute for emirate laparoscopic cholecystectomy versus conventional four-port laparoscopic cholecystectomy.

was no significant advantage in terms of postoperative course, hospital stay, or aesthetic satisfaction. Ultimately, they concluded that SILC should not be used routinely (17). In a recent systematic review and meta-analysis conducted by Cirag and Schankar, it was shown that SILC had a considerably longer operational duration and more complications in comparison to CLC (18).

Despite the fact that transvaginal cholecystectomy as a NOTES procedure currently only applies to female patients, it nevertheless has several drawbacks that are equivalent to those of SILC. A further drawback of transvaginal cholecystectomy is that the majority of institutions execute transvaginal cholecystectomy as a hybrid technique, employing an abdominal trocar for the optic due to issues with instrument triangulation and the lack of flexible tools with acceptable intraperitoneal navigation. A benefit of transvaginal cholecystectomy is the decrease in postoperative pain and the need for opioids. Even for experienced laparoscopic surgeons, however, a steep learning curve using transvaginal cholecystectomy can result in a considerable lengthening of the surgery, in addition to the need for expensive specialized equipment (19). Similar issues are applicable for mini laparoscopy.

A precedent has been set for the suprapubic cholecystectomy, as demonstrated by the work of Degano et al., who described it in 1995 (20). Numerous studies comparing the suprapubic technique to the standard cholecystectomy used a variety of port sizes and numbers. Despite the use of four ports, two of which were 10 mm in the umbilical fold and 12 mm in the suprapubic region, a recent study by Taha et al. demonstrated that the aesthetic effect of the suprapubic method is superior to that of the standard cholecystectomy in a standard context, as judged not by the patient or practitioner directly involved in the therapy, but by those unrelated to the treatment process (21–23).

In the current study we analyzed 280 patients who underwent surgery because of benign gallbladder disorders at our institution (140 ELC vs. 140 CLC). The results show that the two techniques are comparable in terms of preoperative demographics, surgeon expertise, gallbladder stone size, stage of gallbladder inflammation, and preoperative bile duct diagnostics. The perioperative outcomes show that there was a statistically significant difference in the average duration of surgery; however, the ELS had an approximately 9-minute shorter operating time which is related to faster introduction of 5 mm intraumbilical optic trocar and waiving the facia closure by using pure blunt 5 mm trocar, while CLC required Hasson open technique for 10–12 mm perumbilical trocar with consecutive necessarily facia closure. Also waiving a fourth trocar as well as clipping of the artery save time when compared to CLC.

ELS also saved US$265 on average per case. Moreover, in comparison to the CLC, the laboratory parameter demonstrated much lower alkaline phosphatase serum levels. These lower AP levels, even if they have no clinical relevance, could be an expression of reduced manipulation of the gallbladder as a result of direct grasping of the infundibulum and waiving the fourth port that is usually used in the CLC to grasp the fundus with assistance.

The Emirate cholecystectomy, as a modified suprapubic laparoscopic cholecystectomy, has been designed to have a shorter running time and a less steep learning curve than SILC or NOTES. The possibility of using typical CA devices with fewer appliances makes the technique simple and cost-effective to execute. Furthermore, the entire process flow, including the patient position and order of anesthesia equipment, assistant surgeons, and the instrumenting nurse in the surgical setup, remains the same as in a conventional laparoscopic cholecystectomy. In addition to this, it is the responsibility of the academic hospital to keep laparoscopic cholecystectomy simple and easy to learn in order to ensure an adequate residency training curriculum. This is not always the case with SILS and NOTES cholecystectomies, which may be complicated and difficult to learn (24–27).

The current study is not without shortcomings. The study, which was retrospective in nature, was carried out in a single setting. In spite of this, our findings indicate that ELC is both safe and feasible in comparison to CLC, with no statistically significant differences in postoperative morbidity or mortality between the two procedures. However, this paper details the results for a sizable sample of patients who underwent ECL, and those results are similar to those for individuals who underwent CLC. Despite the fact that ELC appears to be more technically demanding than CLC at first glance because of the limited appliances, reduced number of ports, and unusual location of the optic at the suprapubic site, ELC demonstrated faster surgery times and lower costs.

5. Conclusions

In our study, the results of the Emirate laparoscopic cholecystectomy were similar to the results of the standard laparoscopic cholecystectomy. However, new research shows that a suprapubic cholecystectomy is less painful than a regular laparoscopic cholecystectomy. The unique technique hides the suprapubic scar with hair or clothing, which makes patients more satisfied with the cosmetic results of surgery. In order to confirm that Emirate laparoscopic cholecystectomy results in less postoperative discomfort and less visible scarring than standard laparoscopic cholecystectomy, a randomized controlled investigation is required.

Data availability statement

The datasets presented in this article are not readily available because; if needed can be provided. Requests to access the datasets should be directed to; iyad.hassan@burjeel.com.

Ethics statement

The studies involving human participants were reviewed and approved by Institutional Review Board Statement: The study was performed in accordance with the Declaration of Helsinki and was approved by the Institutional Review Board and Ethics

Committee of Burjeel Hospital in Abu Dhabi (BH/REC/Institutional Review Board/032/22). Informed Consent Statement: All patients who took part in the study signed a written informed consent form when they were admitted. The patients/participants provided their written informed consent to participate in this study.

Author contributions

Data curation, MA. Investigation, IH. Project administration, IH. Writing—review and editing, LH, HA, and WH is a promoter and provided inspiration for this work. 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.

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Clinical efficacy of laparoscopic closed hernia ring combined with a patch repair for Gilbert type III indirect inguinal hernia

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Purpose: The incidence of seroma and postoperative pain after Gilbert type III inguinal hernia repair is high. To reduce postoperative complications, this study investigated the clinical efficacy of laparoscopic closed hernia ring combined with a patch repair for Gilbert type III indirect inguinal hernia.

Methods: Through a prospective randomized controlled study, a total of 193 patients with Gilbert type III indirect inguinal hernia admitted to Nanchong Central Hospital affiliated with Chuanbei Medical College from May 2020 to December 2021 were selected and randomly divided into the inner ring closed group (85 patients) and the inner ring non-closed group (95 patients). The patients in both groups underwent laparoscopic tension-free repair of their inguinal hernias. General information such as operative time, postoperative hospital stay, and hospital cost were compared between the two groups, and the patients were followed up at 1, 7, 14, 21, and 28 days and then 3, 6, and 12 months after surgery to compare complications such as incidence of seroma, volume of the seroma fluid, incidence of pain, and visual analogue scale (VAS) pain score.

Results: There was no conversion to open procedures in any of the patients. The operation time of the closed group was significantly longer than that of the non-closed group (64.2 ± 12.2 vs. 55.3 ± 9.5 min, $P < 0.01$). The proportion of patients with postoperative pain in the two groups was 39 (46%) vs. 59 (62%), $P = 0.029$ on 7 days; 17 (20%) vs. 33 (35%), $P = 0.028$ on 14 days; and 6 (7%) vs. 22 (23%), $P = 0.003$ on 21 days in the postoperative closed group and was significantly lower than that in the non-closed group, while we found that the non-closed group had a higher VAS pain score than that of the closed group (2.36 ± 0.61 vs. 1.95 ± 0.71, $P = 0.003$ on 7 days and 2.12 ± 0.49 vs. 1.65 ± 0.49, $P = 0.002$ on 14 days) after surgery according to the statistical results of the VAS pain score. The incidence of postoperative seroma and the amount of seroma fluid decreased gradually in both groups, but when comparing the two groups, the proportion of cases of seroma in the closed group on 7 days [45 (53%) vs. 79 (83%), $P < 0.01$]; 14 days [23 (27%) vs. 43 (45%), $P = 0.011$]; and 21 days [10 (12%) vs. 29 (31%), $P = 0.002$] after the operation were significantly less than that in the non-closed group. For the comparison of the amount of seroma fluid between the groups, the seroma fluid volume in the non-closed group was greater than that in the closed group (34.48 ± 20.40 vs. 43.87 ± 16.40 ml, $P = 0.006$, 7 days) and (21.79 ± 8.42 vs. 30.74 ± 10.39 ml, $P = 0.002$, 14 days) after surgery. There were no differences in the length of stay, total hospital costs, or postoperative complications (urinary retention, intestinal obstruction, nausea, vomiting, bleeding, and infection) between the two groups, and the differences were not statistically significant ($P > 0.05$). The postoperative follow-up period was 3–20 months, and no chronic pain or recurrence occurred during the postoperative follow-up period in either group.

Conclusions: Closure of the hernia ring is safe and effective for laparoscopic hernia repair for Gilbert type III inguinal hernia, and it significantly reduces the incidence of postoperative seroma and further reduces the postoperative pain without increasing the risk of postoperative infection and recurrence.

KEYWORDS

laparoscopy, Gilbert type III indirect inguinal hernia, closed hernia ring, seroma, postoperative pain

Inguinal hernia is a common surgical disease in clinical settings. Every year, there are more than 20 million cases of inguinal hernia repair worldwide (1). With the rapid development of laparoscopic minimally invasive technology in the field of hernia surgery, including endoscopic total extraperitoneal patch plasty (TEP) and laparoscopic transabdominal patch plasty (TAPP) techniques, it has become one of the gold standards for inguinal hernia repair. Currently, laparoscopic inguinal hernia repair (LIHR) has become one of the mainstream surgical methods for inguinal hernia due to its advantages of quick postoperative recovery, low rate of postoperative infection, short hospital stay, mild postoperative pain, low recurrence rate, and good curative effect (2, 3). However, for the cases of large defects of the hernia ring, such as medial defects, large indirect hernias, or scrotal hernias, complications such as seroma formation, pain, infection, and recurrence after laparoscopic repair cannot be ignored. The main postoperative complication was the development of seroma, with an incidence of 3.7%–70%. Although most seromas are considered to be common and minor postoperative complications, a large number of seromas may cause postoperative pain, infection, and even recurrence and reduce the quality of life of patients after surgery (4, 5).

Therefore, it is of great significance to identify the factors related to seroma formation. For direct hernias, there is a clear evidence to support the findings that when the lax transverse fascia is inverted, the incidence of seroma is significantly reduced when the dead space volume is reduced by a direct suture closure of the defect (6). However, for large indirect hernias (Gilbert type Ⅲ) or scrotal hernias, the methods of reducing seroma formation remain undefined, and some scholars have found no obvious improvement by transecting the hernia sac, completing dissection of the hernia, placing a drainage tube, applying prophylactic perforation ice compression, etc. In recent years, some studies have found that by closing the inner ring port and blocking the internal and external communication ports, the occurrence of seroma and postoperative complications can be effectively reduced (7–9), The occurrence of seroma can be effectively controlled and reduced, which will further reduce the incidence of other complications.

Therefore, the aim of this study was to prospectively assess a new simple method to evaluate the clinical effect of laparoscopic closure of the internal ring of Gilbert III indirect inguinal hernia and explore the clinical application value of this technology. This study can provide some reference for surgeons in the treatment of hernia sacs during laparoscopic hernia repair in the future.

Materials and methods

The clinical data of 180 adult male patients with indirect inguinal hernia admitted to Nanchong Central Hospital affiliated to North Sichuan Medical College from May 2020 to May 2022 were selected by a prospective randomized controlled study. The inclusion criteria were as follows: adult male aged ≥18 years old and with unilateral indirect inguinal hernia according to preoperative physical examination and imaging examination. The inclusion criteria were as follows: primary indirect inguinal hernia classified as Gilbert III (defect size diameter ≥3 cm, including scrotal hernias); the American Society of Anesthesiologists (ASA) I, II, or III compensated; when the pneumoperitoneum induced under general anesthesia was tolerated; and when there was no obvious surgical contraindication in the preoperative examination. For the exclusion criteria, patients who could not tolerate general anesthesia, contraindications to laparoscopic surgery, direct inguinal hernia, femoral hernia, recurrent hernia, incarcerated hernia, strangulated hernia, and other hernia types were excluded; patients transferred to laparotomy were excluded; and patients who had emergency surgery were excluded. This study was reviewed and approved by the medical ethics committee of our hospital [no: 2021 annual review (016)]. All patients provided their written informed consent to participate in this study. China Clinical Trial Registration Center (chictr210049027).

Operative technique

The same surgeon performed all the procedures. All patients were operated on under general anesthesia. The procedure for laparoscopic inguinal hernia surgery was performed in strict accordance with the guidelines for laparoscopic (TAPP) and endoscopic (TEP) treatment of inguinal hernia stipulated by the International Endohernia Society (IEHS) (10), In the selection of surgical methods for these cases, patients with ≦3 cm diameter of hernia ring defect <4 cm, no history of surgery in the lower abdomen, TEP or TAPP were selected. In addition, patients with ≦4 cm diameter of hernia ring defect, history of surgery in the lower abdomen, scrotal hernia, and irreducible hernia should be operated on with TAPP. We mainly transect the hernia sac rather than completely remove it, and only a few patients undergo complete dissection of the hernia sac. The intraoperative

pneumoperitoneum pressure was set at 12 mmHg, and the pneumoperitoneum flow was set at 10 L/min. No intraoperative complications occurred during the operation.

In the inner ring closure group, the pneumoperitoneum pressure was appropriately reduced, and the surgical assistant pressed the body surface to reduce the tension intensity. A 2-0 absorbable suture (V905E, VICRYL, Ethicon, USA) was used for reverse needle suturing from the lateral side to the medial side, and the combined tendon was sutured with the iliac pubic tract. The inner ring mouth was covered by the folded transverse abdominal fascia through the posterior part of the blood vessel under the abdominal wall. The suture was continuously returned to the initial section and tied for fixation. During the suturing process, the needle should be maintained at a distance that was not too far, and the needle should not be too deep in order to avoid damaging the nerve [femoral branch of the genitofemoral nerve (GFN), iliohypogastric nerve (IHN), and ilioinguinal nerve (IIN)], and the medial edge should be closed to avoid damaging the vas deferens, spermatic vessels, and inferior abdominal vessels. The spermatic cord passage should be preserved to avoid scrotal edema caused by clamping that is too tight (11). After suturing, the hernia sac was pressed externally to squeeze the gas in the distal hernia sac back into the abdominal cavity (**Figures 1–4**). The control group was operated on directly without closing the inner ring. We used a macroporous, partially absorbable, polypropylene mesh (15 cm × 10 cm) (PASL; TransEasy Medical Tech. Co., Ltd., Beijing, China) for the repair. No drainage tube placement and no fixation (glue or tacks) were performed in our series. The TEP surgical patch was not fixed, while the TAPP surgical patch was fixed with 3-0 VICRYL plus three-point fixation.

Postoperative assessment

The patients were able to eat semiliquid food and get out of bed 6 h after the surgery, and the patients received regular postoperative instructions at discharge, including the use of compression dressings for 7 days, return to normal activities when able, and a temporary cessation of physical activity for 3 months.

All patients provided informed preoperative consent. Patient demographics, the diameter of the great inner ring of the hernia defect, the size of the hernia sac, the selected surgical method, such as the TAPP/TEP, the operation time, and the occurrence of intraoperative bleeding were collected prospectively. Among the available pain scores, the visual analogue scale (VAS) score is widely used. Pain scores were recorded on the first postoperative day using the VAS pain score. Outpatient follow-up visit was performed at 7, 14, 21, and 28 days after discharge, and telephone follow-up or outpatient follow-up visit was performed at 3, 6, and 12 months. The mean follow-up time for the closed group was 13.5 months, ranging from 3 to 24 months, and that for the non-closed group was 11.6 months, ranging from 3 to 22 months. The main contents of follow-up were seroma formation, seroma fluid volume {seroma size was measured by Doppler ultrasonography, and sac volume was calculated using the formula for an ellipsoid [V = (4/3) 5 abc], where a, b, and c represent the radius of the length, width, and height, respectively}, postoperative pain, VAS pain score, hernia recurrence, infection, or any serious adverse event, which were recorded and analyzed. A regular physical examination to diagnose seroma was performed at each follow-up visit by the same surgeon.

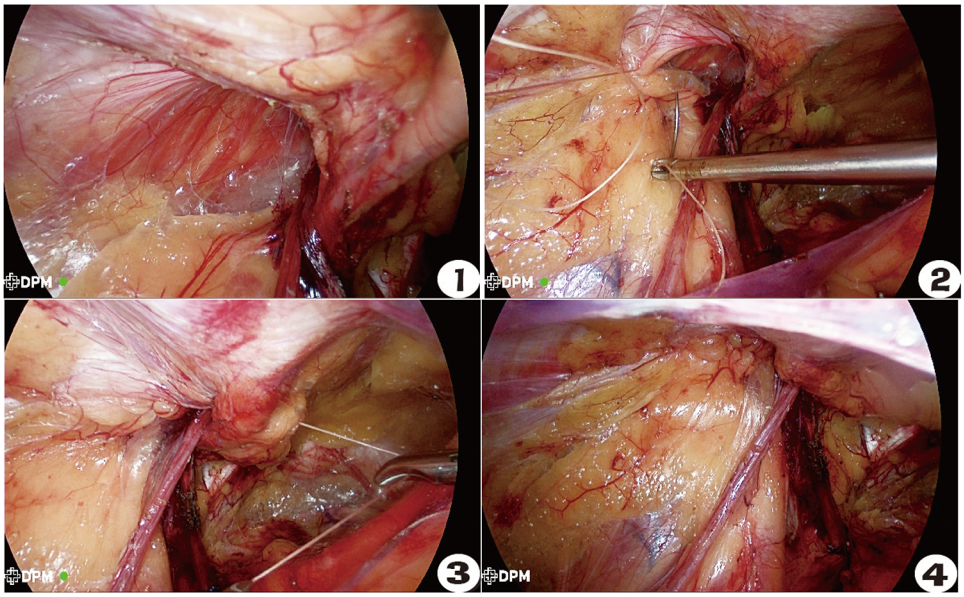

FIGURE 1–4
Operation procedure for closing the inner ring of Gilbert type III indirect inguinal hernia. ① Status before closing the inner ring. ② The ilio-pubic tract and conjoined tendon were sutured. ③ U-shaped suture crossing abdominal wall blood vessels. ④ The closed internal ring.

Statistical analysis

The SPSS 25.0 software was used for analysis. Continuous variables were expressed as the mean ± standard deviation, using *t*-tests and repeated measurement data using ANOVA. Categorical variables were expressed as numbers and percentages, and the χ^2 was used for the analysis of categorical variables. Fisher's exact probability method was used for small probability events. $P < 0.05$ indicates that the difference is statistically significant.

Results

This two-year prospective study involved a total of 180 patients randomized by simple randomization into the inner ring closed group (85 patients) and the inner ring non-closed group (95 patients) (Table 1). Demographic characteristics such as age, body mass index (BMI), hernia duration, comorbidities, hernia location, and hernia size were comparable in the closed and non-closed groups ($P > 0.05$).

There was no conversion to open procedures in any of the patients. By comparing the two groups of patients, we found that the operation method (17.6% vs. 24.2%, TEP; 82.4% vs. 75.8%, TAPP), treatment of hernia sac (83.5% vs. 87.4%, transected hernia sac; 16.5% vs. 12.6%, no-transected hernia sac), blood loss (3.7 ± 4.7 vs. 3.8 ± 4.0 ml), postoperative length of stay (POLS) (2.2 ± 1.4 vs. 2.4 ± 2.0 days), and hospitalization cost (HC) (12,774.6 ± 1,009.3 vs. 12,605.0 ± 1,089.4 RMB) in the closed group were equivalent to those in the non-closed group ($P > 0.05$). However, the operation time of the closed group was significantly longer than that of the non-closed group (64.2 ± 12.2 vs. 55.3 ± 9.5 min, $P < 0.01$). The postoperative complications, including urinary retention (10.6% vs. 17.9%), intestinal obstruction (4.7% vs. 3.2%), sickness and vomiting (2.4% vs. 3.2%), incision bleeding (3.5% vs. 3.2%), and patch infection (0% vs. 0%), were comparable in the closed and non-closed groups ($P > 0.05$) (Table 2).

TABLE 1 General demographics and perioperative data of the patients.

Variable	Closed ($n = 85$)	Non-closed ($n = 95$)	*t/x2*	*P*
Age (years)	64.0 ± 14.6	65.7 ± 11.4	0.855	0.394
BMI (kg/m^2)	24.0 ± 3.0	23.7 ± 2.9	1.000	0.319
Hernia duration (months)	62.4 ± 103.5	42.2 ± 80.9	1.469	0.144
Comorbidities				
Hypertension	13	16	0.08	0.778
Diabetes	14	17	0.064	0.801
COPD	10	14	0.343	0.558
Hernia Location			0.420	0.517
Right	72	77		
Left	13	18		
Hernia defect size (cm)	3.5 ± 0.7	3.6 ± 0.7	0.339	0.735
Length of hernia sac (cm)	9.0 ± 2.1	9.4 ± 2.0	1.311	0.191

BMI, body mass index; COPD, chronic obstructive pulmonary disease.

TABLE 2 Comparison of operative data between the two groups.

Variable	Closed ($n = 85$)	Non-closed ($n = 95$)	*t/x2*	*P*
Operation method			1.160	0.281
TEP	15 (17.6%)	23 (24.2%)		
TAPP	70 (82.4%)	72 (75.8%)		
Transected hernia sac			0.535	0.465
Yes	71 (83.5%)	83 (87.4%)		
No	14 (16.5%)	1,212.6%)		
Blood loss (ml)	3.7 ± 4.7	3.8 ± 4.0	0.042	0.967
OT (min)	64.2 ± 12.2	55.3 ± 9.5	5.405	<0.01
POLS (days)	2.2 ± 1.4	2.4 ± 2.0	1.064	0.289
HC (RMB)	12,774.6 ± 1,009.3	12,605.0 ± 1,089.4	1.080	0.282
Complications				
Urinary retention	9 (10.6%)	17 (17.9%)	0.288	0.592
Sick and vomit	2 (2.4%)	3 (3.2%)	0.108	0.743
Incision bleeding	3 (3.5%)	3 (3.2%)	0.019	0.890
Patch infection	0	0	-	-

POLS, postoperative length of stay; HC, hospitalization cost; OT, operative time.

Pain is an inevitable complication after inguinal hernia surgery. The recovery of the two groups was objectively compared by the VAS pain score. The statistical results showed that the number of postoperative pain cases and VAS scores of the two groups of patients showed a downward trend with time at 1, 7, 14, 21, and 28 days and 3 months after the operation. However, the proportion of the patients with pain at 7 days [39 (46%) vs. 59 (62%), $P = 0.029$]; 14 days [17 (20%) vs. 33 (35%), $P = 0.028$]; and 21 days [6 (7%) vs. 22 (23%), $P = 0.003$] after operation in the closed group was significantly lower than that in the non-closed group (Table 3). At the same time, we showed that the VAS pain score in the non-closed group was higher than that in the closed group (2.36 ± 0.61 vs. 1.95 ± 0.71, $P = 0.003$, 7 days) and (2.12 ± 0.49 vs. 1.65 ± 0.49, $P = 0.002$, 14 days) after surgery according to the statistical results of the VAS pain score (Table 4).

Postoperative seromas usually occur 7 days after the inguinal hernia surgery. The incidence of postoperative seroma and the amount of seroma fluid in the two groups decreased gradually within the group, but compared between the two groups, the proportion of patients with seroma in the closed group on 7 days [45 (53%) vs. 79 (83%), $P < 0.01$]; 14 days [23 (27%) vs. 43(45%), $P = 0.011$]; and 21 days [10(12%) vs. 29(31%), $P = 0.002$] after the operation were significantly less than that in the non-closed

TABLE 3 Comparison of cases of postoperative pain between the two groups.

Group	Number of cases of postoperative pain (%)						
	1 day	7 days	14 days	21 days	28 days	3 m	6 m
Closed ($n = 85$)	63 (74%)	39 (46%)	17 (20%)	6 (7%)	5 (6%)	1 (1%)	0
Non-closed ($n = 95$)	77 (81%)	59 (62%)	33 (35%)	22 (23%)	11 (12%)	2 (2%)	0
t	1.248	4.760	4.856	8.851	1.798	-	-
P	0.264	0.029	0.028	0.003	0.180	-	-

TABLE 4 Comparison of postoperative VAS pain scores between the two groups.

Group	VAS pain score				
	1 day	7 days	14 days	21 days	28 days
Closed ($n = 85$)	3.06 ± 1.06	1.95 ± 0.71	1.65 ± 0.49	1.20 ± 0.45	1.40 ± 0.55
Non-closed ($n = 95$)	3.08 ± 0.89	2.36 ± 0.61	2.12 ± 0.49	1.23 ± 0.43	1.09 ± 0.30
t	0.088	3.033	3.259	0.127	1.476
P	0.930	0.003	0.002	0.900	0.162

group; however, there was no difference in the proportion of patients who developed seromas after surgery between the two groups [4 (5%) vs. 10 (11%), 28 days) ($P > 0.05$] (Table 5). For the comparison of the amount of seroma fluid between the groups, the seroma fluid volume in the non-closed group was greater than that in the closed group (34.48 ± 20.40 vs. 43.87 ± 16.40 ml, $P = 0.006$, 7 days) and (21.79 ± 8.42 vs. 30.74 ± 10.39 ml, $P = 0.002$, 14 days) after surgery. We found that there was no difference in the amount of seroma fluid between the two groups after 21 days (13.60 ± 5.17 vs. 14.69 ± 6.59 ml) and 28 days (11.75 ± 2.36 vs. 13.57 ± 1.99 ml) after surgery ($P > 0.05$) (Table 6).

The mortality of this series was 0%, but one patient had bulging of the abdominal wall in the inguinal region, which returned to normal after compression. No other seroma-related complications, such as hernia recurrence, infection, or mesh rejection, occurred during the study period.

Discussion

Laparoscopic inguinal hernia repair has the advantages of a small incision, less bleeding, less pain, and faster recovery. Laparoscopic inguinal hernia repair has been increasingly affirmed. However, there is still controversy on the laparoscopic repair of Gilbert type III inguinal hernia or scrotal hernia (12). Due to the large defect of the hernia ring in indirect hernia, synthetic mesh bridging is often performed to repair it. The incidence of complications such as infection increases (13).

TABLE 5 Comparison of postoperative seroma cases between the two groups.

	Seroma cases (%)			
Group	7 days	14 days	21 days	28 days
Closed ($n = 85$)	45 (53%)	23 (27%)	10 (12%)	4 (5%)
Non-closed ($n = 95$)	79 (83%)	43 (45%)	29 (31%)	10 (11%)
t	19.112	6.402	9.304	2.119
P	<0.01	0.011	0.002	0.146

TABLE 6 Comparison of the postoperative amount of seroma fluid between the two groups.

	Amount of seroma fluid (ml)			
Group	7 days	14 days	21 days	28 days
Closed ($n = 85$)	34.48 ± 20.40	21.79 ± 8.42	13.60 ± 5.17	11.75 ± 2.36
Non-closed ($n = 95$)	43.87 ± 16.40	30.74 ± 10.39	14.69 ± 6.59	13.57 ± 1.99
t	2.777	3.303	0.474	1.371
P	0.006	0.002	0.638	0.860

Laparoscopic internal ring suturing has been proven to be safe and effective for the treatment of inguinal hernia in adolescents (14). For small groins, the effect of a patch repair can also be achieved by suturing the internal ring, but for large hernias, the incidence of postoperative seroma swelling, pain, and equivalency is high. In addition, the literature reported that in the treatment of direct hernia under laparoscopy, the direct hernia cyst was eliminated by suturing the internal ring, which significantly reduced the incidence of postoperative seroma and did not increase the risk of postoperative infection, pain, or recurrence (15–17). A few reports on Gilbert type III indirect hernia and scrotal hernia stated that the incidence of seroma can also be reduced by closing the inner ring (11). For the cases of Gilbert type III indirect hernia and scrotal hernia prone to seroma and pain after surgery, it is assumed that the internal ring can also be closed to reduce complications.

Therefore, we randomly divided patients with Gilbert type III indirect hernia into a closed group and a non-closed group in a prospective study. Under the same basic conditions of the two groups, it was found that the operation time of the closed group with internal ring defect closure was longer than that of the non-closed group with unclosed hernia ring defects, which was related to the need for an inner ring closure during operation in the closed group. The suturing of the inner ring mainly involves injury to the vas deferens, genitofemoral nerve, spermatic cord, and inferior abdominal vessels. The suture location is in the upper part of the joint tendon and the lower iliopubic bundle. The suture depth should not be too deep in order to avoid injuring the nerves. A U-suture through the inferior epigastric vessels with a loose and tight compression of the spermatic cord led to scrotal swelling and even testicular ischemic necrosis, and inner ring suture relaxation did not affect the closed inner ring (11, 18). Therefore, the operation time of the experimental group was longer, but the average time was controlled within 15 min, which had no effect on the anesthetic effect of the patients. The choice of suture can include inverted thorn sutures and slow absorption sutures. Our center chooses slow absorption sutures because the cost is relatively economical and applicable, and there is basically no difference in the total operation cost between the two groups. After the TAAP/TEP operation, a normal diet was given 8 h after the operation, and the VAS score of pain on the first day after the operation was approximately 3. A few patients were given oral painkillers to relieve symptoms. Patients with type III hernia and scrotal hernia usually have a long history, especially elderly individuals, with more basic diseases and more urinary retention incidence after operation. At the same time, a few patients have other complications, such as intestinal obstruction, nausea, vomiting, and card incision bleeding. All of these complications had resolved and returned to normal after symptomatic treatment and observation. Therefore, there was

no significant difference in postoperative hospital stay or the incidence of short-term postoperative complications between the two groups, and the patients were satisfied with the outcome after the operation.

Although laparoscopic surgery produces less postoperative pain than open surgery, postoperative pain in the operative area is a common complication after laparoscopic inguinal hernia repair with an incidence of approximately 2%–20% (18, 19), which is one of the main reasons affecting the quality of life of patients who underwent surgery. We found no significant difference in the pain incidence and VAS score between the two groups on the first postoperative day, while with the prolongation of postoperative time, the pain incidence and the VAS score in both groups showed a continuous trend of reduction after surgery, reflecting the physiological changes secondary to the patients' gradual recovery and pain reduction after surgery. This process is one of the advantages of laparoscopic inguinal hernia repair. However, the incidence of pain was significantly higher in the control group than in the experimental group at 7, 14, and 21 days after surgery, and the VAS scores of postoperative pain were also found to be higher in the control group than in the experimental group at 7 and 14 days after surgery. In our practice of inner ring closure, the structures of blood vessels and spinal cord are constant and obvious and can be easily avoided. Although the nerves are not easy to see and their positions are different, these two groups of nerves [the GFN and lateral femoral cutaneous nerve (LFCN)] pass under the iliac pubic tract and through the transverse abdominal muscle to reach the inguinal box. The suture is only placed between the iliac pubic tract and the joint tendon. The direction of the suture is basically parallel to the nerve, and the suture needle is visible to avoid reaching too deep. This also avoids the risk of pain caused by suturing the inner loop (11, 19, 20). There are various causes of postoperative pain. In addition to the pain that may result from surgical procedures, changes in the volume of seroma effusion after surgery can also cause varying degrees of pain (21).

The incidence of seroma after inguinal hernia surgery has been shown to be one of the most significant complications, ranging from 0.5% to 12.2% after TEP, 3.0% to 8.0% after TAPP, and up to 80% in type III and scrotal hernias (22). The factors influencing the development of seroma are multifaceted, and patients with a long medical history or large hernia sacs are at high risk for seroma development. Also, this also occurs in patients with underlying diseases such as diabetes mellitus, hypertension, or low protein levels in the body, which reduce the ability of tissue regeneration and the efficiency of absorption of inflammatory substances. The main mechanism for the development of seroma is the inclusion of the peritoneum of the wall of the hernia sac stump, obstruction of lymphatic flow and reduced absorption of the open hernia sac, inflammatory exudation secondary to the trauma of herniorrhaphy, and the continuous secretion of fluid after surgery due to the foreign body stimulation of the surgical wound by the patch, as well as the low position of the open hernia sac, so that the fluid accumulates and is difficult to absorb in the short term, forming a seroma (5, 23, 24).

