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Emerging technologies in occupational health and safety

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Emerging technologies in occupational health and safety

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Editorial: Emerging technologies in occupational health and safety

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Editorial on the Research Topic
Emerging technologies in occupational health and safety

Occupational health and safety (OHS) is a field devoted to the anticipation, recognition, evaluation, and control of these environmental factors or stresses arising in or from the workplace. The application of technology is considered as an effective approach to improve workers' health and safety conditions and ensure health and safety management in general. Research and development is directed toward the advancement of technology, and therefore includes the development of emerging technologies. Emerging technologies (e.g., artificial intelligence, nanotechnology, virtual reality and robotics) are characterized by radical novelty, relatively fast growth, coherence, prominent impact, and uncertainty and ambiguity. Emerging technologies in occupational health and safety are those technical innovations which represent progressive developments within the different fields of OHS (from the point of view of hazardous agents like chemical, physical, biological, ergonomics and safety) in different phases of risk management including identifying, assessing and controlling the risks. Emerging technologies offer challenges and opportunities with regard to worker safety and health. Although the emergence of novel technologies could provide a lasting solution to the problem of workplace health and safety, it is necessary to understand and prevent any hazards arising from them. The scope of this special Research Topic is to introduce the emerging technologies and their practical applications in anticipation, recognition, evaluation, and controlling the hazardous agents including chemical, physical, biological, ergonomics and safety at the workplace. Moreover, it aims at reviewing and assessing the hazards of emerging technologies which may limit their success and offer designs that eliminate the hazards of emerging technologies.

The Editorial aimed to present the contributing articles of the Research Topic related to Section Occupational Health and Safety of Frontiers in Public Health in 2022. The Research Topic has published articles from February to August regarding the use of emerging technologies in assessing workplace stress, preventing chemotherapy agent contamination, detecting driving fatigue, use of e-consultations during the COVID-19 pandemic, implementing a chemical risk assessment, developing an UV protective fabric and building a modified goggle. Also, the studies were conducted in countries such as China, Saudi Arabia, and Iran.

Li et al. assessed workplace stress among nurses using heart rate variability analysis and wearable ECG. They asked 17 nurses from a major public hospital in China to wear an ECG monitor to measure stress level during work, and to complete the Chinese Nurses Stress Response Scale after work as subjective response criteria. They demonstrated that it is feasible to use wearable ECG devices and heart rate variability (HRV) analysis to investigate workplace stress under work conditions in nurses. They also indicated that this approach may serve as a preventive measure for identifying stress-related illnesses in nurses.

In the risk management of OHS, the use of wearable ECG can be useful to investigate work stress and mental workload and also, early identification of at-risk individuals of cardiovascular disorders. HRV analysis can also be used to estimation physical activity levels and energy metabolism, which are two important parameters in assessing heat stress and ergonomic issues.

Tang et al. did a comparative study to evaluate closed system transfer devices (CSTDs) in preventing chemotherapy agents contamination during compounding process and investigate it's their efficacy on the safe management of injectable hazardous drugs (HDs). The exposure assessments of cyclophosphamide and cytarabine were performed under traditional or CSTDs. A total of 96 wiping samples from protective equipment (such as gloves and masks) were collected and the contamination analysis was performed by liquid chromatography with tandem mass spectrometry. They indicated that the proper use of a CSTD may significantly decrease contamination by these drugs and consequently decrease exposure risk on workplace surfaces and personal protective equipment as compared to traditional compounding devices. They concluded that CSTDs are offering progressively more effective alternatives to traditional ones and consequently decrease chemotherapy exposure risk on isolator surfaces.

The topic of measures taken to protect handlers from occupational exposure to chemotherapy has always been controversial. Although work experience can be very effective in the level of exposure to it, in the case of some chemicals, exposure to a low concentration can lead to unpleasant consequences. The use of the isolated unit, which can greatly reduce the possibility of respiratory or skin exposure, is necessary in these high-risk worksites.

Rabiei et al. evaluated the ultraviolet (UV) protective factor (UPF) of workwear fabrics coated with the TiO_2 nanoparticles (NPs) prepared using an *in-situ* synthesis method. They concluded that the UV protective properties of fabrics can be improved by coating the TiO_2 NPs on them without any significant effect on the intrinsic properties of fabrics. However, they indicated that future studies can evaluate the cytotoxicity properties of the TiO_2 NPs to ensure that they have no adverse effects on human skin.

Occupational exposure to UV radiation can occur in many outdoor and indoor workplaces, like welding, healthcaring, laboratories, farming and mining, which can cause skin and eye damage, so that the use of anti-UV clothing can be considered as a preventive measure.

Fatemi et al. developed and implemented a risk assessment method to determine and prioritize hazardous chemicals in academic laboratories. The study was conducted at five academic laboratories and research facilities of a Medical Sciences University in Iran. They reported the adequate safety provisions and procedures in the laboratory operations and also, they found that the lack of awareness concerning health, safety, environmental chemical hazards, and inappropriate sewage disposal systems contributed to the increasing levels of laboratory risk. They suggested the need for improving the risk perception of individuals involved in handling chemicals to prevent exposure to workplace duties and environmental pollution hazards.

Doing the chemical risk assessment in work environments can have different applications, such as:

- Identification of the risks related to all chemicals that are handled, stored or transported,
- Exposure evaluation of individuals to hazardous chemicals,
- Identification of tasks that have a high health and safety risk,
- Assessing the adequacy of available control measures, and
- Adopting the appropriate control measures to eliminate or reduce risk.

Althumairi et al. identified the factors that influence current patient use and the intention of using e-consultation in Saudi Arabia. A cross-sectional survey was distributed online *via* social media platforms targeting the population living in Saudi Arabia from August to December 2020. A total of 150 participants completed the questionnaire. They concluded that participants' trust in and perception of the usefulness of e-consultations were significant factors in their intention to use e-consultation services. They indicated that policymakers' attention to those factors could play a role in increasing public acceptance and the use of e-consultations to improve medical care distance.

One of the most important factors affecting the spread of pandemics is the presence of carriers in crowded places. One of the solutions that can prevent such gatherings in places like hospitals or medical centers is providing remote and electronic services in non-emergency cases, which is considered as a management solution and administrative control measure in occupational health and safety.

Shi et al. assessed a combination of automated pupillometry and heart rate variability to detect driving fatigue. A 90-min monotonous simulated driving task was utilized to induce driving fatigue. During the task, measurements of pupillary light reflex were performed and subjective rating scales and heart rate variability were monitored simultaneously. They concluded that pupillary light reflex variation may be a potential indicator in the detection of driving fatigue, achieving a comparative performance compared with the combination with heart rate variability. They suggested that further work may be involved in developing a commercialized driving fatigue detection system based on pupillary parameters.

The fatigue caused by driving for long periods can affect driver concentration and performance and so jeopardize transportation safety. Predicted driver fatigue and providing warning alarms can make the driver more alert, which is a very important and preventing factor in road traffic crashes.

Shao et al. built a modified goggle (MG) with better physical performance and they used the temperature-humidity index (THI), an indicator to investigate the impact of goggle-related heat strain on the ocular surface. The basic functions of antifog, anti-ultraviolet (UV), and anti-blue-light radiation capabilities were evaluated. They also assessed the clinical impact on non-invasive keratography tear film break-up time (NIKBUT), intraocular pressure, central corneal thickness, Schirmer test I, and the Dry Eye-related Quality of life

Score (DEQS) in 40 healthcare workers by comparing MG with standard goggles (SG). They found that wearing goggles for a long time may cause heat strain to the eyes, thereby leading to eye discomfort and changes in the microenvironment of the ocular surface. Their MG exhibited better antifog, antiultraviolet, and optimal anti-blue-light performance and lower heat strain than SG, thus making it ideally suited for healthcare workers.

During the outbreak of the COVID-19 pandemic, the use of goggles became common among healthcare workers, because one of the ways of transmission of the virus is through the mucous membrane of the eyes. Fogging of goggles can adversely affect the quality of medical work and also increase medical errors (such as needle sticks). The fogging of goggles is often because of the leakage of expired air into it and can result in ergonomic issues due to awkward posutres of healthcare workers like bending, in order to increase precision and visibility. Therefore, the use of antifog goggles, can increase job satisfaction and reduce medical errors and prevent musculoskeletal disorders.

Finally, by reviewing all the articles published in the Research Topic, it can be concluded that the use of emerging technologies (e.g., digitization; novel technology; nanomaterials) in occupational health and safety in many different fields (e.g., Anti-UV fabrics; antifog, anti- UV and anti-blue-light radiation goggles; developed tools for assessing work fatigue and stress) can be possible; from point of view of the development of tools to the designing and manufacturing products related to OHS issues.

Author contributions

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

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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Assessing Workplace Stress Among Nurses Using Heart Rate Variability Analysis With Wearable ECG Device–A Pilot Study

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This study aims to measure workplace stress of nurses using heart rate variability (HRV) analysis based on data derived from wearable ECG heart rate monitors. The study population consists of 17 nurses at a major public hospital in China. Data was collected from 7 DON nurses (department of neurosurgery; all females; mean age: 31.43 ± 4.50), and 9 ICU nurses (intensive care unit; 8 females and 1 male; mean age: 31.33 ± 5.43). Each participant was asked to wear a wireless ECG heart rate monitor to measure stress level during work, and to complete the Chinese Nurses Stress Response Scale (CNSRS) after work as subjective response criteria. Demographic information, body posture, heart rate, R-R intervals (RRI), low frequency components (LF) and high frequency components (HF) were collected. LF%, LnHF and the squared root of the mean squared differences of successive NN intervals (RMSSD) based on HRV analysis were used to estimate the stress level of nurses. DON nurses reported a higher LF%, lower LnHF and lower RMSSD than ICU nurses. Work shifts were shown to have significant effects on LF%, LnHF and RMSSD respectively, with nurses in long shifts and night shifts reported high stress levels. Higher LF%, lower LnHF and lower RMSSD were found during work shift. Posture analysis revealed negative correlations with LnHF and RMSSD in walking and standing/sitting positions, and a significant negative correlation with LF% in lying-down position. Nurses with higher LF% reported higher CNSRS scores in all subscales, whereas nurses with lower LnHF or RMSSD reported higher CNSRS scores in social phobia and fatigue subscales. The results of this study support the idea that HRV can be used to investigate workplace stress among nurses under real work condition, and can serve as a preventive measure for identifying stress-related illnesses among nurses.

Keywords: heart rate variability (HRV), workplace stress, wearable biosensor, nurse, actual work condition

INTRODUCTION

Nurses working in hospitals are exposed to high levels of workplace stress. In their daily routines, nurses can often experience high rates of physical and verbal violence, and harassment (1–3). Such high levels of workplace stress, if left untreated, can have harmful impacts on many aspects of their lives, manifesting into depression, anxiety, insomnia, burnout, poor self-esteem, and other mental-related health problems. It can further lead to poor decision-making, ineffective care, nurse-patient difficulties (4), and negative financial impact on hospitals and related institutions (5, 6). Thus, it is important to identify a reliable, cost-effective, sustainable method for early workplace stress detection in large team setting.

Many stress management programs and strategies for nurses have been evaluated by researchers, and it is notable that most studies investigated workplace stress based on self-report measures (7). However, these measures are mainly used for evaluating chronic stress (8). In recent years, the increasing interest in heart rate variability (HRV) research has produced extensive literature in numerous areas (9–11). In particular, cardiac vagal tone has been proposed as a physiological biomarker of stress (12–15). One non-invasive approach for investigating the vagal tone is by measuring the HRV suing electrocardiography (ECG) recording. With this technique, many studies have performed HRV analysis using ECG signals to investigate the feasibility of stress management (16, 17). HRV refers to the fluctuation of the length of heart beat intervals, and it represents the ability of the heart to respond to a variety of physiological and environmental stimuli (18). The power spectral density of HRV is usually calculated to assess the dynamics of the autonomic nervous system (ANS) (19). A number of neurobiological evidence suggests that HRV can be served as a reliable indicator of parasympathetic and sympathetic balance (7, 20, 21). Several studies investigating HRV measures further provided more complete pictures of ANS activation during stress conditions, with stress increasing sympathetic activity but decreasing parasympathetic activity (22–24). Analysis of HRV frequency components provides a powerful tool for evaluating stress states by simply recording ECG signals (25). In particular, HRV modifications in low-frequency (LF, 0.04 to 0.15Hz) and high-frequency (HF, 0.15 to 0.4 Hz) domains have found to be associated with stress exposure (26, 27). Furthermore, HRV is the beat-to-beat (R-R interval) variation in times between the consecutive heartbeats expressed in normal sinus rhythm on an ECG recording (28, 29). The HRV parameters in time domain, such as the standard deviation of the normal-to-normal interval (SDNN), the squared root of the mean squared differences of successive NN intervals (RMSSD), NN50, pNN50, were significantly decreased in specific experimental tasks for stress anticipation (7, 30). Various studies employed HRV indices to investigate the stress states, but participants in such studies were often placed in simulated experimental environment to induce stress.

This paper is a preliminary attempt to measure workplace stress level in nurses under real-world work conditions, and to examine how the HRV indices are correlated to their work postures, subjective stress response, workload and work shift. We believe this pilot study is a critical step in achieving an effective and comprehensive method to access real workplace stress for nurses.

METHODS

Participants

A total of 17 nurses at the department of neurosurgery (DON) and intensive care unit (ICU) at a major public hospital in Inner Mongolia Autonomous Region of China participated in this study. The participants had no medical history of heart disease or other diseases potentially influencing HRV. All of them signed specific informed consent form prior to the test. Ethical permission was sought from the Ethic Committee of the Affiliated Hospital of Inner Mongolia Medical University.

Wireless ECG Monitor

Each participant was asked to wear a wireless heart rate monitor (myBeat-WHS-1, Union Tool Co., Ltd., Japan) to obtain ECG measurement during work time from one workday. The heart rate monitor and the electrodes were mounted to the chest around the epigastrium by a dedicated chest strap. The triaxial acceleration, heart rate (HR), the time intervals between consecutive R-peaks (RRI), low frequency component (LF: 0.04-0.15Hz) and high frequency component (HF: 0.15-0.4Hz) of HRV signals, were recorded (31). With dedicated software (Viewer ver1.0.0), 3 types of postures (walking, standing/sitting, lying-down) were identified.

As indices of the influence of ANS, three HRV parameters, the LF% (LF/(LF+HF) x 100), LnHF and RMSSD (root mean square successive differences of RR intervals), were included to estimate the objective stress level of nurses in present study. High value of LF% is associated with high level of stress. Conversely, high value of LnHF and RMSSD is associated with low level of stress (7, 30). The LF%, LnHF and RMSSD were separately calculated offline using LF, HF and RRI data.