The occurrence of postoperative seroma affects the outcome of surgical repair and leads to postoperative pain, infection, and recurrence. Most inguinal hernias of types I and II are self-absorbing after surgery. However, type III and scrotal hernias have large postoperative hernia sac stump and a high incidence of seroma, and one problem to be solved is the reduction in the incidence of seroma and the amount of fluid accumulation (25). In the available reports, whether the hernia sac is transected or not has not been shown to be effective in reducing the incidence of seroma and the amount of fluid accumulation, which can be prevented in the short term by giving prophylactic placement of a drainage tube in the trabecular cavity, but after removal of the drainage tube, the seroma reappears. Therefore, at present, the only way to reduce and prevent seroma is to aspirate the effusion to treat the symptoms at the time, and there is no real effective way to reduce and prevent it (8, 26, 27).

Closing the hernia ring in direct hernia repair has proven to be effective in preventing postoperative seroma. By closing the inner ring, we found that on the 7th, 14th, and 21st days after surgery, the incidence of seroma cases was significantly lower than that of the non-closed group, and on the 7th and 14th days after surgery, the cumulative amount of seroma fluid in the non-closed group was also significantly higher than that in the closed group.

Interestingly, through experimental data, we found a correlation between the incidence of postoperative pain, VAS scores, and the incidence of seroma tumors in the two groups of patients. The seroma and pain incidence rates in the non-closed group were significantly higher than those in the closed group with internal ring closure at 7, 14, and 21 days postoperatively, and the VAS scores and seroma volume in the non-closed group were simultaneously higher than those in the closed group at 7 and 14 days postoperatively. With the extension of the postoperative time, the postoperative pain and seroma in both groups gradually decreased without differences. Therefore, we can preliminarily conclude that there is a significant relationship between postoperative pain and seroma for large indirect hernia or scrotal hernia repair, and there is a positive correlation between postoperative pain, seroma, and fluid accumulation. The seroma in the stump space cannot be absorbed automatically within a short period of time and gradually accumulates, leading to pain and discomfort in the inguinal region. When seroma tumors occur and the fluid volume decreases, the postoperative pain is significantly alleviated and disappears.

Conclusion

Laparoscopic closure of the internal ring in Gilbert type III inguinal hernia is safe and effective, especially in reducing the occurrence of postoperative seroma and alleviating postoperative pain. In addition, after closure of the internal annulus, as in strengthening the posterior wall of the inguinal box, a lightweight large mesh patch can be placed, even without fixation, to further reduce postoperative pain and other postoperative complications

and to improve the experience of care without increasing the cost of patient care.

Data availability statement

The original contributions presented in the study are included in the article; further inquiries can be directed to the corresponding authors.

Ethics statement

The studies involving human participants were reviewed and approved by the medical ethics committee of The Second Clinical Medical College of North Sichuan Medical College [no: 2021 annual review (016)]. The patients/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

All authors listed have made substantial, direct, and intellectual contribution to the work and approved it for publication. 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.

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Innovation in gastrointestinal surgery: the evolution of minimally invasive surgery—a narrative review

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Background: Minimally invasive (MI) surgery has revolutionised surgery, becoming the standard of care in many countries around the globe. Observed benefits over traditional open surgery include reduced pain, shorter hospital stay, and decreased recovery time. Gastrointestinal surgery in particular was an early adaptor to both laparoscopic and robotic surgery. Within this review, we provide a comprehensive overview of the evolution of minimally invasive gastrointestinal surgery and a critical outlook on the evidence surrounding its effectiveness and safety.
Methods: A literature review was conducted to identify relevant articles for the topic of this review. The literature search was performed using Medical Subject Heading terms on PubMed. The methodology for evidence synthesis was in line with the four steps for narrative reviews outlined in current literature. The key words used were minimally invasive, robotic, laparoscopic colorectal, colon, rectal surgery.
Conclusion: The introduction of minimally surgery has revolutionised patient care. Despite the evidence supporting this technique in gastrointestinal surgery, several controversies remain. Here we discuss some of them; the lack of high level evidence regarding the oncological outcomes of TaTME and lack of supporting evidence for robotic colorectalrectal surgery and upper GI surgery. These controversies open pathways for future research opportunities with RCTs focusing on comparing robotic to laparoscopic with different primary outcomes including ergonomics and surgeon comfort.

KEYWORDS
laparoscopic, robotic, minimally invasive, colorectal (colon) cancer, rectal cancer

Introduction

Minimally invasive (MI) surgery has revolutionised surgery, becoming the standard of care in many countries around the globe. Observed benefits over traditional open surgery include reduced pain, shorter hospital stay, and decreased recovery time (1). Gastrointestinal surgery in particular was an early adaptor to both laparoscopic and robotic surgery (1).

This narrative review was carried out in accordance with the four steps outlined by Demiris et al. (2). Within this review, we provide a comprehensive overview of the evolution of minimally invasive gastrointestinal surgery and a critical outlook on the evidence surrounding its effectiveness and safety.

History of laparoscopic surgery: a brief timeline

One of the earliest documented instances of minimally invasive (MI) surgery was around 460–375BC, where Hippocrates used an apparatus with structural similarities to endoscopes to examine the rectum under direct vision (3). In 936–1013AD a natural light source was incorporated into early endoscopic tools by Albukasim (4). Whilst there were several changes in the years to come, it wasn't until the invention of the light bulb by Edison in 1,880 endoscopic instrumentation changed significantly (5).

George Kelling, a surgeon in Dresden, attempted the very first laparoscopy in 1901. The technique, named Koelioscopie, entailed inserting a cystoscope through a trocar into a dog's abdominal cavity and insufflating oxygen (5). Kelling reporting of 45 laparoscopies (5), generated worldwide interest in laparoscopic techniques, including at the John Hopkins Hospital, where in 1911, Bertram Bernheim introduced laparoscopy to the United States (6).

In 1924, Zollikofer decided to use carbon dioxide (CO2) instead of atmospheric air for pneumoperitoneum. The rationale was that CO2 reduced discomfort as it is absorbed more easily by the human body, and is less combustible than air, facilitating the use of heat (7).

The next milestone was in 1929 when German physician Heinz Kalk invented a new lens which allowed him to view internal organs obliquely. Combined with the dual trocar puncture technique he developed, he achieved improved organ visualisation and passage of instruments into the peritoneum. Kalk subsequently published over 21 papers reporting laparoscopic operations on patients (6, 8).

In 1938, Janos Veress invented a needle, to help induce pneumothoraces as a treatment for tuberculosis. This was a spring-loaded, blunt needle bearing a cover which sprung forward to conceal a sharp needle in response to alteration in pressure as it entered the pleural cavity. Today the Veress needle is used to induce pneumoperitoneum in the abdominal cavity (8).

At this point in time, increasing interest in laparoscopy brought about rapid advancements for both equipment and operational technique surgery in the next decades- The invention of the "cold light" illuminator with the use of fibreglass in 1952 by Fourestier, Gladiu and Valmiere, eased concerns as it eliminated the occurrence of intraperitoneal burns caused by previous light sources (9, 10).

By the 1960s, laparoscopic surgery was widely used in gynaecological surgery. Kurt Semm, a German gynaecologist, designed an automated insufflator to closely monitor intra-abdominal pressure, increasing the procedure's safety and disposing of the need for a syringe to establish pneumoperitoneum (11). Semm also introduced thermocoagulation in laparoscopy and popularised procedures such as laparoscopic omental adhesiolysis, tumour biopsy, uterine perforation repair, endometrial implant coagulation and bowel suturing (6, 8). He was the first surgeon to perform a laparoscopic appendicectomy in 1983 (12).

In 1986, technological advances allowed for the projection of video camera images onto video screens (8). A laparoscopic cholecystectomy performed by Phillipe Mouret in 1987 was considered to be the first procedure during which this technology was used (10).

Laparoscopic colorectal surgery

Jacobs et al. (13) performed the first laparoscopic-assisted colectomy in 1991. This was significantly more technically challenging compared to other MI operations performed around the same time period.

MI colorectal surgery was initially reserved for benign disease due to reported high port site seeding (21%) in colorectal cancer resections (14). This concern was later refuted with high-quality studies which demonstrated a rate comparable to open surgery in the area of 0.6–1.1% (15–18). Landmark randomised controlled trials (RCTs) were therefore designed to compare the oncological results of open vs. laparoscopic colorectal surgery (19, 20). In particular, the UK multicentre CLASICC trial (20) demonstrated similar short-term outcomes of 30-day mortality, lymph-node harvest, and oncological clearance as well as a long-term outcome of 10-year recurrence rates when comparing laparoscopic assisted to open groups (21). Further trials and meta-analyses demonstrated similar conclusions (21–27), providing evidence that laparoscopic surgery was feasible and safe.

It is to be noted that transverse colon and rectal cancer cases were excluded from some of these trials (19, 22, 25), which limited the generalisability of the conclusion to these patient groups. The introduction of new surgical techniques such as Total Mesorectal Excision, inspired a number of studies to compare MI and open approaches for these groups (28–30). COLOR II assigned adult patients with cancer up to 15 cm from the anal verge to laparoscopic vs. open surgery and cautiously concluded that laparoscopic in selected patients with rectal cancer performed by skilled surgeons demonstrates similar safety and oncological results to that of open surgery and does provide enhanced recovery (28).

Another landmark trial was the COREAN trial, which focused on mid and low rectal cancers after neoadjuvant chemotherapy (29). It demonstrated similar disease-free survival outcomes, whilst the 10-year follow-up trial confirmed the long-term oncological safety of laparoscopic surgery in this patient population (30).

ALaCaRT (Australasian Laparoscopic Cancer of the Rectum) and ACOSOG Z6051 Randomized Controlled Trial (31, 32), failed to demonstrate non-inferiority of laparoscopic surgery compared to open rectal cancer surgery for completion of resection and disease free survival and recurrence respectively. Although these findings are often misinterpreted in the literature as demonstrating inferiority of laparoscopic surgery, the results

are merely inconclusive (33). Nevertheless, the misinterpretation of the two RCTs did create some concern regarding about the oncological outcome of laparoscopic total mesenteric excision (laTME) (33).

TaTME

Transanal TME was proposed to address concerns raised for laTME (34). This involved dual transabdominal and transanal/bottom-up dissection, with the expectation that it will diminish the technical difficulty of TME in narrow male pelvises, in obese patients (35). Several studies have shown TaTME to be safe (36–43), however authors expressed concern regarding the quality of the evidence this judgement was based upon (44, 45). These concerns escalated to the Norwegian moratorium for the technique in 2020. This was based on the high complication and local recurrence rates reported after a national audit (45). This looked at 157 patients who underwent TaTME; local recurrence rate was 7·6 per cent, eight local recurrences were multifocal or extensive. Eleven of 131 patients with an anastomosis (8·4%) had an anastomotic leak compared with 56 of 1,230 (4·5%) in the Norwegian Gastrointestinal surgery registry (45). These concerns were echoed by ACPGBI in the UK, recommending a "pause for reflection" (46).

Subsequent systematic reviews, although based largely on non-randomised studies, showed similar short (47) and long term oncological, functional outcomes (48–50), quality of life (QoL) (49) and complications (47, 50).

Laparoscopic upper gastrointestinal surgery

Since Mühe performed the first laparoscopic cholecystectomy in 1985 (11), the use of laparoscopic techniques has seen a rapid expansion in upper gastrointestinal (GI) surgery. Cholecystectomy is now one of the most frequently performed laparoscopic procedure worldwide (51). Meta-analyses have demonstrated laparoscopic cholecystectomy to be equivalent to both open (52) and mini-open (52, 53) techniques for operative outcomes, while reducing patients' post-operative hospital stay and recovery time.

Laparoscopic surgery for upper GI malignancy has been utilised since the early 1990s with ever increasing scope as operative techniques and laparoscopic technology improve (54). Staging laparoscopy has been demonstrated to be an effective tool in aiding treatment and decision making in a wealth of upper GI cancers, while remaining a low-risk operation for the patient (55).

The first laparoscopic gastrectomy for malignancy was reported by Kitano et al. (56) in 1994, using a laparoscopically assisted technique requiring a mini-laparotomy to perform the anastomosis. Advantages proposed for this included reduced post-operative pain, improved nutrition and return to normal intestinal function, and reduced pulmonary complications. While their subsequent RCT did demonstrate successes in blood loss and wound size (57), there was no significant difference in time to return to oral nutrition or hospital stay. Larger trials have since shown improved post-operative morbidity with laparoscopic assisted surgery while maintaining similar oncological outcomes (58). The largest of these trials, the KLASS-01 (59) demonstrated no significant difference in survival rates between open and laparoscopically treated gastric cancer across 1,416 patients. More recently, total laparoscopic gastrectomy has been shown to be a safe alternative to both laparoscopically assisted and open gastrectomy. The main barrier is operative difficulty in achieving successful reconstruction of the GI tract (60).

Open operative management of oesophageal cancer has been the standard of care worldwide, however is highly invasive with associated morbidity due to the use of a thoraco-abdominal approach (61). The first MI oesophagectomy (MIE) was reported in 1992 by Cushieri et al. (62) utilising a right thoracoscopic approach. In a 115 patient RCT, Biere et al. (63) demonstrated reduced pulmonary complications, blood loss, and hospital stay in the MI approach group. However, operative time was significantly increased, with 14% of cases requiring conversion to open surgery. The ROMIO (Randomised Oesophagectomy: MI or Open) trial is an ongoing RCT comparing MIE with open oesophagectomy, with 526 participants undergoing analysis for operative outcomes (49). While multiple surgical approaches exist within the MI umbrella, there is no consensus on the optimal approach (64, 65).

Natural orifice transluminal endoscopic surgery and single port laparoscopic surgery

Natural orifice transluminal endoscopic surgery (NOTES) builds on the idea of MI surgery promoting scarless, completely non-invasive procedures that do not require any skin incision. The first appendicectomy without an incision of the skin was performed transgastrically by Reddy and Rao in 2004 (66) with the first NOTES cholecystectomy being performed by Marescaux et al. (67) as recently as 2007. Although some isolated human cases of NOTES have been performed, the development of this technique is still in its infancy and has not been accepted as a routine general surgery procedure at present.

A compromise between NOTES and traditional laparoscopic practice is SILS. 1997 saw the first ever single port laparoscopic surgery (SILS) laparoscopic cholecystectomy performed by Navarra et al. (68) in which they inserted 2 trocars into the umbilicus, bridged only by a small strand of fascia which was then divided to aid gallbladder removal. Unlike NOTES, SILS does not accomplish totally non-invasive surgery. SILS does however aim to further minimise invasiveness by making a single abdominal incision to perform an operation via only one access point (69). Research continues into perfecting the technique and establishing it as a new gold standard for various operative procedures.

The reports on colonic surgery NOTES are from experimental settings, clinical studies were not employed due to worrying levels of complications observed in non-clinical projects (70). Conversely, there was a high level of enthusiasm concerning single-port colonic

surgery. However, a number of studies set out to assess the potential impact, showed no significant benefit compared to "traditional" laparoscopic surgery (71–73).

Robotic surgery

Robotic surgery introduced three-dimensional vision output, instrumentation with a significantly higher degree of movement freedom compared to laparoscopic instruments. This came hand-to-hand with increased cost and use of rather sizable pieces of equipment (74, 75).

The Arthrobot was the first robot to assist in surgery in 1983, manipulating the position of the patient's leg on voice command in arthroscopic surgery (76). Following this, robotic-assisted surgical procedures gradually began to emerge. In 1985 the Programmable Universal Machine for Assembly (PUMA) was used to orient a needle for CT brain tumour biopsies in adults (77) and thalamus astrocytomas in children (63), procedures normally suffering errors from unavoidable hand tremors. Three short years later, the PROBOT was used to perform the first robotic-assisted transurethral prostate resection at Imperial London College (78). The precision of robotic-assisted surgery was later applied in orthopaedic surgery with the ROBODOC which was found to be more effective than human hands to hollow the femur in preparation for total hip arthroplasty, avoiding common complications (79).

The Automated Endoscopic System for Optimal Positioning (AESOP), a voice-activated camera assistant, was introduced in 1994 as the first FDA-approved laparoscopic camera holder. Using the AESOP, the ZEUS surgical system used two additional robotic arms and a control console, allowing the benefit of a more ergonomic position for the surgeon (80). Following this, ZEUS was introduced clinically, with notable success in harvesting left internal mammary arteries for coronary artery bypass grafts (81). In 2001, the Lindberg Operation took place where surgeons Jacques Marescauz and Michel Gagner successfully remotely completed a laparoscopic cholecystectomy between New York City, USA and Strasbourg, France using ZEUS (82). However, delays between the control and operating station are notable reasons as to why telesurgery does not have more widespread success.

The da Vinci Surgical System was launched in 1997 and became the first FDA-approved comprehensive robotic system for laparoscopic surgery in 2000, with widespread applications in a variety of surgical fields. This offered the same degree of freedom as the human arm and slowly moved the surgeon further from the patient (80, 83).

Robotically assisted surgery has found a role in many surgical specialities and has allowed for the possibility of fully automated surgical operations. The Smart Tissue Autonomous Robot (STAR), designed at John Hopkins University, performed the first autonomous intestinal anastomosis in 2022 on porcupines over a one week period (84). The results indicated that the automated system outperformed expert surgeons' and robot-assisted surgery in terms of both consistency and accuracy, demonstrating the intricacy of robotics and the potential future of robotic surgery.

Robotic colorectal surgery

Robotic colorectal surgery is becoming increasingly more common due to benefits including dexterity and accessibility, particularly in lower rectal cancer. The first robotic colectomy was performed in 2002 (85). By 2004, D'Annibale et al. (86) reported 52 cases including 10 rectal cases, concluding that similar operative and post-operative results were achieved with robotic and laparoscopic techniques.

In 2006 the first 6 cases of robotic TME were documented (72). Rawlings et al. (73) in 2007 reported 17 robotic right hemicolectomies and 13 anterior resections, concluding that robotic surgery is feasible and safe. A similar outcome was reached by Spinoglio et al. (87) in 2008 who compared 50 robotic resections to 161 laparoscopic operations.

A systematic review in 2014 assessed robotic surgery for rectal cancer (88). According to this report, robotic surgery demonstrated prolonged operative time compared to laparoscopic surgery and no difference in blood loss and oncological effect (positive circumferential margins and number of retrieved lymph nodes). Conversion rates to open surgery were found to be smaller for robotic surgery. Additionally, the substantially higher cost of robotic surgery and the lack of evidence regarding long-term oncological and functional outcomes were highlighted. A second systematic review by Milone et al. showed the robotic approach to be better in achieving a complete TME. However, no randomised controlled trials were included in their analysis (89).

The multicentre ROLARR trial (90) randomised 471 patients with rectal adenocarcinoma to robotic-assisted and conventional laparoscopic surgery. The primary outcome was conversion to open laparotomy and robotic-assisted laparoscopic surgery was found to not significantly reduce the risk of that. There was no significant difference in intraoperative or postoperative complications, 30-day mortality, or circumferential margin positivity.

Robotic upper gastrointestinal surgery

Robotic-assisted upper GI surgery is a rapidly advancing field, due to benefits including providing a high degree of instrument freedom and stabilising the surgeon's tremor. However the current evidence base does not yet fully support its widespread use or justify the associated expense (91).

In 1997, the first robotic cholecystectomy (RC) was performed, marking the first use of the da Vinci Surgical System (83, 92). The current standard of care for the removal of the gallbladder is laparoscopic cholecystectomy (93). A recent systematic review has shown low rates of complications and comparable post-operative outcomes for RC vs. laparoscopic in the elective setting (94). However more studies are needed to assess more complex gallbladder disease outcomes. Several studies have also demonstrated that RC is effective and safe for general surgeons as a tool for robotic surgery training (92, 95).

Robotic-assisted MI oesophagectomy (RAMIE) was introduced in 2003 as a safe and viable option for oesophagectomy. The ROBOT

RCT (96) showed that RAMIE yielded comparable oncologic outcomes to open oesophagectomy, with superior rates of surgically related postoperative complications, lower median blood loss, improved functional recovery at postoperative day 14, and better quality of life at discharge and at 6 weeks post-discharge. Long-term survival analysis showed that overall and disease-free survival was comparable, supporting the use of robotic surgery in oesophageal cancer (97). Additionally, Yang et al. (98) showed that RAMIE yielded shorter operation time with improved lymph node dissection compared to MIE, with no difference in complications including vocal cord paralysis, anastomotic leak, pulmonary complications, blood loss, and conversion rate. Long-term survival data from this trial is currently awaited. Further, a systematic review supports the use of RAMIE showing comparable mortality and reduced morbidity rates, however, operative time was found to be longer in patients receiving RAMIE compared to MIE (99).

Conclusion

The introduction of minimally surgery has revolutionised patient care. Despite the evidence supporting this technique in gastrointestinal surgery, several controversies remain. Here we discuss some of them; the lack of high level evidence regarding the oncological outcomes of TaTME and lack of supporting evidence for robotic colorectal surgery and upper GI surgery. These controversies open pathways for future research opportunities with RCTs focusing on comparing robotic to laparoscopic with different primary outcomes including ergonomics and surgeon comfort.

Author contributions

Writing—original draft: JW, BH, AM, SG, JK, and MY. Writing—reviewing and editing: JW, CB, JT, IC, SD, and MY. All authors contributed to the article and approved the submitted version.

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MY is an NIHR Academic Clinical Lecturer and JK is an NIHR Academic Clinical Fellow.

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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Surgical training in the Caribbean: The past, the present, and the future

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The six million inhabitants of these diverse English-speaking Caribbean countries are grateful to the University of the West Indies, which has been central in the independent training of surgical specialists in all areas of surgery for the past 50 years. Similar to the per capita income, the quality of surgical care, albeit acceptable, is quite variable throughout the region. Globalization and access to information have revealed that the quality of training and surgical care being delivered can be further improved. Technological advances will perhaps never be on par with higher-income countries, but collaborative ventures with global health partners and institutions can ensure that the people of the region will have appropriately trained surgical doctors and, therefore, the provision of accessible quality care will remain a staple, with even the possibility of income generation. This study reviews the journey of our structured surgical training program delivered in the region and outlines our growth plans.

KEYWORDS

surgical training, collaboration, assessment, open surgery, laparoscopy

The past

The University of the West Indies (UWI), having been initially established as the University College of the West Indies under the aegis of the University of London in 1948, received its charter as a full university in 1962. Its main initial function was to provide medical practitioners to serve the needs of the Caribbean. Prior to its inception, bright young talents from the Caribbean were sent on scholarships for their medical training, mostly in the UK, with a few receiving this training in North America, to return. Others were recruited to serve in the Caribbean from these developed countries or India. Patients requiring specialist surgical care relied on a small cadre of specialist surgeons who also received their training in the UK or North America. This model of providing specialists for the region proved challenging to maintain because those trained in the USA found it financially more rewarding to stay there, while those who were successful in the Fellowship of the Royal College of Surgeons (FRCS) examinations were not always trained for consultant appointments. Additionally, those actually receiving specialist training often got trapped in the UK with the advantages of first-world living, and few made a permanent return trip to the underserved Caribbean population (1).

The stage was therefore set, and not surprisingly, the Caribbean governments urged the UWI to develop specialist training in all of the major specialties of medicine to the level of consultant. In 1967, the postgraduate doctor of medicine (DM) programs were conceptualized and commenced at the Mona Campus, with the first graduate in child health in 1973 followed by internal medicine and psychiatry in 1974.

This year (2022) marks the 50th anniversary of the start of postgraduate surgical training in the Caribbean. It had its beginnings in 1967 with the WHO/Pan American Health Organization (PAHO) Commission discussions, and subsequently, the first group of residents was admitted for general surgical training in 1972 (1). In the following year (1973), an otorhinolaryngology training program was implemented. Orthopedic surgery was soon added. The 1980s saw slow growth with high attrition rates, but with the advent of the 1990s, changes in the program directorship and challenges induced by the UK joining the European Union saw an increased interest in the program. The subspecialties of urology, cardiothoracic surgery, neurosurgery, and pediatric surgery were added, and soon afterward, there was the expansion of formal surgical training across the various campuses of the UWI with the introduction of various DMs in Trinidad and Tobago, Barbados, and The Bahamas. The turn of the millennium also saw the addition of ophthalmology (2012) and plastic surgery (2016) as the two most recent addition to our residency program. Today eight subspecialist areas provide training in addition to general surgery (Tables 1, 2).

The next step is the planned introduction of various fellowship programs such as in thoracic surgery, surgical endoscopy, and colorectal surgery.

The first three decades of its existence saw the various DM programs being present only at the Mona Campus of the UWI, with the majority of training taking place at the University Hospital of the West Indies, a few other tertiary hospitals that were accredited for training by the UWI governance body, and the Medical Faculty's Specialty Board in Surgery. This board is usually chaired by the department's head or a senior faculty and reports through the dean to the university's Board of Graduate Studies and Research. For various reasons outlined above, including the success of and wider acceptance of the program, the period of the 2000s saw the various campuses adopting and introducing postgraduate training in surgery disciplines, with general surgery commencing at the Saint Augustine Campus in 2005, Cave Hill Campus in 2012, and School of Clinical Medicine and Research, The Bahamas, in 2014.

TABLE 1 Surgery programs at the University of the West Indies.

Surgery	
General	1972 (as masters)
	1981 DM
Urology	1993
Cardiothoracic	1993
Neurosurgery	1991
Pediatric surgery	1998
ORL	1974
Orthopedics	1984
Emergency medicine	1997
Ophthalmology	2012
Plastic surgery	2016

TABLE 2 General surgery graduates from the UWI by campus.

Campus	Number of graduates
Bahamas	2
Cave Hill	16
Mona	46
Saint Augustine	20

Over the past 50 years, the various DM surgical programs from Mona had produced 46 general surgeons; 12 ophthalmologists; 20 neurosurgeons; 12 ear, nose, and throat (ENT) surgeons; seven cardiothoracic surgeons; 20 urologists; 30 orthopedic surgeons; and 12 pediatric surgeons, and our most recent graduates are three plastic surgeons. Our graduates offer consultant care at the UHWI and all the public hospitals in Jamaica and throughout the Caribbean as far south as Guyana and north as The Bahamas. In addition, they can currently be found on fellowships in the UK, Australia, and Canada, while a few occupy staff positions in the UK and North America.

The DM in general surgery at the Saint Augustine Campus was adapted from the program out of the Mona Campus with an identical structure and identical university examination process. It is accepted as a specialty degree that qualifies the successful candidate to be conferred on the Specialist Register of the Medical Board of Trinidad and Tobago and allows independent practice in the field of general surgery throughout the Caribbean. At Mona, postgraduate specialty training was traditionally sought in the UK and the USA, but these spaces have become quite competitive in recent times, hence the need to introduce postgraduate training in surgery at the Saint Augustine Campus. The environment in 2005 was indeed ripe at the time with the leadership of the UWI, and the recognized need was in sync with the focused goal of introducing this program. The program initially commenced with six candidates in 2005 at San Fernando General Hospital. It was expanded to Eric Williams Medical Sciences Complex, Mount Hope, in 2012 and the Port of Spain General Hospital. At each teaching site, a senior UWI surgery faculty facilitated the implementation and took charge of the leadership.

Since its inception in 2005, 87 candidates have entered the DM surgery program, 32 of whom (37%) were females. Of these 87 candidates, 20 (23%) have successfully exited the program and are now specialists capable of independent practice within the health service. Of these 20 specialist general surgeons, nine have completed fellowships abroad. Fellowships were in the areas of vascular, hepatopancreatobiliary, breast, advanced laparoscopy, and interventional endoscopy. Of these graduates, seven are consultants, two of whom are academic staff of the University of the West Indies. There are currently 19 active candidates in the DM General Surgery Program at the Saint Augustine Campus dispersed throughout the 5-year program, with 13 in the Part 2 phase and the remaining six in the Part 1 phase. Of these current 19 candidates, 12 (63%) are female. This is in marked distinction to the 37% females on entry from program inception and the contrast of 8% females in the first half of the program's existence to 48% in the second half of the program's existence. Of the 11 candidates who voluntarily withdrew from the program before the Part 1 examinations, only two were males.

The Cave Hill Campus has graduated 16 candidates from the DM General Surgery Program thus far. Of these 16, one

completed a fellowship in breast surgery, one in vascular surgery, one in hepatopancreatobiliary surgery, one in advanced laparoscopy, and two in renal transplant.

The School of Medicine and Clinical Research at The Bahamas commenced postgraduate training in general surgery in 2014, and free exchange is encouraged with the Mona Campus, especially in the basic sciences at the pre-Part 1 level. To date, they have graduated three general surgeons including one who has gone on to complete a fellowship renal transplant.

The present structure of the program

Today, the various DM surgery programs on all campuses offer a robust curriculum on par with those of North America or Europe with competency-based clinical training supplemented by didactic evidence-based tutorial sessions and certified skills-based workshops conducted in a simulated environment with the occasional wet labs. Our residents are encouraged to teach medical students and also participate in clinical research with many graduates having published in recognized regional and international journals.

The structure of the program needed a few changes over the last 50 years. It is a competitive program, and candidates are selected after a careful interview with considerations including their grade point average (GPA), clinical interest, research, and publications and references. Successful candidates then spend the first 2 years acquiring a solid foundation in the basic sciences of anatomy, physiology, pathology, and general surgery, by means of 3-monthly rotations in the disciplines of general surgery (9 months), orthopedics, neurosurgery, cardiothoracic surgery, urology, and pediatric surgery. During this period, the residents receive interactive lectures and tutorials in the basic sciences and research methods. All residents are encouraged to do the ATLS course prior to completing Part 1 of the program at the end of the first 2 years. In addition, there are mandatory workshops such as the recently introduced Laparoscopic Surgery Skills for Surgeons (LSSS) modeled after the SAGES course and others that led to the introduction of laparoscopic surgery throughout the Caribbean and a sustainable Laparoscopic Basic Skills Course as facilitated by the Caribbean College of Surgeons and the Royal College Surgeons of England (RCSEng) (2, 3). The Saint Augustine Campus of the UWI is an approved site for the RCSEng Intercollegiate Basic Surgical Skills course. At the Mona Campus, most of the skills workshops are delivered in the CHASE Carnegie Surgical Skills Laboratory based at the Department of Surgery. The CHASE Carnegie Skills Laboratory allows our residents to practice various surgical techniques including microsurgery in a simulated environment and is made accessible during their personal time. This was necessary as it was generally acknowledged by both residents and faculty as the need to increase training opportunities in minimally invasive surgery (4, 5).

Our residents are expected to be proctors in gross anatomy to our medical students and informal teaching to the medical students are encouraged. The first 2 years culminate with written and oral examinations in the basic sciences of anatomy, physiology, pathology, and principles of surgery (Part 1 examinations). The successful candidates then continue their training to spend another 3, 4, or 5 years depending on their chosen area of specialization. All residents undergo an assessment process at regular intervals to assess their progress in professionalism, communication, patient care, knowledge, and scholarly activity to identify strengths and weaknesses. Candidates are mentored during their training and are "signed off" by their supervisors as being technically competent, having high ethical standards, and exercising good leadership and judgment prior to being allowed to do their exit Part 2 examinations. Their expectations and responsibilities are increased in the apprenticeship manner much reminiscent of traditional surgical training. The dependence on and technological advances in surgery over the more recent decades have not been met by a proportionate increase in budgetary support (6) resulting that the more recent additions of neurosurgery, urology, cardiothoracic surgery and ophthalmology, and plastic surgery intrinsically have a mandatory elective period for the residents to experience surgery in a high volume first world site to enhance their training. These residents usually leave for their elective with excellent clinical acumen and work ethics and are usually good ambassadors to surgical training in the region. This elective has served these programs well with the added benefits of research collaboration and networking for fellowship training for academic surgeons.

The candidate must also participate in research activities. This now takes the form of case reports on 10 surgical cases and a clinical research project, with earlier candidates producing a "Book of 20 Case Reports." This book must be reviewed and certified acceptable by three independent examiners before the candidate is allowed to proceed to the final DM exam. The DM Part 2 final examination is a combination of written essay-type questions as well as a grueling 90 min oral exam. Examinations are conducted twice per year by a board of regional examiners, and these are headed by a university examiner and an invited external examiner, usually a full professor of surgery from North America or Europe. The rigor of our exit examination has been praised by all external examiners as being fair and robust, with candidates being able to demonstrate their knowledge and capabilities, on par with their own training programs. The external examiners' reports often provide good feedback to the university faculty and are used for validation of the various programs. This is in addition to feedback from external faculty when our graduates are reaccepted for fellowship or are employed as consultant staff throughout the region. While this feedback is into quality improvement, a formal system of quality assurance and feedback from trainers and trainees is lacking.

The future of surgery and surgical training in the Caribbean

The Caribbean surgeon prior to the start of our own residency programs generally would have done undergraduate medical education at the UWI and then to the USA or more commonly

the UK to train in surgery and then return to practice. This still happens in a limited manner, but by far the majority of surgeons who remain in the West Indies are trained in the Caribbean (some with a fellowship training of 1–2 years externally during or after residency). The advantage of the external experience is tremendous and extremely important for the establishment of new procedures and standards (7), even if the differences in resources in being trained in a developed world university and working in a resource-restricted environment provided by most Caribbean hospitals can be challenging. Notwithstanding this fact, the future of surgery in the Caribbean is bright. The success of the DM program has resulted in adequate numbers of surgeons distributed throughout the region, even though other countries were affected by inequality of the rural–urban distribution. The prospects for surgery in the region are demonstrated by the number of UWI DM graduates who have gone on to do fellowships in the subdivision of general surgery and have returned to work in and train the next generation of Caribbean surgeons. This is facilitating a gradual move away from a multispecialist surgeon to a superspecialist surgeon. At most of our teaching hospitals, the colorectal surgeon now performs procedures in the treatment of rectal cancer, and our hepatopancreaticobiliary team performs the Whipples procedure or major hepatic resections. While most of our graduates are equipped to perform everyday laparoscopic resections, such as for cholecystitis, appendicitis, and right hemicolectomy, our more advanced procedures such as bariatric surgery are confined to a few surgical teams distributed across the region.

The overall landscape of surgical care and therefore the need for more training are not without its challenges. The Caribbean exposure provides a wide range of pathology and late presentations. The patients present with more advanced diseases as programmatic screening programs are not present. Surgical exposure is quite good for residency training, especially for common conditions and trauma. The areas for strengthening include where the pathologies are less common and where highly specialized equipment is required. With lower volumes in these areas, the exposure for the residents may be lacking. Hence, the value of fellowships for a more concentrated exposure to these areas.

A further challenge is that the resident may attain the skills (for instance, robotics) and then return to the Caribbean where they are unable to practice these skills. There are limited intergovernmental arrangements for Caribbean patients from one island to get surgery on another island where the skillset and equipment may exist. This affects patient numbers, and a highly trained subspecialty surgeon may not be fully supported, which may lead to the surgeon seeking greener pastures in the first world. Another challenge rests with the significant costs to perform high-end surgeries in the private sector.

The working hour restriction which limits US residency programs as a result of the Bell Commission (8) is not much of an issue in the Caribbean, at least for the moment. The COVID-19 pandemic has brought to the fore the importance of working conditions and the mental health of our residents. This pandemic has further reduced the size of the globe with the online format of teaching, conferences, and other means of professional development made much more accessible. We are now benefiting from training with the use of electronic and augmented learning, simulation labs with online proctoring, and soon the introduction of virtual reality in our surgical training. Nevertheless, training and procedures requiring high capital demands, such as robotics, greater accessibility of minimally invasive surgery to all members of the population, and newer techniques such as endovascular repair of aneurysms, remain a challenge. Their solutions are being explored including the introduction of specialized centers providing high-quality surgical care with the possibilities of partnerships with leading centers, thus introducing exchange and external training with capacity building. These can be mutually beneficial as leading first-world universities explore the practice of better corporate social responsibility in this era of global surgery. Currently, minimal access surgery is not accessible to all patients within some countries and even in some entire countries in the Caribbean. As we expand and saturate the markets of the countries where residency training programs exist, it is expected that there will be an overflow of trained surgeons to the islands where this skill set is required.

So what might the true future of surgery and surgical training be like in the Caribbean? Or a better question, what would we like to see as the future of surgical training in the Caribbean? Over the next few years, the number of general surgeons will gradually be reduced, and we will have superspecialists for all areas. This growth rate will be a bit slower than that in the USA, but there will always be a role for the general surgeon, especially in rural areas. It is hoped that the many "toys" that exist in the first world today will also be available in the Caribbean. However, there must be a balance between conventional traditional approaches and highly specialized approaches such as robotics. Our feeling is that this balance will be preserved based on the costs associated with these at least for the next few decades. Better yet, the Caribbean exposure may be of interest to the first world with regard to the potential for rotations for residents who may not be used to seeing traditional open surgery.

The hope is that specialized referral centers will be established and there would be government arrangements in place to manage difficult cases in all islands making healthcare accessible to all. This will also address another challenge in the Caribbean with regard to residents in the four territories of the University of the West Indies not having ready exchange rotations among the islands. CARICOM Single Market and Economy is a first step in this direction, but financial arrangements will have to be put in place for these to happen. The resident rotations which do happen in an *ad hoc* manner may be an easier challenge to address.

In terms of training, it is expected that simulation labs will be commonplace and become a requirement for the acquisition of skills to allow for a smoother transition to the operating room. Regarding electronic learning, augmented learning, and virtual reality, the bottom line is again financial, but if the UWI is to stay in the game of training surgeons, this is a key investment. The leadership of the UWI in partnership with the various national or regional surgical bodies, including the Caribbean College of Surgeons, must see this as an imperative (9). There are various "low-hanging fruits," such as greater cooperation at

the postgraduate level, and not just examinations but, in fact, teaching and training. Didactic teaching sessions should be held simultaneously across the various teaching sites reducing costs and taking advantage of expertise. The COVID-19 pandemic has taught us that there are so many opportunities to use the Internet for education and training. Online proctoring has already been used in the Caribbean for assisting surgeons and will become more commonplace. This will also be the same for the surgical training of residents. Well-crafted training grants including partnerships with sister faculties from North America will provide training opportunities, and by building centers of excellence in various areas, they will be income-generating and increase opportunities for fellowship training, while expanding medical tourism, especially with the Diaspora as the intended target.

The Caribbean has always been considered too small to generate high-powered research. This false perception must change. We do have the materials and caseload as a combined unit to do multicenter randomized controlled trials. We may not have the resources or the skillset to do all of the work, but we have a more agile workforce and policies that will facilitate the research process. This is certainly an area that needs the right attention. We would have to work out common standards for a start, and these may be a bit different for our population as compared to the USA. The National Comprehensive Cancer Network (NCCN) has recently developed guidelines for the Caribbean in cancer care while the University Hospital of the West Indies and the Association of Surgeons in Jamaica published Guidelines for Selected Surgical Diseases (10). These are areas where guidelines specific to the Caribbean were developed by consensus and are being implemented. We must look at other regionally important surgical diseases such as gastrointestinal bleeding, diverticulitis, and diabetic foot care just to name a few.

Another area that is required and to which we must strive is the creation of an independent examination board for our graduating residents. As it exists now, we have a fairly rigid process using external examiners combined with regional examiners from campuses to which the student does not belong. Nevertheless, those are the same UWI lecturers who teach, examine, and award the professional degree. While this approach was initially necessary, the UWI should now be responsible for training and an examination body for licensure. Similar to the undergraduate medical degree, our postgraduate medical training should be accredited by the Caribbean Accreditation Authority in Medicine and other health professionals. Again, the partnership with the Caribbean College of Surgeons can provide a solution. This needs the buy-in of the UWI and also CARICOM. Additionally, surgical leaders in the region must participate and take advantage of established initiatives that will benefit the region, such as the Lancet Commission on Global Surgery and the Latin American Indicator Research Collaboratory aimed at increasing access to timely, high-quality, affordable surgical care, and data-driven surgical education and training, respectively (11, 12).

In conclusion, the Caribbean is proud of the quality of surgical training being delivered currently, and the leadership at the University of the West Indies is aware of its limitations. Investments in infrastructure are needed, and surgical fellowships in specialized areas will have to be created. Better distribution of human resources is needed, and greater cooperation with government and institutions external to the region has a role. Appropriately placed income-generating specialized centers of excellence meeting the needs of the region while facilitating research with first-world institutions is the ultimate goal. Thankfully, the leadership is aware and capable as our failure to act will stagnate the future of Caribbean surgery and surgical training. The people of the region deserve and will receive better.

Data availability statement

The original contributions presented in the study are included in the article; further inquiries can be directed to the corresponding author.

Author contributions

The authors listed here equally contributed to this final manuscript being submitted. 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.

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PRESS survey: PREvention of surgical site infection—a global pan-specialty survey of practice protocol

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Background: Surgical site infections (SSI) complicate up to 40% of surgical procedures, leading to increased patient morbidity and mortality. Previous research identified disparities in SSI prevention guidelines and clinical practices across different institutions. The study aims to identify variations in SSI prevention practices within and between specialties and financial systems and provide a representation of existing SSI preventative measures to help improve the standardization of SSI prevention practices.

Methods: This collaborative cross-sectional survey will be aimed at pan-surgical specialties internationally. The study has been designed and will be reported in line with the CROSS and CHERRIES standards. An international study steering committee will design and internally validate the survey in multiple consensus-based rounds. This will be based on SSI prevention measures outlined in the CDC (2017), WHO (2018), NICE (2019), Wounds UK (2020) and the International Surgical Wound Complications Advisory Panel (ISWCAP) guidelines. The questionnaire will include demographics, SSI surveillance, preoperative, peri-operative and postoperative SSI prevention. Data will be collected on participants' surgical specialty, operative grade, of practice and financial healthcare system of practice. The online survey will be designed and disseminated using Qualtrics^{XM} Platform^{TM} through national and international surgical colleges and societies, in addition to social media and snowballing. Data collection will be open for 3 months with reminders, and raking will be used to ascertain the sample. Responses will be analyzed, and the chi-square test used to evaluate the impact of SSI prevention variables on responses.

Discussion: Current SSI prevention practice in UK Vascular surgery varies considerably, with little consensus on many measures. Given the inconsistency in guidelines on how to prevent SSIs, there is a need for standardization. This survey will investigate the disparity in SSI preventative measures between different surgical fields and countries.

KEYWORDS

survey, surgical wound infection, surgery, practice, guidelines

1. Introduction

Over 300 million surgical procedures are performed annually worldwide (1). Up to 40% of surgical procedures are complicated by surgical site infections (SSI) (2–4). SSI rates vary by specialty, procedure, duration of the procedure and category of urgency. This variation may be due to differences in patient demographics across categories or underlying etiology of infection (5–7). Largely, SSI rates within RCTs report substantially higher incidences than nationally collected registries, owing to surveillance and diagnostic challenges within clinical practice. They are responsible for a substantial clinical burden, equating to one-third of all hospital-acquired infections (5). SSIs result in increased morbidity and mortality, with a 98% increased length of stay and a four-fold increased risk of readmission after discharge (3). Further, SSIs have a significant negative impact on the quality of life of patients, causing pain, immobility and psychological distress (8). SSIs require antimicrobial treatment, which can contribute to the development of antibiotic resistance (9). In addition, SSIs are associated with substantial healthcare costs due to protracted hospital stays, readmission, reoperation, pharmacological treatments, complex wound management systems and increased demands on staff resources (10). The true financial cost of SSI is likely to be underestimated due to wound surveillance challenges and limited access to outpatient services. However recent estimates suggest the cost to the NHS per infection is over £6103 (11).

In recent years, guidance on the prevention of SSI has been published by key organizations; National Institute for Health Care and Excellence (NICE), Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) (12–14). However, a national survey of UK Vascular surgeons conducted by our group identified disparity in recommendations across these guidelines, which was noted to be due to the lack of underlying evidence (15). This study found variability in SSI prevention practices across different institutions, as well as a lack of relevant registries, clinical perception and literature data for SSI rates (15). This follow-on survey aims to assess the barriers in establishing uniform practice including the development of registries. As wound infections can occur after every type of surgery, wherever in the world it may take place, the steering committee of the current project decided to disseminate the follow-on survey to surgeons from all specialties internationally.

2. Methods

2.1. Objectives

Primary objective:

- To identify the barriers to establishing standardized SSI prevention practice.

Secondary objectives:

- To identify intra- and inter-specialty variations in surgical site infection prevention practice.
- To identify variations in practice amongst financial systems such as state and privately funded healthcare systems and economical classifications.

2.2. Study design

This is an international, pan-specialty, collaborative cross-sectional survey. A global panel of experts will form the study steering committee (SSC), providing a consensus-based approach to survey development, validation, and distribution. This study will be reported in line with the checklist for reporting of survey studies (CROSS) and the checklist for reporting results of internet E-surveys (CHERRIES) (16, 17). Ethical approval is provided by the Hull York Medical School Ethics Committee (REF22-23 10).

To collect data, the survey will be delivered electronically online using the Qualtrics^{XM} Platform^{TM}, Utah, USA. The format will be designed to include a combination of binary, Likert or multi-select. Free text comments will be used to collect further detail but will be kept to a minimum to help ensure good completion rates.

2.3. Questionnaire development

A pilot questionnaire will be developed based on SSI prevention measures outlined in the CDC (2017), WHO (2018), NICE (2019), Wounds UK (2020) and the International Surgical Wound Complications Advisory Panel (ISWCAP) guidelines. Additionally, feedback from the survey of surgical site infection prevention practice in UK vascular surgery will be used to inform survey questions/design (12–14, 18, 19). Since the survey will be targeting participants across multiple specialties, it will only contain general prevention measures widely applicable. A draft survey will be provided in **Supplementary Material 1**.

The questionnaire will be structured into five sections; demographics, SSI surveillance, preoperative, peri-operative and postoperative SSI prevention domains. Data will be collected on participant surgical specialty, operative grade, country of practice and financial healthcare system of practice. SSI data will include criteria used for diagnosis. There were 15 perioperative domains formulated the UK questionnaire, which will be scrutinized against the CDC, WHO, NICE and ISWCAP guidelines outlined above by the SSC, to form a pilot questionnaire. The process of questionnaire development will be carried out through discussion by members of the SSC and a record of any question refinement will be documented. The number of questions will not be rigidly defined but the SSC will consider the impact on survey duration which can influence completion rates.

The pilot questionnaire will be distributed to at least two consultants of each surgical specialty; vascular, general, orthopedic and trauma, urology, plastic and reconstructive, cardiothoracic, neurosurgery and otolaryngology for multiple rounds of validation. After each round feedback will be analyzed by the SSC and consensus-based changes will be adopted. Any alterations will be done so on unanimous decision and documented as major (questions removed or added), and minor (wording alterations). The survey will be validated further in subsequent rounds until the SSC agrees no further alterations are required.

2.4. Sample characteristics

The survey will be sent out electronically to surgeons of any specialty and at all levels of training worldwide. This includes consultants, and surgical trainees (specialties registrars/residents). To be included in the study, surgeons must be currently practicing and be registered with the national surgical body/college/society. The validated online survey will be distributed through Qualtrics^{XM} for single-stage cluster sampling in addition to dissemination through social media, where snowballing may occur. Each network of distribution will provide a cluster, i.e., VERN for the vascular surgeons and PIACO group for general surgery. The study population will provide a representation of existing SSI preventative measures used worldwide.

Given the global nature of the survey, no sample size will be calculated. Raking will be used to assign weight values to each survey respondent in such a manner, that the weighted distribution of the sample is in very close agreement with two or more marginal control variables. Socio-economic (developing vs. developed countries) variables and surgical specialties will be used to weigh the sample of responses. As such, results will be able to be extrapolated into wider populations, irrespective of the distribution of responses received.

2.5. Survey administration

The survey will be advertised in weekly rounds, 1 month prior to dissemination using affiliated society social media accounts and the Surgical Infection Research Network Twitter account (@SIRNglobal).

The survey will be disseminated worldwide, with an international SSC to establish a network of distribution. The committee has been involved in previous successful surveys and collaborative projects through the PIACO group, the Vascular Endovascular Research Network (VERN), James Lind Alliance (JLA) and ISWCAP surveys (20–23). The committee will also identify new routes of distribution within this project. The validated online survey will be distributed using an electronic link. Participants will receive an email via their affiliated membership organization, inviting them to take part and will include a direct link to the online survey. Following the invitation, surgeons will have 3 months to complete the survey, with reminders sent every 2 weeks. The survey will also be promoted via social media platforms, using the SIRN Twitter account in addition to affiliated organization accounts. The "prevent multiple submissions" option in Qualtrics will be enabled to prevent multiple participation of participants. A secondary IP address check will follow to ensure there are no remaining duplicate entries. No two entries from the same IP address will be allowed within 24 h. After the data collection window, the survey will lock out, preventing further responses. Participants will be offered an opportunity to win a £20 Amazon voucher as an incentive to participate in the survey. Survey items will not be randomized to improve participation, as the logical order of each survey section was unanimously agreed by the SSC to improve the response flow. Adaptive questioning will be used depending on the following questions from a response. The number of items and screens or pages on mobile and personal computers will be reported in the manuscript write-up.

3. Discussion

Current SSI prevention practice in UK Vascular surgery varies considerably, with little consensus on many measures (15). SSI prevention guidelines recommended by international bodies (12–14), include over 15 generic methods of preventing SSIs. Some of them are supported by evidence from randomized control trials (RCTs), such as avoiding razors for preoperative hair removal and the decolonization with intranasal antistaphylococcal agents for high-risk procedures. Both methods have been shown to reduce the SSI rate. The use of the WHO surgical checklist leads to a lower SSI rate after its implementation. The exact mechanism of this is suspected to be multifactorial (6). Multiple guidelines (12–14) recommend using antiseptic skin agents, though specific recommendations vary. Using alcohol-based chlorhexidine reduces the risk of SSI compared with aqueous iodine (24). Body surface warming systems to maintain normothermia perioperatively have strong evidence in preventing complications of hypothermia and lowering SSI rates (25). Postoperative negative pressure wound therapy decreases SSI rates in vascular surgeries but was not associated with a statistically significant decrease in SSI rates in other surgical disciplines (6). Antibiotic prophylaxis is recommended by all

guidelines (12–14), RCTs focusing on vascular surgery demonstrated a significant reduction in SSI rate (26, 27). Although there are no RCTs on the effect of perioperative glycemic control and its impact on SSI rates, this is recommended in all major guidelines (6, 12–14). Retrospective studies do however confirm a higher risk of SSI rates in patients with postoperative hyperglycemia (6).

The incidence of SSI varies across surgical procedures, specialties, and conditions. Diagnostic and reporting challenges make true SSI rates difficult to capture. SSI rates are reported to vary from 0.1% to 40%. There are several patient- and procedure-related factors that influence the incidence of SSI. Patient comorbidities, advanced age, frailty and surgical complexity can increase the risk of developing an SSI. Additionally, prolonged duration and classification of the surgery are important procedure-related factors (28).

Given the inconsistency in guidelines on how to prevent SSIs, there is a need for standardization. This survey will investigate the disparity in SSI preventative measures between different surgical fields and countries. It will ascertain whether surgeons could feasibly participate in recruiting to platform randomized controlled trials assessing multiple interventions, including antibiotic prophylaxis.

3.1. Limitations

Reminders will be sent on a 2-weekly basis to increase the response rate and to prevent sampling bias. Additionally, the study will be advertised on its own Twitter account to gain attention. Response fatigue is a common issue, leaving some questions unanswered. To keep this to a minimum, the survey has been designed to only ask relevant questions and to be succinct, clear, and unambiguous.

Due to the nature of the study, there is room for responder and recall bias. To minimize this, questions wording and survey length have been considered carefully during all steps of the development of the survey. Questions will be categorized into SSI-related preoperative, perioperative, and postoperative themes to preserve the structure and enable ease of organization for respondents to follow.

Additionally, there may be discrepancies in the response rates between different countries, not providing an accurate representation of certain regions. There may also be different local/national guidelines and unequal access to certain resources depending on the geographical regions. As this survey will be delivered worldwide, questions are based on guidelines from the National Institute for Health and Care Excellence (NICE), Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO). These guidelines are internationally recognized and available, therefore discrepancies between geographical regions and differences in local guidelines should be kept to a minimum.

There is no standardized consensus recommendation on SSI prevention regarding perioperative practice. Unsurprisingly this can lead to a discrepancy in clinical practice, as shown by a questionnaire study within the UK (15). If international and pan-surgical SSI prevention practices also vary, guidance recommended by international bodies is not being followed. This may be due to the lack of underlying evidence for SSI prevention practice, and thereby the necessity for high-quality RCTs to establish the best practice for patients and surgeons worldwide.

Author contributions

Authors contributed to the following roles as per CRediT taxonomy; Conceptualisation: RL, JL, IC, MY. Methodology: JH, JW, JK, JL, DC, JT (6th author), KK, PL, LH, GS, BH, DG-O, DS, CB, JT (16th author), ML, RG, RL, IC, MY. Writing—original draft: JH, RL. Writing—review and editing: JH, JW, JK, JL, DC, JT (6th author), KK, PL, LH, GS, BH, DG-O, DS, CB, JT (16th author), ML, RG, RL, IC, MY. Visualisation: JH, RL, MY. Supervision: RL, IC, MY. Project administration: RL, MY. Funding acquisition: RL. 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.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fsurg.2023.1251444/full#supplementary-material

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Time for change: compliance with RCS green theatre checklist—facilitators and barriers on the journey to net zero

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Background: Climate change is an era-defining health concern, with healthcare related emissions paradoxically compounding negative impacts. The NHS produces 5% of the UK's carbon footprint, with operating theatres a recognised carbon hotspot. NHS England aims to become Net Zero by 2045. Consequently, UK Royal Colleges of Surgery have published guidance to foster an evidence-based sustainable transformation in surgical practice.
Methods: A single-centre quality improvement project was undertaken, aiming to provide an overview of sustainable practice locally. The Intercollegiate "Green Theatre Checklist" was taken as an audit standard, focusing on "preparing for surgery" and "intraoperative equipment" subsections. Any general surgical procedure was eligible for inclusion. Usage of reusable textiles, non-sterile gloves, catheters, antibiotics, alcohol vs. water-based scrub techniques, skin sterilisation choices, and skin closure materials were recorded. Baseline data collection occurred over a 3 week period, followed by dissemination of results locally via clinical governance meetings and poster displays. A re-audit of practice was conducted using the same methodology and duration.
Results: Datasets 1 ($n = 23$) and 2 ($n = 23$) included open ($n = 22$), laparoscopic ($n = 24$), elective ($n = 22$) and non-elective ($n = 24$) cases. Good practice was demonstrated in reusable textiles (trolley covers 96%, 78%, drapes 100%, 92%) however procurement issues reduced otherwise good reusable gown use in Dataset 2 in (90%, 46%). No unnecessary catheter use was identified, and loose skin preparations were used unanimously. Uptake of alcohol-based scrubbing techniques was low (15%, 17%) and unnecessary non-sterile glove use was observed in >30% of procedures. All laparoscopic ports and scissors were single use. Carbon footprints were 128.27 kgCO2e and 117.71 kgCO2e in datasets 1 and 2 respectively.

Conclusion: This project evidences good practice alongside future local focus areas for improved sustainability. Adoption of hybrid laparoscopic instruments, avoiding unnecessary equipment opening, and standardising reusable materials could reduce carbon and environmental impact considerably. Successful implementation requires considered procurement practices, improved awareness and education, clear leadership, and a sustained cultural shift within the healthcare community. Collaboration among professional institutions and access to supporting evidence is crucial in driving engagement and empowering clinicians to make locally relevant changes a reality.

KEYWORDS

climate change, surgery, sustainability, green, theatre

Introduction

Climate change is an era-defining concern, with varied and profoundly negative impacts (1). At 1.1°C of warming from pre-industrial averages, we are already witnessing the direct and immediate effects of this upward trend, including more frequent and severe weather events, increased morbidity and mortality across various health outcomes, and higher rates of vector-borne diseases (2). Ongoing global dependency on fossil fuel consumption is likely to see such trends continue, with existing policies putting the world on track for a 2.4–3.5°C rise by 2,100, far exceeding the 1.5°C target set by the Paris Agreement in 2015 (2).

Heath services contribute to 4%–5% of global greenhouse gas emissions. This is predominantly carbon dioxide, along with nitrous oxide, methane, and anaesthetic gases (1). Recognising the urgency of the situation, the United Nations Climate Change Conference (COP26) in 2021 outlined initiatives on climate-resilient and sustainable low-carbon health systems (3). Fifty countries committed to this action plan, with fourteen countries setting targets for achieving net zero emissions by 2050 (4). In line with these efforts, UK National Health Service (NHS) aims to achieve Net Zero emissions for both direct and indirect sources by 2045 through reducing the carbon footprint of healthcare services and promoting sustainable practices across all areas, including surgical settings (5). These targets, combined with the concerted efforts of healthcare professionals, policymakers, and researchers, demonstrate a collective commitment to driving positive change and promoting sustainability within the healthcare sector (6).

In response to these challenges, healthcare institutions are increasingly adopting sustainable practices to minimise their environmental impact. Operating theatres in particular are recognised as carbon and resource-intensive areas within hospital settings, contributing to 25% of carbon emissions despite less than 5% of inpatients undergoing surgery (7). To address this issue, the collaborative "Intercollegiate Green Theatre Checklist" has been developed, offering evidence-based guidelines for sustainable practice in surgical settings, and serving as an established benchmark for improving practice (8).

The aim of this quality improvement (QI) project is to comprehensively assess and implement sustainable theatre practices in a surgical setting, utilising strategies based on the "Green Theatre Checklist" to align with national targets. We will also use the Life Cycle Assessment (LCA) approach to map carbon emissions to evaluate the environmental impact of our interventions. The findings of this project will not only provide insights into the current state of sustainable practices in this clinical setting, but also offer valuable recommendations for healthcare institutions seeking to implement similar initiatives.

Methods

This initiative received local approval by the clinical effectiveness team at Bradford Teaching Hospitals. The framework of this article is reported in accordance with Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) (9).

Context

This single-centre QI project was undertaken in the Department of General Surgery at Bradford Royal Infirmary, Bradford Teaching Hospitals NHS Foundation Trust, UK. This busy teaching hospital surgery department provides Colorectal, Upper Gastrointestinal, and Emergency General Surgery to serve a population of around 500,000 people from the surrounding area (10).

The Intercollegiate "Green Theatre Checklist", collaboratively published by the Royal College of Surgeons of Edinburgh, Royal College of Surgeons of England, Royal College of Surgeons of Ireland and Royal College of Physicians and Surgeons of Glasgow, was taken as an audit standard. Outcomes based on the "preparing for surgery" and "intraoperative equipment" subsections were chosen. This decision was driven by a desire to look most closely at areas of influence and importance for clinical members of the operating team specifically.

A bespoke data collection form was created on Google Forms (**Supplementary Appendix S1**). No patient identifiable information was gathered. Demographic parameters for each recorded procedure included the responsible consultant surgeon, acuity (emergency, sub-acute or elective), open vs. laparoscopic methods, procedure title/description and the number of scrubbed

staff members within the sterile field. A QR code linking to the data collection form was disseminated to surgical trainees and use was encouraged during the data collection period. Baseline data was collected during a 3 week period between February and March 2023 prospectively by surgical trainees participating in each of the procedures.

Interventions

The results obtained from the initial data collection period were analysed and disseminated to the department during the local clinical governance meeting. As part of this process, education was provided to raise awareness about the environmental impact of the operating theatre. Additionally, posters illustrating the environmental impacts and promoting positive behaviour changes, in accordance with the recommendations outlined by the "Green Theatre Checklist", were prominently displayed in the General Surgery theatres (**Supplementary Appendix S2**). Following these interventions, a re-audit of practice was conducted over a 3 week period in May and June 2023 using the same method as the pre-intervention data collection period.

Sustainability criteria

Measured sustainability criteria included the number of reusable and disposable textiles (gowns, hats, trolley covers and drapes), number of staff performing alcohol based scrubbing techniques (as opposed to water/soap based techniques), catheter use, antibiotic use, use of reusable and disposable kidney dishes, choice of skin sterilisation method, choice of skin closure materials, observation of un-necessary glove use, use of sterile gowns around the theatre when not a performing a sterile task, and opening/disposal of unused equipment.

Carbon emission analysis

A LCA approach was used to map greenhouse gas emissions, in line with ISO 14,067 Guidelines (11) (emissions were reported as kilogram carbon dioxide equivalent (kgCO2e). Wherever possible, carbon footprint estimates were based on data from published, comprehensive life-cycle analyses, using bottom up methodology from UK based, up to date datasets (12–14). These estimates account for raw material manufacture, use, transport, associated packaging, laundering/sterilisation processes in the case of reusable items and eventual disposal. Life-cycle estimates were possible for most textiles and surgical equipment with the exception of trolley covers, scrubbing soaps, specialised equipment (e.g., purse string clamp) and antibiotics. For some of these items financial proxies have been used to produce top down figures. Alternative comparisons based on reduction or increase in resource use without specific carbon quantification have also been used where relevant e.g., % change in observations of unnecessary non-sterile glove use or water usage in litres resulting from water based scrubbing (15).

Assumptions and definitions

For elective and sub-acute cases, it was assumed that when disposable hats were worn, each staff member wore the same hat throughout a given ½ day operating session. For emergency cases it was assumed that a new disposable hat was donned for each new case. Where reusable garments such as hats and gowns are used, estimated lifespan was 75 uses—an average derived by life-cycle analysis source data via direct discussions with manufacturers. In the case of hats each "use" could account for up to 4 operations as it was assumed that hats were laundered on average after this many cases. The carbon footprint of reusables becomes smaller with increased uses over their lifespan.

Inappropriate non-sterile glove use was defined as glove use in the absence of potential contact with bodily fluid, mucous membranes, non-intact skin or specific infection control measures.

The use of alcohol based scrubbing techniques were deemed appropriate when being performed after at least one prior thorough water/soap based scrub, as per NICE guidance (16).

The average water consumption per water/soap based scrub was 18.5l (15) and carbon footprint of 1 litre of water was taken to be 0.00136927 kgCO2e (17).

Whilst variation in practice based on patient specific factors exists, for the purposes of this study indications for appropriate antibiotic use were a) the use of surgical implants or b) surgery on a contaminated site (16).

Results

Overall, 46 surgical procedures were assessed. Baseline data from 23 procedures, overseen by 8 consultants, with a mix of elective ($n = 16$) and non-elective ($n = 7$) General Surgical caseload were recorded over the initial period of 3 weeks in February and March 2023. There were 13 procedures, involving a total 53 scrubbed staff members, during which it would have been clinically appropriate to choose an alcohol-based scrubbing technique—i.e., not the first procedure of the day/session. The mean number of staff scrubbed per case over all 23 procedures was 4 (range 3–6).

Following education and poster displays, a further 23 procedures overseen by 7 consultants with a mix of elective ($n = 6$), non-elective ($n = 17$) General Surgical caseload were recorded over a period of 3 weeks in May and June 2023. There were 12 procedures involving 35 scrubbed staff members during which it would have been clinically appropriate to choose an alcohol base scrubbing technique—i.e., not the first procedure of the day/session. The mean number of staff scrubbed per case over all 23 procedures was 3 (range 2–5).

We summarised the operation characteristics for each data collection period in **Table 1**.

Section 7: reusable textiles

Hats

A total of 106 hats were used in the first data collection period, of which 2 (2%) were re-usable. During the second data collection

TABLE 1 Procedure descriptions arranged according to surgical approach (laparoscopic vs. open).

	Dataset 1 (*n*)	Dataset 2 (*n*)	Totals (*n*)
Laparoscopic procedures			
Laparoscopic cholecystectomy	8	1	9
Laparoscopic appendicectomy	2	2	4
Laparoscopic sleeve gastrectomy and cholecystectomy	1	0	1
Laparoscopic nissen fundoplication	1	0	1
Laparoscopic subtotal colectomy	1	0	1
Laparoscopic giant hiatus hernia repair	1	0	1
Laparoscopic inguinal hernia repair	2	0	2
Laparoscopic adhesiolysis	0	1	1
Laparoscopic converted to open bowel resection with ileostomy	0	1	1
Laparoscopic high anterior resection	0	1	1
Totals (laparoscopic)	16	6	22
Open procedures			
Epigastric hernia repair	1	0	1
Incisional hernia repair	1	0	1
Peristomal hernia repair	1	0	1
Open inguinal hernia repair	0	1	1
Umbilical hernia repair	0	1	1
Incision and drainage of abscess	0	8	8
Laparotomy and right hemicolectomy with anastomosis	0	1	1
Laparotomy and small bowel bypass	0	1	1
Laparotomy and adhesiolysis	0	1	1
EUA umbilicus and toilet	1	0	1
EUA and banding of haemorrhoids	1	0	1
EUA anorectum and manual disimpaction	0	1	1
EUA anorectum, abscess drainage and insertion of seton	0	1	1
Left groin lymph node dissection	0	1	1
Excision of papillomas	0	1	1
Reversal loop ileostomy	1	0	1
Total Gastrectomy	1	0	1
Totals (Open)	7	17	24
Totals (laparoscopic and open)	23	23	46

period 101 hats were used, $n = 18$ (18%) of which were re-usable. The carbon footprint of 1 disposable hat was estimated to be 0.00354 kgCO2e, whilst a reusable equivalent was 0.00366 kgCO2e. The carbon footprint for hats during data collection period 1 was 0.38 kgCO2e, and during data collection period 2 was 0.35 kgCO2e—this amounted to a 0.021 kgCOe reduction.