Chinese Nurses Stress Response Scale

CNSRS is a scale designed to measure the subjective stress response of Chinese nurses (32), and it consists of 4 sub-scales (19 items): physiological reaction, irritability, social phobia, and fatigue. Subject is asked to rank each item along a 5-point scale from (1) "extremely uncharacteristic of me" to (5) "extremely characteristic of me." A high score indicates high level of stress response. The scale has been tested and validated with 3,800 Chinese nurses (Cronbach's α ranged from 0.86 to 0.93, test-retest reliability coefficient = 0.86). In this study, CNSRS was used to evaluate workplace stress of nurses subjectively (Cronbach's α = 0.96, 4 sub-scales ranged from 0.78 to 0. 94).

Work-Rest Record

During the experiment, the participants were asked to record work-rest at 15 min interval.

Procedure

Before the experiment, information about the study was presented to the hospital management, the head nurses, and all the participants. Written approvals from the participants were also received. ECG signals were recorded continuously throughout the experiment during the entire work shift from one workday, including any break time or lunchtime. The participants were asked to record their work-rests at 15 min interval, and complete the CNSRS after their work shifts. For quality control, in each work shift, another nurse was designated as a research assistant to supervise the use of ECG device, the filling of work-rest record forms and psychological scales, and the recovery of ECG device from the participants.

Statistical Analysis

We began with a preliminary analysis of the group differences for the demographic data of the participants. T-test for independent sample was, respectively, used to investigate the statistical significances (p-value < 0.05) of HRV parameters (LF%, LnHF, RMSSD) between work and rest phases, DON and ICU, different work postures (lying-down vs. standing/sitting vs. walking), while Pearson's correlation analysis was conducted between postures and HRV parameters. Analysis of variance (ANOVA) was performed on work shifts to examine the effect of work shifts on HRV parameters. For subjective measurement, multivariate ANOVA was used to analyze stress responses in different groups (HRV parameters × departments). The Statistical Package for the Social Science (SPSS) version 25.0 was used for all analysis.

RESULTS

Demographic Characteristic

ECGs data from 17 healthy participants were collected, but data from 1 subject was excluded, due to corrupted data from a malfunctioned device. **Table 1** presents the demographic information, which consists of 7 DON nurses (all females; mean age: 31.43 ± 4.50), and 9 ICU nurses (8 females and 1 male; mean age: 31.33 ± 5.43). There was no statistical difference in age ($t = 0.037$, df = 14, $P = 0.971$) and years of experience ($t = -0.175$, df = 14, $P = 0.863$) between two departments. No significant correlations were found between HRV parameters, age and years experience ($r = -0.153 \sim 0.142$). The number of nurses and patients in each shift on the test day is also presented in **Table 1**. By the Shapiro-Wilk test, all studied variables were normally distributed ($P > 0.05$).

The HRV Parameters Changes in 24 H by Departments

Figure 1 shows the changes in LF%, LnHF and RMSSD for DON and ICU nurses within the 24 h experimental period. Data was computed as average value of every hour. As shown in **Figure 1**, LF% decreased, LnHF and RMSSD increased during lunch break and the period after mid-night. For different departments, the LF% values in DON nurses were higher than ICU nurses, whereas LnHF and RMSSD in DON nurses were lower than ICU nurses. The results suggested that stress level of ICU nurses was lower than that of DON nurses in general. In addition, correlation analysis revealed that LF% was strongly correlated with LnHF ($r = -0.856$, $P = 0.000$) and RMSSD ($r = -0.821$, $P = 0.000$), while a strong correlation was found between LnHF and RMSSD ($r = 0.852$, $P = 0.000$).

The mean values and standard deviations of LF%, LnHF and RMSSD are presented in **Table 2**. T-test result showed there were significant differences in LnHF and RMSSD, and no significant difference in LF% between DON and ICU nurses. In particular, LnHF ($t_{(14)} = -2.956$, $p = 0.010$) and RMSSD ($t_{(14)} = -2.887$, $p = 0.012$) of DON was lower than the ones of ICU, respectively.

TABLE 1 | Demographic characteristic.

		DON (*N* = 7)	ICU (*N* = 9)	t /χ2 -value	df	*p*-value
Age		(M = 31.43, SD = 4.50)	(M = 31.33, SD = 5.43)	0.037	14	0.971
Gender	Males	0 (0%)	1 (11%)	0.744	1	
	Females	7 (100%)	8 (89%)			
Professional status	Staff nurse	3 (42.9%)	3 (33%)	3.73	2	0.155
	Nurse practitioner	4 (57.1%)	2 (22%)			
	Charge nurse	-	4 (40%)			
Education	Bachelor	7	9	-	-	-
Work shifts	(I) 7:00∼18:00	4 (57.1%)	-	-	-	-
	(II) 18:00∼7:00	3 (42.9%)	-			
	(III) 8:00 ∼15:00	-	3 (33%)			
	(IV) 15:00∼22:00	-	3 (33%)			
	(V) 22:00∼8:00	-	3 (33%)			
Patient number		17	9	-	-	-
Nursing Experience		1∼15 years	1∼16 years	−0.175	14	0.863
		(M = 8.86, SD = 5.27)	(M = 9.24, SD = 6.02)			

DON, department of neurosurgery; ICU, intensive care unit; M, mean value; SD, standard deviation.

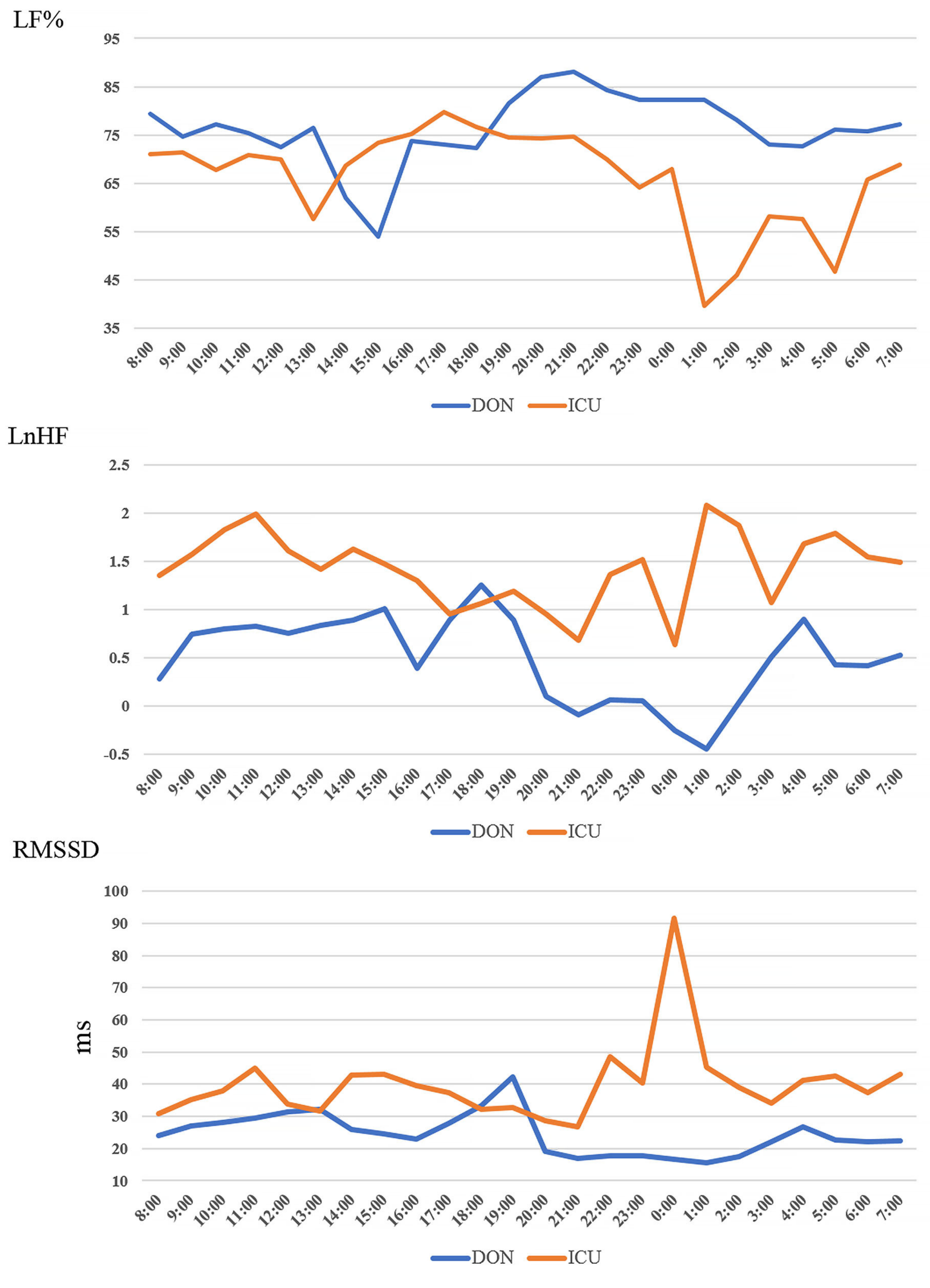

FIGURE 1 | Changes of HRV parameters for DON and ICU nurses in 24 h.

TABLE 2 | The mean differences and standard deviations of HRV parameters.

		n	Mean ± SD	P25	P50	P75	*t*-value	df	Sig
LF%	DON	7	75.61 ± 7.88	68.40	78.74	82.17	1.707	14	0.110
	ICU	9	67.56 ± 10.32	62.37	66.33	75.46			
LnHF	DON	7	0.56 ± 0.60	0.02	0.43	1.10	−2.956	14	0.010
	ICU	9	1.43 ± 0.56	1.00	1.19	1.82			
RMSSD	DON	7	24.95 ± 7.45	19.15	21.43	29.17	−2.887	14	0.012
	ICU	9	37.91 ± 9.88	27.26	37.89	47.08			

DON, department of neurosurgery; ICU, intensive care unit; LF, low frequency components; HF, high frequency components. RMSSD, the squared root of the mean squared differences of successive NN intervals; SD, standard deviation; P25, 25th percentile; P50, 50th percentile (same as median); P75, 75th percentile.

TABLE 3 | Mean differences and standard deviations of HRV parameters by work shifts.

	I	II	III	IV	V	*F*-value	df	sig	*Post-hoc*
LF%	71.86 (8.87)	80.60 (1.73)	68.66 (5.13)	76.77 (2.27)	57.24 (10.29)	5.129	4	0.014	II, IV > V*
LnHF	0.84 (0.67)	0.19 (0.21)	1.65 (0.35)	1.03 (0.13)	1.60 (0.89)	3.692	4	0.038	II < III*, II < V†
RMSSD	28.6 (8.20)	19.99 (1.25)	37.28 (9.16)	33.67 (12.44)	42.78 (9.40)	2.940	4	0.070	II < V†

*Work shifts I: 7:00∼18:00; II: 18:00∼7:00; III: 8:00∼15:00; IV: 15:00∼22:00; V: 22:00∼8:00. LF, low frequency components; HF, high frequency components. RMSSD, the squared root of the mean squared differences of successive NN intervals; *p < 0.05; $^{\dagger}p < 0.1$.*

TABLE 4 | Mean differences of HRV parameters in work and rest phases.

		Nn	Mean ± SD	P25	P50	P75	*t*-value	df	Sig
LF%	work	517	74.83 ± 11.00	67.71	76.14	83.42	9.293	106.538	0.000
	rest	97	54.92 ± 20.55	36.89	55.54	71.00			
LnHF	work	517	1.14 ± 1.06	0.38	1.21	1.80	−4.319	152.432	0.000
	rest	97	1.57 ± 0.89	0.87	1.58	2.13			
RMSSD	work	517	30.24 ± 15.88	18.84	26.65	36.98	−2.232	612	0.026
	rest	97	34.13 ± 14.98	22.24	32.31	41.42			

SD, standard deviation. LF, low frequency components; HF, high frequency components. RMSSD, the squared root of the mean squared differences of successive NN intervals; SD, standard deviation; P25, 25th percentile; P50, 50th percentile (same as median); P75, 75th percentile.

HRV Parameters Correlations With Work Shifts

ANOVA testing with the *post hoc* Tukey HSD was used to assess the effects of work shifts on three HRV parameters. The results revealed that the mean value of LF%, LnHF and RMSSD were significantly different in work shifts groups ($F_{(4, 12)} = 5.129$, $P = 0.014$, $F_{(4, 12)} = 3.692$, $P = 0.038$, and $F_{(4, 12)} = 2.940$, $P = 0.070$, respectively). By mean differences comparison, the nurses in shifts II, IV reported higher values of LF% than in shift V, while those who worked in shift II reported lower levels of Ln HF and RMSSD than in shift III and V (see **Table 3**).

HRV Parameters Correlations With Work and Rest Phases

A participant is recognized as in rest phase if there isn't any work in two consecutive 15-min periods. Otherwise it is regarded as in work phase. Mean and standard deviation were calculated to describe the distribution of HRV parameters during work and rest phases. As shown in **Table 4**, the LF% during work phase was significantly higher than that during rest phase ($t_{(106.538)} = 9.293$, $p = 0.000$), while the values of LnHF ($t_{(152.432)} = -4.319$, $p = 0.000$) and RMSSD ($t_{(612)} = -2.232$, $p = 0.026$) during work phase were significantly lower respectively.

HRV Parameters Correlations With Work Postures

T-test was performed on work postures and departments, and the result is shown in **Table 5**. DON nurses were found to be in walking position ($t = 2.013$, $df = 14$, $P = 0.064$) and standing/sitting position ($t = 3.530$, $df = 7.511$, $P = 0.009$) more often than ICU nurses. Moreover, correlation analysis was performed on HRV parameters and postures. The result revealed that lying-down was significantly related to LF% ($r = -0.613$, $P < 0.05$). Meanwhile, LnHF and RMSSD were negatively correlated with walking ($r = -0.471$; $r = -0.482$), and standing/sitting ($r = 0.466$; $r = -0.464$), respectively, (see **Table 6**).

HRV Parameters Correlations With Subjective Responses Using CNSRS

Table 7 lists the result of comparison between the objective stress level and the subjective stress response scores measured by the CNSRS in the two departments groups. The participants were assigned into low or high stress groups by their mean values of three HRV parameters, LF%, LnHF, and RMSSD. MANOVA was then used to explore the impact of HRV parameters and department (ICU, DON) on subjective stress responses.

TABLE 5 | Posture differences in ICU and DON departments (n = 16).

	ICU	DON	*t*-value	df	*P*-value
Walking	83.44 ± 42.73	135.29 ± 60.47	2.013	14	0.064
Standing/ Sitting	333.44 ± 56.29	531.86 ± 140.18	3.530	7.511	0.009
Lying-down	57.89 ± 89.22	57.00 ± 45.29	−0.026	12.369	0.980

The results showed the mean value of time of three postural patterns in ICU and DON groups. ICU, intensive care unit; DON, department of neurosurgery.

TABLE 6 | Correlations among HRV-based variables and work postures (N = 16).