Gowns

Reusable gowns accounted for 90% ($n = 84$) of gowns used in the first data collection window, however this fell to 46% ($n = 33$) in the second. A reusable gown was estimated to have a carbon footprint of 0.253 kgCO2e per use compared to 0.649 kgCO2e for its disposable equivalent. The footprint from gowns in dataset 1 was 27.04 kgCO2e compared with 32.97 kgCO2e in dataset 2. Despite using 22 fewer gowns in total during the second data collection window, carbon footprint increased by 5.93 kgCO2e as a result of the higher proportion of disposables in use.

As well as gowns used within the sterile field, sterile gowns are sometimes donned informally outside this field as an extra clothing layer. In dataset 1, $n = 9$ gowns (8 reusable (2.02 kgCo2e), 1 disposable (0.65 kgCO2e)) were noted to be used in this way. In dataset 2, $n = 11$ gowns (7 reusable (1.77 kgCO2e), 4 disposable (2.60 kgCO2e)) were noted to be used in this way. Elimination of this practice would save 6.44 kgCO2e collectively.

Drapes

Reusable drapes were invariably used in the first data collection period (100%, 3.20 kgCO2e total), whilst in the second, a disposable drape was used in one procedure ($n = 1$) and a combination of disposable and reusable drapes were used in another ($n = 1$) with reusable drapes still being used in the majority of instances (91%) giving a total carbon footprint of 5.50 kgCO2e. This amounts to a net increase of 2.30 kgCO2e in the second data collection period.

Trolley covers

In the first data collection period 96% of cases ($n = 22$) made use of reusable trolley covers compared with 78% ($n = 18$) in the second. The carbon footprint of a disposable trolley cover was 0.740 kgCO2e. There was insufficient data for the calculation of reusable trolley covers.

Section 8: reduce water consumption and energy consumption

Overall water consumption was 1573l (2.12 kgCO2e) and 1203l (1.64 kgCO2e) in data collection windows 1 and 2 respectively. Uptake of the alcohol scrubbing techniques for eligible cases was 15% (8/53) during dataset 1% and 17% (6/35) during dataset 2, equating to 148l (0.2 kgCO2e) and 111l (0.15 kgCO2e) water and carbon savings respectively.

Section 9: avoiding clinically unnecessary interventions

Antibiotics

In both the first and second data collection windows there were $n = 2$ instances of antibiotics used without clear clinical indication, representing 20% (2/10) and 22% (2/9) of total antibiotic use respectively. The carbon footprint for antibiotic use in data collection periods 1 and 2 were 10.85 kgCO2e and 9.77 kgCO2e respectively. Elimination of non-indicated antibiotic use would reduce these totals by 2.17 kgCO2e each.

Catheters

13% ($n = 3$) of patients were catheterised for surgery in data collection period 1. This included patients undergoing laparoscopic subtotal colectomy, parastomal hernia repair and total gastrectomy. 17% of patients were catheterised for surgery in data collection period 2. This included patients undergoing laparotomy, right hemicolectomy and anastomosis, laparotomy and small bowel bypass, laparotomy and adhesiolysis and laparoscopic converted to open bowel resection with ileostomy. Catheter usage contributed 11.4 kgCO2e to the surgical carbon footprint of data collection window 1 and 15.2 kgCO2e to data collection period 2. In all cases where catheters were used patients were undergoing procedures of prolonged duration and as such all were deemed to be clinically appropriate.

Section 10: review and rationalise

In data collection period 1, $n = 14$ sutures (0.25 kgCO2e) were opened but unused. In data collection period 2, $n = 11$ sutures (0.2 kgCO2e), $n = 1$ sorbsan surgical packing ribbon (0.44 kgCO2e), $n = 2$ syringes (0.13 kg CO2e), $n = 2$ needles (0.007 kgCO2e) and $n = 1$ automatic purse string clamp (25.6 kgCO2e) were opened but unused, with a collective carbon footprint of 26.63 kgCO2e.

Section 11: reduce

Section 11 advises avoidance of unnecessary equipment e.g non-sterile gloves. Observation of unnecessary non-sterile glove use occurred in 34% ($n = 8$) of cases in the first data collection period, and 43% ($n = 10$) of cases in the second. Exact quantification of carbon footprint was not possible given the outcome metric used, however for context a 100 glove box represents 2.6 kgCO2e. Annual glove usage in NHS England and social care for 2020/21 was 5.5 billion (18).

Section 12: reuse

Kidney dishes and gallipots

We found that aside from 1 procedure in the first data collection window all kidney dishes and gallipots used were re-usable. Single use, individually packaged kidney dishes are estimated to have a 118 fold greater carbon footprint than reusable alternatives included as part of sterilised surgical trays; 0.073 kgCO2e and 0.00063 kgCO2e respectively. Assuming one kidney dish per case, current practice represents carbon savings of 1.58 kgCO2e and 1.65 kgCO2e over each data collection window compared with using only single use alternatives.

Laparoscopic equipment

The majority of laparoscopic equipment used was hybrid, however suction catheters, scissors and ports were identified as being single use. We were not able to identify sufficient information to compare suction catheter impact, however footprint estimates for single use scissors (1.14 kgCO2e) and ports (3.50 kgCO2e) amount to 74.14 kgCO2e ($n = 16$ laparoscopic procedures Dataset 1) and 27.80 kgCO2e ($n = 6$ laparoscopic procedures Dataset 2) respectively for current practice. Switching to procurement of hybrid scissors and ports could reduce this impact by 56.36 kgCO2e and 16.74 kgCO2e respectively over each data collection window.

Section 13: replace

We found that loose skin prep was unanimously used for all procedures in both data collection periods, however there was insufficient data to quantify a comparative carbon footprint.

We found that of the procedures involving skin closure in data collection window 1 ($n = 21$) 48% of these ($n = 10$) were completed using sutures, compared with 54% ($n = 7$) of procedures involving skin closure ($n = 13$) in data collection window 2. The carbon footprint of a stapler (0.37 kgCO2e) is 20 times that of a 3–0 absorbable monofilament suture (0.018 kgCO2e). The carbon footprint of skin closure in data collection window 1 was 4.23 kgCO2e. The carbon of skin closure in data collection window 2 was 2.34 kgCO2e. This is likely an underestimate of the sustainability savings associated with sutures over staplers, as it does not account for carbon, money or patient/staff time embedded in the required return to a healthcare centre for subsequent staple removal.

Total carbon footprint for all measured outcomes was 128.27 kgCO2e in dataset 1 and 117.71 kgCO2e in dataset 2 (Table 2). This is equivalent to driving 432 miles and 396 miles respectively in the average petrol car. If we fully optimised all potential sustainable changes currently available (full reusable textile use, full uptake of alcohol-based scrubbing techniques where appropriate, elimination of opened but unused equipment and non-indicated antibiotic use, switching from staplers to sutures and from single use to hybrid laparoscopic equipment) total carbon footprint could be reduced from 246 kgCO2e to 101 kgCO2e (Figure 1).

Discussion

Summary of findings

The sampled procedures in this quality improvement project offer a comprehensive representation of the varied caseload covered by the general surgical department. We included cases from both Colorectal and Upper Gastrointestinal sub-specialties, encompassing a mix of acuity levels and approach types (open vs. laparoscopic). Good practice was demonstrated in areas such as reusable textiles, avoiding unnecessary catheter use, and loose skin preparation use.

TABLE 2 Carbon footprints (kgCO2e) according to current practice in datasets 1 and 2, with combined totals over both data collection periods.

	1 item/ unit (kgCO2e)	Dataset 1 (kgCO2e)	Dataset 2 (kgCO2e)	Combined dataset total (kgCO2e)
Gowns in sterile field				
Disposable	0.649	5.842	24.668	30.511
Reusable	0.253	21.224	8.338	29.562
Gowns outside sterile field				
Disposable	0.649	0.649	2.597	3.246
Reusable	0.253	2.021	1.169	3.190
Hats				
Disposable	0.004	0.368	0.294	0.662
Reusable	0.004	0.007	0.066	0.073
Drape				
Disposable	1.290	0.000	2.580	2.580
Reusable	0.139	3.197	2.919	6.116
Trolley Cover				
Disposable	0.740	0.740	3.702	4.443
Reusable	–	–	–	–
Water (/L)	0.001	2.154	1.647	3.801
Catheter use	0.863	2.589	3.452	6.041
Antibiotic use (/dose)	1.085	10.846	9.761	20.607
Sutures	0.018	0.182	0.127	0.309
Staplers	0.368	4.049	2.209	6.258
Laparoscopic				
Ports	3.495	55.920	20.970	76.890
Scissors	1.139	18.224	6.834	25.058
Unused opened equipment				
Sutures	0.018	0.254	0.200	0.454
Packing material	0.445	–	0.445	0.445
Auto purse string clamp	25.600	–	25.600	25.600
Needle & syringe	0.069	–	0.137	0.137
Totals	–	128.268	117.714	245.982

Small improvements were made in adoption of alcohol-based scrubbing techniques however overall uptake remained low (15%, 17%) and unnecessary non-sterile glove use was observed in >30% of procedures. Further diverse and sustained interventions may be required to influence areas requiring a change in clinical decision making. This evidence can be used to direct local initiatives towards areas with the highest potential for positive impact, and can act as a baseline from which to measure change over time.

Findings in relation to current literature

The area offering the highest potential for carbon reduction as a single intervention going forward is the adoption of hybrid laparoscopic scissors and ports. This aligns with the observation that consumables account for 32% of operating theatre emissions (8). Hybrid laparoscopic instruments have been found to have a lower environmental impact compared to single-use equivalents, with an average reduction of 60% across 17 environmental impacts. Even when considering factors such as low instrument reuse, decontamination with separate packaging, use of fossil fuel-rich energy sources, or variations in carbon intensity during transportation, hybrid instruments still exhibited better environmental performance. Furthermore, the total financial cost of using hybrid instruments is less than half of that associated with single-use equivalents (19). Given the trend towards minimally invasive, often laparoscopic, techniques over open approaches, this is a particularly poignant area for consideration as its impact will only grow in years to come.

Another considerable saving could also be made by avoiding the opening of equipment that is subsequently discarded unused. The identification of equipment to be ready but unopened is already common practice at the time of briefing within surgical settings (20). Therefore, there may be fewer barriers to further emphasising the importance of adherence to this principle from an environmental, as well as an economical sustainability perspective compared with other changes.

Positive practices of note include the standardisation of reusable drapes and trolley covers, and the unanimous use of loose skin prep. When clinically appropriate choices exist, making these decisions at a procurement level allows the most cost-effective and sustainable choices to be embedded into clinical practice to maximum effect. For example, where supply arrangements are already established for reusables, e.g., in the case of reusable gowns, eliminating the procurement of disposable options would be a feasible step to rapidly and decisively minimise environmental impacts (21, 22). Furthermore, feedback and negotiation with manufacturers can lead to both carbon and financial savings e.g., reduction of excessive product packaging or removal of unnecessary items included within pre-prepared clinical packs (21). It is important to note however, that establishing reliable supplies and sufficient stockpiles is vital if a single procurement route is to be relied upon, as evidenced by the reduced usage of reusable gowns during the second dataset, which was due to temporary supply issues in at least 5 procedures.

While procurement decisions ensure the availability of sustainable resources, awareness and action regarding the judicious use of these resources by clinical staff remain crucial (6, 23). Healthcare professionals recognise climate change as a potential threat to human health and desire to effect positive change. Nevertheless, a high proportion perceive a lack of education and awareness regarding how climate change relates specifically to the healthcare setting, and what actions are appropriate to take, as a key barrier to implementation (21, 22).

Significant differences can be made when staff are educated and empowered to make more sustainable choices. "The Gloves are Off" campaign at Great Ormond Street Hospital (GOSH) NHS Trust in 2018 encouraged staff to make more considered risk assessments before reaching for non-sterile gloves (24). This led to a reduction of >36,000 gloves per week, equating to a saving of 21 tonnes of plastic over the subsequent year. They also observed reduced instances of dermatitis among staff, improved healthcare anxiety among patients and financial savings associated with both purchasing and disposal without any increase in hospital-acquired infections. Considering that an estimated 5.5 billion gloves are used

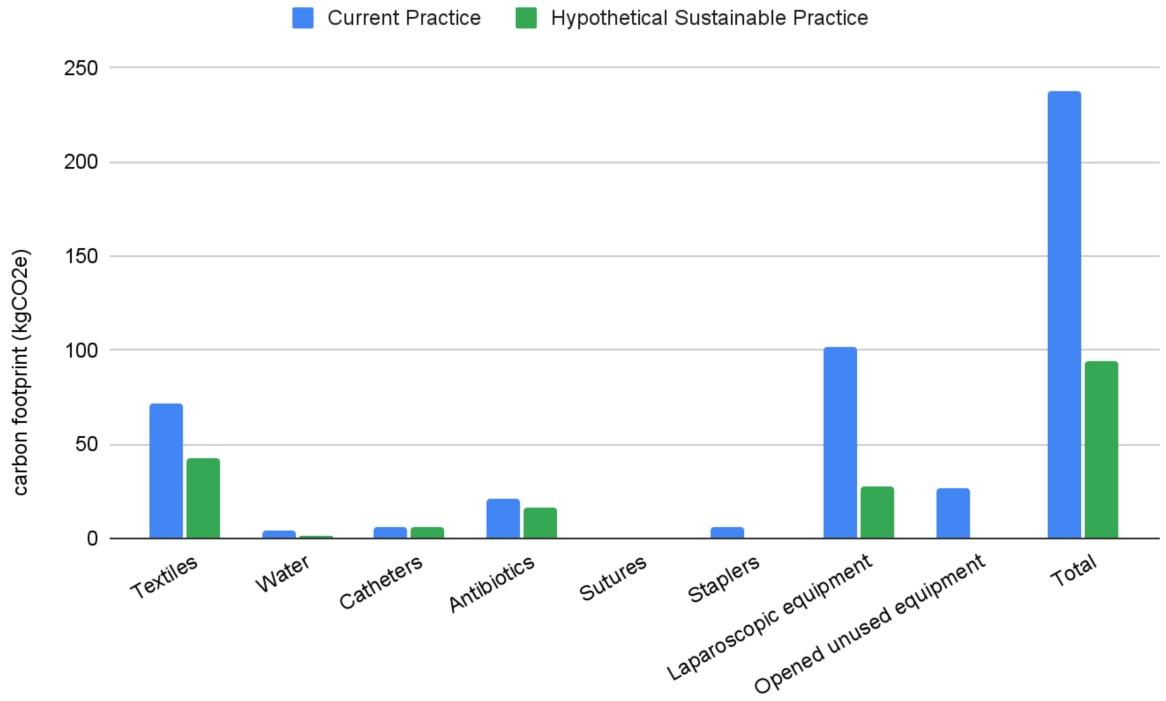

FIGURE 1
Barchart comparing relative carbon footprint of current practice compared to fully optimised, hypothetical "sustainable practice" scenario over the same time period.

across the NHS and social care sectors annually, scaling up such actions nationwide could have a huge potential impact (18, 24). Overuse of non-sterile gloves is a key area for potential improvement locally, however culture change is difficult. GOSH attests that it was only through varied and sustained education and awareness campaigns that they achieved these improvements (24). Furthermore, the normalisation of PPE use in all patient encounters during the COVID-19 pandemic could potentially make this shift more difficult (25).

"The Gloves are Off" campaign exemplifies how sustainable options often yield system-wide co-benefits (25–28). Sustainable development is the ability to meet the needs of the present without compromising the ability of future generations to meet their own needs (29). This encompasses economic and social factors, alongside the more widely recognised environmental aspects (28). Co-benefits are crucial for achieving a holistic definition of sustainable value, and can be a key facilitator for improving engagement. Demonstrating simultaneous financial savings or improvements in patient and staff outcomes, means changes are more likely to be embraced on a broader scale (30).

After engaging in conversations with staff members following the initial data collection period, it became evident that there was a lack of awareness and confidence in the alcohol scrub option, despite this being endorsed by NICE and its ready availability throughout operating theatres. If the remaining 73 out of 88 staff members across both datasets who used water-based scrubbing had chosen alcohol-based alternatives, an additional reduction in water usage of 1350l (equivalent to 1.87 kgCO2e) could have been achieved. As with glove use, the evolution in clinical decision making and establishment of new cultural and behavioural norms needed for successful uptake of practices such as alcohol-based scrubbing will require improved awareness, education, and clear, consistent leadership (16). Endorsement and support from professional institutions is a key facilitator in improving healthcare staff confidence in taking action on climate change (21). This emphasises the importance of visible national leadership and guidance from bodies such as NICE and the various Royal Colleges in empowering clinicians to embrace changes in the status quo, however this must be followed by dissemination and support at a local level for change to occur (6).

Future research and action

To enable clinicians to make informed decisions regarding the environmental impacts of their practices, it is essential to improve access to supporting evidence. For several outcomes, there was insufficient information to calculate environmental impact and carbon footprint. When accessible, information was obtained through open-source databases generated by public institutions or extrapolated from previously published research. Given their direct oversight in the manufacture and supply chain of consumables, the medical technology and pharmaceutical industries are ideally positioned to provide comprehensive analysis. As such, alongside advocating for further development of reusable and responsibly sourced technology, the surgical community should emphasise the need for the generation and transparent reporting of environmental impact data going forward (30).

With a forward-looking approach, we can consider the incorporation of artificial intelligence (AI) in healthcare. Proposed

sustainability-driven AI advancements include improvements in remote monitoring and telemedicine, self-care and prevention, and optimisation of resource allocation. However, the substantial carbon and resource demands of AI, particularly in its development stages, present a challenge. Although many promising use cases have been proposed, few have been successfully implemented at scale. Balancing these impacts against potential benefits is crucial, as is recognising the environmental and ethical issues linked to AI's hardware supply chains and inherent data biases. Making a careful and holistic cost-benefit analysis is vital to ensuring ethical and effective application (31–35).

Limitations

While both datasets were representative overall, the variability in the types of procedures captured in each dataset is likely to have influenced certain outcomes. For example, the higher number of emergency cases, particularly "incision and drainage of abscess" cases likely contributed to lower numbers of scrubbed staff in the second data set. These procedures also require no primary closure, affecting absolute values for carbon footprints from sutures/staples. This contextual variation should be taken into account when considering the resulting carbons footprints presented.

Due to practical constraints, the duration of data collection periods were necessarily short. Longer periods of data collection may have enhanced procedure comparability, increasing the probability that differences in carbon footprints were attributable to interventions made in the interim period. Despite this we feel this project lays the groundwork for demonstrating a feasible method for measuring environmental impact within our operating theatres. There is potential for it to be repeated at regular time intervals, monitoring progress chronologically, or used as a baseline from which single parameters could be isolated and explored in greater depth.

All interventions implemented as part of this audit underwent validation and evaluation by the Royal College of Surgeons of England, Edinburgh, Glasgow and Ireland during creation of the Green Theatre Checklist, including consideration of safety and clinical impacts. It was not within the scope of this project to further assess causality or association of clinical outcomes due to practical and resource constraints, however it could be a useful addition to future iterations of this work.

These results are not intended to provide a comprehensive analysis of the entire patient or procedure pathway. Non-clinical carbon sources, such as operating theatre energy consumption and ventilation systems, as well as clinical anaesthetic choices contribute considerably to overall footprint but were beyond the scope of this project. Therefore, findings should be interpreted within the context of the specific clinical practices examined. Anaesthetic gas and ventilation system related emissions contribute considerably to operating theatre emission profiles and future work considering their impact will be needed in order to holistically address whole pathway emissions. The accuracy of carbon footprinting is limited by extrapolation of data calculated within similar but non-identical settings, and the boundaries set for the project.

Conclusion

This quality improvement project highlights the potential for implementing sustainable practices within the general surgical department and establishes a foundation for continued efforts towards a more environmentally conscious and sustainable surgical environment. By focusing on areas such as the adoption of hybrid laparoscopic instruments, avoiding unnecessary equipment opening, and standardising reusable materials, significant reductions in carbon footprint and environmental impact can be achieved. The successful implementation of these practices requires improved awareness, education, leadership and a cultural shift within the healthcare community. Collaboration among professional institutions and access to supporting evidence is crucial in driving engagement and empowering clinicians on the ground to make locally relevant sustainable change happen.

Data availability statement

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

Author contributions

EW: Conceptualization, Data curation, Formal analysis, Methodology, Project administration, Writing – original draft, Writing – review & editing. JW: Writing – original draft, Writing – review & editing. KB: Data curation, Formal analysis, Methodology, Writing – original draft. WC: Writing – original draft. SD: Writing – original draft. HK: Writing – original draft. RL: Data curation, Formal analysis, Methodology, Writing – original draft. JW: Writing – original draft. SL: Supervision, Writing – review & editing. MY: 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.

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Suppementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fsurg.2023.1260301/full#supplementary-material

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Operating room nurse's awareness and implementation status of the prevention of patient's intraoperative acquired pressure injuries: design and validation of a questionnaire

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Aim: To compile the awareness and implementation status of patients with intraoperative acquired pressure injuries prevention by operating room nurses and to test its reliability and validity.
Design: This is an equipment development research based on recommendations for developing a reliable and valid questionnaire.
Methods: The research was carried out in two phases from February to November 2022. Through a panel discussion, expert consultation, and literature review, the questionnaire for operating room nurses on the current status of awareness and implementation of the prevention of intraoperative acquired pressure injuries was preliminarily formulated. The formal questionnaire was developed through validity analysis, reliability analysis and item analysis, and reliability and validity tests were conducted. Moreover, according to the questionnaire survey results, confirmatory factor analysis was carried out to construct the structural equation model.
Results: The initial questionnaire consisted of five dimensions with 48 items, which was finalized to five dimensions with 38 items after reliability and validity testing and analysis. The five dimensions included implementation of intraoperative acquired pressure injuries prevention, intraoperative acquired pressure injuries preventing cognitive conditions, preoperative intraoperative acquired pressure injuries preventing cognitive conditions, basic knowledge of pressure injuries, and implementation of intraoperative acquired pressure injuries prevention in special patients. Cronbach's α of the overall questionnaire was 0.969 while that of each dimension was 0.846–0.959. The KMO value of structural validity was 0.945 ($P < 0.001$), and the contribution rate of cumulative variance was 70.694%. The fitting of confirmatory factor analysis was found to be generally ideal: $\chi^2/df = 2.382$, $RMR = 0.027$, $TLI = 0.894$, $RMSEA = 0.072$, $IFI = 0.905$, $CFI = 0.904$.

Conclusions: The study and design of the questionnaire for operating room nurses on the current status of awareness and implementation of the prevention of intraoperative acquired pressure injuries are scientific and rational, providing a scientific basis for the standardized reform of hospitals and the optimization of the intraoperative acquired pressure injuries management system of the operating room.

KEYWORDS

intraoperative acquired pressure injuries, operating room nursing, cognitive conditions, status of implementation, instrument development, surveys and questionnaires, validation study

1 Introduction

The prevention of intraoperative acquired pressure injuries (IAPI) is an important part of operating room care, which is also a global health issue of great concern. Several objective factors, such as the position during operation, the methods of anesthesia; and patient factors, such as individual tolerance capacity (1). It may cause a range of psychological problems and prolonged hospitalization (2, 3). In addition, it will increase the cost burden of patients and healthcare systems to some extent (4). Combine risk assessment prevention and prevention strategies to increase the nurses' awareness of pressure injuries (PI), thereby reducing the incidence of PI (5). This study intended to design a questionnaire for nurses in the operating room on the cognitive and operational status of IAPI, investigate the current status of IAPI prevention, and provide specific assessment tools for further optimizing prevention and management.

2 Background

2.1 Basic concepts and characteristics of pressure injury

IAPI often occurs within 48 to 72 h after operation, which is characterized by acupressure pale erythema, purple skin, and blistering (6). Factors such as intraoperative hypothermia and long surgical immobilization time increase the incidence of IAPI. Studies have shown that most patients with PI of varying degrees will occur after the operation time is greater than 4 h, and the risk of PI increases by 33% for every 0.5 h increase (7).

2.2 Staging of pressure injury

The first staging system was recognized by Shea in 1975. Subsequently, in 1991, the International Association of Enterostomal Therapists (IAET) simplified and refined the system of Shea (8), however, PI is divided into four stages as before: ruddy bruising, inflammatory infiltrates, superficial ulcers, and deep ulcers. In addition, the National Pressure Ulcer Advisory Panel (NPUAP) staging system is the most widely used staging scale for PI, which was last revised in 2016 (9). Depending on the current understanding of the etiology of PI and the recent release of ICD-11 by the World Health Organization (WHO) in 2018, PI is classified into six stages in NPUAP: nonblanchable erythema of intact skin, partial skin defects with the exposed dermis, full skin defects, full skin, and tissue defects, obscured full skin and tissue defects and persistent nonblanchable erythema of deep tissue (10).

2.3 Development of questionnaires on the prevention of pressure injuries

At present, the most widely used pressure injury risk assessment scales include the Braden scale, the Norton scale, and the Waterlow scale. Although these scales have a good effect on the application process, there are also some disadvantages. The Braden scale is currently the most widely used pressure injury risk assessment scale in the world, and although it is good for predicting pressure injury, it is not suitable for surgical patients (11). In contrast, the Norton scale and the Waterlow scale are more suitable for use in the operating room, and the Waterlow scale is more comprehensive and requires higher expertise from the evaluator (12). Moreover, the CORN-IAPI scale evaluates surgical patients from three aspects: preoperative, intraoperative and postoperative, including 2 dimensions and 10 factors, which are defined by anesthesia risk classification, body mass index (BMI), skin condition of the pressure site, preoperative limb activity, planned operation time, high-risk diseases, factors of body temperature loss, brought in PI, surgical blood loss, pressure shear force change, actual operation time, and postoperative skin results, and the scale is being promoted for use in China and has been shown to be effective in the prevention of IAPI (13).

With the improvement of measures to prevent IAPI, it is significant to discuss the understanding and implementation of operating room nurses on the prevention of IAPI in patients. A review of the literature revealed that most of the current studies have focused mainly on IAPI preventive measures or IAPI treatment strategies, ignoring the importance of the operating room nurse in the process of preventing or treating IAPI (14). Although some studies have investigated the awareness of IAPI among OR nurses, there is no specific research instrument to measure it (15). Scholars have developed IAPI-related test papers to determine OR nurses' IAPI knowledge through the scores of the test paper, which is very limited. Firstly, the content of the test papers produced by different scholars is not the same, and the test papers have not been developed through scientific and standardized methods, which lacks reliability and validity. On the other hand, there is a lack of specific tools to measure the current status of IAPI implementation among OR nurses.

3 The study

3.1 Aim

The aim of this study was to develop a questionnaire for operating room nurses on the current status of awareness and implementation of the prevention of IAPI. Moreover, it provides a reference for further improving the preventive measures of IAPI.

3.2 Study design

This was a methodological study of scales conducted in a multi-centre (China) between February and November 2022. The study was conducted in two phases, the first involving the design and commissioning of the questionnaire, and the second phase including a formal validation process.

3.3 Sample/participants

In both phases, the subjects involved a sample of 530 operating room nurses from three 3-A-class hospitals in Shandong Province, which are regional hospitals that can provide high-level specialized medical and health services and perform higher education and scientific research tasks. Inclusion criteria were as follows: ① have a nurse qualification certificate; ② voluntary participation in this study; ③ professional nursing in the operating room. Exclusion criteria were as follows: ① unable to attend on time due to further education or vacation.

The principle of determining the sample size of this study was as follows: the number of nurses included is 5–10 times the number of survey items and the sample number is ≥100 cases; The sample size taken by the structural equation model is at least 200 cases, and for each additional variable, the sample size increases by 5–10 times on the basis of the independent variable.

3.4 Procedure

3.4.1 Preparation of questionnaires by operating room nurses on the awareness and implementation status of prevention of patient's acquired pressure injury during surgery

This study combined expert consultation method, literature analysis method and group discussion method to compile a questionnaire for operating room nurses on the cognition and implementation status of prevention of patient's acquired pressure injury. Through reviewing relevant literature at home and abroad, after intensive discussion by members of the research group, and combined with clinical post management measures, a questionnaire entry pool of 48 items in five dimensions including IAPI prevention implementation, IAPI preventive cognition, preoperative IAPI preventive cognition, basic knowledge of pressure injury, and special patient IAPI prevention implementation was preliminarily formed.

TABLE 1 Characteristics of the participants [phase 1 & phase 2; (n = 530)].

Item	n	%
Age		
≤25	104	19.6
26–30	128	24.2
31–35	166	31.3
36–40	90	17
>40	42	7.9
Gender		
Female	416	78.5
Male	114	21.5
Initial academic qualifications		
Secondary degree	72	13.6
Associate degree	124	23.4
Bachelor	326	61.5
Master's degree and above certification	8	1.5
Highest academic qualification		
Master's degree and above certification	26	4.9
Bachelor	490	92.5
Associate degree	10	1.9
Secondary degree	4	0.7
Professional title		
Nurse	114	21.5
Senior nurse	172	32.5
Supervisor nurse	232	43.8
Associate chief nurse	12	2.3
Level		
N0	2	0.4
N1	160	30.2
N2-1	94	17.7
N2-2	136	25.7
N3-1	102	19.2
N3-2	36	6.8
Whether or not a specialist team leader		
No	484	91.3
Yes	46	8.7
Specialist departments		
Gastroenterology	48	9.1
Hepatology	36	6.8
Joint surgery	20	3.8
Wound surgery	48	9.1
Hand and foot surgery	28	5.3
Spine surgery	16	3.0
Neurosurgery	34	6.4
Ophthalmology	22	4.2
Otorhinolaryngology	24	4.5
Oral surgery	14	2.6
Cardiac surgery	44	8.3
Thoracic surgery	36	6.8
Vascular surgery	26	4.9
Urinary surgery	40	7.5
Gynecology	40	7.5
Obstetric	12	2.3
Pediatrics	22	4.2
Liver transplantation	12	2.3
Robot	8	1.5
Post		
Surgical post	454	85.7
Logistics post	60	11.3
Management post	8	1.5
Other	8	1.5

(*Continued*)

TABLE 1 Continued

Item	*n*	%
Years of working experiences		
≤1	58	10.9
2–5	134	25.3
6–10	106	20.0
11–15	156	29.4
>15	76	14.3
Whether or not a subspecialty nurse		
No	402	75.8
Yes	128	24.2

The expert consultation method was used to conduct 2 rounds of expert consultation for 10 experts, and the questionnaire on the cognition and implementation status of the nurses in the operating room on the prevention of patient's acquired PI was revised, and the expert inclusion criteria were as follows: ① engaged in clinical nursing or nursing management in the operating room; ② voluntary and guaranteed continuous participation in the subject; ③ have more than 10 years of clinical work experience; ④ intermediate or above professional title; ⑤ bachelor's degree or above. The experts were contacted before issuing the letter inquiry form through e-mail or on-site distribution to obtain their advice, and eventually, a questionnaire of prevention of IAPI containing 45 items in five dimensions for the cognition and implementation status of operating room nurses was developed.