	Standing/Sitting	Lying-down	LF%	LnHF	RMSSD
Walking	−0.043	−0.182	0.410	−0.471†	−0.466†
Standing/ Sitting		−0.104	0.301	−0.482†	−0.464†
Lying-down			−0.613*	0.222	0.298

*LF, low frequency components; HF, high frequency components. RMSSD, the squared root of the mean squared differences of successive NN intervals; *p < 0.05; †p < 0.1.*

The mean differences between the low and high groups of LF% on physiological reaction, irritability, social phobia, and fatigue were statistically significant, with high groups reporting significantly higher subjective response than the low groups ($F_{(1, 12)} = 5.071$, $P = 0.044$, $F_{(1, 12)} = 5.424$, $P = 0.038$, $F_{(1, 12)} = 4.915$, $P = 0.047$ and $F_{(1, 12)} = 5.736$, $P = 0.034$, respectively). The mean difference between department groups was only found on physiological reaction and irritability subscales, with ICU groups reporting higher scores on the physiological reaction ($F_{(1, 12)} = 10.864$, $P = 0.006$) and irritability ($F_{(1, 12)} = 10.241$, $P = 0.008$). Divided by the mean value of LnHF, the group difference was only found on social phobia subscale, with low groups reporting higher scores than the high ($F_{(1, 12)} = 4.038$, $P = 0.068$). And ICU nurses reported higher scores on physiological reaction ($F_{(1, 12)} = 8.144$, $P = 0.015$) and irritability ($F_{(1, 12)} = 7{,}125$, $P = 0.017$) than DON nurses. The low value of RMSSD groups reported higher scores on two subscales, social phobia ($F_{(1, 12)} = 6.649$, $P = 0.024$) and fatigue ($F_{(1, 12)} = 3.524$, $P = 0.085$) than the high groups, respectively. The group differences were found on physiological reaction ($F_{(1, 12)} = 6.920$, $P = 0.022$) and irritability ($F_{(1, 12)} = 7.113$, $P = 0.021$), with ICU nurses reporting higher scores than DON nurses. There was no significant interaction effect between departments and HRV parameters (LF%, LnHF, RMSSD).

DISCUSSION

In general, our results demonstrated that it is feasible to use HRV analysis, based on ECG signal collected by wearable ECG device, to investigate stress under real work conditions among nurses. In fact, using wearable devices and HRV to monitor mental stress level is gaining attention among the scientific community (33).

TABLE 7 | Mean differences of CNSRS subscale for HRV parameters and department (N = 16).

		DON nurses		ICU		Main effects (*F*-value)		Interaction (*F*-value)
		Low	High	Low	High	Group effect (Low vs. high)	Departments (DON vs. ICU)	
LF%	Physiological reaction	1.25 ± 0.35	1.93 ± 0.77	2.33 ± 0.85	3.38 ± 0.50	5.071*	10.864**	0.219
	Irritability	1.25 ± 0.35	2.50 ± 1.18	2.93 ± 0.95	4.00 ± 0.59	5.424*	10.241**	0.034
	Social phobia	1.83 ± 0.24	3.33 ± 0.71	1.93 ± 0.80	2.67 ± 1.41	4.915*	0.316	0.579
	Fatigue	2.00 ± 0.35	3.55 ± 1.04	3.05 ± 1.55	4.36 ± 0.60	5.736*	2.44	0.035
LnHF	Physiological reaction	1.93 ± 0.77	1.25 ± 0.35	3.11 ± 0.26	2.63 ± 1.05	1.651	8.144*	0.055
	Irritability	2.50 ± 1.18	1.25 ± 0.35	3.56 ± 0.42	3.33 ± 1.16	1.699	7.725*	0.828
	Social phobia	3.33 ± 0.71	1.83 ± 0.24	2.67 ± 1.53	2.06 ± 0.93	4.038†	0.179	0.716
	Fatigue	3.55 ± 1.04	2.00 ± 0.35	4.08 ± 0.38	3.42 ± 1.63	2.722	2.107	0.432
RMSSD	Physiological reaction	1.78 ± 0.79	1.50 ± 0.00	3.44 ± 0.59	2.47 ± 0.83	1.553	6.920*	0.479
	Irritability	2.25 ± 1.22	1.50 ± 0.00	4.17 ± 0.60	3.03 ± 0.88	2.139	7.113*	0.091
	Social phobia	3.11 ± 0.83	1.67 ± 0.00	3.22 ± 1.07	1.78 ± 0.81	6.649*	0.039	0.000
	Fatigue	3.33 ± 1.07	1.75 ± 0.00	4.50 ± 0.66	3.21 ± 1.44	3.524†	2.938	0.036

*Values are means (SD) of each subscale. DON, department of neurosurgery; ICU, intensive care unit; Low or High, low or high stress groups by their mean values of three HRV parameters; LF, low frequency components; HF, high frequency components. RMSSD, the squared root of the mean squared differences of successive NN intervals; **P < 0.01; *P < 0.05; †P < 0.1.*

DON nurses were found to have higher LF%, lower LnHF and lower RMSSD than ICU nurses, which indicates that DON nurses experienced higher level of objective stress than ICU nurses. One possible explanation is that while the number of nurses on-duty were similar in DON and ICU, there were 17 patients in DON and only 9 patients in ICU.

The study also highlighted how work shifts affected LF%, LnHF and RMSSD. It is critical to note that the work shifts were different in DON (shift I and II) and ICU (shift III, IV and V). The results showed higher mean values of LF% and lower means of LnHF and RMSSD in DON shifts. Our findings are consistent with previous studies, which suggested that long hour shift significantly affects the overall physical and mental health of nurses, and job-related stress varies across working unit (34, 35). For mean differences comparison among work shifts, we found that LF% in shift II and IV was significantly higher than shift V, while LnHF and RMSSD in shift II was lower than III and/or V. This indicated that nurses working in night shifts experienced higher level of physical and mental stress than those who worked in day shifts.

In contrast, LF% at work phase was significantly higher than at rest phase, while LnHF and RMSSD at work phase were significantly lower than at rest phase. These findings are in good agreement with previous study, which suggested that work-rest schedules influence physiological and postural workload, and cause worker to subjectively feel more fatigue during work phase (36). Long work hours may lead to fatigue and different types of injuries during the operation (37, 38), which may cause psychological, physiological and musculoskeletal disorders in long run (39).

Regarding work postures, only lying-down was found to have significant negative correlation with LF%. For walking and standing/sitting positions, negative correlations with LnHF and RMSSD were found, and no significant correlation with LF%. This discrepancy may be caused by the small sample size and the hardware limitation. Since the ECG monitor used in present study cannot recognize the standing and sitting positions separately, the combined measurement of work postures may have affected the result. Overall, our findings are consistent with previous studies which indicated that walking and standing/sitting for long time are shown to influence physiological and psychological responses linked to an increased risk of stress (40–42). Prolonged poor posture can lead to a prolonged distressed state. Improvement in postural changes may increase positive effect, reduced fatigue, and alleviate stress (43). In addition, the result showed that DON nurses spent more time in walking and standing/sitting positions than ICU nurses, which may explain the higher LF%, lower LnHF and RMSSD among DON nurses.

The CNSRS result showed that nurses with high LF% reported higher levels of physiological reaction, irritability, fear for social activity and fatigue. Also, nurses with high LnHF and RMSSD reported lower level of social phobia and fatigue. This confirms that the HRV parameters (LF%, LnHF and RMSSD) are in line with the results from subjective measurements.

It is important to note that ICU nurses showed higher scores of physiological reaction and irritability than DON nurses in CNSRS. This finding may seem to be in contradiction with the result measured by the HRV parameters, in which ICU nurses had a lower objective stress response than DON nurses. However, according to the experiment log, the workload of ICU on the experiment day was considerably lower than average. As a result, it can be argued that ICU nurses experienced lower acute stress on the experiment day, while they were experiencing higher chronic stress as shown in the CNSRS. In fact, previous finding has indicated that ICU nurses generally report feeling higher stress and experience stress responses (e.g., fatigue, distress, irritability, etc.) at a higher rate than nurses in other units (44).

A number of limitations might influence the results obtained. The sample size of this study is small, and it may affect the statistical power. The experimental period was only 1 day, so it may affect the generality of our results. In future studies, individual differences among nurses should also be considered. Additionally, nearly half of the participants reported certain discomfort when wearing the ECG device, and this issue should be addressed in future research. Also, there exists other devices with less intrusive data acquisition methods such as the Oura Ring, Fitbit Charge and Apple Watch. In future study, these devices should be considered and evaluated against the present ECG device in their feasibility in monitoring workplace's stress states of nurses under normal working-conditions. Future works exploring the effects of extended use of ECG device and HRV analysis for measuring stress, as well as studies on nurses at other departments should be conducted.

CONCLUSION

In conclusion, this pilot study investigated the method of using ECG heart rate monitor and LF%, LnHF and RMSSD as HRV-based stress indicators to assess workplace stress in nurses under real-working condition. CNSRS was used as subjective stress evaluation criteria, and it was shown to be correlated to the values of LF%, LnHF and RMSSD. The results also showed that departments, work shifts, and work posture were correlated to the stress level of nurses. Overall, this pilot study demonstrated that it is feasible to use wearable ECG device and HRV analysis to investigate workplace stress under work conditions in nurses. This approach may also serve as a preventive measure for identifying stress-related illnesses in nurses.

DATA AVAILABILITY STATEMENT

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

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Ethic Committee of the Affiliated Hospital of Inner Mongolia Medical University. The participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

XL contributed to conceptualization, supervision, project administration, and funding acquisition. XS investigated the resource. AZ and LC participated in the data collection. LL contributed to formal analysis. WZ wrote the first draft of the paper. XL and WZ revised and edited the final manuscript. All authors have read and agreed to the published version of the manuscript.

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Assessment of Combination of Automated Pupillometry and Heart Rate Variability to Detect Driving Fatigue

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Objectives: Approximately 20∼30% of all traffic accidents are caused by fatigue driving. However, limited practicability remains a barrier for the real application of available techniques to detect driving fatigue. Use of pupillary light reflex (PLR) may be potentially effective for driving fatigue detection.

Methods: A 90 min monotonous simulated driving task was utilized to induce driving fatigue. During the task, PLR measurements were performed at baseline and at an interval of 30 min. Subjective rating scales, heart rate variability (HRV) were monitored simultaneously.

Results: Thirty-two healthy volunteers in China participated in our study. Based on the results of subjective evaluation and behavioral performances, driving fatigue was verified to be successfully induced by a simulated driving task. Significant variations of PLR and HRV parameters were observed, which also showed significant relevance with the change in Karolinska Sleepiness Scale at several timepoints ($|r| = 0.55 \sim 0.72$, $P < 0.001$). Furthermore, PLR variations had excellent ability to detect driving fatigue with high sensitivity and specificity, of which maximum constriction velocity variations achieved a sensitivity of 85.00% and specificity of 72.34% for driving fatigue detection, vs. 82.50 and 78.72% with a combination of HRV variations, a nonsignificant difference (AUC = 0.835, 0.872, $P > 0.05$).

Conclusions: Pupillary light reflex variation may be a potential indicator in the detection of driving fatigue, achieving a comparative performance compared with the combination with heart rate variability. Further work may be involved in developing a commercialized driving fatigue detection system based on pupillary parameters.

Keywords: driving fatigue, traffic safety, pupillary light reflex (PLR), heart rate variability, automated pupillometry

INTRODUCTION

Road traffic accidents has become the eighth leading cause of death worldwide (1). They killed nearly 1.35 million people every year, and caused up to 50 million injuries (1), resulting in huge losses for societies with regard to population health and economic matters. However, ∼20∼30% of all traffic accidents are caused by fatigue driving, which is in fact preventable (2). Driving fatigue is often induced by prolonged driving without due rest, being presented with deteriorated concentration, low alertness, slow reaction to emergencies, etc., all of which can lead to road traffic crashes (3). Continuous efforts have been made to develop reliable indicators of driving fatigue to warn drivers of their fatigue status promptly and thus preventing possible accidents from occurring (4–10).

Among these exploratory studies, the detection systems incorporating physiological signals of drivers, which mainly involves extracting and analyzing characteristics of electroencephalogram (EEG) (6, 11–13), heart rate variability (HRV) (5, 14, 15), electromyogram (EMG) (7, 16), etc., are considered as the most accurate and reliable ones to reflect the mental states. However, due to the inconvenience to wear, and various complicated algorithms, the real application of these techniques still remains a challenge. In contrast, eye metrics also offers a promising method for monitoring fatigue (17), including the percentage of eyelid closure (8, 18), blink-based (19) and pupil-based features (10, 20, 21) in an eyewear system. These eye-tracking data provide additional evidence for motivational disengagement, describing the effect of fatigue on attention and task performance (22). However, detection systems using a camera-based approach has a limitation of illumination, and most of those need computers, image processing algorithms and feature extraction techniques to extract drowsy symptoms (19). The effectiveness of pupillary light reflex (PLR) on the assessment of sleep deprivation was recently explored (23), suggesting that PLR variables might also be able to indicate fatigue. Automated pupillometry, which has been utilized in different clinical settings (24, 25), enables to provide several accurate and reliable parameters with respect to pupil size and PLR (26, 27). To date, no study has been conducted to analyze the association between PLR variations with driving fatigue.

Our aim was to investigate the effectiveness of quantitative PLR on driving fatigue detection, as well as the possible detection performances of a combination of PLR and HRV, which may very likely promote the further development of a driving fatigue detection system in the future.

Abbreviations: ACV, average constriction velocity; ADV, average dilation velocity; AUC, area under curve; HF, high frequency; HFnu, normalization of HF power by the formula: HF / (LF + HF) * 100; HRV, heart rate variability; LF, low frequency; LFnu, normalization of LF power by the formula: LF / (LF + HF) * 100; Lat, latency; Max, maximum pupil size; MCV, maximum constriction velocity; Min, minimum pupil size; %PLR, constriction percentage; SDNN, standard deviation of the NN intervals; T75, time to 75% recovery; Δ, differences in all variables from baseline to the measurement at each timepoint.

MATERIALS AND METHODS

Study Population

We conducted a single center, prospective, observational diagnostic study using a volunteer sample between November, 2020, to April, 2021. Thirty-two healthy postgraduate students from Zhejiang University School of Medicine in China voluntarily participated in our study, among whom 20 were male. All participants held valid driving license of more than 2 years, with at least half of a year driving experience, had regular sleep pattern, normal or corrected to normal vision and no history of any psychiatric disorder. All participants were asked to follow the below requirements before the tests: (1) refrain from alcohol, caffeine and tea within 12 h; (2) adequate sleep (almost 6∼8 h) the day before the experiment; (3) wash the hair within 24 h. The study was approved by the ethics committee of Second Affiliated Hospital of Zhejiang University School of Medicine (approval number: 2020-893). Informed written consent and training were provided prior to entering the experiment.

Driving Fatigue Induction

Among all recruited participants, a 90 min monotonous simulated driving task was conducted in a darkened room, involving in a simple driving simulator (Nanjing Shengguan Jinbang Electronic Technology, China). A straight and monotonous route with low traffic density was designed in advance. The performance method in the simulator was the same as that in a real car. The visual display of the driving simulated environment was a 14-inch liquid crystal display at 80 cm in the front of the subjects' eyes. Current speed and car gear were showed on the screen, and the engine noises as well as nearby traffic noises were provided. During the driving task, the subjects were asked to restrict all unnecessary movements and drive in the center of the road, maintaining a constant speed between 70 and 90 km/h.