3.4.2 Reliability and validity test of the questionnaire of the operating room nurse on the prevention of patients' cognition and implementation status of intraoperative acquired pressure injury

The questionnaire of prevention of IAPI with five dimensions and 45 items to the cognition and implementation status of operating room nurses was verified through two stages. The first stage was as follows: operating room nurses from three 3-A-class hospitals in Shandong Province were selected to fill in the questionnaire for project analysis, reliability analysis and validity analysis. The questionnaire consisted of three parts: ① general profile of the study subject; ② purpose and description of the survey; ③ the main part of the questionnaire consists of 45 entries. A 5-point Likert scale was adopted for the 45 items. The higher the score, the clearer the understanding of the operating room nurse in the prevention of patient-acquired PI and the better able to implement it. Before the questionnaire is distributed, the research purpose and precautions were explained to the research objects. After the questionnaire was collected, the contents were carefully verified and incomplete questionnaires were eliminated. Based on the results of the initial questionnaire data analysis, the questionnaire was revised and entered the second stage. The second phase was as follows: operating room nurses from three 3-A-class general hospitals in Shandong Province were selected for the confirmatory factor analysis and structural equation construction. Nurses who had participated in the previous phase were excluded. Based on the research results, the questionnaire was revised, revealing a questionnaire of the prevention of patient's IAPI composed of five dimensions and 38 items that can be applied to the the operating room nurse's awareness and implementation status.

3.5 Statistical analysis

The data used are entered and proofread through Microsoft Excel. Demographic characteristics are described through descriptive

TABLE 2 The analysis results of the project analysis.

Title	Group mean score ± SD (%)		*T*-value	*P*-value
	Low score (*n* = 74)	High score (*n* = 72)		
Q1	3.4 ± 0.7	4.8 ± 0.5	−14.313	0.000*
Q2	3.3 ± 0.7	4.7 ± 0.5	−13.149	0.000*
Q3	3.2 ± 0.6	4.8 ± 0.5	−16.042	0.000*
Q4	3.2 ± 0.7	4.7 ± 0.6	−13.383	0.000*
Q5	3.8 ± 0.7	5.0 ± 0.1	−15.177	0.000*
Q6	3.6 ± 0.6	4.9 ± 0.4	−15.396	0.000*
Q7	4.0 ± 0.7	5.0 ± 0.0	−11.941	0.000*
Q8	3.8 ± 0.6	4.9 ± 0.2	−14.368	0.000*
Q9	4.0 ± 0.6	5.0 ± 0.1	−13.449	0.000*
Q10	3.7 ± 0.5	4.9 ± 0.3	−17.597	0.000*
Q11	3.7 ± 0.6	4.9 ± 0.3	−16.617	0.000*
Q12	3.8 ± 0.5	5.0 ± 0.1	−18.254	0.000*
Q13	3.5 ± 0.6	4.9 ± 0.3	−17.117	0.000*
Q14	3.8 ± 0.5	4.9 ± 0.3	−15.896	0.000*
Q15	3.6 ± 0.7	4.9 ± 0.3	−15.617	0.000*
Q16	4.1 ± 0.6	5.0 ± 0.0	−12.801	0.000*
Q17	4.0 ± 0.7	4.9 ± 0.4	−9.907	0.000*
Q18	4.0 ± 0.6	5.0 ± 0.1	−12.663	0.000*
Q19	3.7 ± 1.1	4.9 ± 0.4	−8.848	0.000*
Q20	4.1 ± 0.6	5.0 ± 0.1	−13.866	0.000*
Q21	3.8 ± 0.7	4.9 ± 0.3	−11.756	0.000*
Q22	4.0 ± 0.6	5.0 ± 0.1	−14.401	0.000*
Q23	3.7 ± 0.8	4.8 ± 0.5	−10.528	0.000*
Q24	4.0 ± 0.6	5.0 ± 0.0	−14.414	0.000*
Q25	3.9 ± 0.6	4.9 ± 0.4	−11.698	0.000*
Q26	3.9 ± 0.5	5.0 ± 0.0	−11.698	0.000*
Q27	3.7 ± 0.7	4.9 ± 0.3	−13.619	0.000*
Q28	3.8 ± 0.6	5.0 ± 0.0	−17.381	0.000*
Q29	3.6 ± 0.7	4.9 ± 0.2	−15.340	0.000*
Q30	3.9 ± 0.5	5.0 ± 0.0	−17.614	0.000*
Q31	3.9 ± 0.5	5.0 ± 0.2	−15.893	0.000*
Q32	3.9 ± 0.5	5.0 ± 0.1	−19.053	0.000*
Q33	3.9 ± 0.7	4.9 ± 0.4	−11.258	0.000*
Q34	3.9 ± 0.5	5.0 ± 0.1	−17.078	0.000*
Q35	3.9 ± 0.7	4.9 ± 0.2	−13.053	0.000*
Q36	4.0 ± 0.5	5.0 ± 0.2	−16.100	0.000*
Q37	3.8 ± 0.7	4.9 ± 0.3	−13.934	0.000*
Q38	3.9 ± 0.5	5.0 ± 0.2	−18.694	0.000*
Q39	3.7 ± 0.7	4.8 ± 0.6	−9.841	0.000*
Q40	4.1 ± 0.5	5.0 ± 0.0	−14.561	0.000*
Q41	4.0 ± 0.7	5.0 ± 0.2	−10.440	0.000*
Q42	4.1 ± 0.5	5.0 ± 0.2	−15.041	0.000*
Q43	4.0 ± 0.5	4.9 ± 0.3	−11.654	0.000*
Q44	4.1 ± 0.5	5.0 ± 0.0	−14.720	0.000*
Q45	4.2 ± 0.5	5.0 ± 0.2	−11.689	0.000*

*Indicated significance set at.01.

statistics, such as the average of continuous variables and the frequency of category variables. Date analysis was performed using IBM SPSS software version 26.0, such as project analysis and reliability analysis, with a significance value of p set at <0.05. In addition, AMOS 24.0 statistical software was used to validate factor analysis and construct structural equation.

4 Results

4.1 General profile information about the study subject

The questionnaire was revised in two stages and 530 valid questionnaires were received. Table 1 shows general information about participants in both phases.

4.2 Phase 1. Initial data analysis of the questionnaire

4.2.1 Item analysis

Project analysis is used to assess the effectiveness and applicability of questionnaire items. The principle is to summarize the conditions first, with the first 27% of subjects recorded as high and the second 73% as low. The T-test is then used to compare the difference between high and low-score groups. If there is a difference, the design of the scale item is appropriate. Otherwise, the scale item is indistinguishable from the information and the design is unreasonable. It should be deleted (16).

As can be seen from Table 2, high and low scores showed significance for Q1 to Q45 items ($p < 0.05$), indicating that all 45 projects were well differentiated and did not require the deletion of the analysis items.

4.2.2 Reliability analysis

Reliability analysis, which is primarily used to evaluate the reliability and accuracy of quantitative data answers, should be guided by the following principles: (1) the Cronbach α coefficient ≥0.8, indicating high reliability; (2) if Corrected Item-Total Correlation (CITC) ≤0.3, consider deleting the item; and (3) if the "deleted α coefficient" is significantly higher than the α coefficient, consider deleting the item and re-analyzing it. Details are shown in Table 3.

As can be seen from Table 3, the reliability coefficient value is 0.970, as it is greater than 0.9, indicating a very high reliability quality of the study data. For the "deleted item alpha factor", the reliability coefficient would increase significantly if Q19 and Q23 were deleted, so consider correcting or deleting them. For the "CITC value", all items meet the standard.

In summary, consider deleting Q19 and Q23.

4.2.3 Validity analysis

Validity analysis is used to determine the relevance of tool items to the concepts being assessed (17). Content validity and structural validity are selected for analysis in this study.

TABLE 3 Reliability analysis.

Title	Corrected item-total correlation (CITC)	Cronbach's alpha if item deleted	Title	Corrected item-total correlation (CITC)	Cronbach's alpha if item deleted	Cronbach's α
Q1	0.544	0.970	Q24	0.758	0.969	0.970
Q2	0.592	0.970	Q25	0.585	0.970	
Q3	0.605	0.970	Q26	0.769	0.969	
Q4	0.579	0.970	Q27	0.587	0.970	
Q5	0.665	0.970	Q28	0.792	0.969	
Q6	0.650	0.970	Q29	0.690	0.970	
Q7	0.651	0.970	Q30	0.750	0.969	
Q8	0.628	0.970	Q31	0.679	0.970	
Q9	0.688	0.970	Q32	0.770	0.969	
Q10	0.692	0.970	Q33	0.624	0.970	
Q11	0.666	0.970	Q34	0.765	0.969	
Q12	0.728	0.969	Q35	0.663	0.970	
Q13	0.708	0.969	Q36	0.741	0.969	
Q14	0.723	0.969	Q37	0.685	0.970	
Q15	0.707	0.969	Q38	0.766	0.969	
Q16	0.656	0.970	Q39	0.585	0.970	
Q17	0.530	0.970	Q40	0.735	0.970	
Q18	0.683	0.970	Q41	0.632	0.970	
Q19	0.483	0.971	Q42	0.562	0.970	
Q20	0.702	0.970	Q43	0.624	0.970	
Q21	0.556	0.970	Q44	0.594	0.970	
Q22	0.676	0.970	Q45	0.590	0.970	
Q23	0.474	0.971				

Standardized Cronbach's Alpha:0.973.

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TABLE 4 Results of validity analysis.

Title	Factor loading (Rotated)						Communality
	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6	
Q1	0.215	0.007	0.138	0.814	0.121	0.033	0.743
Q2	0.202	0.188	0.108	0.767	0.043	0.110	0.689
Q3	0.134	0.204	0.207	0.799	0.018	0.073	0.746
Q4	0.122	0.178	0.180	0.785	0.073	0.061	0.704
Q5	0.418	0.057	0.564	0.364	0.022	0.114	0.642
Q6	0.087	0.141	0.441	0.674	0.120	0.171	0.720
Q7	0.350	0.062	0.793	0.178	0.061	0.070	0.796
Q8	0.152	0.147	0.564	0.525	0.012	0.086	0.646
Q9	0.391	0.073	0.785	0.155	0.119	0.106	0.824
Q10	0.190	0.200	0.592	0.516	0.082	0.046	0.702
Q11	0.143	0.185	0.629	0.492	0.032	0.112	0.705
Q12	0.425	0.165	0.685	0.281	0.018	0.076	0.762
Q13	0.094	0.302	0.465	0.614	0.079	0.186	0.734
Q14	0.336	0.236	0.666	0.268	0.091	0.085	0.700
Q15	0.115	0.309	0.492	0.595	0.066	0.120	0.723
Q16	0.383	0.062	0.762	0.145	0.064	0.139	0.776
Q17	0.017	0.307	0.395	0.174	0.377	0.214	0.468
Q18	0.651	0.059	0.380	0.172	0.318	0.059	0.705
Q19	0.183	0.227	0.050	0.077	0.740	0.268	0.713
Q20	0.713	0.151	0.325	0.086	0.322	0.076	0.753
Q21	0.176	0.345	0.138	0.089	0.789	0.091	0.807
Q22	0.685	0.254	0.176	0.092	0.380	0.027	0.717
Q23	0.221	0.353	−0.001	0.089	0.751	−0.051	0.748
Q24	0.744	0.253	0.269	0.172	0.178	0.135	0.770
Q25	0.200	0.679	0.022	0.168	0.313	0.051	0.631
Q26	0.726	0.318	0.241	0.277	0.075	0.049	0.771
Q27	0.233	0.671	−0.046	0.307	0.139	0.057	0.623
Q28	0.688	0.418	0.235	0.241	0.068	0.110	0.778
Q29	0.266	0.737	0.087	0.279	0.140	0.080	0.725
Q30	0.678	0.422	0.288	0.130	0.034	0.094	0.748
Q31	0.348	0.647	0.180	0.089	0.242	0.099	0.649
Q32	0.680	0.420	0.280	0.133	−0.010	0.235	0.790
Q33	0.273	0.663	0.235	0.086	0.042	0.135	0.596
Q34	0.693	0.461	0.225	0.099	0.064	0.186	0.792
Q35	0.280	0.696	0.191	0.028	0.268	0.155	0.696
Q36	0.697	0.355	0.231	0.140	0.085	0.183	0.725
Q37	0.327	0.704	0.082	0.219	0.154	0.102	0.691
Q38	0.701	0.410	0.275	0.154	0.100	0.043	0.770
Q39	0.185	0.676	0.134	0.131	0.167	0.110	0.566
Q40	0.649	0.302	0.287	0.153	0.008	0.334	0.730
Q41	0.198	0.491	0.236	0.149	0.088	0.528	0.644
Q42	0.529	0.058	0.067	0.189	0.154	0.563	0.665
Q43	0.185	0.496	0.142	0.159	0.196	0.555	0.672
Q44	0.547	0.055	0.118	0.202	0.063	0.643	0.775
Q45	0.094	0.413	0.279	0.141	0.158	0.600	0.662
Eigen value (Unrotated)	20.890	4.058	2.814	1.591	1.377	1.265	-
% of Variance (Unrotated)	46.42%	9.02%	6.25%	3.54%	3.06%	2.81%	-
Cumulative % of Variance (Unrotated)	46.42%	55.44%	61.70%	65.23%	68.29%	71.10%	-
Eigen value (Rotated)	8.229	6.695	6.279	5.631	2.794	2.366	-
% of Variance (Rotated)	18.29%	14.88%	13.95%	12.51%	6.21%	5.26%	-
Cumulative % of Variance (Rotated)	18.29%	33.17%	47.12%	59.63%	65.84%	71.10%	-
KMO	0.946						-
Bartlett's Test of Sphericity	11,295.984						-
df	990						-
P value	0						-

The blue numbers in the table indicate that the absolute value of the factor loading is greater than 0.5.

TABLE 5 Total variance explained.

Component	Initial eigenvalues			Extraction sums of squared loadings			Rotation sums of squared loadings		
	Total	% of variance	Cumulative %	Total	% of variance	Cumulative %	Total	% of variance	Cumulative %
1	17.897	47.096	47.096	17.897	47.096	47.096	6.911	18.186	18.186
2	3.644	9.589	56.685	3.644	9.589	56.685	6.785	17.855	36.041
3	2.619	6.892	63.577	2.619	6.892	63.577	5.550	14.606	50.646
4	1.466	3.857	67.434	1.466	3.857	67.434	4.982	13.111	63.757
5	1.239	3.261	70.694	1.239	3.261	70.694	2.636	6.937	70.694
6	0.964	2.538	73.232						
7	0.795	2.093	75.325						
8	0.780	2.053	77.378						
9	0.677	1.781	79.159						
10	0.605	1.593	80.752						
11	0.553	1.456	82.207						
12	0.520	1.369	83.577						
13	0.498	1.311	84.887						
14	0.471	1.240	86.127						
15	0.438	1.154	87.281						
16	0.392	1.031	88.312						
17	0.372	0.980	89.292						
18	0.321	0.845	90.137						
19	0.312	0.821	90.958						
20	0.283	0.746	91.704						
21	0.279	0.735	92.439						
22	0.267	0.702	93.141						
23	0.251	0.660	93.800						
24	0.244	0.642	94.442						
25	0.229	0.603	95.045						
26	0.210	0.553	95.598						
27	0.203	0.534	96.132						
28	0.189	0.497	96.629						
29	0.177	0.467	97.096						
30	0.166	0.437	97.533						
31	0.151	0.397	97.930						
32	0.145	0.381	98.311						
33	0.139	0.366	98.677						
34	0.122	0.322	98.999						
35	0.116	0.305	99.304						
36	0.102	0.268	99.572						
37	0.093	0.244	99.816						
38	0.070	0.184	100.000						

Extraction method: principal component analysis.

4.2.3.1 Content validity

The average content validity index (S-CVI) of the questionnaire was 0.926, and the content validity index (I-CVI) of the entry level was 0.821∼1.000.

4.2.3.2 Structural validity

The validity analysis of the data was verified by a comprehensive analysis of KMO, commonality, variance explanation rate, and factor loading coefficient.

The KMO test and the Bartlett test allow for assessing the applicability factor analysis for a particular data or the adequacy of sampling (18). Common values are used to eliminate irrational research projects; variance explanation rates are used to illustrate the level of information extraction; and the factor loading coefficients are used to measure the correlation between factors and problems.

The KMO value is 0.946 with a result greater than 0.8, indicating good validity of the study data. As can be seen from Table 4, two factors in Q8, Q10, Q42, and Q44 load simultaneously >0.5, while factors in Q17 load less than 0.5, so the five items with invalid headings should be deleted. In addition, the variance interpretation rate values of the six factors were 18.29%, 14.88%, 13.95%, 12.51%, 6.21%, and 5.26%, respectively. The cumulative variance explanation rate after rotation is 71.10% > 60%. This means that the amount of information on the research item can be extracted efficiently.

In summary, seven questions were excluded from the analysis of the initial questionnaire: Q8, Q10, Q17, Q19, Q23, Q42, and Q44. At the same time, the remaining questions were adjusted and the questionnaire was sent out again for hypothesis verification.

TABLE 6 Rotated component matrix[a].

	Component				
	1	2	3	4	5
B21	0.648				
B22	0.635				
B24	0.702				
B26	0.624				
B28	0.618				
B30	0.687				
B32	0.663				
B34	0.662				
B36	0.646				
B37	0.675				
B38	0.633				
B15		0.646			
B17		0.700			
B20		0.725			
B23		0.681			
B25		0.686			
B27		0.687			
B29		0.715			
B31		0.718			
B33		0.730			
B35		0.651			
B5			0.572		
B7			0.770		
B8			0.780		
B9			0.607		
B10			0.689		
B12			0.675		
B14			0.773		
B1				0.824	
B2				0.779	
B3				0.813	
B4				0.794	
B6				0.659	
B11				0.596	
B13				0.589	
B16					0.753
B18					0.779
B19					0.778

Extraction Method: Principal Component Analysis.
Rotation Method: Varimax with Kaiser Normalization.
[a]Rotation converged in 9 iterations.

4.3 Phase 2. Formal validation and final questionnaire

4.3.1 Reliability analysis

After the reliability analysis of the revised questionnaire, the overall Cronbach's α coefficient was 0.969. Moreover, Cronbach's alpha coefficients for each dimension were as follows: implementation of IAPI prevention, 0.927; IAPI prevents cognitive conditions, 0.959; preoperative IAPI to prevent cognitive conditions, 0.939; basic knowledge of PI, 0.926; implementation of IAPI prevention in special patients, 0.846. All indicators were above 0.7, indicating good reliability value of the questionnaire.

4.3.2 Factor analysis

Principal component analysis was performed on the revised questionnaire data to test the validity of the variables. Before factor analysis, each variable was tested for the KMO test and Bartlett's test of sphericity to determine if factor analysis is possible.

The KMO value is 0.945 > 0.6, and the significance value of the Bartlett sphericity test is <0.05, indicating that there are common factors and are suitable for factor analysis.

A total of 5 factors were extracted using principal component analysis, with a cumulative variance interpreted as 0.71, indicating that of all variables, 71% of variable information could be aggregated by extracting 5 factors, as detailed in Table 5. By factor rotation, the maximum variance method is used and the factor load of each component was greater than 0.5, as shown in Table 6. A total of five components were identified, which is in line with the revised questionnaire. In conclusion, the structure of this survey questionnaire is reasonable.

4.3.3 Confirmatory factor analysis

In this study, we performed a validation factor analysis using AMOS 24.0 software for a questionnaire on the patients' cognition and implementation status of surgical acquired pressure injury among operating room nurses. Key indications included: Root Mean Square Residual (RMR), Tucker-Lewis Index (TLI), Incremental Fit Index (IFI), Comparative Fit Index (CFI), and Root-Mean-Square Error of Approximation (RMSEA). By testing the goodness-of-fit coefficient of the model, the results show that all indicators are within a reasonable range. The model path is significantly tested, the model factor load is greater than 0.5, and the path is significant, which proves once again that the model has good structural validity. The AMOS verification model is shown in Figure 1, and the path fit and path coefficient are shown in Tables 7, 8.

The data after the correction of the model shows that: $\chi^2/df =$ 2.382; RMR = 0.027; TLI = 0.894; RMSEA = 0.072; IFI = 0.905; CFI = 0.904. The overall display model structure is well valid, as shown in Figure 1. The final version of the questionnaire is shown in Table 9.

5 Discussion

5.1 The significant nature of the questionnaire of operating room nurses on the cognition and implementation status of the prevention of patient IAPI

The operating room is an important department that is independently managed in the operation of the hospital, and the patient's time in the operating room is usually an independent event during the hospitalization, and IAPI mostly occurs within hours to up to 5 days after surgery (19). Continuously refining the nursing management mode of the operating room and improving the prevention awareness of the nursing staff in the operating room is the key to strengthening standardized nursing.

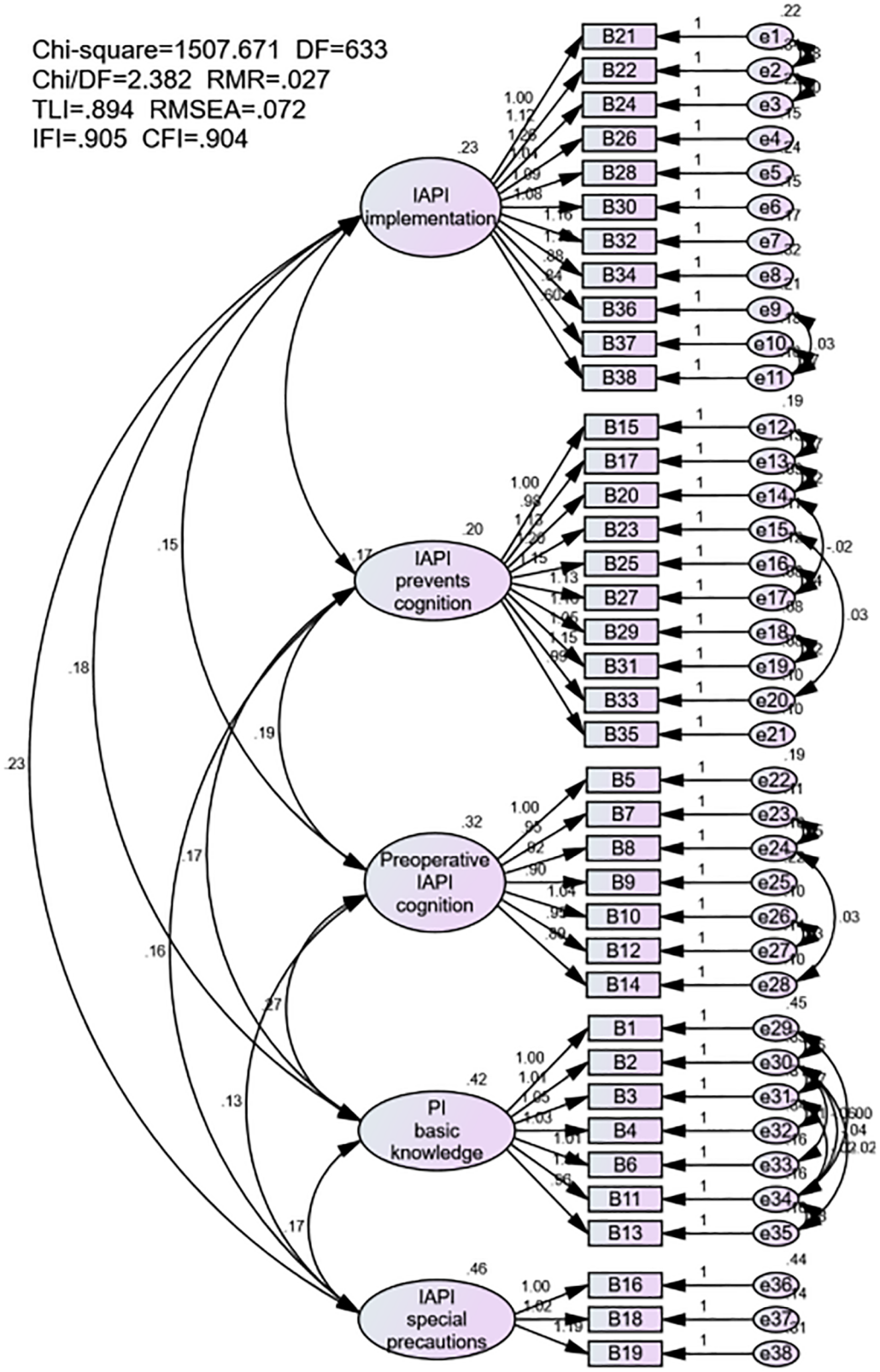

FIGURE 1
Model of structural equations.

TABLE 7 Model fit summary.

Model	Critical value	Data for test results	Judgment of model adaptation
χ^2/df	<3.00	2.382	Yes
RMR	<0.05	0.027	Yes
TLI	>0.80	0.894	Yes
IFI	>0.90	0.905	Yes
CFI	>0.90	0.904	Yes
RMSEA	<0.08	0.072	Yes

At present, although there are relevant scales to assess IAPI, they are less involved in the cognition of prevention related to operating room nurses, and a systematic prevention management questionnaire has not been formed. This study conducted in-depth research on the cognition and implementation status of IAPI prevention in patients in operating room nurses, analyzed various influencing factors of IAPI prevention, understood the implementation status of preventive measures, and provided the reference for further optimizing the prevention and management of IAPI through scientific evaluation.

5.2 The scientific nature of the questionnaire of operating room nurses on the cognition and implementation status of the prevention of patient's IAPI

The overall Cronbach's alpha coefficient of the questionnaire was 0.969, whereas that of each dimension of the questionnaire was above 0.70, which is consistent with the criterion that the reliability coefficient should preferably be above 0.70. This indicated that the internal consistency of the questionnaire is great.

TABLE 8 Path coefficient analysis.

Path relationships			Estimate	AVE	CR
B21: Do you think it is important to observe the color and swelling of the skin in the area where the patient is compressed?	<—	IAPI implementation	0.720	0.532	0.926
B22: Do you decompress the patient's area of pressure at least every 2 h during the procedure, without medical contraindications and with the consent of the surgeon?	<—	IAPI implementation	0.681		
B24: Do you decompress your patient's skin by moving or adjusting palpable non-surgical compression areas, positional pads, etc. during surgery?	<—	IAPI implementation	0.792		
B26: Do you use the appropriate type, material, and model of instruments during the procedure according to the patient's body shape and local skin condition?	<—	IAPI implementation	0.788		
B28: Do you give patients the right to wear and immobilize instruments in surgical patient care?	<—	IAPI implementation	0.736		
B30: Do you apply prophylactic dressings or pads for protection before using the device?	<—	IAPI implementation	0.804		
B32: Do you regularly monitor the tightness of your medical devices during surgery?	<—	IAPI implementation	0.809		
B34: Do you move or adjust your instruments in small areas at least every 2 h during surgery?	<—	IAPI implementation	0.710		
B36: Do you think it is important to conduct an intraoperative risk assessment of the patient according to the CORN-IAPI assessment scale, with relevant preventive measures based on the patient's risk level?	<—	IAPI implementation	0.679		
B37: Do you taking steps to prevent intraoperative hypothermia in your surgical patient care?	<—	IAPI implementation	0.686		
B38: Do you check the condition of the skin in the area where the patient is compressed, and accurately record and hand it over after the procedure?	<—	IAPI implementation	0.588		
B15: Do you think prophylactic dressings are important for patients at risk of IAPI with extreme obesity (BMI > 40), or surgery time > 6 h, or age > 75 years?	<—	IAPI prevents cognition	0.722	0.694	0.958
B17: Do you think it is important to choose and use prophylactic dressings, decompression pads, etc. for skin decompression in patients at high risk of IAPI?	<—	IAPI prevents cognition	0.775		
B20: Do you think it is important to observe the color and swelling of the skin in the area where the patient is compressed?	<—	IAPI prevents cognition	0.861		
B23: Do you think it is important to decompress the patient's skin by moving or adjusting the palpable non-surgical compression area, position pad, etc. during surgery?	<—	IAPI prevents cognition	0.857		
B25: Do you think it is important to select the appropriate type, material, and model of instruments to prevent device-related pressure injuries in surgical patient care based on the patient's body shape and local skin condition?	<—	IAPI prevents cognition	0.831		
B27: Do you think it is important to properly wear and immobilize the device to prevent device-related pressure injuries in patients?	<—	IAPI prevents cognition	0.872		
B29: Do you think it is important to protect against device-related pressure injuries with a prophylactic dressing or pad before using the device?	<—	IAPI prevents cognition	0.874		
B31: Do you think it is important to regularly monitor the tightness of medical devices during surgery to prevent device-related pressure injuries?	<—	IAPI prevents cognition	0.857		
B33: Do you think it is important to move or adjust the instrument in small areas at least every 2 h without affecting the surgery to prevent device-related pressure injuries?	<—	IAPI prevents cognition	0.850		
B35: Do you think preventing maceration of the patient's skin is important to prevent the patient's acquired pressure injury during surgery?	<—	IAPI prevents cognition	0.820		

(*Continued*)

TABLE 8 Continued

Path relationships			Estimate	AVE	CR
B5: Do you think it is important to know the patient's general profile, such as age, body mass index (BMI), physical activity, current risk level of pressure injury, previous or existing pressure injury, diabetes, history of cardiovascular and cerebrovascular diseases, etc.?	<—	Preoperative IAPI cognition	0.790	0.679	0.937
B7: Do you think it is important to know the patient's surgical situation, such as the type of surgery, estimated length of surgery, surgical position, anesthesia method, etc. before surgery?	<—	Preoperative IAPI cognition	0.845		
B8: Do you think it is important to evaluate the color, temperature, integrity, presence of edema, tenderness, etc. of the patient's whole body before surgery, and focus on the skin of the compressed area related to the surgical position?	<—	Preoperative IAPI cognition	0.858		
B9: Do you focus on understanding the condition of the patient's skin at the site of compression in relation to the surgical position before surgery?	<—	Preoperative IAPI cognition	0.731		
B10: Do you think it is important to conduct a preoperative risk assessment of the patient according to the CORN-IAPI assessment scale, with relevant preventive measures based on the patient's risk level?	<—	Preoperative IAPI cognition	0.877		
B12: Do you think it is important to apply a dressing under the disinfected area before surgery and remove the dressing after disinfection to prevent maceration of the patient's skin and prevent IAPI?	<—	Preoperative IAPI cognition	0.815		
B14: Do you think it is important to use the pressure relief tool correctly, choose and use positional cushions such as headrests, knee pillows, shoulder pads, chest pads, and heel pads to disperse the skin pressure of surgical patients?	<—	Preoperative IAPI cognition	0.843		
B1: Can you accurately distinguish between intraoperative acquired pressure injuries, inductive pressure injuries, and device-related pressure injuries?	<—	PI basic knowledge	0.694	0.607	0.915
B2: Can you accurately identify the stage of a surgical acquired pressure injury?	<—	PI basic knowledge	0.753		
B3: Are you proficient in timing the assessment of the risk of acquired pressure injury?	<—	PI basic knowledge	0.774		
B4: Are you proficient in using the CORN Acquired Stress Injury Risk Assessment Scale?	<—	PI basic knowledge	0.753		
B6: Are you proficient in the general profile of the surgical patient before surgery, such as age, body mass index (BMI), limb activity, existing pressure injury risk level, previous or existing pressure injury, diabetes, history of cardiovascular and cerebrovascular diseases, etc.?	<—	PI basic knowledge	0.853		
B11: Are you proficient in the preoperative risk assessment level of your patients before surgery and taking appropriate precautions according to the patient's risk level?	<—	PI basic knowledge	0.852		
B13: Are you proficient in determining the patient's intraoperative risk assessment level and taking appropriate preventive measures according to the patient's risk level?	<—	PI basic knowledge	0.839		
B16: Do you have prophylactic dressings for skin protection in surgical patient care for patients at intermediate risk of IAPI with extreme obesity (BMI > 40), or surgery time > 6 h, or age > 75 years?	<—	IAPI special precautions	0.717	0.656	0.850
B18: Do you use prophylactic dressings, decompression pads, etc. for skin decompression for patients at high risk of IAPI in your surgical patient care?	<—	IAPI special precautions	0.881		
B19: Do you use prophylactic dressings for skin protection in diabetic surgery patients in surgical patient care?	<—	IAPI special precautions	0.823		

TABLE 9 The final version of the questionnaire.

Questionnaire on the status of awareness and implementation of the prevention of intraoperative acquired pressure injuries in patients by operating room nurses
1. Can you accurately distinguish between intraoperative acquired pressure injuries, inductive pressure injuries, and device-related pressure injuries?
① Very uncertain ② Uncertain ③ Rather certain ④ Certain ⑤ Very certain
2. Can you accurately identify the stage of a surgical acquired pressure injury?
① Very uncertain ② Uncertain ③ Rather certain ④ Certain ⑤ Very certain
3. Are you proficient in timing the assessment of the risk of acquired pressure injury?
① Very unskilled ② Incompetent ③ Relatively skilled ④ Skilled ⑤ Very skilled
4. Are you proficient in using the CORN Acquired Stress Injury Risk Assessment Scale?
① Very unskilled ② Incompetent ③ Relatively skilled ④ Skilled ⑤ Very skilled
5. Do you think it is important to know the patient's general profile, such as age, body mass index (BMI), physical activity, current risk level of pressure injury, previous or existing pressure injury, diabetes, history of cardiovascular and cerebrovascular diseases, etc.?
①Very unimportant ② Unimportant ③ Relatively important ④ Important ⑤ Very important
6. Are you proficient in the general profile of the surgical patient before surgery, such as age, body mass index (BMI), limb activity, existing pressure injury risk level, previous or existing pressure injury, diabetes, history of cardiovascular and cerebrovascular diseases, etc.?
① Very unskilled ② Incompetent ③ Relatively skilled ④ Skilled ⑤ Very skilled
7. Do you think it is important to know the patient's surgical situation, such as the type of surgery, estimated length of surgery, surgical position, anesthesia method, etc. before surgery?
① Very unimportant ② Unimportant ③ Relatively important ④ Important ⑤ Very important
8. Do you think it is important to evaluate the color, temperature, integrity, presence of edema, tenderness, etc. of the patient's whole body before surgery, and focus on the skin of the compressed area related to the surgical position?
① Very unimportant ② Unimportant ③ Relatively important ④ Important ⑤ Very important
9. Do you focus on understanding the condition of the patient's skin at the site of compression in relation to the surgical position before surgery?
① Very little knowledge ② No knowledge ③ Some knowledge ④ Knowledge ⑤ Very much knowledge
10. Do you think it is important to conduct a preoperative risk assessment of the patient according to the CORN-IAPI assessment scale, with relevant preventive measures based on the patient's risk level?

(Continued)

TABLE 9 Continued

① Very unimportant ② Unimportant ③ Relatively important ④ Important ⑤ Very important
11. Are you proficient in the preoperative risk assessment level of your patients before surgery and taking appropriate precautions according to the patient's risk level?
① Very unskilled ② Incompetent ③ Relatively skilled ④ Skilled ⑤ Very skilled
12. Do you think it is important to apply a dressing under the disinfected area before surgery and remove the dressing after disinfection to prevent maceration of the patient's skin and prevent IAPI?
① Very unimportant ② Unimportant ③ Relatively important ④ Important ⑤ Very important
13. Are you proficient in determining the patient's intraoperative risk assessment level and taking appropriate preventive measures according to the patient's risk level?
① Very unskilled ② Incompetent ③ Relatively skilled ④ Skilled ⑤ Very skilled
14. Do you think it is important to use the pressure relief tool correctly, choose and use positional cushions such as headrests, knee pillows, shoulder pads, chest pads, and heel pads to disperse the skin pressure of surgical patients?
① Very unimportant ② Unimportant ③ Relatively important ④ Important ⑤ Very important
15. Do you think prophylactic dressings are important for patients at risk of IAPI with extreme obesity (BMI > 40), or surgery time > 6 h, or age > 75 years?
① Very unimportant ② Unimportant ③ Relatively important ④ Important ⑤ Very important
16. Do you have prophylactic dressings for skin protection in surgical patient care for patients at intermediate risk of IAPI with extreme obesity (BMI > 40), or surgery time > 6 h, or age > 75 years?
① Nearly always ② Sometimes ③ Sometimes ④ Most of the time ⑤ All of the time
17. Do you think it is important to choose and use prophylactic dressings, decompression pads, etc. for skin decompression in patients at high risk of IAPI?
① Very unimportant ② Unimportant ③ Relatively important ④ Important ⑤ Very important
18. Do you use prophylactic dressings, decompression pads, etc. for skin decompression for patients at high risk of IAPI in your surgical patient care?
① Nearly always ② Sometimes ③ Sometimes ④ Most of the time ⑤ All of the time
19. Do you use prophylactic dressings for skin protection in diabetic surgery patients in surgical patient care?
① Nearly always ② Sometimes ③ Sometimes ④ Most of the time ⑤ All of the time
20. Do you think it is important to observe the color and swelling of the skin in the area where the patient is compressed?
① Very unimportant ② Unimportant ③ Relatively important ④ Important ⑤ Very important
21. Do you regularly observe the colour and swelling of the patient's pressure area during the procedure?
① Nearly always ② Sometimes ③ Sometimes ④ Most of the time ⑤ All of the time
22. Do you decompress the patient's area of pressure at least every 2 h during the procedure, without medical contraindications and with the consent of the surgeon?
① Nearly always ② Sometimes ③Sometimes ④ Most of the time ⑤ All of the time
23. Do you think it is important to decompress the patient's skin by moving or adjusting the palpable non-surgical compression area, position pad, etc. during surgery?
① Very unimportant ② Unimportant ③ Relatively important ④ Important ⑤ Very important
24. Do you decompress your patient's skin by moving or adjusting palpable non-surgical compression areas, positional pads, etc. during surgery?
① Nearly always ② Sometimes ③ Sometimes ④ Most of the time ⑤ All of the time
25. Do you think it is important to select the appropriate type, material, and model of instruments to prevent device-related pressure injuries in surgical patient care based on the patient's body shape and local skin condition?
① Very unimportant ② Unimportant ③ Relatively important ④Important ⑤Very important
26. Do you use the appropriate type, material, and model of instruments during the procedure according to the patient's body shape and local skin condition?
① Nearly always ② Sometimes ③ Sometimes ④ Most of the time ⑤ All of the time
27. Do you think it is important to properly wear and immobilize the device to prevent device-related pressure injuries in patients?
① Very unimportant ② Unimportant ③ Relatively important ④ Important ⑤ Very important
28.Do you give patients the right to wear and immobilize instruments in surgical patient care?
① Nearly always ② Sometimes ③ Sometimes ④ Most of the time ⑤ All of the time
29. Do you think it is important to protect against device-related pressure injuries with a prophylactic dressing or pad before using the device?
①Very unimportant ② Unimportant ③ Relatively important ④ Important ⑤ Very important
30. Do you apply prophylactic dressings or pads for protection before using the device?
① Nearly always ② Sometimes ③ Sometimes ④ Most of the time ⑤ All of the time
31. Do you think it is important to regularly monitor the tightness of medical devices during surgery to prevent device-related pressure injuries?
① Very unimportant ② Unimportant ③ Relatively important ④ Important ⑤ Very important
32. Do you regularly monitor the tightness of your medical devices during surgery?
① Nearly always ② Sometimes ③ Sometimes ④ Most of the time ⑤ All of the time
33. Do you think it is important to move or adjust the instrument in small areas at least every 2 h without affecting the surgery to prevent device-related pressure injuries?
① Very unimportant ② Unimportant ③ Relatively important ④ Important ⑤ Very important
34. Do you move or adjust your instruments in small areas at least every 2 h during surgery?
① Nearly always ② Sometimes ③ Sometimes ④ Most of the time ⑤ All of the time
35. Do you think preventing maceration of the patient's skin is important to prevent the patient's acquired pressure injury during surgery?
① Very unimportant ② Unimportant ③ Relatively important ④ Important ⑤ Very important
36. Do you think it is important to conduct an intraoperative risk assessment of the patient according to the CORN-IAPI assessment scale, with relevant preventive measures based on the patient's risk level?
① Very unimportant ② Unimportant ③ Relatively important ④ Important ⑤ Very important
37. Do you taking steps to prevent intraoperative hypothermia in your surgical patient care?
① Nearly always ② Sometimes ③ Sometimes ④ Most of the time ⑤ All of the time
38. Do you check the condition of the skin in the area where the patient is compressed, and accurately record and hand it over after the procedure?
① Nearly always ② Sometimes ③ Sometimes ④ Most of the time ⑤ All of the time

In this study, the questionnaire for operating room nurses on the current status of awareness and implementation of the prevention of IAPI was constructed using the expert consultation method, literature analysis method, and group discussion method. The scientific and reasonable verification of the entries through structural validity, exploratory factor analysis, and validation factor analysis confirmed that each dimension and item met the research theme. In the exploratory factor analysis, the principal component analysis method was used, and five principal components were obtained, which cumulatively explained 70.694% of the total variance. The factor load matrix of each factor is 0.572~0.824, which met the requirements that the factor load should be greater than 0.400. Additionally, validation factor analysis showed that $\chi^2/df = 2.382$, RMR = 0.027, TLI = 0.894, RMSEA = 0.072, IFI = 0.905, CFI = 0.904 met the statistical criteria, which indicates that this model fits well and has a better simulation degree. Thus, the questionnaire structure has a great fit, and the structural validity of the questionnaire is excellent.

6 Conclusions

The questionnaire for operating room nurses on the current status of awareness and implementation of the prevention of IAPI is beneficial for nursing managers to understand the current mastery of IAPI prevention knowledge and the implementation of nursing measures by operating room nurses, and to investigate the areas in which IAPI preventive management can be improved in operating room nursing management. Thereby, this study provides a reference basis for the optimization of scientific preventive management in the operating room.

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 Ethics Committee of Provincial Hospital of Shandong First 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.

Author contributions

ZZ: Conceptualization, Data curation, Investigation, Methodology, Resources, Writing – original draft, Writing – review & editing. SL: Data curation, Investigation, Writing – review & editing. QG: Conceptualization, Investigation, Supervision, Writing – review & editing. XZ: Investigation, Supervision, Writing – review & editing. JM: Investigation, Resources, Supervision, Writing – review & editing.

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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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Faecal incontinence—a comprehensive review

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Introduction: Faecal incontinence (FI) is a distressing and often stigmatizing condition characterised as the recurrent involuntary passage of liquid or solid faeces. The reported prevalence of FI exhibits considerable variation, ranging from 7 to 15% in the general population, with higher rates reported among older adults and women. This review explores the pathophysiology mechanisms, the diagnostic modalities and the efficiency of treatment options up to date.
Methods: A review of the literature was conducted to identify the pathophysiological pathways, investigation and treatment modalities.
Result and discussion: This review provides an in-depth exploration of the intricate physiological processes that maintain continence in humans. It then guides the reader through a detailed examination of diagnostic procedures and a thorough analysis of the available treatment choices, including their associated success rates. This review is an ideal resource for individuals with a general medical background and colorectal surgeons who lack specialized knowledge in pelvic floor disorders, as it offers a comprehensive understanding of the mechanisms, diagnosis, and treatment of faecal incontinence (FI).

KEYWORDS

faecal incontinence, fecal incontinence, conservative management, surgical management, sphincter injury

Background

Faecal incontinence (FI) is a distressing and often stigmatising condition characterised as the recurrent involuntary passage of liquid or solid faeces (1). Anal incontinence (AI) is FI encompassing the inclusion of flatus and mucus into the definition (2). The reported prevalence of AI exhibits considerable variation, ranging from 7 to 15% in the general population, with higher rates reported among older adults (1, 3, 4) and women (5). Three main subtypes have been delineated: (1) Passive incontinence, characterised by the involuntary passage of stool or gas without conscious awareness. (2) Urge incontinence, whereby faecal contents are expelled despite efforts to prevent such occurrences and (3) faecal seepage, entailing the leakage of stool following otherwise typical bowel movements (5). The extent of the incontinence spans from occasional episodic faecal leakage to complete loss of bowel control (3). Irrespective of its severity, FI poses a considerable physical, psychological, and social challenge for those affected, often leading to a diminished quality of life (6).

Due to its complex origins, faecal incontinence (FI) requires a thorough grasp of its causes, physical processes, methods for diagnosis, and treatment methods. This all-encompassing review aims to delve into the present level of understanding regarding FI. By attaining a well-rounded comprehension of FI, medical professionals can play a role in enhancing patient results and their overall quality of life.

Physiology of bowel control

Bowel control is a complex physiological process that involves intricate coordination between the nervous system, the gastrointestinal system and pelvic floor muscles. FI can result from various physiological abnormalities and disruptions in the complex process of bowel control.

Anal sphincter muscles

The anal sphincter muscles, the involuntary internal anal sphincter (IAS) made of smooth muscle, and the voluntary external anal sphincter (EAS) made of skeletal muscle, are vital for maintaining continence. The IAS remains contracted at rest, preventing stool leakage, while the EAS adds extra control. It can be consciously contracted for increased anal pressure during activities like coughing. Coordination between these muscles and the puborectalis muscle is crucial for continence. Weakness or damage to these muscles, including but not limited to obstetric trauma during vaginal delivery, anorectal surgical procedures including anal dilation, haemorrhoidectomy, fistulotomy and sphincterotomy can result in leakage (7).

Pelvic floor muscles

The pelvic floor muscles provide support to the pelvic organs and contribute to continence. The puborectalis muscle is a critical component of the pelvic floor, forming a sling around the anorectal junction. This muscle's function is to maintain the angle between the rectum and anal canal, creating a kink that helps prevent involuntary stool leakage (7). During the defecation process, the puborectalis muscle relaxes to straighten the rectal angle, allowing for easier stool passage (7). Impaired coordination between the pelvic floor muscles and the anal sphincter can compromise the ability to maintain continence during activities such as coughing, sneezing, or physical exertion (1).

Rectal sensation and compliance

The rectum functions as a storage reservoir for faeces. As stool accumulates, it distends the rectal walls, leading to the activation of the rectal mechanoreceptors (1). They detect the stretching and transmit sensory signals to the central nervous system, providing the sensation of rectal fullness and triggering the urge to defecate (1). The rectum also exhibits compliance, allowing it to accommodate faecal material until it is appropriate to initiate defecation. When the rectal volume increases, it triggers the urge to defecate, and coordinated relaxation of the IAS occurs (1).This sensory feedback is essential for recognizing the appropriate time to initiate a bowel movement (1). Alterations in the sensory perception of the rectum, for instance due to neurological disorders affecting the central or peripheral nervous system or the spinal cord, neuropathy secondary to diabetes mellitus (8), can lead to a diminished awareness of rectal filling and urge sensation, resulting in involuntary bowel movements.

Stool consistency and volume

The texture and quantity of stool are directly linked to gastrointestinal transit time. Typically, loose stools are associated with rapid transit, while constipation is linked to slow gastrointestinal transit and diminished motility (9). Prolonged transit time facilitates increased water absorption from bowel contents. The entry of stool or flatus into the rectum leads to distention and temporary relaxation of the internal sphincter, allowing the highly innervated anal transition zone to sample the contents (10). Subsequent higher centre perception enables additional relaxation of the sphincter complex at an opportune moment for stool passage. Any interference, dysfunction, or overwhelming of this process may result in incontinence (10). Hard stools resulting in a palpable rectal mass have been shown to have a significant correlation with "overflow" faecal soiling (11), whereas the mechanism of loose stools leading to larger quantities of liquid faecal material may overpower the continence mechanism (9).

Neural control

The coordinated function of the central nervous system (CNS), autonomic nervous system (ANS), and enteric nervous system (ENS) is vital for maintaining continence. The brain processes the sensory information from the rectal mechanoreceptors and makes a conscious decision about when and where to initiate the defecation process. The prefrontal cortex is particularly involved in the voluntary control of defecation. It evaluates the sensory input and decides whether to initiate or suppress the urge to defecate based on various factors, including social norms, personal habits, and environmental cues (1). The CNS also coordinates the relaxation and contraction of the anal sphincters and pelvic floor muscles during the defecation process (1).

The ANS, operating largely involuntarily influences bowel motility and sphincter function. The sympathetic nervous system is responsible for the "fight or flight" response and is generally inhibitory to the digestive process (3). It helps maintain faecal continence by promoting the contraction of the internal anal sphincter and reducing motility in the colon, contributing to the storage of stool (3). Conversely, the parasympathetic nervous system is responsible for the "rest and digest" response, and it

plays a vital role in promoting defecation. When the urge to defecate is sensed, the parasympathetic nerves stimulate peristaltic contractions in the colon and rectum, while also relaxing the internal anal sphincter to allow stool to pass (3).

ENS, an intrinsic network of nerves located entirely within the walls of the gastrointestinal tract, regulates bowel movements locally and coordinates defecation. It functions independently but is influenced by both the CNS and ANS (12). The ENS receives input from sensory neurons within the gut walls, detecting factors like stretching of the intestines and the presence of faecal material. It then coordinates local reflexes that control smooth muscle contractions and regulate the opening and closing of the anal sphincters (12). This local control helps ensure that bowel movements occur in a coordinated and timely manner.

The CNS, ANS, and ENS work in tandem to maintain faecal continence and regulate bowel movements. The CNS processes sensory input from the rectum, generating the sensation of the urge to defecate and coordinating voluntary control. The ANS modulates the balance between storage and elimination, while the ENS provides local control within the gut to regulate motility and sphincter function. Nerve damage, often associated with conditions like diabetes or previous pelvic surgeries, can disrupt the communication between the rectum, anal sphincter, and the brain, leading to loss of bowel control (1).

Causes

Any disruption or dysfunction to the process of bowel control can lead to faecal incontinence. For example, weakness or injury to the anal sphincter muscles can result in the inability to maintain anal closure, while damage to the nerves controlling bowel function can cause impaired rectal sensation or coordination. Structural abnormalities, such as anorectal malformations or rectal prolapse, can also contribute to faecal incontinence. Hence, FI can have various causes, and the underlying factors can differ depending on the age group and individual circumstances (8).

Acquired structural abnormalities

Acquired structural abnormalities can have significant implications for bowel control and may result in FI. This occurs from various conditions that impact the anatomical integrity of the rectal and anal region. One common cause is obstetric injury, particularly to individuals who have undergone instrument-assisted vaginal delivery or experienced traumatic deliveries involving significant vaginal tears (10, 13). Anorectal surgeries, such as procedures for haemorrhoids, fistulas, or fissures, can also contribute to structural abnormalities that disrupt bowel control (8). Surgical interventions in the anorectal area may result in scarring, nerve damage, or altered sphincter function, affecting the ability to maintain continence (14). Rectal prolapse is another structural abnormality that can lead to faecal incontinence. In this condition, the rectum protrudes through the anus due to impaired rectal closure (14). The eversion of the sensing zone of the anal canal leads to feedback about arriving stool being delayed too late or absent (14). Rectocele, a condition where the rectum bulges into the posterior vaginal wall, can also impact bowel control (8). Over time, the positional instability of pelvic structures and the inadequate start and finish of defecation can lead to a decrease in functional capacity and potentially more frequent and unintended evacuations, in addition to everting the crucial sensing zone of the anal canal, such that feedback about arriving stool comes too later or not all (14). Finally, trauma, such as pelvic fractures resulting from accidents or injuries, can cause damage to the pelvic floor and anal sphincters leading to FI (15).

Congenital disorders

Congenital disorders can significantly impact bowel control and lead to faecal incontinence from an early age. Anorectal malformations (ARM) encompass a diverse group of congenital defects that affect the development of the anus and rectum (16). Imperforate anus, one of the most common types of ARM, refers to the absence or abnormal location of the anal opening, hindering the normal passage of stool (16). Cloacal defects, another form of ARM, involve the presence of a single common channel for the rectum, vagina, and urinary tract, leading to challenges in bowel and urinary control (16). Another congenital disorder is spina bifida, a neural tube defect, affects the development of the spinal cord and surrounding structures. Severe forms of spina bifida, such as myelomeningocele or meningocele, involve the protrusion of the spinal cord through an opening in the vertebral column (17). Patients commonly display motor and sensory neurological impairments below the affected area. Urinary and faecal incontinence are prevalent issues (17).

Defecation disorders

Several factors can affect the normal mechanisms of bowel control and cause FI. Chronic or frequent episodes of diarrhoea can have a negative impact on faecal continence. The increased frequency and urgency associated with diarrhoea can overwhelm the anal sphincters' ability to hold stool, resulting in faecal leakage (12). A further cause is faecal impaction causing paradoxical diarrhoea, whereby liquid stool leaks around a large, impacted mass in the rectum (18). This can create an atypical "obstruction" that prevents normal stool passage and results in the involuntary leakage of liquid stool (12). Similarly, prolonged constipation can cause a build-up of hard, impacted stool in the rectum. The stretched rectum can lose its ability to sense fullness, leading to reduced awareness of the need to defecate (19). As a result, the weakened rectal muscles may not be able to generate the force required to expel stool properly, leading to involuntary leakage (19).

Co-existence of constipation and FI is well-known within the elderly and paediatric population, This is known to present as

stool withholding behaviour and subsequent overflow in paediatric populations, and faecal impaction with overflow in the elderly population (20). In contrast to this, FI and constipation in adults are often regarded as distinct and separate conditions. Vollebregt et al. studied 4,027 (aged 18–80) patients, referred to a tertiary unit for investigation of refractory faecal incontinence and/or constipation, to assess the frequency in which coexistent diagnosis were made (20). The outcomes were that over 40% of patients who were referred for anorectal physiological investigation had co-existing FI and constipation. Notably, 86.4% of the patients had recognition of only constipation or FI alone, rather than co-existent pathologies when initially referred (20).

Pelvic floor dysfunction is another significant cause of faecal incontinence. Weakened support to the rectum and sphincter complex can lead to inadequate control of motions and FI (21).

Additionally, certain psychological factors, such as severe anxiety, depression, or cognitive impairments, can influence bowel control (8). Emotional and behavioural factors can lead to alterations in gut motility and exacerbate existing bowel problems, contributing to faecal incontinence (19). In some cases, cognitive impairment may lead to difficulties in recognizing the urge to defecate or in communicating the need for assistance, contributing to incontinence (19).

Neurological disorders

Nerve function plays a vital role in the coordinated control of bowel movements. When nerves supplying the rectum and anus are damaged or dysfunctional, the communication between the rectum and the brain can be disrupted (18). This can lead to a loss of sensation, preventing individuals from detecting rectal fullness or the urge to defecate, and can also impair the signals needed to contract and relax the anal sphincters effectively (1). Neurological disorders and nerve problems can significantly impact bowel control and lead to faecal incontinence.

Pudendal neuropathy, resulting from nerve damage or compression of the pudendal nerve, can arise from various causes, such as radiation therapy, diabetes, or chemotherapy (18). The pudendal nerve plays a critical role in controlling the anal sphincters and pelvic floor muscles, and its dysfunction can lead to impaired coordination and weakness, contributing to faecal incontinence (18). Spinal cord injury is another major cause of neurological-related faecal incontinence (3). Damage to the spinal cord, often due to accidents or trauma, can disrupt the communication between the rectum and the brain, leading to impaired sensation, muscle control, and reflexes essential for maintaining continence (1). Depending on the level and extent of the injury, faecal incontinence can range from occasional leakage to complete loss of bowel control (1). Similarly, another cause of FI is multiple sclerosis (MS), which is an autoimmune disorder that affects the central nervous system by causing demyelination of nerves, leading to impaired nerve signals. This can result in disrupted bowel control and contribute to faecal incontinence (3). Furthermore, various neurological conditions, such as stroke, Parkinson's disease, or dementia, can affect the nerves involved in bowel control (1). The altered nerve function can disrupt the communication between the rectum and the brain, leading to impaired rectal sensation and coordination, ultimately resulting in faecal incontinence (1). In all these neurological disorders and nerve problems, the communication between the rectum, nerves, and brain is compromised, leading to deficits in bowel control.

Other contributing factors

Conditions such as inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), or infections can lead to chronic diarrhoea, contributing to the development of faecal incontinence (8). In addition, IBD, can also contribute to faecal incontinence due to the inflammation and damage to the intestinal lining, affecting rectal sensation and sphincter function (12).

Medications can play a significant role in causing or exacerbating faecal incontinence by influencing bowel motility, consistency, and nerve function. Laxatives, commonly used to treat constipation, can lead to faecal incontinence when overused or misused (8). Prolonged use of laxatives can result in chronic diarrhoea or loose stools, overwhelming the rectum and anal sphincters' capacity to hold stool properly, and leading to accidental leakage (19). On the other hand, antidiarrhoeal drugs, prescribed to manage diarrhoea, can also have unintended consequences for bowel control. While they can help control frequent bowel movements, they may cause stool to become more solid, leading to faecal impaction. Paradoxically, liquid stool may leak around the impacted mass, resulting in incontinence (19).

In addition, medications that alter nerve function can also impact bowel control and contribute to faecal incontinence (14). Some nerve-altering medications, such as those used to manage chronic pain or neurological conditions, can interfere with the normal signalling between the rectum and the brain, disrupting the coordination of bowel movements (14). As a result, individuals may experience diminished sensation or impaired voluntary control over bowel function, leading to faecal incontinence (14).

Work up and diagnosis

The work-up for FI involves a comprehensive evaluation of the individual's medical history, physical examination, and diagnostic tests to identify the underlying physiological factors contributing to the condition and guide appropriate treatment strategies.

History

The Rome IV criteria, a classification system used to aid in the diagnosis of functional gastrointestinal disorders, are perhaps the most commonly employed criteria for diagnosing of FI. According to this classification, a confirmed diagnosis of FI involves recurrent involuntary passage of faecal matter in individuals aged ≥4 years, consistently experienced for at least 3 months. Interestingly, for

research studies, symptoms should be evident for around 6 months with 2–4 instances of FI occurring within a 4-week span. It's worth noting that the Rome IV criteria have evolved from previous versions, but discussing their complete history is beyond the scope of this review (22).

When taking a FI history, the duration and frequency of symptoms should be evaluated to understand the chronicity and pattern of incontinence. Characteristics of FI, such as the consistency and volume of stool, whether it is associated with urgency and identifying trigger factors including coughing, sneezing, or exertion are key in a FI history (23). Associated symptoms including diarrhoea, constipation, and bloating can also provide valuable clues to the underlying cause (3).

Past medical history should be explored to identify relevant medical conditions (inflammatory bowel disease, neurological disorders), surgical procedures (haemorrhoidectomy, fistulotomy, low anterior resection), obstetric history (primiparity, instrumental delivery, perineal tears) or treatment (pelvic radiation) that could potentially lead to FI (3, 18). Medication history should also be considered, as certain drugs can affect bowel function and contribute to FI such as opioids and laxatives (23). The impact of FI on the individual's daily life, including quality of life, social interactions, work, and emotional wellbeing is important to provide a comprehensive understanding of the overall burden of the condition on the patient (23).

Physical examination

Physical examination should be performed to facilitate a reliable diagnosis whilst ensuring patient comfort (24). The perianal area should be inspected to reveal potential signs including irritation, deformities, haemorrhoids or previous surgical scars (15). A digital rectal examination (DRE) is performed to assess sphincter integrity, tone, and assess for the presence of rectocele, faecal impaction, or masses. Asking the patient to bear down during the DRE allows for the assessment of the function of pelvic floor muscles and puborectalis (3). Additionally, a vaginal examination should be performed where appropriate to assess for prolapse, rectocele, cystocele, or enterocele (15). Anoscopy may also be performed to directly visualise the anal canal and lower rectum to allow for the identification of anorectal lesions including fistulas, haemorrhoids, and proctitis (25).

Severity scoring systems

Scoring systems play a crucial role in providing a standardised and quantitative assessment of FI and are valuable tools when used in conjunction with clinical evaluation and individualised assessment to comprehensively understand the condition and guide management. Several commonly used scoring systems have been developed to assess the severity and frequency of FI symptoms and the impact on patients quality of life. These include the Wexner Score (Cleveland Clinic Fecal Incontinence Severity Scoring System or CCIS) (26), Vaizey Score (St Mark's Incontinence Score) (27), and Faecal Incontinence Severity Index (FISI) (28). However, there is currently no globally accepted scoring algorithm for diagnosing FI (29).

The Wexner score is perhaps the most widely used scoring tool to assess FI, and has been shown to closely correlate with patient perception of symptoms and clinical assessment (26, 29, 30). However, the Wexner score gives equal weight to all symptoms potentially making assessment of sphincter impairment challenging and does not take into account faecal urgency (30). The Vaizey score was developed based on the Wexner score, with the addition of faecal urgency and constipating medications, however has been reported to be more difficult to understand due to the clinical language (27).

The American Society and of Colon and Rectal Surgeons Pelvic Floor Disorders Consortium recommended the routine use of "IMPACT" (Initial Measurement of Patient Reported Pelvic Floor Complaints Tool), which is a combination of the Wexner and Vaizey scores, whilst limiting the number of questions asked to patients (31).

FISI was developed using both surgeon and patient input and gives variable weights to symptoms based on the subjective experience (28). However, it excludes lifestyle impact, which is seen within other scoring tools and is a crucial component in understanding a patient's experience living with FI (30).

Despite a variety of scores being available many do not monitor symptoms of urgency (32), although the Vaizey score evaluates urgency it does not consider the frequency of urgency (33).

It has been shown that patients with the primary complaint of urgency FI report a significantly worse quality of life compared to those with passive FI as their primary complaint (34). Additionally, distinguishing between urgency and passive FI is important as functional differences can be found between the two groups which can then affect management (34). Passive incontinence is associated with those who have structural or functional damage to the IAS, whereas patients with damage to the EAS present with a primary complaint of urgency and frequent passage of stool (34).

The Low Anterior Resection Syndrome (LARS) score is primarily to assess LARS which is a collection of symptoms, including FI and frequency of urgency, which may impair quality of life in patients post complete or partial resection of the rectum (32). Bowel dysfunction and symptoms are seen in other anorectal complaints and as such the LARS score has previously been used to assess these symptoms, for example in women who have undergone surgery for endometriosis with and without bowel resection (35).

Notably, the Wexner score, the most widely used scoring system, is more likely to identify individuals with passive FI rather than those experiencing urgency FI (33). Recent literature on FI in women with previous obstetric injury suggests that combining the Wexner score with the LARS score can provide additional important information especially regarding urgency symptoms (33).

Diagnostic tests

The treating physician may wish to perform luminal examination in the form of colonoscopy or similar to exclude

malignancy, if "red flag" symptoms were elicited during history taking (36).

Depending on clinical findings and suspected underlying causes, additional diagnostic tests may be conducted to further evaluate FI. Most centres will opt for High Resolution Anorectal Manometry (HRAM), as per the American Gastroenterology guidelines (36). HRAM plays a crucial role in evaluating the function of the anorectal region, encompassing both motor and sensory aspects (37). Its use is pivotal in diagnosing FI, as it deepens the understanding of FI's underlying pathophysiology, thus enabling tailored therapies for individual patients. HRAM offers a dynamic analysis of anal sphincters and intraluminal rectal pressures, making it the most established method for objectively assessing various elements of anal and rectal function, including basal tone, contractility, recto-anal coordination, and reflex functions like recto-anal inhibitory reflex (37). Moreover, it measures rectal sensation thresholds, a valuable predictor of response to biofeedback training (38).

When contemplating surgery for individuals with incontinence and diminished anal pressures, it's important to assess the structural integrity of the anal sphincters, rectal wall, and the puborectalis muscle region. This can be accomplished using either endoscopic anal ultrasound (EAUS) or MRI (36). While these tests share some commonalities in identifying issues like scars, defects, or thinning, each offers unique diagnostic capabilities. For instance, ultrasound excels at detecting tears in the IAS, whereas MRI is more adept at identifying atrophy in the EAS (28, 39). Furthermore, distinguishing between an EAS tear and a scar is more accurate with MRI (36).

EAUS is the gold standard examination for assessing the anal sphincter integrity. It is well tolerated and widely available (8). Nevertheless, its efficacy is contingent upon the operator's proficiency, and there is ongoing debate regarding its sensitivity in accurately identifying anal sphincter integrity (40). MRI is less easily accessible, more costly, and poses limitations in patients with defibrillators, metal implants, or those who experience claustrophobia. In the absence of these concerns, initiating the diagnostic process with ultrasound and subsequently advancing to MRI is deemed appropriate (8).

Additional tests may include defecography, endoanal MRI or Pudendal nerve terminal motor latency (PNTML) (15).

Defecography is a diagnostic procedure used to evaluate the function and anatomy of the pelvic floor during defecation. It provides valuable insights into the mechanisms of stool evacuation and can help diagnose various conditions related to the pelvic floor, such as rectal prolapse, rectoceles, intussusception, and obstructive defecation syndrome (39).

Fluoroscopic x-ray defecography involves the patient ingesting a contrast medium, typically a barium-based solution, before having x-rays taken while they expel the contrast medium during defecation. This allows real-time visualisation of the movement of the pelvic structures and the rectal contents. Fluoroscopic defecography is advantageous for its ability to capture dynamic images and assess the coordination and mechanics of the pelvic floor muscles during evacuation (41).