The experiment started between 9:00 and 11:00 a. m. or 3:00 and 5:00 p. m. for every subject to minimize the effect of circadian variance. After 10 min of rest, 3 min of HRV were recorded, which was regarded as the baseline data (T0). Meanwhile, subjective assessments and pupillary measurements were taken. In order to evaluate fatigue level over the course of the experiment, the task was divided into three 30-min sections. When each section was completed, the HRV and PLR data were recorded. Meanwhile, subjective ratings were performed. The flowchart of the study was shown in **Figure 1**.

Subjective Assessments

Subjects completed the Karolinska Sleepiness Scale (KSS) (28), which is a nine-point scale for assessing sleepiness with responses ranging from extremely alert (1) to very sleepy (9). Driving fatigue was defined as KSS $\geq$ 7. Fatigue Grade (FG) scale, which is a five-point scale designed by our team with responses ranging from no fatigue (0) to severe fatigue (5), was also completed.

Heart Rate Variability Data Acquisition

HRV was assessed with a protocol of 3 min sampling using the SA-3000P (Medi-core, Korea). Subjects were instructed to stay with eyes open, be silent, and breath normally during

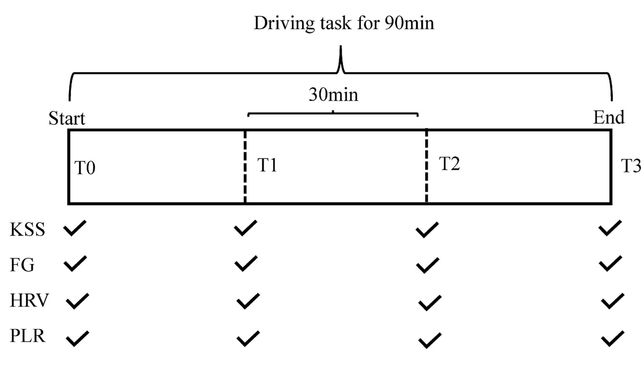

FIGURE 1 | Schematic diagram for the entire experimental framework. FG, fatigue grade; HRV, heart rate variability; KSS, Karolinska Sleepiness Scale; PLR, pupillary light reflex.

measurement. Standard deviation of the NN intervals (SDNN) and frequency domain indicators including low frequency (LF, 0.04∼0.15 Hz), high frequency (HF, 0.15∼0.4 Hz), normalized LF (LFnu), normalized HF (HFnu), LF/HF ratio were measured and showed automatically on the screen. The SDNN, LFnu, HFnu, and LF/HF were collected for further analysis.

Pupillary Light Reflex Data Acquisition

PLR were measured using the PLR-3000 pupillometer (NeurOptics, CA, USA). It was performed with a rubber cup covering the measured eye and the subject's hand covering the non-measured eye. A flash of visible white light with a duration of 0.8 s and a pulse intensity of 120 μW was delivered to induce a pupillary reflex, and repeated video images at more than 30 frames/s were stored for 3.21 s. The device provided with maximum and minimum pupil size (Max and Min), constriction percentage (%PLR), latency (LAT), constriction and dilation velocity (CV and DV), and T75. PLR measurement was performed on each eye for a series of three stimuli, then the data was averaged, producing one PLR data point for each subject. Maintaining eye opening during the recording was encouraged, but if interrupted, the test would be repeated after 5 s rest.

Statistical Analysis

Normal distribution was confirmed with the Kolmogorov–Smirnov test. For normally or non-normally distributed continuous variables, results are given as mean ± SD or median (IQR), respectively. Repeated measures analysis of variance or Friedman test was used to test the variability of different approaches. When the main effect was significant, a *post-hoc* analysis with Bonferroni correction was conducted. Correlations were determined by Spearman analysis. Considering the between-subject differences at baseline, differences between the baseline and the measurement at each time point were utilized to conduct the Spearman's correlation. Due to there are a total of 24 correlational analyses and the *P*-values have to be adjusted for the number of tests, $P < 0.002$ (0.05/24) of two-sided was considered to be significant. Detective performances of each indicator and the combination of two indicators were analyzed by calculating specificity, sensitivity, and the area under the receiver operating characteristic curve (AUC). $P < 0.05$ of two-sided was considered to be significant. All analyses were performed using Prism software (version 7.0; GraphPad, USA) and Medcalc software (version 19.0; Belgium).

RESULTS

Subjective Rating Results and Behavioral Performances

The subjects' mean ± SD age was 25.5 ± 3.1 years, sleeping hours in the past 24 h were 7.4 ± 0.9 h, driving experience was 4.3 ± 1.9 years. To test whether our fatigue model was successful, we analyzed the subjective fatigue ratings and behavioral performances. Compared to the beginning of the experiment, we found significantly higher fatigue scores after the experiment [KSS: T0: 3 (2–4), T1: 5 (4–6) ^{a}, T2: 6 (5.25–7) ^{ab} vs. T3: 7 (6–8) ^{ab}, $P < 0.001$; FG scale: T0: 0, T1: 0 (0–1) ^{a}, T2: 2 (1.25–3) ^{a} vs. T3: 3 (2.25–4) ^{abc}, $P < 0.001$]. Additionally, the number of accidents increased significantly from the beginning to the end of the driving task [T0: 0, T1: 1 (0–1), T2: 1 ^{a} vs. T3: 2 (2, 3) ^{abc}, $P < 0.001$], indicating that the manipulation was successful (note: $^{a}P < 0.05$ vs. T0; $^{b}P < 0.05$ vs. T1; $^{c}P < 0.05$ vs. T2).

Fluctuations of Heart Rate Variability

Significant differences in HRV indicators between the first and last section of driving task were observed. Mean SDNN increased across long-term driving (T0: 39.04 ± 12.33 ms, T1: 50.60 ± 16.63 ms ^{a}, T2: 56.43 ± 17.41 ms ^{ab} vs. T3: 63.34 ± 19.00 ms ^{abc}, $P < 0.001$, **Figure 2A**). The mean power of HRV in LFnu and LF/HF also significantly increased in a linear fashion [LFnu: T0: 51.96 ± 16.25 μV^2, T1: 61.63 ± 17.51 μV^{2a}, T2: 68.58 ± 19.24 μV^{2ab} vs. T3: 72.12 ± 18.16 μV^{2abc}; LF/HF: T0: 1.23 (0.68–1.70), T1: 1.91 (0.97–3.19) ^{a}, T2: 2.63 (1.06–4.66) ^{a} vs. T3: 3.29 (1.49–7.57) ^{ab}; both $P < 0.001$, **Figures 2B,C**], while there was a mild decline in the mean power of HRV in HFnu, from T0: 44.99 (37.06–59.92) μV^2, T1: 35.68 (23.81–51.24) μV^2, T2: 29.05 (16.24–49.71) μV^{2a} to T3: 22.94 (11.46–44.15) μV^{2a} ($P < 0.001$, see **Figure 2D**) (note: $^{a}P < 0.05$ vs. T0; $^{b}P < 0.05$ vs. T1; $^{c}P < 0.05$ vs. T2).

Variations of Quantitative Pupillary Light Reflex

With the increase of driving hours, Min significantly decreased and %PLR increased (Min: T0: 4.40 ± 0.7 mm, T1: 4.20 ± 0.7 mm ^{a}, T2: 4.08 ± 0.7 ^{ab} vs. T3: 3.99 ± 0.6 mm ^{ab}; %PLR: T0: 36.1 ± 4.6 %, T1: 37.4 ± 4.2 % ^{a}, T2: 38.9 ± 4.6 % ^{ab} vs. T3: 39.7 ± 3.8 % ^{ab}; both $P < 0.001$, **Table 1**). Similarly, significant increases in ACV and MCV were also observed with the increase of the driving hours (ACV: T0: 3.20 ± 0.43 mm/s, T1: 3.34 ± 0.46 mm/s ^{a}, T2: 3.50 ± 0.44 mm/s ^{ab} vs. T3: 3.68 ± 0.47 mm/s ^{abc}; MCV: T0: 5.19 ± 0.74 mm/s, T1: 5.53 ± 0.75 mm/s ^{a}, T2: 5.72 ± 0.74 mm/s ^{ab} vs. T3: 5.90 ± 0.71 mm/s ^{ab}; both $P < 0.001$, **Table 1**). However, the differences in Max, Lat, ADV and T75 were not statistically significant at different timepoints (note: $^{a}P < 0.05$ vs. T0; $^{b}P < 0.05$ vs. T1; $^{c}P < 0.05$ vs. T2).

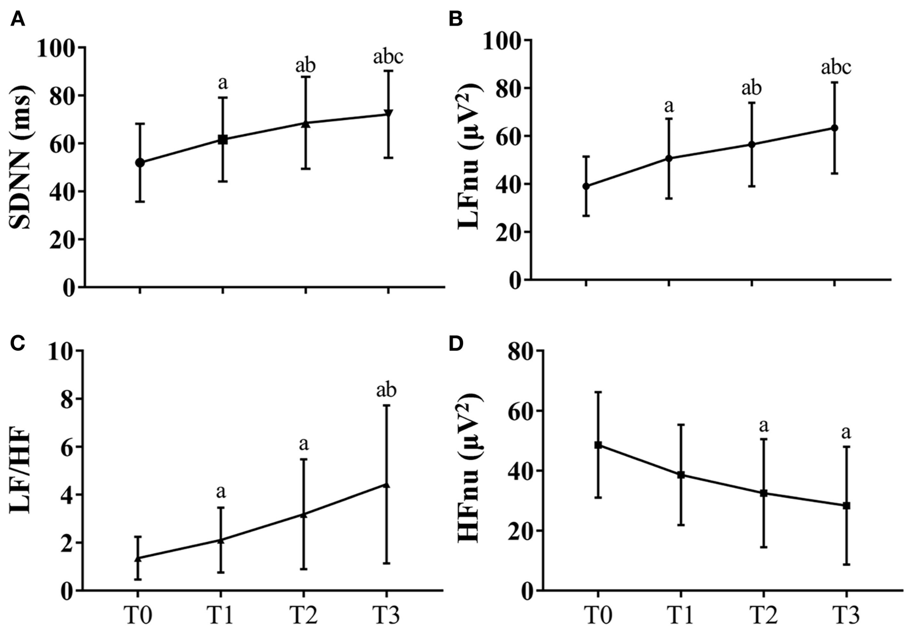

FIGURE 2 | HRV fluctuations during the driving task for all participants. Due to missing data of HRV of two participants, the data at these two timepoints were the results of data analysis of 30 participants. The error bars in this figure represent mean ± SD. **(A)** The variations of SDNN for HRV. **(B)** The variations of LFnu for HRV results. **(C)** The variations of LF/HF for HRV results. **(D)** The variations of HFnu for HRV. HF indicates high frequency; HFnu, normalization of HF power by the formula: HF / (LF + HF) * 100; HRV, heart rate variability; KSS, Karolinska Sleepiness Scale; LF, low frequency; LFnu, normalization of LF power by the formula: LF / (LF + HF) * 100; SDNN, standard deviation of the NN intervals. $^{a}P < 0.05$ vs. T0; $^{b}P < 0.05$ vs. T1; $^{c}P < 0.05$ vs. T2.

TABLE 1 | The results of PLR for both eyes through the whole process of driving task.

Variables	T0 ($n = 31$)	T1 ($n = 31$)	T2 ($n = 31$)	T3 ($n = 31$)	*P*-value
Max, mean ± SD, mm	6.88 ± 0.7	6.74 ± 0.7^{a}	6.70 ± 0.7^{a}	6.76 ± 0.7^{a}	<0.001
Min, mean ± SD, mm	4.40 ± 0.7	4.20 ± 0.7^{a}	4.08 ± 0.7^{ab}	3.99 ± 0.6^{ab}	<0.001
%PLR, mean ± SD, %	36.1 ± 4.6	37.4 ± 4.2^{a}	38.9 ± 4.6^{ab}	39.7 ± 3.8^{ab}	<0.001
Lat, median (IQR), s	0.23 (0.21 ∼ 0.25)	0.23 (0.21 ∼ 0.25)	0.22 (0.21 ∼ 0.25)	0.22(0.21 ∼ 0.23)	0.11
ACV, mean ± SD, mm/s	3.20 ± 0.43	3.34 ± 0.46^{a}	3.50 ± 0.44^{ab}	3.68 ± 0.47^{abc}	<0.001
MCV, mean ± SD, mm/s	5.19 ± 0.74	5.53 ± 0.75^{a}	5.72 ± 0.74^{ab}	5.90 ± 0.71^{ab}	<0.001
ADV, mean ± SD, mm/s	1.37 ± 0.16	1.40 ± 0.20	1.42 ± 0.22	1.42 ± 0.22	0.812
T75, median (IQR), s	2.69 (2.15 ∼ 3.14)	2.54 (2.08 ∼ 3.25)	2.73 (2.35 ∼ 3.37)	2.70 (2.40 ∼ 3.14)	0.084

ACV, average constriction velocity; ADV, average dilation velocity; Lat, latency; MCV, maximum constriction velocity; Min, minimum pupil size; %PLR, constriction percentage; T75, time to 75% recovery.

Due to missing data of PLR of one participant, the data at all timepoints were the results of data analysis of 31 participants. Values are presented as mean ± SD for normally distributed data or as median (IQR) for non-normally distributed data, $^{a}P < 0.05$ vs. T0; $^{b}P < 0.05$ vs. T1; $^{c}P < 0.05$ vs. T2.