On the other hand, magnetic resonance imaging (MRI) defecography employs advanced imaging technology to create detailed, high-resolution images of the pelvic structures and their movement during defecation. MRI defecography provides a more comprehensive definition of all 3 compartments (42, 43).

The choice between these two imaging modalities depends on factors such as the specific clinical question, patient comfort, and the availability of equipment. Fluoroscopic x-ray defecography offers dynamic insights, while MRI defecography provides precise anatomical detail. Both techniques play a crucial role in diagnosing and understanding pelvic floor dysfunction, helping guide appropriate treatment strategies (44).

PNTML (Pudendal Nerve Terminal Motor Latency) is a test used to assess the time it takes for an electrical signal to travel along the pudendal nerve from the ischial spine to the anal verge. This test aids in evaluating the neuromuscular integrity of the pelvic floor. The pudendal nerve is stimulated near the ischial spine through the anus, and the time between nerve stimulation and muscle response is measured. Any impairment in the neuromuscular unit can lead to a lengthened latency period (45).

Numerous studies have revealed that PNTML prolongation is observed after uncomplicated vaginal delivery. Although PNTML values tend to approach the reference range three months postpartum, Tetzschner et al. discovered that a significant and lasting PNTML prolongation persisted in incontinent women compared to continent women at the three-month postpartum mark. Furthermore, abnormal PNTML was identified as the sole predictor for the development of anal incontinence 2–4 years postpartum in women who had experienced anal sphincter rupture (46).

Although initial studies have demonstrated prolonged PNTMLs in individuals with idiopathic faecal incontinence compared to healthy controls (47), subsequent studies have also identified PNTML prolongation in other conditions including chronic constipation and proctalgia (48). In addition, half of those patients with prolonged PNTML exhibited normal anal canal squeeze pressures (48). The lack of association between PNTML prolongation and decreased anal canal squeeze pressures has been demonstrated in further studies (49, 50) Failing to control for age could contribute to poor correlation as PNTML has been shown to increase with age, independent of continence status (49). Furthermore, PNTML measures only the conduction time of the fastest fibers in the pudendal nerve, with the potential for normal conduction times despite nerve damage if some fast-conducting fibers remain intact (49).

The poor sensitivity and specificity of PNTML in detecting EAS muscle weakness resulting from pudendal nerve damage remains a concern (51). Moreover, it is an operator dependent test with a poorly defined upper limit given the large variation in healthy individuals. As a result its clinical utility is limited (38) and PNTML should considered primarily of research interest only (24).

Role of multidisciplinary team (MDT)

The complexity of FI lends itself to an MDT approach with studies confirming effectiveness of the MDT in enhancing patient satisfaction and promoting greater adherence to treatment (52, 53). A typical MDT could include specialist surgeons (colorectal,

gynaecology, urology) physiotherapists, clinical scientists, specialist nurses and radiologists for example (54). The MDT facilitates discussions regarding patients where current treatment is ineffective, enables the review of imaging and results, and allows for the consideration of additional non operative or surgical procedures including joint procedures in individuals with multicompartment prolapse (54). The MDT also provides the opportunity for less specialised surgeons to attend, either face to face or via videoconferencing to gather support and increased knowledge from the established expert network (55).

Treatment

Management of faecal incontinence (FI) is complex and challenging, therefore a holistic approach that gives careful consideration of not only the aetiology but of a patient's psychosocial and medical background is required. Currently there is not an abundance of high-quality evidence for the management of FI and successful outcomes appear dependent on the interplay of many factors. The international consensus is that conservative interventions are recommended initially. Adopting this approach first mainly aims at reducing risk factors for FI and avoiding morbidity associated with more invasive interventions (19).

Non operative management

Conservative management includes lifestyle changes mainly weight reduction, smoking cessation, dietary modification, pelvic floor physiotherapy, bowel retraining, medication and environmental review. Research has shown that dedicated nurse specialist clinics alone can improve symptoms (56). They offer education and support into establishing a consistent routine. When appropriate and relevant, the involvement of caregivers is essential in maintaining any positive outcomes.

Dietary modification that involves increasing fibre and reducing fluid intake to optimise stool consistency is advised (except for patients with FI related to constipation) (57). Patients are recommended to maintain incontinence journals to identify possible triggers. It is advised to avoid the consumption of caffeine, particularly coffee, due to its recognised laxative properties, as well as lactose, excessive vitamin C, magnesium phosphorus, artificial sweeteners, alcohol and chilli (31, 58).

Physiotherapy was found to be a fundamental component in the treatment of individuals with faecal incontinence (FI) and enhancing their overall quality of life (59). The benefits in primary prevention were also described. Medication review is essential to rule out side effects from their regular prescription medications which may be contributing to urgency or diarrhoea such as Donepezil and Rivastigmine, calcium channel agonists and metformin (31, 58) Whilst awaiting referral and review by a specialist, short term management such as foam plugs, and RADAR Keys can be offered (58).

Medical management involves more specialised interventions such as drug prescription, rectal irrigation, physiotherapy and biofeedback. Pharmacological interventions aim to decelerate colonic motility and enhance stool consistency by reducing intestinal fluid secretion, promoting absorption, and minimising sphincter relaxation. The addition of fibre in treatment can effectively manage variations in stool consistency and is recommended by National Institute of Clinical Excellence (NICE) and the International continence society (ICS) (60). In a randomised controlled trial involving 39 patients, the group receiving fibre supplementation experienced a decrease in the percentage of incontinent stools to less than half compared to the placebo group, demonstrating an improvement in stool consistency (61). Anti-diarrhoeal medications are suggested for FI with pre-existing diarrhoea (31). The initial treatment is loperamide hydrochloride. For patients who require additional options or cannot tolerate loperamide, codeine phosphate may be offered. Alternatively, co-phenotrope can be considered for those who are intolerant to loperamide (58). Laxatives are only recommended for those with faecal loading (58). There is mixed guidelines regarding Colestyramine, the ASCRS recommends in those with a history of cholecystectomy or ileocolonic resection, but other guidelines do not yet include it (60).

Biofeedback of different modalities (such as EMG and manometric biofeedback) coupled with pelvic floor exercises or electrostimulation can enhance treatment outcome (62). As well as individually, evidence has described how a combination of therapies such as medications, biofeedback and pelvic floor exercises can lead to an improvement in symptoms (62).

Once less invasive measures have failed bowel management programmes are tried, training patients to facilitate emptying with enemas and suppositories, or more complex regimens using trans anal irrigation (TAI), ensuring no absolute contraindications prior to doing so. TAI requires specific devices and education on how it should be administered and should only be done if suitable. A recent systematic review found for a cohort of patients improvement in bowel function and quality of life (62). TAI is indicated prior to surgery but dependent on patient preference, it is most effective in those with faecal loading or spinal or neurological disease or injury (58, 60).

Role of primary and secondary care

The role of primary care in managing faecal incontinence is contingent on local resources. Initial assessment and management should commence in the community, emphasising dietary and fluid modifications for stool consistency and regular bowel emptying. Other interventions might include addressing home toilet accessibility, providing necessary equipment, and reviewing regular medications. Depending on the underlying cause, loperamide or laxatives may be considered in the community as appropriate, along with the provision of radar keys, anal plugs, skin care guidance, barrier products, and disposable gloves (58).

Signposting routes to access emotional and psychological wellbeing may be provided by either primary or secondary care as appropriate depending on access (58).

More specialised services like pelvic floor muscle retraining, physiotherapy, rectal irrigation, biofeedback and specialised dietary assessment and management are usually offered within

secondary care environment. Individuals being considered for surgery should be evaluated in secondary care (58).

Surgical management

If non-operative measures are ineffective, surgical options can be offered. Obvious structural deformities such as full thickness rectal prolapse or fistula must be repaired first (14). Surgical approach then aims at restoration of anatomy, improvement of sphincteric complex functioning or lastly diversion. A summary of previous, current and future surgical options can be seen in Table 1.

Biomaterial injectables

A distinct method for enhancing the sphincter complex is Injection or implantation of bulking agents. The rationale is to achieve increased passive outlet resistance by adding volume to the anal canal or perianal tissues. Various techniques and materials have been used for this purpose. Patient selection remains undefined but could encompass those with mild passive incontinence due to internal anal sphincter weakness or postsurgical deformities altering the anal canal shape (14).

A systematic review encompassing 16 studies (none of which was randomised) involving 420 patients examined conventional injectables (Carbon, Teflon or silicon, collagen, autologous fat) revealing limited evidence for their efficacy in passive faecal incontinence. Only 2 studies achieved over 50% improvement, while others reported 15%–50% improvements at long-term follow-ups. Complications affected up to 10%, with side effects reaching 12% (63). Newer materials include non-animal stabilised hyaluronic acid/dextranomer. They gained popularity amongst both specialists and general practitioners, with an outpatient/office-based injection approach gained momentum in 2011 after a randomised, placebo-controlled trial involving 206 patients showed a greater than 50% improvement in 53.2% vs. 30.7% in the intervention vs. sham groups, respectively (64). However, the intervention did not stand the test of time as complete continence rate at 6 months was 6%. Selection criteria uncertainty and durability and cost concerns, impeded the technique's widespread adoption (65).

TABLE 1 Summary of current availability of surgical options.

Sphincteroplasty	Available
SNS	Available
Antegrade Colonic Enema	Available
Artificial Bowel Sphincter Implantation	In phase of study
Magnetic Anal Sphincter Implantation	Not available
Biomaterial injectables	Available
	New materials in phase of study
Dynamic Gracioplasty	Not available
Adynamic Gracioplasty	Available—selected patients
Theirsch wire	Available in rectal prolapse—palliative approach
Pelvic sling	Available in rectal prolapse
Colostomy (faecal diversion)	Available—Final option

Two recent strategies include the implantation of self-expandable hyexpan (polyacrylonitrile) prosthesis via an applicator gun (66) and the use of stem cells (67). Although they have been evaluated through small cohort studies (67–69), results from larger randomised trials are awaited.

Sphincter repair

If a segmental sphincteric defect is identified, normally related to obstetric injury which involves the full length of the EAS and a defect of 90 degrees, or greater than, sphincteroplasty can be considered to directly repair the injured muscles (42). Good to excellent results have been observed in around 85% of patients in the short term. However, long term positive outcomes are rarely maintained and only 10%–14% of patients with sphincteroplasty exhibited sustained improvement in function at 5 years (31). Given this, the patient must be properly counselled prior to such procedure (31). The efficacy of sphincteroplasty has come under scrutiny, especially in women experiencing faecal incontinence decades after obstetric trauma so careful consideration is needed in these patients (31).

Sacral neuromodulation

Enhancement of the sphincter can occur with the placement of a sacral (SNS) or a percutaneous tibial nerve stimulator (PTNS) (14). Over the last decades, SNS has brought about a transformative shift in the management of faecal incontinence (70). The technique involves two outpatient procedures under light anaesthesia. In the initial procedure, a 4-point electrode is placed at the sacral root S3 and connected to a temporary external stimulation device. If the patient responds positively during the subsequent 2-week trial period, a permanent implantation of the stimulator device similar to a pacemaker is carried out in the second surgery; otherwise, the electrode is removed. While the exact mechanism remains partially understood, SNS is thought to reactivate a dysfunctional pelvic floor and receptor pathway while also engaging the brain's afferent pathway related to continence (71, 72).

Regardless of the precise mechanism, the outcomes are impressive, with over two-thirds of patients experiencing over 50% improvement, leading to permanent stimulator implantation (65). This positive impact consistently maintained, both immediately and over the long term. After the permanent implantation, 86%–87% of patients reported over 50% improvement, and around 40% achieved complete control, with these successes lasting beyond 3–5 years (65, 73). The complication rate is relatively low, with infection and electrode dislocation being the most common, occurring at rates of 3% and 12%, respectively (45, 74). However, subsequent interventions for revision or device replacement (due to battery life) are required in 19%–36% of cases (74, 75). Recent advancements have brought about the utilisation of rechargeable batteries with a claimed lifespan of more than 20 years, requiring recharging every 6 to 10 months (76).

NICE recommends SNS when sphincter surgery is deemed inappropriate for example where there is no defect, or there is sphincter disruption or sphincter defect with atrophy, denervation, a small defect, absence of voluntary contraction or poor quality muscle (77). However, the ASCRS recommends SNS as first line treatment for those with or without sphincter defects (31, 60).

Beyond sphincter modifications, a variety of methods of replacing the anal sphincter have been attempted, some more effectively than others. These approaches are geared towards either restoring or enhancing the functionality of the anal sphincter muscles (14). They can be categorised to dynamic and non-dynamic techniques (14).

Dynamic sphincter replacement

Artificial Bowel Sphincter Implantation: This method involves surgically implanting an artificial device to mimic the role of the natural anal sphincter. This artificial sphincter allows for dynamic control of bowel movements. However, its use has been restricted due to the risk of infection and potential long-term device-related complications (59).

Magnetic Anal Sphincter Implantation: In this approach, a magnetic ring is implanted around the anal canal. By creating passive resistance, the device contributes to controlling faecal continence (65). While initial feasibility studies showed promise, due to high rates of significant events, complications and explanation, both this and dynamic graciloplasty are no longer available (78).

Dynamic Graciloplasty: This technique utilises the gracilis muscle harvested from the thigh, wrapping it around the anal canal. Although voluntary control of this muscle is limited, an implanted pulse generator can transform its properties over time, leading to improved faecal control (79). For similar reasons as for magnetic sphincters this technique is no longer popular or available (78).

Nondynamic sphincter

Thiersch and Similar Procedures: Encircling materials are placed around the anal canal to narrow it and heighten passive resistance. While the aim is to enhance control over bowel movements, limited data exist to support its effectiveness (14). It is normally reserved for patients who are in a debilitated state, with the primary goal being symptom palliation (72).

Non-dynamic Graciloplasty/Gluteoplasty: This technique involves wrapping muscles like the gracilis or gluteus around the anal canal without stimulation. However, its application is limited due to the heightened risk of complications and limited functional improvement (80). A systematic review encompassing 14 studies involving 450 patients identified similar functional results between dynamic and adynamic graciloplasty, but with a higher risk of reoperation and complications in the dynamic graciloplasty. Consequently, non-dynamic graciloplasty is the preferred approach (81).

Pelvic Floor Repairs/Sling: Addressing pelvic floor support to restore anorectal angles and improve faecal control is the focus of this approach. Recent attention has been directed towards an investigational trans-obturator posterior anal sling system. Results from clinical trials have shown promising outcomes, including treatment success and enhanced continence rates (14).

These replacement techniques offer diverse strategies for tackling faecal incontinence, accommodating varying patient needs and conditions. The selection of the most suitable technique hinges on factors such as the specific condition of the patient, expected outcomes, and potential risks associated with the procedure (14).

Percutaneous tibial nerve stimulation (PTNS) is another nerve stimulation method employed in the management of faecal incontinence (82). Through the use of either transcutaneous or percutaneous electrodes, the posterior tibial nerve is stimulated during sessions lasting around 30 min, carried out over a period of at least 3 months (82). While the specific benefits and mechanism of action of tibial nerve stimulation are less straightforward and remain somewhat elusive, it is believed to influence faecal control by activating the central nervous system and supra-sacral neural centres via the afferent fibres of the peripheral nervous system. Given that the posterior tibial nerve originates from lumbar and sacral nerve ventral branches, a similar response as seen with SNS is anticipated (83).

Despite the anticipation, favourable results were not noted in CONFIDeNT, a double-blind, multicentre, pragmatic, randomised controlled trial conducted in 17 UK hospital units specialising in faecal incontinence management (84). Participants with substantial faecal incontinence not responding to conservative treatments were randomly assigned to receive either percutaneous tibial nerve stimulation (PTNS) or sham stimulation for 12 weeks. The primary outcome was a 50% reduction in weekly faecal incontinence episodes (84). Among the 227 eligible patients assigned to PTNS ($n = 115$) or sham ($n = 112$), 38% in the PTNS group and 31% in the sham group met the primary outcome. No serious treatment-related adverse events occurred. PTNS did not significantly outperform sham stimulation in this 12-week trial (84).

Another surgical option is ACE (antegrade colonic enema) mainly utilised in paediatrics or those with colonic motility disorders (85, 86). Initially introduced by Malone et al. in 1990, subsequent refinements to the ACE procedure have resulted in well-established laparoscopic techniques that are employed for children experiencing persistent constipation issues (85, 86). The treatment encompasses flushing colonic contents in a forward direction through a surgically formed catheterisable channel in the abdominal wall (85, 86). This is performed most commonly either through an appendicostomy or a caecostomy (87). Studies have shown this to be effective for children with refractory FI or constipation (87).

Finally, faecal diversion through the establishment of a colostomy or ileostomy represents a definitive solution for managing faecal incontinence. While an ileostomy might be considered for patients with colonic transit irregularities, the

colostomy is the standard ostomy approach employed in treating faecal incontinence (88). Although a colostomy carries short and long-term risks, it is a viable, secure and efficient intervention for severe faecal incontinence (88).

Whilst patients often harbour apprehensions about permanent colostomy due to concerns over its management, self-image, and social interactions; when individuals who underwent colostomy for faecal incontinence were surveyed, their overall quality of life and faecal incontinence-specific quality of life scores were higher compared to those of other individuals with faecal incontinence (89). Furthermore, a separate study revealed that patients generally expressed high levels of satisfaction with their stomas for faecal incontinence, with over 80% indicating they would willingly undergo the procedure again (90). Colostomy offers the most cost-effective approach in terms of quality-adjusted life years (91).

Conclusion

FI is a complex and multifaceted medical condition, often posing a diagnostic and management challenge for the generalist as well as the specialised colorectal surgeon. This narrative review aims to give a comprehensive overview of the pathophysiology, the diagnostic mechanisms and the treatment options, to assist the generalist to manage FI.

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

ED: Writing – original draft, Writing – review & editing. JW: Writing – original draft, Writing – review & editing. HW: Writing – original draft, Writing – review & editing. SD: Writing – original draft, Writing – review & editing. AL: Writing – review & editing. IL: Writing – review & editing. MY: 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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Telemedicine for sustainable postoperative follow-up: a prospective pilot study evaluating the hybrid life-cycle assessment approach to carbon footprint analysis

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Introduction: Surgical site infections (SSI) are the most common healthcare-associated infections; however, access to healthcare services, lack of patient awareness of signs, and inadequate wound surveillance can limit timely diagnosis. Telemedicine as a method for remote postoperative follow-up has been shown to improve healthcare efficiency without compromising clinical outcomes. Furthermore, telemedicine would reduce the carbon footprint of the National Health Service (NHS) through minimising patient travel, a significant contributor of carbon dioxide equivalent (CO_2e) emissions. Adopting innovative approaches, such as telemedicine, could aid in the NHS Net-Zero target by 2045. This study aimed to provide a comprehensive analysis of the feasibility and sustainability of telemedicine postoperative follow-up for remote diagnosis of SSI.
Methods: Patients who underwent a lower limb vascular procedure were reviewed remotely at 30 days following the surgery, with a combined outcome measure (photographs and Bluebelle Wound Healing Questionnaire). A hybrid life-cycle assessment approach to carbon footprint analysis was used. The kilograms of carbon dioxide equivalent ($kgCO_2e$) associated with remote methods were mapped prospectively. A simple outpatient clinic review, i.e., no further investigations or management required, was modelled for comparison. The Department of Environment, Food, and Rural Affairs (DEFRA) conversion factors plus healthcare specific sources were used to ascertain $kgCO_2e$. Patient postcodes were applied to conversion factors based upon mode of travel to calculate $kgCO_2e$ for patient travel. Total and median (interquartile range) carbon emissions saved were presented for both patients with and without SSI.
Results: Altogether 31 patients (M:F 2.4, ±11.7 years) were included. The median return distance for patient travel was 42.5 (7.2–58.7) km. Median reduction in emissions using remote follow-up was 41.2 (24.5–80.3) $kgCO_2e$ per patient ($P < 0.001$). The carbon offsetting value of remote follow-up is planting one tree for every 6.9 patients. Total carbon footprint of face-to-face follow-up was 2,895.3 $kgCO_2e$, compared with 1,301.3 $kgCO_2e$ when using a remote-first approach ($P < 0.001$). Carbon emissions due to participants without SSI were 700.2 $kgCO_2e$ by the clinical method and 28.8 $kgCO_2e$ from the remote follow-up.

Discussion: This model shows that the hybrid life-cycle assessment approach is achievable and reproducible. Implementation of an asynchronous digital follow-up model is effective in substantially reducing the carbon footprint of a tertiary vascular surgical centre. Further work is needed to corroborate these findings on a larger scale, quantify the impact of telemedicine on patient's quality of life, and incorporate $kgCO_2e$ into the cost analysis of potential SSI monitoring strategies.

KEYWORDS

telemedicine, sustainability, surgical site infection, surveillance, carbon emissions

Introduction

Surgical site infections (SSI) pose a significant disease burden globally, complicating 5%–20% of operations (1, 2). With the move towards earlier patient discharge in the current healthcare landscape, the majority of SSI occur after discharge (1). Early diagnosis and treatment of SSI are essential to reduce associated morbidity and mortality; however, access to healthcare services, lack of patient awareness of signs, and inadequate wound surveillance may limit timely diagnosis (3).

Telemedicine has emerged as an innovative method for monitoring patients remotely using electronic communication and information technologies (4). In 2021–2022, 22.9% of the 95.5 million attended outpatient appointments were classified as telemedicine, a substantial increase from 4.3% the previous year (5, 6). Telemedicine is becoming increasingly common in postoperative surgical care and has been shown to improve patient care through the reduction of time to diagnosis and patient travel, without compromising clinical outcomes (7, 8). Furthermore, evidence suggests that telemedicine is highly specific for the diagnosis of SSI and could be utilised as an effective screening tool (9).

In 2019, the National Health Service (NHS)contributed to around 25 million tonnes of carbon dioxide equivalent (CO_2e) emissions equating to around 7% of the total UK carbon footprint that year (10). A significant contributor of CO_2e emissions is patient travel, which has almost doubled since 1990 (10). For the NHS to achieve the Net-Zero carbon emission service target by 2045 through the Greener NHS campaign (11), the NHS must adopt innovative approaches to patient care and minimise unnecessary patient travel.

This pilot study aims to evaluate a novel methodology for mapping carbon footprint reduction when modelling remote-first approaches to postoperative follow-up.

Methods

Study design

This pilot cohort study mapped carbon emissions of patients followed-up remotely at 30 days after lower limb vascular surgery and modelled clinic carbon footprint for comparative impact assessment. The International Standard Organisation (ISO) 14060:2006 standards for quantification and reporting of greenhouse gases (GHG) were followed (12). All participants provided written consent as part of an ongoing randomised controlled trial (NCT02992951). Ethical approval for this trial was obtained (16/LO/2135) from London–Harrow Research Ethics Committee, and study conduct was in accordance with the Declaration of Helsinki (1975) (13).

The participants were recruited between 6 September 2022 and 1 December 2022, in a tertiary vascular centre in the UK. The eligibility criteria followed those set in the ongoing trial (NCT02992951), which included patients undergoing lower limb vascular surgery closed by primary intention with capacity. Those on antibiotics for conditions not related to their index procedure or had used an investigational device on operative site within four weeks were ineligible for inclusion. Patients were eligible for inclusion even if they did not own a smartphone to transfer wound images. In this instance, relatives, carers, or community nursing teams provided data with patient consent.

Outcomes

Primary outcome

Median reduction in kilograms of carbon equivalent ($kgCO_2e$) emissions per patient.

Secondary outcomes

- Total metric tonnes of carbon dioxide equivalent ($mtCO_2e$) emissions avoided using remote-first postoperative follow-up.
- Median reduction in $kgCO_2e$ emissions by participants diagnosed with SSI.
- Median reduction in $kgCO_2e$ by participants without SSI.
- Total distance (km) saved.

Data collection

Process analysis and life-cycle inventory analysis

Participants submitted wound images and completed the Bluebelle Wound Healing Questionnaire (WHQ) at 30 days following surgery, or earlier if a wound-related problem was identified (14). The submitted wound images and Bluebelle questionnaires were reviewed by a trained medical practitioner with experience in diagnosing SSI after vascular procedures. Carbon emissions ($kgCO_2e$) for the remote review were mapped based on healthcare resource use of the participants in addition to those incurred due to surgical site infection (such as antibiotic prescription). The patients who

developed wound-related problems sought medical advice and treatment through the standard care pathway. Participants also attended face-to-face wound review in comparison with remote review, which occurred on the same day as the remote assessment. Additional healthcare resource use data were collected on general practitioner face-to-face and remote reviews, community and general practice nurse review, antibiotic prescription, blood tests, microbiological sampling, further radiological investigations, and surgical intervention. As the purpose of this study was to model environmental emissions inclusive of postoperative follow-up, $kgCO_2e$ for the initial admission and initial index procedure were not included within this analysis. The potential $kgCO_2e$ savings for utilising a telemedicine-first approach were calculated by subtracting the model clinic emissions from the remote emissions.

Carbon emissions were mapped using a hybrid life-cycle assessment approach addressing environmental impact from both bottom-up (prospective item process analysis) and top-down (using a national economic approach to input–output analysis) directions. Utilising a bottom-up approach yields maximum accuracy although it requires physical mapping of individual resources and hence is labour and cost intensive, whereas top-down modelling encompasses system-wide factors beyond the scope of bottom-up assessment. All items are weighed using Model Scout Pro (SPU123) Electronic Balance for items ≤120 g and Marsden medical weighing scales (DS-673SS) for items >120 g.

The footprint analysis covers GHG emissions under Scopes 1–3 of the Greenhouse Gas Protocol (15), in addition to personal travel emissions not usually covered within these analyses, providing a comprehensive NHS Carbon Footprint Plus model (16) (Figure 1).

Scope 1

Data on anaesthetic gases were collected prospectively through a combination of operative time and anaesthetic agent applied with emissions factors provided by the Sustainable Development Unit (17) and Association of Anaesthetists Anaesthetic Gas Calculator (18). Emissions factors for surgical interventions were applied to operative time providing CO_2 equivalent for reoperation. No fossil fuels or NHS fleet vehicles were accounted for in this analysis.

Scope 2

The Department for Environment, Food, and Rural Affairs (DEFRA) and Business, Energy, and Industrial Strategy (BEIS) GHG conversion factors were applied to the data collected on electricity to provide $kgCO_2e$ within this scope (19). Electricity data accounted for lighting in both remote and clinic models, and for personal computer use.

Scope 3

DEFRA/BEIS GHG conversion factors for water use in addition to waste incineration factors were integrated with resource data providing emissions mapping. Water data collected accounted for handwashing in clinic models (19, 20). The NHS supply chain online catalogue provided individual clinic item costings (21). The National Institute of Health Research (NIHR) interactive costing tool for investigation and intervention tariff provided radiological investigation costs (22). No business travel or metered dose inhaler emissions were utilised within this study.

Pharmaceutical data comprised antibiotics prescribed for SSI. The British National Formulary (BNF) pricing information provided cost information for medications used (23). Medication costs were multiplied by accompanying emissions factors for pharmaceutical data. For oral medications, empty blister packs were weighed and quantified before mapping incineration factors. Intravenous antibiotic packaging were weighed and quantified before applying incineration factors.

National tariff data from the Personal Social Services Research Unit (PSSRU) provided hourly cost data for hospital clinician, general practitioner, and community nurse time (24). For remote review, time to complete assessment was applied to clinician cost and staff services emissions factor. For clinic review, allotted appointment time was multiplied by cost and the staff services emissions factor.

No additional medical devices, freight transport, business services, construction, food and catering, commissioned services, manufacturing, or commuting services' emissions were utilised or calculated within this study.

Emissions outside GHG protocol scope

Patient travel emissions were evaluated by collecting mode of transport, return mileage from home postcode to clinic postcode, and application of the emissions factor for method of transport (DEFRA/BEIS conversion factors) (19).

Statistics

Data were collected and entered into IBM SPSS (IBM SPSS Corporation, version 28; Rochester, NY, USA), and a two-sided

Scope 1	Scope 2	Scope 3	Non-Protocol
Anaesthetic Gases	Electricity	Water and Waste Pharmaceuticals ICT Medical devices Commissioned services	Patient and visitor travel

FIGURE 1
NHS carbon footprint plus evaluated emissions by GHG protocol scopes.

TABLE 1 Baseline characteristics of participants.

	Participants ($n = 31$)	SSI ($n = 9$)	No SSI ($n = 22$)
Sex			
Male	22 (71.0)	5	17
Female	9 (29.0)	4	5
Age (years)			
Mean (SD)	66.7 (11.7)	65.6 (13.8)	67.2 (11.0)
Ethnicity			
White	31 (100.0)	9 (29.0)	22 (100.0)
BMI			
Obese	5 (16.1)	3 (9.2)	2 (6.5)
Not obese	26 (83.9)	7 (22.6)	20 (64.5)
Smoking status			
Smoker	11 (35.5)	5 (16.1)	6 (19.4)
Ex-smoker	14 (45.2)	3 (9.7)	11 (35.5)
Non-smoker	6 (19.4)	1 (3.2)	5 (16.1)
Diabetes			
Insulin dependent	4 (12.9)	2 (6.5)	2 (6.5)
Non-insulin dependent	9 (29.0)	1 (3.2)	8 (25.8)
None	18 (58.1)	6 (19.4)	12 (38.7)
CVA			
Yes	2 (6.5)	0 (0.0)	2 (6.5)
No	29 (93.5)	9 (23.0)	20 (64.5)
Hypertension			
None	10 (32.3)	3 (9.7)	7 (22.6)
No medication	6 (19.4)	2 (6.5)	4 (12.9)
One agent	5 (16.1)	1 (3.2)	4 (12.9)
Two agents	7 (22.6)	1 (3.2)	6 (19.4)
Three or more agents	3 (9.7)	2 (6.5)	1 (3.2)
Peripheral vascular disease			
Yes	31 (100.0)	9 (29.0)	22 (71)
Respiratory disease			
Yes	9 (29.0)	4 (12.9)	5 (16.1)
No	22 (71.0)	5 (16.1)	17 (54.8)
Renal disease			
Yes	4 (12.9)	2 (6.5)	2 (6.5)
No	27 (87.1)	7 (22.6)	20 (64.5)
Immunosuppressants			
Yes	1 (3.2)	1 (3.2)	0 (0.0)
No	30 97.8)	8 (25.8)	22 (71.0)
Baseline creatinine			
Umol/L	83.5 (27.7)	86 (27.3)	82.5 (28.5)
Index procedure			
Common femoral endarterectomy	9 (29.0)	4 (12.9)	5 (16.1)
Femoral-distal bypass	7 (22.6)	2 (6.5)	5 (16.1)
Femoral-popliteal bypass	11 (35.5)	2 (6.5)	9 (23.0)
Femoral-femoral bypass	1 (3.2)	0 (0.0)	1 (3.2)
Aorto-bifemoral bypass	2 (6.5)	1 (3.2)	1 (3.2)
Below knee amputation	1 (3.2)	0 (0.0)	1 (3.2)

CVA, cerebrovascular accident.

P-value of <0.05 was accepted as a suitable level of significance. Descriptive statistics are presented as proportions or mean ± standard deviation as appropriate. Emissions outcomes are reported as median [interquartile range (IQR)] and groups were compared using the Wilcoxon signed-rank Test. When comparing participants with and without SSI, Mann–Whitney *U* test was used to assess significance across groups. Calculations for carbon offsetting value in trees planted are based upon the $kgCO_2e$ sequestered by a 10-year-old, 5-m tall, 25-cm diameter tree with dry weight of 155.6 kg (25).

Results

A total of 57 patients were eligible to be included, with 31 agreeing to participate (54.4%). Table 1 outlines baseline characteristics of the included participants. At day 30 follow-up, 28 patients had completed remote follow-up. There were two (6.5%) perioperative mortalities due to ischaemic heart disease and irretrievable limb ischaemia. One (3.2%) participant developed surgical site infection postoperatively requiring significant re-intervention. This resulted in a prolonged admission; hence, the 30-day follow-up was conducted on the ward. This patient was excluded, leaving 28 patients within this analysis. At follow-up, 8 of the 28 participants had developed SSI, giving an infection rate of 28.6%. One patient required readmission for further investigation but not surgical intervention. The remote assessment method correctly identified 7 participants with SSI and 18 participants without SSI. The sensitivity and specificity for identifying SSI were 87.5% and 90.0%, respectively. Using a remote assessment approach resulted in a mean reduction in review time of 12.8 ± 7.5 min per patient (Clinic vs. Remote; 16.6 ± 7.6 vs. 3.8 ± 0.3).