Correlation Analysis Between Different Methods

Due to the missing data of PLR of one participant and missing data of HRV of two participants, there were a total of 31 and 30 values for deprived PLR and HRV parameters for correlation analysis at each timepoint. Change in KSS (ΔKSS) were not correlated with the change in PLR parameters at T1 and T2 (all $P > 0.002$, **Figures 3A–H**). Change in KSS (ΔKSS) was moderately correlated with the change in Min (ΔMin), %PLR (Δ%PLR) and ACV(ΔACV) ($r = -0.66$, 0.60, 0.55, all $P < 0.001$, **Figures 3I–K**) at T3. Similarly, ΔKSS was highly correlated with the change in SDNN (ΔSDNN) at T1 and T2 ($r = 0.71$ and 0.72, both $P < 0.001$, **Figures 4A,E**), and moderately correlated with change in LFnu (ΔLF) at T1 ($r = 0.65$, $P < 0.001$, **Figure 4B**). However, ΔKSS was not correlated with change in LF/HF (ΔLF/HF) and HF (ΔHF) at T1 (**Figures 4C,D**), ΔLF, ΔLF/HF and ΔHF at T2 (**Figures 4F–H**), change in all HRV parameters at T3 (**Figures 4I–L**)

Performance of Pupil Light Reflex and Heart Rate Variability Variations in Driver Fatigue Detection

ROC analysis showed that both PLR and HRV variations had a significant discriminatory power to detect driver fatigue

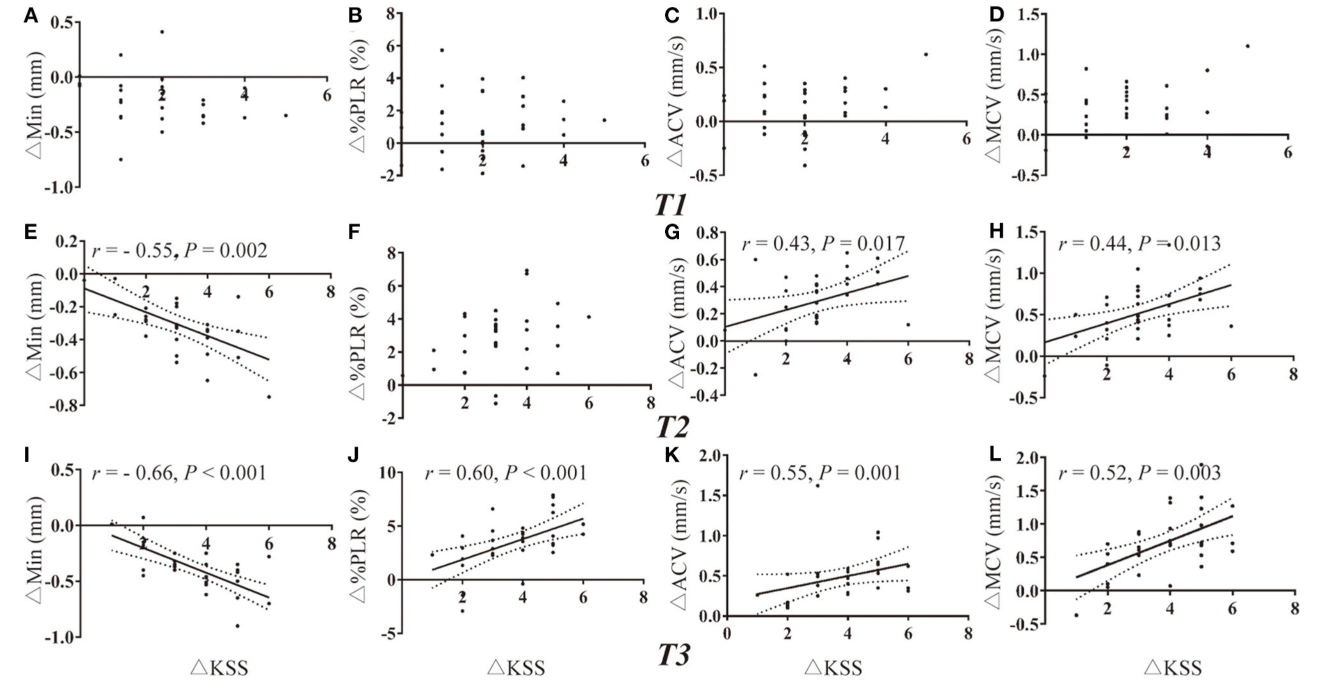

FIGURE 3 | Correlations of PLR variations with the change in KSS. **(A–D)** Correlation of ΔKSS with the change in PLR parameters at T1. **(E–H)** Correlation of ΔKSS with the change in PLR parameters at T2. **(I–L)** Correlation of ΔKSS with the change in PLR parameters at T3. ACV, average constriction velocity; KSS, Karolinska Sleepiness Scale; MCV, maximum constriction velocity; Min, minimum pupil size; %PLR, constriction percentage; Δ, differences in all variables from baseline to the measurement at each timepoint.

(**Table 2**), which was defined as KSS more than seven in the present study. The Youden index identified a ΔMCV cut-off of 0.43 mm/s for driving fatigue detection with a sensitivity of 85.00% and a specificity of 72.34% (AUC = 0.835, $P < 0.001$, **Figure 5A**). Similarly, best cut-off of ΔSDNN was > 13.01 ms, with an AUC of 0.805 ($P < 0.001$, sensitivity 85.00%, specificity 63.83%, **Figure 5B**). A combination of ΔMCV and ΔSDNN achieved an AUC of 0.872 ($P < 0.001$, sensitivity 82.50%, specificity 78.72%), yet no significant differences were found among the performances of ΔMCV, ΔSDNN and their combination (all $P > 0.05$, Delong test).

DISCUSSION

This study investigated the effectiveness of pupillary light reflex and heart rate variability in driving fatigue detection. The findings are as follows: (1) significant increases in several variables of PLR and HRV were observed at fatigue state; (2) the variations of PLR and HRV showed significant relevance with the change in KSS; (3) PLR variations had excellent ability to detect driving fatigue, with a comparative performance with HRV or a combination of PLR and HRV.

In our study, a simple driving simulator was applied to induce driving fatigue. For safety reasons, experimental tests for the fatigue detection are often conducted on driving simulators in a controlled environment. Previous literature suggested that driving fatigue could occur in a monotonous driving environment with a duration of 90 min (3, 13, 14). Among many endogenous factors, time-on-task and high workload accumulate mental fatigue, while the sleep-related causal factors worsen sleepiness (29). In our study, all participants were asked to refrain from alcohol, caffeine and tea within 12 h and obtain adequate sleep (almost 6∼8 h) the day before the experiment to avoid the sleep-related causal factors. Then, based on the increased scores of subjective ratings and deteriorated driving performances of subjects, a conclusion could be drawn that a 90-min driving task successfully induced driving fatigue.

It has been indicated that HRV is the most sensitive index assessing the regulation between sympathetic and parasympathetic nervous systems (15). An increase in SDNN, LFnu, LF/HF ratio, and a decrease in HFnu in this study corroborates earlier findings (14). The results implied that the dominating activity turned from parasympathetic to sympathetic activity. In the first section, without obvious fatigue, sympathetic activity increased due to the task of simulated driving. With fatigue increased and performance deteriorated, participants counteracted the sleep demand by trying to stay awake to complete the task, resulting in consistent sympathetic activation.

Most importantly, significant differences of pupillary parameters between different periods of task were found. For the automated pupillometer, %PLR depends on the intensity and duration of the stimulus (30), while CV are related to reflex amplitude except in cases of unusual pupillary syndromes (30).

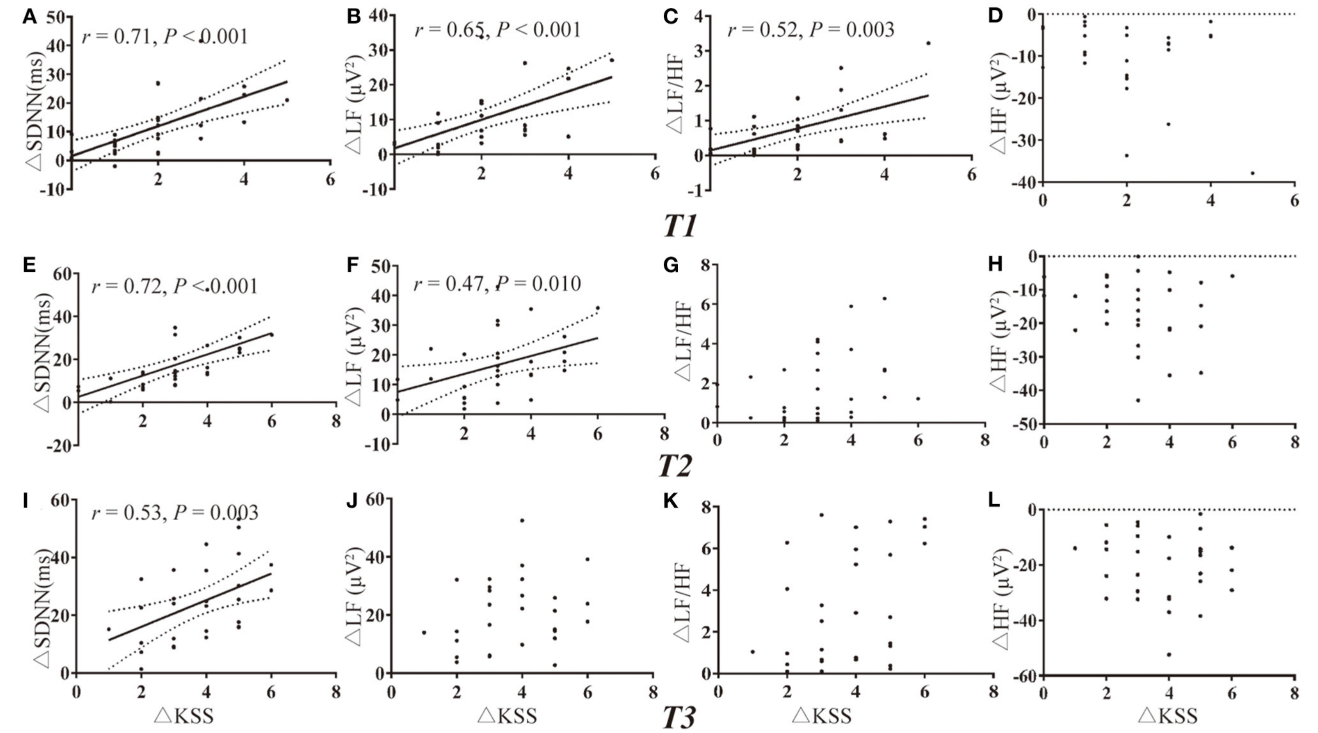

FIGURE 4 | Correlations of HRV variations with the change in KSS. **(A–D)** Correlation of ΔKSS with the change in HRV parameters at T1. **(E–H)** Correlation of ΔKSS with the change in HRV parameters at T2. **(I–L)** Correlation of ΔKSS with the change in HRV parameters at T3. HF indicates high frequency; HFnu, normalization of HF power by the formula: HF / (LF + HF) * 100; HRV, heart rate variability; KSS, Karolinska Sleepiness Scale; LF, low frequency; LFnu, normalization of LF power by the formula: LF / (LF + HF) * 100; SDNN, standard deviation of the NN intervals; Δ, differences in all variables from baseline to the measurement at each timepoint.

TABLE 2 | The characteristics of ROC curves.

Variables	*AUC*	*95%CI*	*P*-value	Cutoff	Sensitivity	Specificity
PLR variations						
ΔMin	0.699	0.592 ~ 0.793	< 0.001	< −0.29 mm	77.50%	59.57%
Δ%PLR	0.709	0.601 ~ 0.801	< 0.001	> 3.19 %	67.50%	74.47%
ΔACV	0.743	0.638 ~ 0.830	< 0.001	> 0.26 mm/s	80.00%	61.70%
ΔMCV	0.835[a]	0.740 ~ 0.906	< 0.001	> 0.43 mm/s	85.00%	72.34%
HRV variations						
ΔSDNN	0.805	0.706 ~ 0.882	< 0.001	> 13.01 ms	85.00%	63.83%
ΔLFnu	0.797	0.697 ~ 0.876	< 0.001	> 14.32 μV^2	80.00%	76.60%
ΔHFnu	0.720	0.614 ~ 0.811	< 0.001	< −14.59 μV^2	67.50%	74.47%
ΔLF/HF	0.711	0.604 ~ 0.803	< 0.001	> 1.15	67.50%	74.47%
Combinations of variables for PLR and HRV						
ΔMCV + ΔSDNN	0.872	0.784 ~ 0.934	<0.001	/	82.50%	78.72%

*ACV, average constriction velocity; AUC, area under curve; HF, high frequency; HFnu, normalization of HF power by the formula: HF / (LF + HF) * 100; HRV, heart rate variability; LF, low frequency; LFnu, normalization of LF power by the formula: LF / (LF + HF) * 100; MCV, maximum constriction velocity; Min, minimum pupil size; SDNN, standard deviation of the NN intervals. %PLR, constriction percentage; Δ, differences in all variables from baseline to the measurement at each timepoint; [a]P < 0.05 vs. ΔMin.*

With identical intensities and durations of all stimuli in our study, the PLR variations were associated with the occurrence of fatigue. Sympathetic and parasympathetic fibers dictate the pupil diameter to contract or dilate by balanced activation of the dilator and sphincter pupillae muscles in changing the light exposures toward the eyes (17). When fatigued, sympathetic activity would increase, with greater contraction in a shorter time to respond to the light stimulus, which might explain the variations of PLR. In addition, the measurements reported were not independent. As the parameters of Max and Lat were unchanged across the four measurements, the increase in the %PLR would result in an increase in velocity.

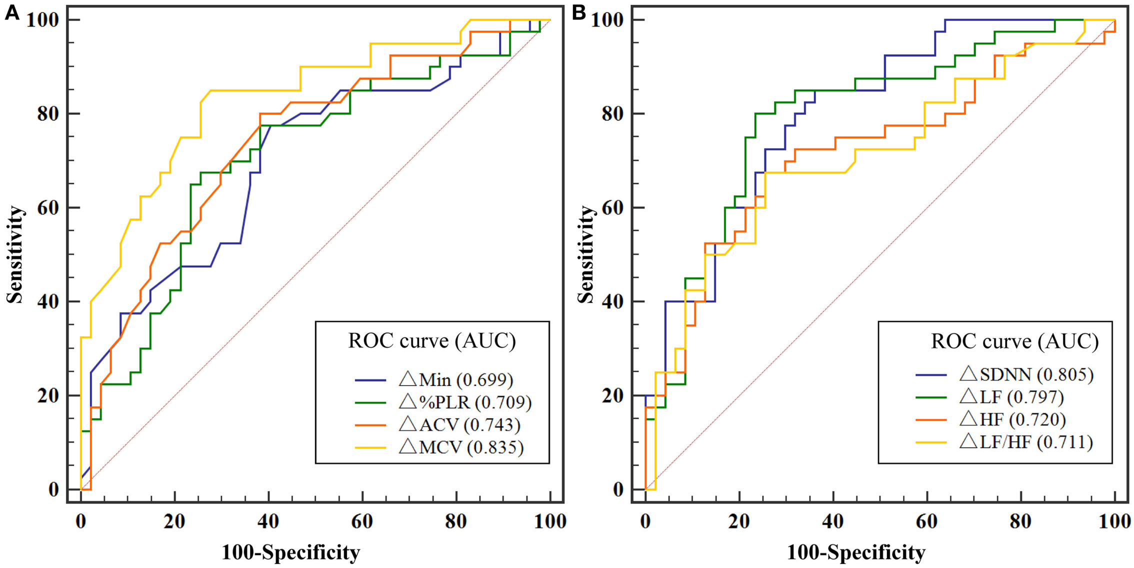

FIGURE 5 | (A) ROC analysis for the detection of driving fatigue with PLR variations. **(B)** ROC analysis for the detection of driving fatigue with HRV variations. Due to missing data of HRV of two participants, and missing data of PLR of one participant, the data of 29 participants were used for ROC analysis. ACV, average constriction velocity; AUC, area under the curve; Min, minimum pupil size; HF indicates high frequency; HFnu, normalization of HF power by the formula: HF / (LF + HF) * 100; HRV, heart rate variability; KSS, Karolinska Sleepiness Scale; LF, low frequency; LFnu, normalization of LF power by the formula: LF / (LF + HF) * 100; MCV, maximum constriction velocity; ROC, receiver operating characteristic curve; SDNN, standard deviation of the NN intervals; %PLR, constriction percentage; Δ, differences in all variables from baseline to the measurement at each timepoint.

To validate the effectiveness of HRV and PLR variations on driving fatigue detection, significant correlations were found between these two methods with KSS. ROC analysis also showed PLR variations achieved high AUCs for driver fatigue detection, with high sensitivities and specificities, a comparative performance with HRV variations. However, a combination of PLR and HRV variations did not significantly increase the performance, suggesting that PLR variations, especially ΔMCV, could be potential indicators of driving fatigue in the future.

So far, no reliable commercialized driving fatigue detection system has been developed. The technology used in the present study lays a good foundation for the later development of such a detection system. It is expected that the system will be reliable, portable, sensitive and convenient to control, and can be applied to a variety of scenarios.

This study also has several limitations. As a preliminary study to determine the effectiveness of automated pupillometry to detect driving fatigue, a uniform sample who were all medical postgraduates with a fixed age, and a small sample size recruited from a single institution, are potential limitations. Then, limited degree of fatigue existed in the present fatigue model, the results in a more fatigued state remain unknown. Thirdly, an intervention outcome is not compared to a suitable control group that undergoes a different experience to assess effects of passage of time. Last, considering individual differences in pupil measures, thresholds for pupillary variables should be further validated through a large-scale, randomized, controlled trial in the future.

Pupillary light reflex variation may be a potential indicator in the detection of driving fatigue, achieving a comparative performance compared with the combination with heart rate variability. Further work may be involved in developing a commercialized driving fatigue detection system based on pupillary parameters.

DATA AVAILABILITY STATEMENT

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

ETHICS STATEMENT

Approval for the study was obtained from the Ethics Committee of Second Affiliated Hospital of Zhejiang University School of Medicine (approval number: 2020-893). The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

MZ and ZL designed the study. LS, LZ, DJ, and QZ performed the experiment. LS carried out statistical analyses and drafted the manuscript. MZ and LZ revised the manuscript for important intellectual content. All authors interpreted the study results and contributed with manuscript revisions.

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Evaluation of Closed System Transfer Devices in Preventing Chemotherapy Agents Contamination During Compounding Process—A Single and Comparative Study in China

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Aim: We performed a comparative study to investigate the efficacy of closed system transfer devices (CSTDs) on the safe handling of injectable hazardous drugs (HDs).

Methods: The exposure assessments of cyclophosphamide and cytarabine were performed under traditional or CSTDs. For preparation activity, chemotherapy contamination samples on protective equipment (such as gloves and masks) were collected. The contamination analysis was performed by liquid chromatography with tandem mass spectrometry (LC-MS/MS). A 6-item form was distributed monthly (form M1–M6, total 6 months) to assess the pharmacists' experience on ergonomics, encumbrance, and safety impression.

Results: Totally, 96 wiping samples were collected throughout the study. The numbers of contaminated cyclophosphamide samples reduced under CSTD were −37.8, −41.6, −67.7, −47.3, and −22.9% and cytarabine were −12.3, −12.1, −20.6, −69.6, and −56.7% for left countertop, right countertop, medial glass, air-intake vent and door handle, as compared to traditional devices. The reduction was similar to pharmacist devices, i.e., −48.2 and −50.0% for masks and gloves cyclophosphamide contamination, −18.0 and −42.4% for cytarabine. This novel system could improve contamination on dispensing table, transfer container, and dispensing basket by −16.6, −6.0, and −22.3% for cyclophosphamide and −28.5, −22.5, and −46.2% for cytarabine. A high level of satisfaction was consistently associated with ergonomics for CSTD during the compounding process. Meanwhile, a slightly decreased satisfaction on ergonomics, encumbrance, and safety impression was observed for the traditional system between M2 and M3.

Conclusion: Closed system transfer devices are offering progressively more effective alternatives to traditional ones and consequently decrease chemotherapy exposure risk on isolator surfaces.

Keywords: CSTD, pharmacy, chemotherapy agents, closed system transfer devices, occupational protection

INTRODUCTION

Since long-term occupational exposure to chemotherapeutic agents in the pharmacy intravenous admixture service (PIVAS) was associated with serious health risks for compounding personnel, and furthermore, the health hazards were increased with the volume and frequency of exposure (1, 2). It was well known that exposure to certain antineoplastic drugs was hazardous to healthcare providers even at a very low exposure level, and currently, it was regarded as a crucial issue to limit the hazards with the protective equipment for healthcare providers who were exposed to chemotherapeutic agents (3). A previous study indicated that healthcare providers under the equipment with gloves, gowns, and goggles cautiously were less likely to be exposed to hazardous drugs (HDs) during compounding (4).

Nowadays, many health institutions, such as Occupational Safety and Health Administration (OSHA) or National Institute for Occupational Safety & Health (NIOSH), had realized the exposition hazards to chemotherapeutic agents and published guidelines to diminish professional risks, such as adverse reproductive reactions (including infertility and congenital malformations), skin rashes, and leukemia (5–7). As for the NIOSH alert publication, the application of closed system transfer devices (CSTD) for the preparation of chemotherapeutic agents has been increasing in hospitals (8). The application of CSTD is a drug transfer device that mechanically prevents the transfer of environmental contamination into the system and the leakage of dangerous drugs or vapor concentrates out of the system. Meanwhile, a national pharmacy practice survey supported by the American Society of Health-System Pharmacists (ASHP) found that about 41% of hospitals currently used CSTD to prevent HDs in an airtight and leak-proof manner (9). A current report documented that the CSTD could furthest diminish the potential exposure hazards to aerosols generated from chemotherapeutic agents and reduce the surface drug contamination (10).

Although the introduction of biological safety cabinet (BSC) had brought a reduction in exposure chemotherapeutic agents, which was recommended by current guidelines, preparation of anticancer drugs under conditions of BSC is still limited in China. Currently, the application advantages of CSTDs are recognized as effective prevention or reduction of HD exposures for health providers and pharmacists working in PIVAS. As a new protective measure, little information is available due to the production technology procurement and other reasons, limiting the development of CSTD in China. With the increasing number of CSTD, it is necessary to establish a process to determine various CSTDs available in the market. To investigate current conditions of CSTD in PIVAS, we performed a study to test the contamination of chemotherapeutic agents in working surfaces, gloves, gowns, and goggles followed the methodology outlined by the 2015 proposed NIOSH protocol.

MATERIALS

This study was conducted to evaluate the contamination in the chemotherapy agent compounding unit located in a teaching hospital of the university from January 2020 to January 2021. This is a tertiary hospital with 800 beds serving more than 25,000 people in Shanghai, China, and includes a comprehensive cancer center. The hospital PIVAS constantly provides dispensary, clinical and aseptic manufacturing services to the hospital cancer centers with a purpose-built aseptic suite and two pharmaceutical bio-safety cabinets dedicated to the preparation of chemotherapy agents according to USP 800.

The exposure assessments of cyclophosphamide and cytarabine were performed in personal protective equipment and different compounding areas in PIVAS. For preparation activity, contamination samples on the environment and protective equipment (such as gloves and masks) were handled and collected. The details of chemotherapy agent preparation activities (e.g., whether a spill occurred) and administration method were also recorded.

Description of Chemotherapy Compounding Unit

The pharmaceutical team staffed with 8 pharmacists and 6 pharmacy technicians completed the preparations of 4,500 agents in the chemotherapy compounding unit annually. This isolated unit was designed according to International Organization for Standardization (ISO)-controlled atmosphere area equipped with biological safety cabinet (BSC-IIA2), which was filtered with High Efficiency Particulate Air filter (HEPA filter) with 70 kPa over-pressure toward the outside. Two pharmacists were engaged to chemotherapy agent compounding and wore disposable polychloroprene gloves and a disposable polypropylene gown, which had long sleeves and closed fronts throughout the procedure.

The BSC surfaces were cleaned thoroughly with 75% ethanol solution before the workday began. At the end of the work shift, the working surfaces were disinfected again and deep cleaning of the room floor and walls was conducted with chlorine-containing disinfectants.

Study Design

Our study was designed to evaluate the effectiveness of the CSTD system in reducing exposures of HDs from a stainless-steel surface of BSC. We collected two samples for each chemotherapy agents' measurement from the traditional and CSTD systems in the same chamber. The first sample was obtained prior to the mixture, and the second sample was obtained after compounding completion. All tested samples were collected by the pharmacists in PIVAS. The chemotherapy compounding process was completed through traditional needle syringe technique or CSTD systems, as shown in **Figure 1**. CSTD is mainly composed of a vial airtight access device, enclosed syringe safety device, enclosed baggage/line access device, and so on. All components in CSTD are sealed with resealing membranes. When components are joined together, the two membranes are pressed together and then pierced by the steel needle. The elastomeric double-membrane technology can ensure that there is no liquid medicine leakage of each component in the assembly and separation state. Therefore, the whole CSTD mechanically prohibits the transfer of environmental contaminants into the

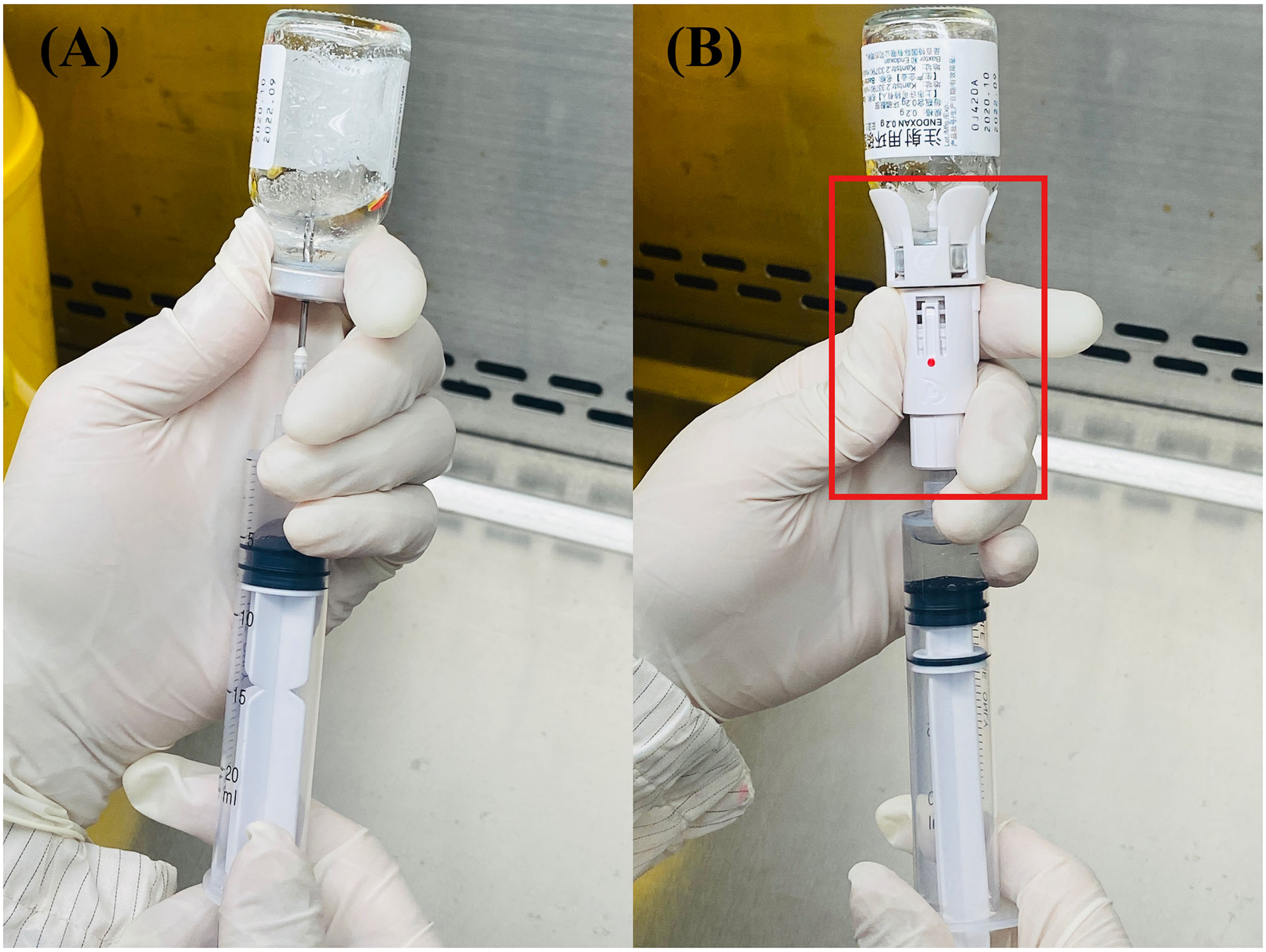

FIGURE 1 | The structure of these two systems: traditional **(A)** and closed system transfer devices (CSTD) **(B)** From Shinva Ande Healthcare Apparatus Co., Ltd.

system and the escape of the HD or vapor concentrations outside the system.

Surface contamination reductions of chemotherapy medications in traditional and CSTD units were compared to assess the effectiveness of the CSTD system. As for the traditional group, all chemotherapy agents compounding was completed with standard medical devices. For the CSTD group, the chemotherapy compounding was performed under personal protective equipment, which covered the whole process of injection preparation and administration (**Figure 2**).

Sample Collection

The wiping sampling method allowed the verification of possible drug dispersion on the surfaces. Before the drug is flushed, we used 75% ethanol solution to thoroughly clean up the platform decently. During compound preparation, we took samples of various handles and pharmacist-used protective equipment (such as gloves and masks) in the active work area. Wipe samplings were conducted before cleaning and after preparation in both traditional and CSTD units. The sampled areas included left and right countertops of the operating area of the two BSCs, the inner side of the glass window of the BSC, and the front drain grooves. Each set of samples was taken before the isolator was cleaned at the end of the work session using a fresh 2×2 cm^2 filler paper saturated by 100 µl prepared solution [Acetonitrile-0.1% formic acid aqueous solution (20:80)] for each surface. The area wiped from each location was 10×10 cm^2 from two different directions, from up to down and from left to right in accordance with validated protocols. The collected samples did not touch any other surface and new pairs of gloves were provided to avoid potential contamination. The wipe papers were stored at 4°C prior to analysis. The details of chemotherapy agent preparation activities (e.g., prepared, checked, and whether a spill occurred) and administration method were also recorded.