The median (IQR) reduction in carbon emissions of remote compared with clinic follow-up was 41.2 (24.5–80.3) $kgCO_2e$ ($P < 0.001$). The carbon offsetting value using remote-first follow-up is planting one tree for every 6.9 patients. Total carbon footprint of face-to-face follow-up was 2,895.3 $kgCO_2e$, compared with 1,301.3 $kgCO_2e$ when using a remote-first approach ($P < 0.001$), providing an offsetting value of planting 5.6 trees.

Median and total emissions values for participants with SSI are provided in Table 2, in addition to healthcare resource use. Of those who had a diagnosis of SSI (eight), most (five of eight, 62.5%) had 7 days of antibiotics, half (four of eight, 50.0%) had three additional healthcare visits with equal numbers receiving one and two additional visits (two of eight, 25.0%). One participant (12.5%) required readmission for intravenous antibiotics, and subsequently incurred 13 additional bed days. In the 20 participants without wound complications, utilising a remote-first approach improved the environmental impact of follow-up. Median (IQR) reduction in emissions for participants without infection reviewed by remote compared with clinic models were 32.4 (24.4–43.9) $kgCO_2e$ ($P < 0.001$). Total carbon footprint without wound complications was 700.2 $kgCO_2e$ for the clinic method and 28.8 $kgCO_2e$ for remote follow-up.

Using a clinic approach would have incurred a total of 1,424.3 patient return km travelled. Subsequently, this would result in 300.9 $kgCO_2e$, with a carbon offsetting value of 1.1 trees. Median (IQR) distance travelled per patient was 42.5 (7.2–58.7) km.

Discussion

This pilot study outlines the successful implementation of a prospective hybrid accounting method to model the carbon

TABLE 2 Healthcare resource use for participants with SSI.

Patient	GP face-to-face	GP remote	Clinic face-to-face	DN F2F	Nurse clinic face-to-face	Antibiotics	Antibiotic days	Blood bottles	MCS swabs	CT imaging	USS imaging	Hospital bed days	Re-intervention	$kgCO_2e$ by postoperative remote follow-up	$kgCO_2e$ by face-to-face follow-up	*P*-value
1	1	0	0	2	0	Flucloxacillin	14	0	1	1	1	0	0	20.43	192.92	
2	1	0	0	0	1	Flucloxacillin	7	0	0	0	0	0	0	2.12	114.91	
3	0	1	0	0	0	Flucloxacillin	7	0	0	0	0	0	0	3.40	187.85	
4	0	1	0	2	0	Flucloxacillin/ Co-trimoxazole	14	20	2	1	0	13	0	1,183.76	1,219.93	
5	1	0	0	2	0	Flucloxacillin	14	0	0	0	0	0	0	20.22	126.03	
6	0	0	1	2	0	Co-amoxiclav	7	0	0	0	0	0	0	20.77	126.52	
7	1	0	0	0	0	Flucloxacillin	7	0	0	0	0	0	0	19.67	92.96	
8	0	0	0	2	0	Flucloxacillin	7	0	0	0	0	0	0	2.12	124.08	
Median $kgCO_2e$ (IQR)														19.95 (3.1–20.5)	129.16 (125.6–190.0)	0.012
Total $kgCO_2e$ by follow-up method														1,272.50	2,195.0	0.012

GP, general practitioner; MCS, microcopy culture and sensitivity; USS, ultrasound sonography.
Median and total $kgCO_2e$ are presented for both remote and face-to-face groups.

footprint of healthcare activity. To the authors' knowledge, it is the first study to prospectively model NHS Carbon Footprint Plus emissions in a comparative cohort, assessing two potential environmental interventions. These results may provide a reference case for further prospective environmental analysis. The "remote-first" postoperative follow-up appears to reduce the carbon footprint in this surgical tertiary centre by 41.2 (24.5–80.3) $kgCO_2e$ per patient. Widespread deployment of a "telemedicine-first" approach to postoperative follow-up could potentially reduce national surgical emissions in line with the NHS long-term plan and Net-Zero 2045 initiatives (16, 26). Extrapolating data presented here to UK Health Security Agency surveillance reports would provide an annual reduction of 4,524.30 $mtCO_2e$, with a carbon offsetting value of 15 trees planted or return flights from London, UK, to Perth, Australia (19, 27). Extrapolating data presented here to UK Health Security Agency surveillance reports would provide an annual reduction of 4,524.30 $mtCO_2e$, with a carbon offsetting value of 15,900 trees planted or 2,100 return flights from London, UK, to Perth, Australia (19, 27).

Implementing routine remote-first follow-up is safe and accurate for detecting postoperative wound complications (9). This pilot study highlights the feasibility of employing simple measures to achieve asynchronous data collection, although an effective user-friendly interface has been utilised elsewhere (28). The Department of Health and Social Care Medical Technology Strategy and Royal College of Surgeons guidance outline the significance of adopting efficient models of care and improving patient outcomes through early detection (29, 30). In the wake of the SARS-CoV-2 pandemic, innovative strategies are required to streamline surgical care services that can be achieved through remote postoperative follow-up.

SSI rates captured in this study are high (28.6%), but comparative to other literature involving vascular groin incisions (31, 32). The mean age of participants was 66.7 years, reflecting good engagement with elderly population. Previous studies have included younger participants in postoperative telemedicine studies, which may have reflected age-related usability (3). Interestingly, readmission with SSI without any surgical intervention resulted in emissions of 1,219.93 $kgCO_2e$, substantially higher than SSI managed in the community (137.90 $kgCO_2e$ if clinic review and 12.68 $kgCO_2e$ if reviewed remotely). The small sample of infections here warrants further investigation into the beneficial environmental impact of preventing SSI.

This study does have some limitations. The hybrid accounting methodology has been proposed as the optimum strategy to achieve accuracy, precision, and cost efficiency in carbon footprint modelling (33), and has been successfully employed previously (10). Telemedicine has also been the focus of a recent retrospective life-cycle assessment; however, prospective assessment enables greater granularity of process analysis within the hybrid approach suggested here (34). While utilising this method enables flexibility in bottom-up and top-down approaches to study design, numerous sources are required to comprehensively cover the emissions factors outlined within and out of scopes 1–3 in the GHG protocol (15–24). A carbon accountant was not utilised in this study, although future projects may consider this addition to augment

study methodology. However, systematic processes were followed to map carbon emissions within this study, although specific factors continue to be challenging to quantify, such as room kilowatt hour heating and cubic metre water use. To date, there are no universally agreed upon outcome metrics for carbon footprint analysis. Several outcomes for GHG emissions have been outlined dependent on the project objectives, such as emissions intensity, weighted average carbon intensity, absolute emissions among others, although these are not emphasised in a healthcare context (35). There is significant need for the development and regular updates of core outcome sets and checklists in ensuring comparable and rigorous methodological design of environmental studies in healthcare settings.

Carbon offsetting was presented here in number of trees planted, although an alternative approach would be to standardise this value per patient. For reference, remote clinics would have an overall offsetting value of 0.13 trees/patient with the figures here as follows: 0.37 trees/patient for those with infection and 0.11 trees/patient without SSI. While projections based upon national registry data are proposed, the sample size within this pilot study is small, limiting the generalisability of findings. Further studies in pan-specialty postoperative clinics are needed to corroborate these models. For holistic assessment of the environmental impact, all postoperative infections should be mapped with full cost analysis, both of which were beyond the scope of this study.

As a pilot environmental modelling study, this methodology has shown to be achievable and reproducible. It provides a possible reference case to base prospective comparisons of environmental interventions on, which may become key outcomes within future trial methodology alongside cost utility analyses. In addition, it adds key data to the growing body of evidence supporting the benefits of remote postoperative follow-up. A larger cohort will follow this pilot, aligning monetary values with carbon footprint outcomes to further quantify the benefits evidenced here.

Data availability statement

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

Ethics statement

All participants provided written consent as part of an ongoing randomised controlled trial (NCT02992951). Ethical approval for this trial was obtained (16/LO/2135) from London–Harrow Research Ethics Committee. 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

RL: Conceptualization, Data curation, Formal Analysis, Funding acquisition, Investigation, Methodology, Project administration, Validation, Writing – original draft. LH: Data curation, Formal Analysis, Methodology, Writing – original draft. JW: Data curation, Methodology, Validation, Writing – original draft. BR: Data curation, Formal Analysis, Methodology, Writing – review & editing. DC: Formal Analysis, Validation, Writing – review & editing. GS: Formal Analysis, Supervision, Writing – review & editing. IC: Formal Analysis, Supervision, Validation, Writing – review & editing. MY: Conceptualization, Funding acquisition, 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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Saliva stress biomarkers in ERCP trainees before and after familiarisation with ERCP on a virtual simulator

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Background: Stress during the early ERCP learning curve may interfere with acquisition of skills during training. The purpose of this study was to compare stress biomarkers in the saliva of trainees before and after familiarisation with ERCP exercises on a virtual simulator.

Methods: Altogether 26 endoscopists under training, 14 women and 12 men, completed the three phases of this study: Phase 1. Three different ERCP procedures were performed on the simulator. Saliva for α-amylase (sAA), Chromogranin A (sCgA), and Cortisol (sC) were collected before (baseline), halfway through the exercise (ex.), and 10 min after completion of the exercise (comp.); Phase 2. A three-week familiarisation period where at least 30 different cases were performed on the virtual ERCP simulator; and Phase 3. Identical to Phase 1 where saliva samples were once again collected at baseline, during, and after the exercise. Percentage differences in biomarker levels between baseline and exercise ($Diff_{ex}$) and between baseline and completion ($Diff_{comp}$) during Phase 1 and Phase 3 were calculated for each stress marker.

Results: Mean % changes, $Diff_{ex}$ and $Diff_{comp}$, were significantly positive ($p < 0.05$) for all markers in both Phase 1 and Phase 3. $Diff_{ex}$ in Phase 1 was significantly greater than $Diff_{ex}$ in Phase 3 ($p < 0.05$) for sAA and sCgA. $Diff_{comp}$ for sAA in Phase 1 was significantly greater than $Diff_{comp}$ in Phase 3 ($p < 0.05$). No significant differences were found in sC concentration between Phases 1 and 3.

Conclusion: This study shows that familiarisation with the ERCP simulator greatly reduced stress as measured by the three saliva stress biomarkers used with sAA being the best. It also suggests that familiarisation with an ERCP simulator might reduce stress in the clinical setting.

KEYWORDS

ERCP, virtual simulator, training, stress, saliva biomarkers

1 Introduction

ERCP is a technically demanding endoscopic procedure requiring a high level of expertise to provide effective and safe patient care. Somehow, trainees must be able to practice effectively without putting the safety of the patient in jeopardy. Simulator-based training is thus highly recommended (1).

Virtual reality simulation is an established method for acquiring and improving technical and non-technical skills in a controlled, reproducible, and quantitative environment that replicates real psychological challenges and mental stress. Simulation training has been used to assess stress and to develop intraprocedural stress management (2). The complexity of stress mechanisms makes acute stress measurement difficult to quantify and interpret. There is no universally recognised non-invasive gold standard technique for the assessment of stress. Instead, subjective, and objective surrogate methods have been proposed, such as measuring acute changes in the autonomic nervous system (ANS). Furthermore, non-invasive measurement of actual stress during a clinical procedure is not practically feasible (3).

There are objective biomarkers of stress in the blood and saliva. The use of blood biomarkers involves the invasive procedure of taking blood, whereas saliva sampling is relatively non-invasive and thus a better way to analyse stress. According to the literature, the most effective salivary biomarkers of stress are cortisol (sC), alpha-amylase (sAA), and chromogranin A (sCgA) (4). Since stress is not dichotomous there are no specific thresholds for these biomarkers that indicate a high level of stress (5). Furthermore, stress is usually associated with impaired performance which, in the clinical situation, could lead to complications. Moreover, it has been shown that trainees suffer greater stress than more experienced practitioners (6).

When training individuals in colonoscopy, steeper learning curves and fewer complications have been observed when employing a simulator-based program in training (7). These benefits have yet to be shown for ERCP (8). Furthermore, in a recent systematic review on the use of simulators to acquire ERCP skills, only one study conformed with validation criteria (9).

Our primary objective was thus to non-invasively measure stress levels of ERCP trainees by means of saliva stress biomarkers before and after familiarisation with virtual reality (VR) ERCP simulation. A secondary outcome was to assess any differences in stress between men and women.

2 Materials and methods

2.1 Participants

Fifty-one trainee residents aged 28–34 years were enrolled. All participants were residents in gastroenterology and general surgery, without any previous experience in ERCP. Written informed consent was obtained from each participant. The experiments were performed at the Medical Simulation Training Centre at the Medical University, Plovdiv, Bulgaria.

2.2 Experiments procedure

2.2.1 Initial exercise: phase 1

All subjects answered a baseline questionnaire for information on demographic data and prior endoscopic or simulator experience. They conformed with the following inclusion criteria: (1) no current prescribed or non-prescription medication; (2) no flu or symptom of upper respiratory tract infection; (3) non-smoker; (4) no alcohol, coffee, or exercise within 12 h prior to testing; and (5) no food or brushing of teeth within 1 h of the experiment. A post-experiment questionnaire regarding the participant's perception of the project was answered.

After a rest period of 30 min, a baseline saliva sample was collected using an unstimulated passive drool technique. The subjects then spent 30 min getting used to the ERCP modules on the GI-Mentor II simulator (Surgical Science Sweden AB, Gothenburg, Sweden) as well as add-on software (guidewires *etc*). Then they watched a video prepared by the second author, demonstrating the three ERCP exercises to be performed in the hands-on session. They then performed virtual bile duct cannulation three times to become acquainted with the simulator. The participants then completed, to the best of their ability, the following three virtual ERCP exercises with increasing level of difficulty:

a. *ERCP Exercise 1: Bile duct stone removal (ERCP Module 1, Case Study 4).*

Deep cannulation of the bile duct (BD) with a sphincterotomy catheter, contrast injection to diagnose the common bile duct stone (CBDS), then sphincterotomy followed by stone extraction using an extraction balloon.

b. *ERCP Exercise 2: Diagnosis of hilar stenosis, and brush cytology (ERCP Module 1, Case Study 2).*

Cannulation of the BD and insertion of a guidewire. Contrast injection to reveal hilar stenosis. After sphincterotomy, brush cytology of the stenosis is performed.

c. *ERCP Exercise 3: Diagnosis of cystic bile duct leakage and treatment with placement of a bile duct stent (ERCP Module 2, Case Study 4).*

BD cannulation using a sphincterotomy catheter followed by contrast injection revealing cystic leakage. After sphincterotomy, a plastic stent is introduced to cover the site of the cystic duct leakage.

No mentor intervention was allowed during the exercise session. Halfway through the first exercise (Phase 1), an "exercise" saliva sample was collected, and 10 min after completing the exercise a third "completion" saliva specimen was taken as before. The saliva samples were refrigerated and subsequently stored at −20 °C within 4 h of collection pending analysis. Participants unable to complete the three ERCP exercises of Phase 1 were excluded as no comparison with the reciprocal exercises of Phase 3 could be achieved. Therefore, only the remaining 26 proceeded on to Phase 2.

2.2.2 Familiarisation: phase 2

During the following three weeks, the participants remaining became familiar with the ERCP simulator by performing at will at least 30 procedures supervised by a mentor (not including the initial three exercise procedures in Phase 1).

2.2.3 Repetition: phase 3

After familiarisation, the remaining participants completed the three exercises exactly as in Phase 1 described above, and new saliva specimens (baseline, exercise, and completion) were collected and stored for analysis.

2.3 Data analysis

All saliva samples were assessed using commercially available kits. For salivary cortisol (SME-1- 3002 Salivary Cortisol Research ELISA kit) and for α-amylase (SME-1- 1902 Alpha-amylase Kinetic Reaction Kit Research) were used, both from Salimetrics, Carlsbad, CA, USA (www.salimetrics.com). Human Chromogranin A (sCgA) was measured with an EIA Kit (Cat. No.: RSCYK070R, BioVendor GmbH Germany). Concentrations of the saliva biomarkers were determined following the manufacturer's instructions.

To reduce multifactorial stress bias from external factors, the percentage difference ($Diff_{ex}$) of each saliva biomarker was calculated from its baseline and exercise values, as well as the corresponding difference ($Diff_{comp}$) between baseline and completion values. Accordingly, $Diff_{ex} = 100 \times (Value_{ex} - Value_{bas})/Value_{bas}$ and $Diff_{comp} = 100 \times (Value_{comp} - Value_{bas})/Value_{bas}$.

2.4 Statistical analysis

The normality of the collected data was tested using the Kolmogorov–Smirnov test. The R software version 3.5.0 was used for statistical analysis (10).

We used paired *t*-test to compare mean $Diff_{ex}$ between Phases 1 and 3 as well as between $Diff_{comp}$ between Phases 1 and 3. We also used one-sided t- test to determine whether mean $Diff_{ex}$ or $Diff_{comp}$ in Phases 1 and 3 were positive showing that saliva parameter values during exercise and completion were significantly greater than their corresponding baseline.

3 Results

Twenty-five of the 51 participants were unable to complete Phase 1 and were therefore excluded from the study. Thus, our final group consisted of 26 participants (12 men and 14 women), 7 were 20–30 years of age and the remaining ($n = 19$) 30–40 years of age.

All participants experienced saliva collection to be problem-free and did not cause distraction. The distribution of the collected data was tested using the Kolmogorov–Smirnov test and found to be normal.

$Diff_{ex}$ and $Diff_{comp}$ values were calculated from the Phase 1 and Phase 3 saliva biomarker data. Thus, six percentage differences $Diff_{ex}$ and $Diff_{comp}$ for the three saliva biomarkers were estimated in Phase 1 and six in Phase 3 (see Tables 1–3).

3.1 α-amylase

Mean $Diff_{ex}$ and $Diff_{comp}$ (% ± SD) for saliva α-amylase in Phase 1 were 185.0 ± 457.3 and 264 ± 585.3 respectively, both significantly positive ($p < 0.05$). This suggests that α-Amylase is a stress biomarker since it increased during and immediately after the exercise session compared to baseline values. Mean $Diff_{ex}$

TABLE 1 $Diff_{ex}$(%) and $diff_{comp}$(%) for saliva biomarkers (mean + SD) in phases 1 and 3.

a-amylase	Phase 1		Phase 2		*p*-value
	Mean	SD	Mean	SD	
$Diff_{ex}$	185	457.3	8.6	53.2	<0.05
$Diff_{comp}$	264	585.3	28.7	83.1	<0.05
Chromogranin A					
$Diff_{ex}$	71	97.7	42.4	49.7	<0.05
$Diff_{comp}$	47.9	81.3	32.9	41.4	0.23
Cortisol					
$Diff_{ex}$	31.4	32.3	22.5	33.7	0.18
$Diff_{comp}$	46.4	36	42	51.4	0.36

TABLE 2 Male group ($n = 12$): $diff_{ex}$(%) and $diff_{comp}$(%) (mean + SD) for each saliva biomarker in phases 1 and 3.

a-amylase	Phase 1		Phase 3		*p*-value
	Mean	SD	Mean	SD	
$Diff_{ex}$	−4.4	28.2	−5.1	36.2	0.47
$Diff_{comp}$	56.6	92.3	30.7	113.4	0.27
Chromogranin A					
$Diff_{ex}$	91.5	122	53.9	65.6	0.13
$Diff_{comp}$	57.9	100.7	39.7	43.4	0.31
Cortisol					
$Diff_{ex}$	33.2	35.7	31.6	30.3	0.46
$Diff_{comp}$	46.2	36.7	56.2	66.7	0.33

TABLE 3 Female group ($n = 14$): $diff_{ex}$(%) and $diff_{comp}$(%) (mean + SD) of for each saliva biomarker in phases 1 and 3.

a-amylase	Phase 1		Phase 3		*p*-value
	Mean	SD	Mean	SD	
$Diff_{ex}$	347.4	583.1	20.3	63.3	<0.05
$Diff_{comp}$	441.8	760.2	27.1	48.8	<0.05
Chromogranin A					
$Diff_{ex}$	53.5	71.1	32.5	29.5	0.11
$Diff_{comp}$	39.3	62.9	27.2	40.4	0.29
Cortisol					
$Diff_{ex}$	29.9	30.4	14.7	35.5	0.12
$Diff_{comp}$	46.6	36.9	29.9	31.2	0.12

and $Diff_{comp}$ in Phase 1 (see above) were significantly greater than the corresponding figures in Phase 3 (8.6 ± 53.2 and 28.7 ± 83.1 resp, $p < 0.05$) (Table 1).

Mean $Diff_{ex}$ (−4.4 ± 28.2) and $Diff_{comp}$ (56.6 ± 92.3) for men in Phase 1 were no different to the corresponding figures in Phase 3 (−5.1 ± 36.2. $p = 0.47$, and 30.7 ± 113.4. $p = 0.27$ resp) (Table 2).

For the women, mean $Diff_{ex}$ (347.4 ± 583.1) and $Diff_{comp}$ (441.8 ± 760.2) in Phase 1 were significantly different from the corresponding figures in Phase 3 (20.3 ± 63.3 and 27.1 ± 48.8, $P < 0.05$) (Table 3).

3.2 Chromogranin A

Mean $Diff_{ex}$ and $Diff_{comp}$ for sCgA in Phase 1 were 71.0 ± 97.7 and 47.9 ± 81.3 respectively, both significantly positive ($p < 0.05$). This again suggests that chromogranin A is an indicator of stress as it increased during and immediately after the exercise session compared to baseline. Mean $Diff_{ex}$ in Phase1 was significantly higher than $Diff_{ex}$ (42.4 ± 49.7) in Phase 3 ($p < 0.05$), whereas mean $Diff_{comp}$ in Phase 1 was not significantly different from mean $Diff_{comp}$ (32.9 ± 41.4) in Phase 3 ($p = 0.23$) (Table 1).

In the male group, mean $Diff_{ex}$ (91.5 ± 122.0) and $Diff_{comp}$ (57.9 ± 100.7) in Phase 1 were not significantly different from $Diff_{ex}$ (53.9 ± 65.6) and $Diff_{comp}$ (39.7 ± 43.4) values in Phase 3 ($p = 0.13$ and $p = 0.31$ for $Diff_{ex}$ and $Diff_{comp}$ respectively) (Table 2).

For the women, mean $Diff_{ex}$ (53.5 ± 71.1) and $Diff_{comp}$ (39.3 ± 62.9) in Phase 1 were not significantly different from mean $Diff_{ex}$ (32.5 ± 29.5) and $Diff_{comp}$ (27.2 ± 40.4) in Phase 3 ($p = 0.11$ and $p = 0.29$ for $Diff_{ex}$ and $Diff_{comp}$ respectively) (Table 3).

3.3 Saliva cortisol

Mean $Diff_{ex}$ and $Diff_{comp}$ for saliva cortisol in Phase 1 were 31.4 ± 32.3 and 46.4 ± 36.0 respectively, both significantly positive ($P < 0.05$), indicating that Cortisol is also a stress biomarker as it has increased during and immediately after the exercise session compared to baseline. Mean $Diff_{ex}$ and $Diff_{comp}$ in Phase 1 were not significantly different from $Diff_{ex}$ (22.5 ± 33.7) and $Diff_{comp}$ (42.0 ± 51.4) in Phase 3 ($p = 0.18$ and $p = 0.36$ respectively) (Table 1).

The mean $Diff_{ex}$ (33.2 ± 35.7) for men in Phase 1 was not significantly different from $Diff_{ex}$ (31.6 ± 30.3) in Phase 3 ($p = 0.46$), nor was $Diff_{comp}$ (46.2 ± 36.7) in Phase 1 significantly different from $Diff_{comp}$ (56.2 ± 66.7) in Phase 3 ($p = 0.33$) (Table 2).

Mean $Diff_{ex}$ (29.9 ± 30.4) and $Diff_{comp}$ (46.6 ± 36.9) values for the women in Phase 1 were not significantly different from the corresponding figures in Phase 3 (14.7 ± 35.5 and 29.9 ± 31.2, $p = 0.12$ for both) (Table 3).

4 Discussion

The saliva stress biomarkers sAA, sCgA, and sC reliably correlated with mental stress while training on an ERCP simulator. The most accurate prediction of degree of change is obtained by sAA. The response to acute stress involves a complex process which is mediated by the hypothalamic-pituitary-adrenal (HPA) axis, as well as psychological and social reactions.

In the clinical setting, acute stress has a direct impact on performance and patient safety. Endoscopists performing ERCP, frequently encounter highly complex and thus stressful situations. Stress assessment and coping is thus relevant and necessary in this field (2). Thus, the ability to implement a coping strategy to deal with stress is thus important for enhancing performance (11).

Stress is a psychological construct and thus inherently difficult to measure objectively in terms of physiological parameters. Methods assessing autonomic nervous system (ANS) responses in various organ systems have been suggested as surrogate stress markers. These markers include: (a) changes in heart rhythm, measured by heart rate (HR), heart rate variability (HRV), or inter-beat interval (IBI); (b) electrodermal activity (EDA) levels; (c) thermal activity; and (d) saliva stress biomarkers (*i.e.,* sAA, sCgA, sC, and secretory immunoglobulin A). There is a lack of consistent methodology that has led to rather inconclusive and, in certain cases, conflicting results (12).

To our knowledge, this study is the first to use three commercially available saliva stress biomarkers in an ERCP simulation setting. No previous study has reported acute mental strain measurements during endoscopy in clinical and simulation settings (13). In this study, we concomitantly measured saliva a-amylase, saliva chromogranin A, and saliva cortisol, all of them potential stress biomarkers, in a reproducible virtual simulation setting (14–16).

A previous study showed that the biomarkers we used have strong correlations with stress (3). sAA is secreted from the salivary glands but great intra-individual variations are observed (17). It has been suggested that sAA could be used as a surrogate marker of norepinephrine in a variety of stressful conditions (18). In contrast to sC, sAA activity is affected by salivary flow rate and pH (19). Furthermore, in a study stressful situations were associated with higher sAA levels (20).

Chromogranin A (CgA) is a glycoprotein that mediates intracellular storage of catecholamines and is released together with these by the sympathetic nervous system into the blood circulation (21). Previous studies have shown that sCgA responds rapidly to mental stress such as psychosomatic stress [25], academic assessment stress, and computer operation psychological stress (22, 23). Furthermore, it has been observed that sCgA levels increase during mental stress but decrease during intermissions, suggesting that sCgA can be used for short-term assessment of mental workload (24). sCgA is a more accurate indicator than sC since it responds more rapidly and more sensitively to psychological stressors (12). Others, however, have questioned the ability of sCgA to measure stress and/or ANS activity (25).

Plasma cortisol enters the saliva through passive diffusion leading to a stable plasma/saliva ratio. Saliva cortisol levels can thus be used to assess stress related HPA activity, and this has become the most widely used biomarker for studies on mental stress. Saliva cortisol levels begin to rise within 5 min of an increase in plasma cortisol reaching a peak 31–40 min after the onset of the stressor, and saliva levels correlate strongly with

plasma cortisol concentrations. Studies have shown that acute stress increases sC levels (3). Some studies have failed to observe such an increase (26) and even a reduction in cortisol level after stress has been reported (11).

The use of saliva stress biomarkers in this study, proved to be simple and without distraction and preferable to invasive methods such as blood sampling (3). Biochemical stress markers were elevated during Phase 1 *i.e.*, during the first attempts to perform ERCP simulator exercises, and decreased as the trainees became acquainted with the simulation environment. This should be considered when planning simulator and clinical training. There were also some differences between the male and female trainees.

As $Diff_{ex}$ and $Diff_{comp}$ in Phase 1 were all significantly positive, we conclude that sAA, sCgA, and sC may be used as stress biomarkers. Of these, the best stress marker appeared to be sAA as it showed the greater percentage increase compared to increases in sCgA and sC (Table 1). It is also evident that familiarisation with the ERCP simulator during Phase 2 led to a reduction in stress while performing exercise in Phase 3, as indicated by the biomarkers used.

Throughout the world, women are highly underrepresented in the field of advanced endoscopy (8). In this study, however, more women participated than men. The stress response appears to be lower in women than in men (27). It has been suggested that this could be caused by a stronger cortisol response in women in the luteal phase than in those in the follicular phase. The menstrual cycle should thus be taken into consideration when assessing the reaction to stress. The cortisol levels may also be affected by oral contraceptives (28). Thus, saliva secretion differs between the sexes, and may be due to variations in the secretion of gonadal steroids and ANS regulation (29).

Our results partially support this observation since sAA $Diff_{ex}$ and $Diff_{comp}$ in the women during Phase 1 were greater than the corresponding values in men. However, sCgA $Diff_{ex}$ and $Diff_{comp}$ were higher in men, and no difference was seen between men and women for sC (Tables 2, 3). When comparing saliva results for sAA, sCgA, sC between Phase 1 and Phase 3, there were no differences in the male group, but sAA showed a statistically significant increase in the female group. Moreover, as can be seen from Tables 2, 3, during Phase 3 both sexes had similar $Diff_{ex}$ and $Diff_{comp}$ for all saliva biomarkers measured (sAA, sCgA, sC).

It should be noted that performance in basic endoscopy does not necessarily correlate with ERCP performance, since no relationship between basic handling skills and therapeutic skills has been demonstrated (30). Furthermore, extrapolation of results from a simulator to the clinical setting should be made with extreme caution. For practical reasons, *in vivo* measurements of physical examination cannot routinely be measured. Endoscopy simulators could, however, play a role in the trainee screening process (31).

In this study, mean sCgA $Diff_{ex}$ and $Diff_{comp}$ during Phase 1 were significantly positive ($p < 0.05$), suggesting that Chromogranin A may be used as a stress biomarker. We also saw that the percentage difference in sCgA between exercise and baseline in Phase 1 was significantly greater than the corresponding difference in Phase 3, indicating that familiarisation in Phase 2 reduced stress in Phase 3.

During Phase 1, mean sC $Diff_{ex}$ and $Diff_{comp}$ were significantly positive ($p < 0.05$), suggesting that saliva cortisol may be used as a stress indicator. This finding concurs with the findings of a study assessing sAA and sC during acute mental stress in 51 surgeons in the OR (25).

This study has some limitations. The sample size was small, and our findings must be interpreted with caution. Secondly, any delayed salivary cortisol response would have been missed and delay in saliva sampling may be necessary to fully detect stress-induced cortisol response (32). No comparison with the FES score was made, and finally, the study focused on simulated ERCP training only, so extrapolation to clinical practice is not feasible. Furthermore, another limitation of the study is that we did not check the oral hygiene of the participants. As it is suggested the latter could influence the accuracy of the saliva biomarkers.

Nevertheless, this study sheds some light on the feasibility of using non-invasive assessment of stress experienced by trainee endoscopists using easy to collect saliva biomarkers. Larger, controlled studies with participants that have different clinical experience is needed to further evaluate and monitor stress during simulation training using saliva biomarkers.

Finally, this was a laboratory study conducted in a controlled environment, whereas stress monitoring in the clinical setting is more complex due to the influence of social, cultural, and psychological factors (33).

5 Conclusion

In conclusion, the use of saliva biomarkers for assessing mental stress was easy to implement and well-accepted by all participants in this virtual simulation ERCP training setting. Familiarisation with the ERCP simulator greatly reduced stress when performing ERCP exercises afterwards. The saliva stress biomarkers sAA, sCgA, and sC may all be used to assess mental stress while training on an ERCP simulator, but the best of the three, judging by the degree of change, appears to be sAA. No conclusive difference in stress response between men and women was observed. Further studies including a larger number of trainees with different levels of ERCP experience are needed to exploit performance enhancement and error reduction techniques in ERCP training.

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 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

KG: Data curation, Methodology, Resources, Writing – original draft, Writing – review & editing. NB: Data curation, Methodology, Project administration, Resources, Supervision, Writing – review & editing. DT: Data curation, Formal Analysis, Validation, Writing – review & editing. GS: Formal Analysis, Supervision, Writing – review & editing. DL: Writing – review & editing. LE: Conceptualization, Formal Analysis, Software, 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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Publisher's note

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