Contamination Samples Analysis

Cytarabine, cyclophosphamide, and verapamil (internal standards), all >98% purity, were obtained from Macklin Biochemical (Shanghai, China). Sample collection and preparation were conducted as the following process. A

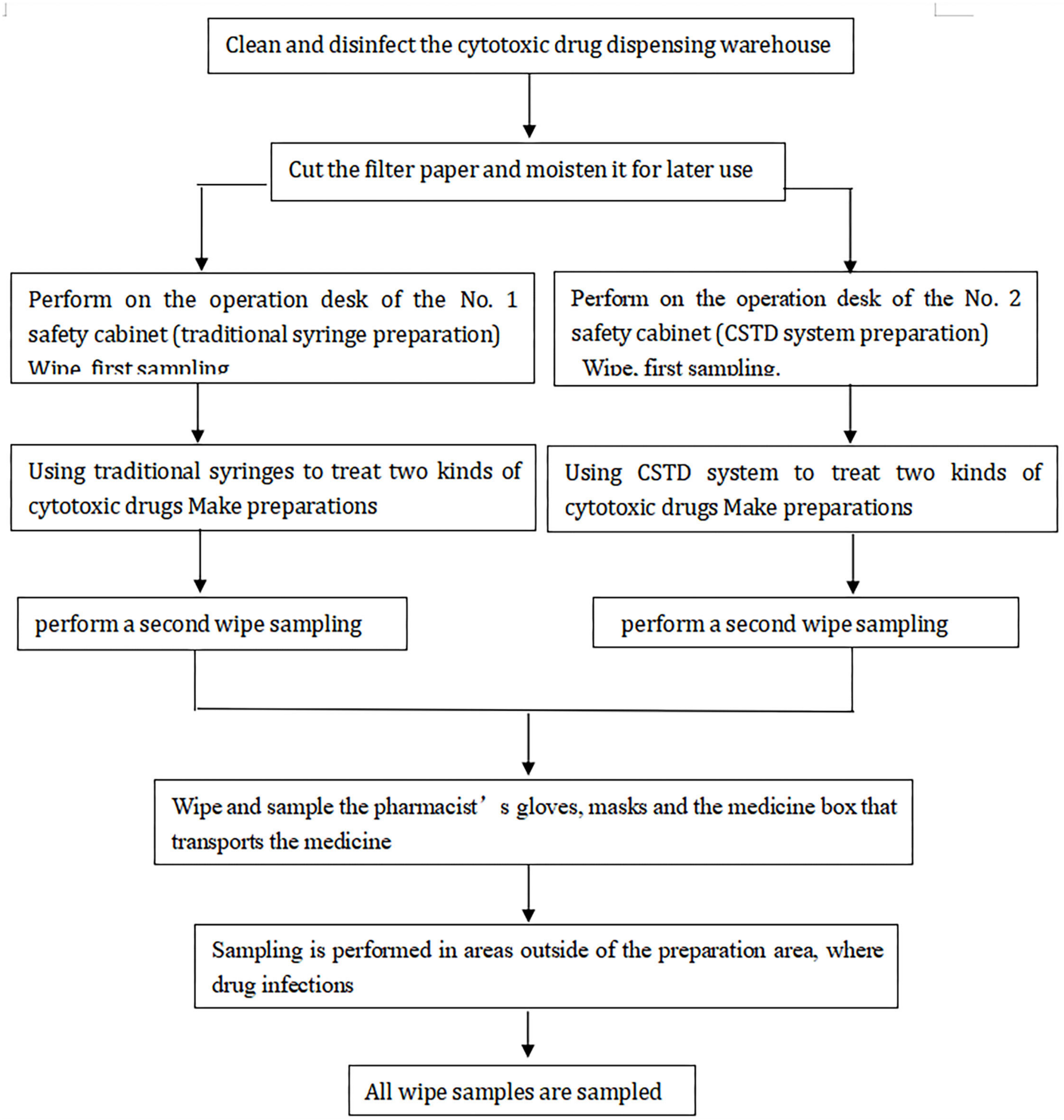

FIGURE 2 | The study process for contamination prevention of two systems.

size of the filter paper (2 cm × 2 cm) was placed into 1.5 ml centrifuge tube. A volume of 950 µl acetonitrile and 0.1% formic acid (20:80) was added and after that 50 µl of internal standards verapamil, 10 ng/ml vortex was mixed for at least 15 s. The fully adsorption dissolving filter paper was taken out and the residual solution was centrifuged at 4°C and 11,000 r/min for 10 min. Then, transfer supernatant fluid of 300 µl was injected into LC-MS/MS for analysis. The limit of quantification (LOQ) was determined as the lowest concentration of the calibration curve, which met the following acceptance criteria was 0.5 ng/ml. The regression coefficients *r* were all >0.99, indicating good linearity. Blank samples were spiked at seven different concentrations of cyclophosphamide and cytarabine (10, 20, 100, 200, 1,000, 2,000, 4,500, and 5,000 ng/ml in the final extract) with a volume of

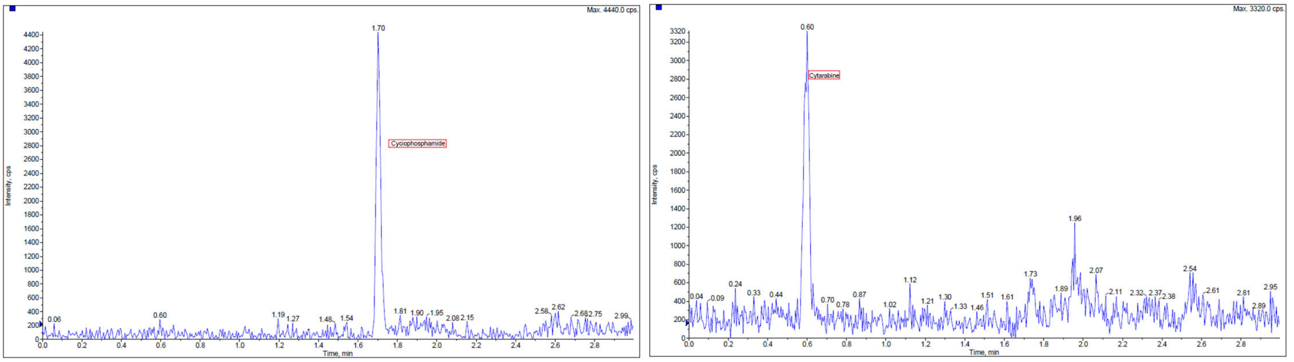

FIGURE 3 | High performance liquid chromatography-mass spectrometry (HPLC-MS) chromatogram of extracted wipe samples containing two chemotherapy agents, cyclophosphamide and cytarabine, and verapamil as internal standards.

TABLE 1 | Evaluation items on ergonomics, encumbrance, and safety impression.

6-item Form evaluation for compounding devices
Ergonomics
1) Connecting protector to vials
2) Connecting injector to syringes and protector
3) Injecting liquids into vials and containers
4) Withdrawing solution from vials and infusion bags
Encumbrance
Safety impression in compounding process

50 μl and carried out in accordance with the process of sample collection and preparation. A combination solution of 900 μl acetonitrile and 0.1% formic acid (20:80) and 50 μl internal standards verapamil 10 ng/ml was added. Calibration curves were constructed by plotting the concentrations on the X-axis vs. the chromatographic peak area ratio of ionic compounds internals standards on the Y-axis. Linear regression analyses were performed using the calibration curve data. The results of high performance liquid chromatography-mass spectrometry (HPLC-MS) profile for contamination wiping samples detection are reported in **Figure 3**.

Estimation of the Usability of Devices by Pharmacists

A 6-item form was distributed monthly (form M1–M6, total 6 months) to assess the pharmacists' experience on ergonomics, encumbrance, safety impression and to establish a direct comparison between CSTD and traditional compounding process (**Table 1**). Each evaluation item was assigned a score from 0 to 5 points (1 = very bad, 2 = bad, 3 = neutral, 4 = good, and 5 = very good) with a total score of 30.

Statistical Analysis

This trial was established to evaluate the impact of the CSTD system on exposure reduction of HDs of BSC. Based on the results of the previous clinical study, we supposed a difference of contamination variation between two compounding systems in prespecified analysis. Therefore, to preserve a one-sided type I error of 5% and adequate power, we selected a sample size of 84 samples to demonstrate a non-inferiority of different systems on contamination changes. Assuming subsequent losses to 15%, a whole study sample with 96 was required.

The reduction of contamination exposure levels of cyclophosphamide and cytarabine was compared between traditional and CSTD systems. The comparison general satisfaction on ergonomics, encumbrance, and safety impression of pharmacists were performed during the compounding process. The descriptive statistical results of continuous variables were expressed as means ± standard deviations (SD) and were compared using two-tailed Student's *t*-test between groups. Categorical data were presented as percentages. The chi-squared test was performed to compare the correlation of categorical variables. Statistical analysis was conducted using SPSS (IBM SPSS Statistics 22.0) and Prism 5 (GrandPad Software). The value of $p < 0.05$ was considered to be statistically significant.

RESULTS

Contamination Wiping Samples Detection

Totally, 96 wiping samples were collected throughout the study, and wipe sample sites are presented in **Table 2**. The exposure reduction efficiency was calculated by contamination per square centimeter and all results were underestimated.

Contamination Description of two Systems

There was almost no chemotherapy agent residual prior to compounding. After compounding, the levels of the chemotherapy agent contamination of cyclophosphamide and cytarabine were recovered from wipe samples during traditional and CSTD phases, which are shown in **Table 2**.

In the BSC area, CSTD could significantly reduce cyclophosphamide contamination exposure as compared to the traditional system. Similarly, cytarabine contamination in the location of the air-intake vent and door handle could be significantly reduced under the condition of CSTD. Meanwhile, no significant decrease in cytarabine exposure contamination

TABLE 2 | Summaries of wiping samples for traditional and closed system transfer device (CSTD) systems.

Area (cm^2)	No. of detectable samples (Traditional)	No. of detectable samples (CSTD)
BSC		
Countertop, Left (100 cm^2)	5	5
Countertop, Right (100 cm^2)	5	5
Medial glass (100 cm^2)	5	5
Air-intake vent (100 cm^2)	5	5
Door handle (48 cm^2)	5	5
Pharmacist devices		
Masks (16 cm^2)	4	4
Gloves (4 cm^2)	4	4
Drug administration		
Dispensing table (100 cm^2)	5	5
Transfer container (100 cm^2)	5	5
Dispensing basket (100 cm^2)	5	5

BSC, biosafety cabinet; cm^2, square centimeter.

was found between the two systems. As for protective equipment, the chemotherapy agent contamination was significantly lower under the CSTD, whatever the localization. During the administration process, CSTD could significantly decrease cytarabine contamination.

As depicted in **Figure 4**, the percentage decrease values under CSTD are −37.8, −41.6, −67.7, −47.3, and −22.9% of cyclophosphamide samples and −12.3, −12.1, −20.6, −69.6, and −56.7% of cytarabine samples for left countertop, right countertop, medial glass, air-intake vent, and door handle when compared to traditional units. Similar trends were observed in pharmacist-used protective equipment: −48.2 and −50.0% for cyclophosphamide and −18.0 and −42.4% for cytarabine. Likewise, cyclophosphamide contamination percentage was found with −16.6, −6.0, and −22.3% for dispensing table, transfer container, and dispensing basket under CSTD conditions, respectively. The percentages of contaminated cytarabine samples are −28.5, −22.5, and −46.2%, respectively, with the traditional devices, as shown in **Figure 4**.

Usability Evaluation of Devices by Pharmacists

Totally, 14 pharmacists completed the 6-item form each month during the study. At the beginning of the study, the general satisfaction on ergonomics, encumbrance, safety impression of pharmacists was moderate (medium) for both CSTD and traditional systems.

As depicted in **Figure 5**, the satisfaction on encumbrance and safety impression for the CSTD system is good from the start and remained constant throughout the whole study. A high level of satisfaction was consistently associated with ergonomics for CSTD during the compounding process. Meanwhile, a slightly decreased satisfaction on ergonomics, encumbrance, and safety impression is observed for the traditional system between M2 and M3, as shown in **Figure 5**.

DISCUSSION

Reduction in surface contamination for compounding areas and pharmacist devices had raised major concern for many years in PIVAS. Our study indicated that adjacent preparation areas in BSCs, pharmacist device, and drug administration locations might be associated with decreased contamination during the chemotherapy agent compounding process when CSTD systems were used. Moreover, a superior experience on ergonomics, encumbrance, and safety impression was found during CSTD system application as compared to the traditional system. The results showed that CSTD could greatly reduce the pollution of cytotoxic on the BSC and the environment and reduce the waste of medical resources.

This is the first direct comparative study to investigate the degree of contamination by chemotherapeutic agents in the working environment or to healthcare providers who applied the traditional or CSTD handling practice in China. Our results demonstrated that CSTDs could significantly reduce chemotherapy agent contamination, including cyclophosphamide and cytarabine, on isolate surfaces as compared to traditional systems. Currently, CSTDs are not widely used and accessible to chemotherapy agents compounding in hospital settings, and this study might provide clinical evidence for the superiority of CSTDs.

The preliminary results indicated that contamination with cyclophosphamide and cytarabine was primarily identified in most areas of the aseptic dispensary unit and pharmacist device. Surface contamination might be caused by several factors in the clinical settings, including the original pollution residue of the medicine bottle, the indirect pollution caused by the contaminated gloves, and the improper operation (9). One common source of contamination originated from aerosol formation due to the pressure inside the drug vial (11, 12). Previous literature also demonstrated residual chemotherapy agent contamination on the exterior of vials received from pharmaceutical manufacturers (13, 14). High concentration level of chemotherapy agent contamination was identified on the countertop location inside the BSC, personal protective equipment, such as masks, gloves, and drug administration areas. It could be explained that cyclophosphamide and cytarabine spillage are easily exposed in those areas during the compounding process. Our results were consistent with the previously reported articles, which had conducted the residual cyclophosphamide contamination concentration assessment in a similar method (10, 15, 16). It was reported that the inside areas of aseptic dispensary unit were associated with a high possibility of contamination and the countertop inside the BSC was considered as a higher possibility of contamination location. The phenomenon could be explained by some spillage occurrences during the compounding process.

Many cautionary documents demonstrated that the lymphocyte DNA damage was 5–7-fold more common in

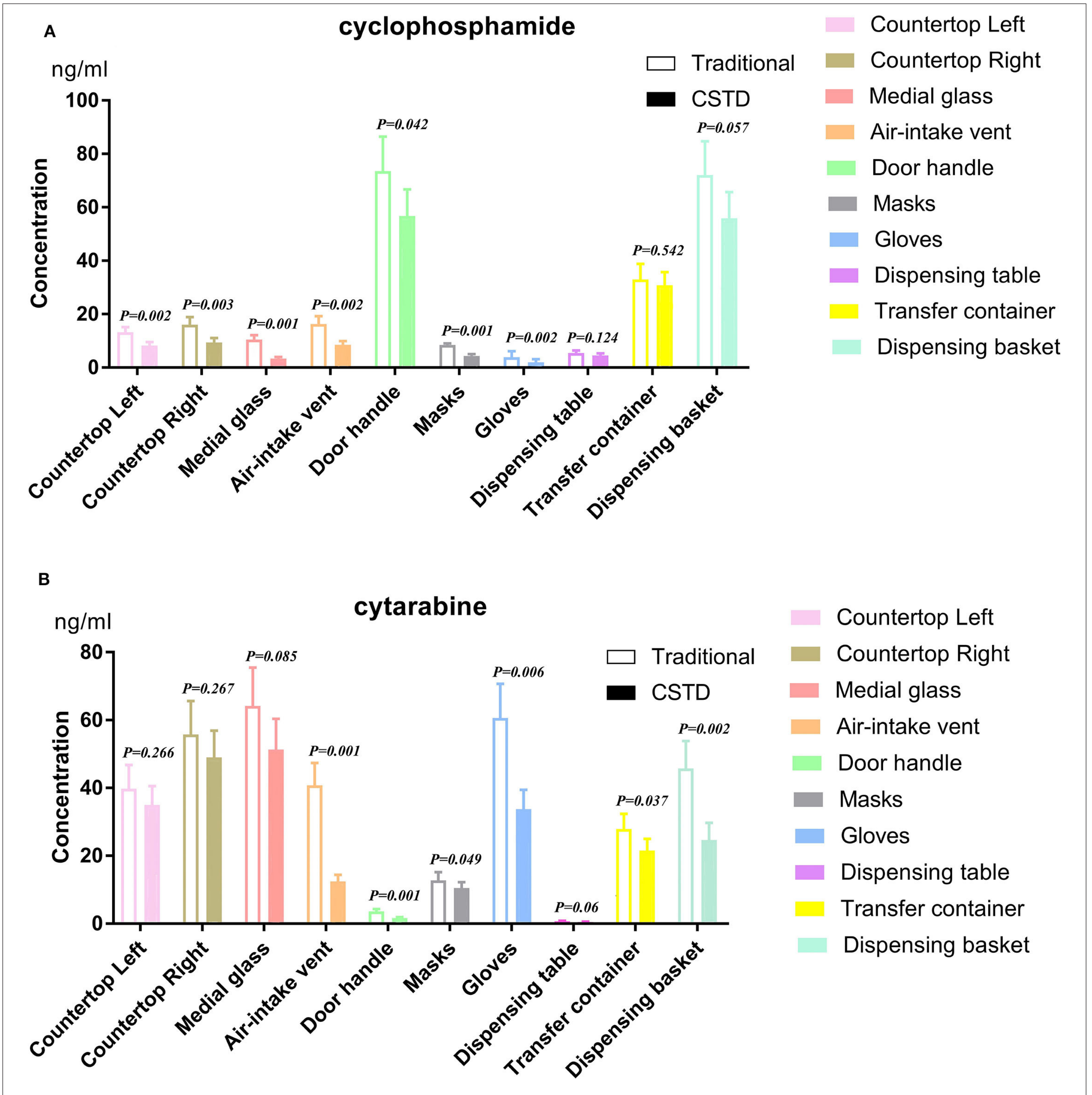

FIGURE 4 | Cyclophosphamide and cytarabine on isolator surfaces and preparation with traditional and CSTD intervention. $p < 0.05$ was regarded as a significant difference. **(A)** cyclophosphamide, **(B)** cytarabine.

healthcare providers who handle chemotherapy agents than the normal (17–19). Although BSC could prevent most environmental contamination that is mainly caused by hazardous spills and aerosol, residual contamination still existed which might bring long-term hazards. Many studies reported that healthcare providers handling with HDs who suffered a miscarriage, fertility, and birth defects were detected measurable urine chemotherapy agent concentrations (2, 9). CSTDs could limit the chemotherapy agent spillage and provide a safer environment, mainly attributing to the high efficiency of particulate air (HEPA) filter supply and air extraction from the BSC (20, 21).

Our results demonstrated a significant reduction in the cyclophosphamide and cytarabine contamination levels in most detected areas after implementing CSTD methods during the preparation process. As shown in **Table 2** of our study, CSTDs

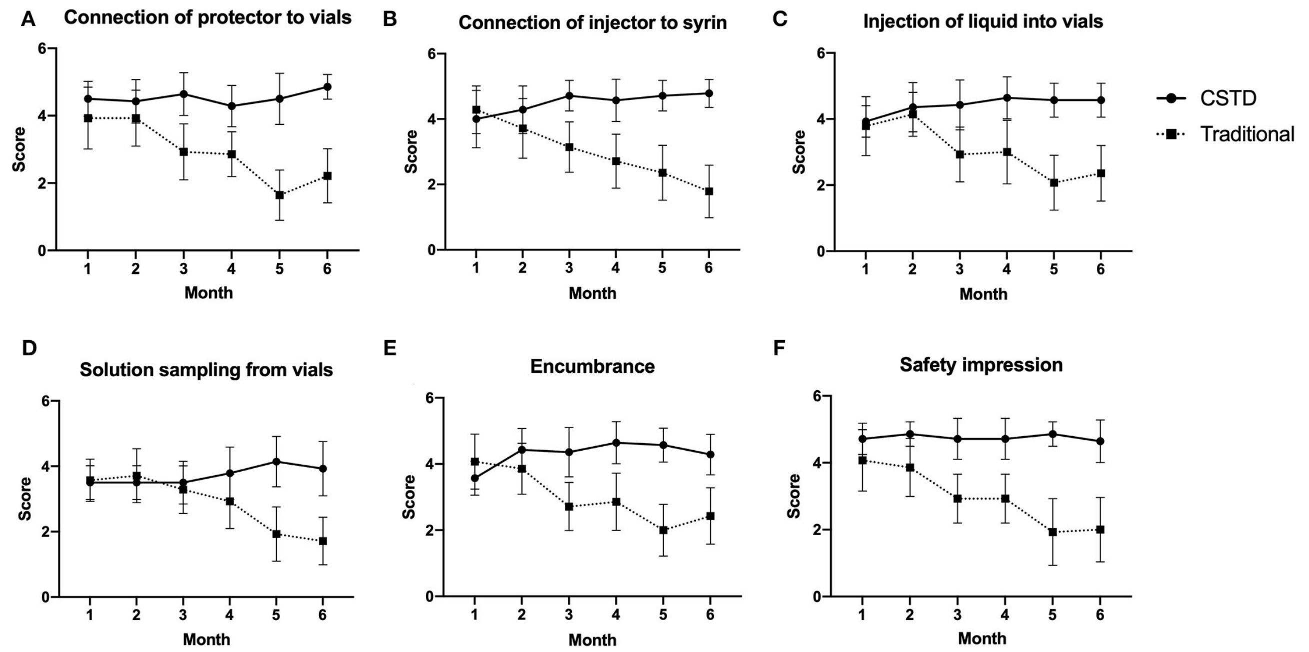

FIGURE 5 | The satisfaction comparison of ergonomics, encumbrance, and safety impression. **(A)** Connection of protector to vials, **(B)** connection of injector to syrin, **(C)** injection of liquid into vials, **(D)** solution sampling from vials, **(E)** encumbrance, **(F)** safety impression.

could significantly reduce average values of cyclophosphamide and cytarabine contamination concentration. Especially for masks and gloves directly exposed to chemotherapy agents, CSTDs could reduce the percentage of contamination by 48.2 and 50.0%, respectively, based on the average contamination of the traditional method, in agreement with similar studies performed earlier (22, 23). The present study was consistent with this conclusion. The probable explanation might be that CSTDs could mechanically prevent the contamination of environmental impact on the system and the leakage or vapor concentrates of HDs out of the system.

As for pharmacists' observations, general satisfaction with the CSTDs remained constantly good throughout this study, while it was good from the beginning and continuously decreased over the whole study period for traditional systems. The application of CSTDs was now hailed as an alternative safety measure due to the full awareness of relatively high risks of chemotherapy agent handled in clinical settings. Our teams were trained to operate this novel device correctly during the compounding process to avoid technical problems caused by human factors. The results indicated that CSTDs could improve pharmacists' satisfaction on ergonomics, encumbrance, and safety impressions. The probable reason might be that the safety of CSTDs helped pharmacists to modify perception, which not only increased the degree of satisfaction but also improved the effectiveness of the operation.

CONCLUSION

Currently, the topic of measures taken to protect handlers from occupational exposure to chemotherapy has always been controversial. The proper use of a CSTD may significantly decrease contamination by these drugs and consequently decrease exposure risk on workplace surfaces and personal protective equipment as compared to traditional compounding devices.

Limitations

We acknowledge several limitations in our work. First, owing to the nature of this observational study, we have some relevant limitations, such as selection bias or the single-center observation, which might have an impact on research quality. Second, the study included a limited number of samples obtained during this preliminary study. Hence, large sample size is needed in further study. Third, the absent determination of contamination on the drug vials might influence the statistical summary of the accuracy and precision, and further study and statistical analyses are needed to investigate the containment effectiveness of the two systems in a controlled setting.

DATA AVAILABILITY STATEMENT

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

ETHICS STATEMENT

Ethical review and approval was not required for the study of human participants in accordance with the local legislation and institutional requirements. Written informed consent from the patients/ participants was not required to participate in this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

YT: conceptualization, methodology, and writing—original draft. YW: writing—review & editing. WC and XY: supervision. YLW: validation. XC: acquisition of data, analysis, and interpretation of data. All authors contributed to the article and approved the submitted version.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2022.827835/full#supplementary-material

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Implementation of Chemical Health, Safety, and Environmental Risk Assessment in Laboratories: A Case-Series Study

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Introduction: Characterizing risks associated with laboratory activities in universities may improve health, safety, and environmental management and reduce work-related diseases and accidents. This study aimed to develop and implement a chemical risk assessment method to determine and prioritize more hazardous chemicals in the academic laboratories.

Methods: A case-series study was conducted at five academic laboratories and research facilities of an Iranian medical sciences university in 2021. A risk assessment was developed and implemented in three phases to identify, evaluate, and classify potential risks and hazards. The approach provided an innovative tool for evaluating and prioritizing risks in chemical laboratories. Hazards were classified on a five-level scale. The technique reviewed both quantitative and qualitative data and pieces of evidence using Laboratory Safety Guidance (OSHA), Occupational Hazard Datasheet (ILO), the standards of the American Conference of Governmental Industrial Hygienists (ACGIH), International Agency for Research on Cancer (IARC), and National Fire Protection Agency (NFPA) codes.

Results: Overall, the frequency of risks rated from "moderate" to "very high" levels was determined for the health hazards (9.3%), environmental hazards (35.2%), and safety hazards (20.4%). Hydrochloric acid had a high consumption rate in laboratory operations and received the highest risk levels in terms of potential hazards to employees' health and the environment. Nitric acid, Sulfuric acid, Formaldehyde, and Sodium hydroxide were assessed as potential health hazards. Moreover, Ethanol and Sulfuric acid were recognized as safety hazards. We observed adequate security provisions and procedures in academic laboratory operations. However, the lack of awareness concerning health, safety, environmental chemical hazards, and inappropriate sewage disposal systems contributed to the increasing levels of laboratory risk.

Conclusions: Chemicals used in laboratory activities generate workplace and environmental hazards that must be assessed, managed, and risk mitigated.

Developing a method of rating health, safety, and environmental risks related to laboratory chemicals may assist in defining and understanding potential hazards. Our assessment suggested the need for improving the risk perception of individuals involved in handling chemicals to prevent exposure from workplace duties and environmental pollution hazards.

Keywords: chemicals, risk assessment, academic, laboratories, safety

INTRODUCTION

Laboratories and research facilities are considered a fundamental part of universities playing a crucial role in preparing students and researchers to obtain skills that are valuable in their future careers (1). The presence of numerous chemicals in laboratories has faced safety and health managers with challenges in estimating their risks and hazards. The chemicals and equipment that are used by laboratory personnel and students present a number of serious, sometimes life-threatening hazards and accidents. Laboratory managers are responsible to protect their personnel and students from exposure to chemical, biological, and physical hazards (2). Therefore, the presented risk assessment method for the academic laboratories and applying prevention and mitigation measures in this study enable the laboratory managers to do their responsibility to their personnel and students.

A survey by OSHA has reported that the potential hazards associated with conducting research at laboratories in academic institutions were 11 times more dangerous as compared to commercial laboratories in a range of industrial sectors with labs (3). Literature review on the safety and health of laboratories in higher education institutions has shown many laboratory incidents leading to fatalities and injuries caused by fires, explosions, and equipment resulting in debilitating injuries and death (4). Previous studies on health-related hazards have reported both acute and chronic poisonings following exposure to various chemicals in laboratory environments (5). Moreover, laboratory wastewater consists of hazardous chemicals that have been considered a substantial environmental threat (6). In the United States, about 18% of occupational accidents in higher education institutions were related to laboratory environments and in approximately one-third of accidents, students were the main victims (7–9). A review of reported cases in the literature evidence suggests that the trend of accidents was on the rise in academic laboratories over the past several years (10, 11). Lack of awareness of various safety and health hazards has triggered accidents, mainly related to the unsafe work practices of chemicals and equipment in laboratories (12).

Integrated health, safety, and environmental risk assessment would be beneficial in understanding risks, evaluating hazards, and planning a strategy to prevent accidents in laboratories (13, 14). International occupational safety and health organizations have developed standards and instructions to prevent and control hazards in laboratory environments. Training of students and laboratory workers provided a culture of safety, health, and environmental consciousness in dealing with laboratory risks and hazards (15). Although risk assessment has shown to be an efficient approach to identify and introduce appropriate measures to manage risks and hazards, workplace risk levels may differ based on tasks and unsafe acts even in the same work environment. In essence, the laboratory risk assessment should be implemented for individual specific laboratory settings and each work task and role to effectively apply controls (16). Obtaining objective and comprehensive data concerning risks and hazards has presented challenges for health, safety, and risk management professionals in chemical laboratories. Planning a risk assessment requires the definition of an assessing project with an educated team. Hazard prediction and recognition are the beginning or first step to measure the strength of the impact of a threat (2).

Many research activities are performed in chemical laboratories at universities, which are seldom assessed by occupational safety and health engineers (11). This study performed an integrated health, safety, and environmental risk assessment to determine the level of risks for potential workplace exposure in terms of different jobs and work duties in academic lab settings. The process includes prediction, recognition, classification, and evaluation of risks and hazards in chemical laboratories. The plan for adequate measures to prevent and mitigate risks and fitness of work to laboratory personnel and the student will be discussed.

METHODS

Design and Setting of the Study

A cross-sectional design and action research were applied to develop and conduct a comprehensive risk assessment to determine a range of health, safety, and environmental risks associated with the activities in academic laboratories. This study was implemented at five medical and health sciences laboratories affiliated to Semnan University in 2021.

Suggested Steps of Risk Assessment

Figure 1 demonstrates the methodology steps proposed for assessing risks in chemical laboratories in university environments. These include developing an integrated risk approach, collecting information to categorize risk factors, calculating risk levels, and proposing health, safety, and environmental measures.

Development of an Integrated Risk Assessment Approach

Our methodology is based on the use of a structured checklist to integrate the process of predicting and recognizing hazards,

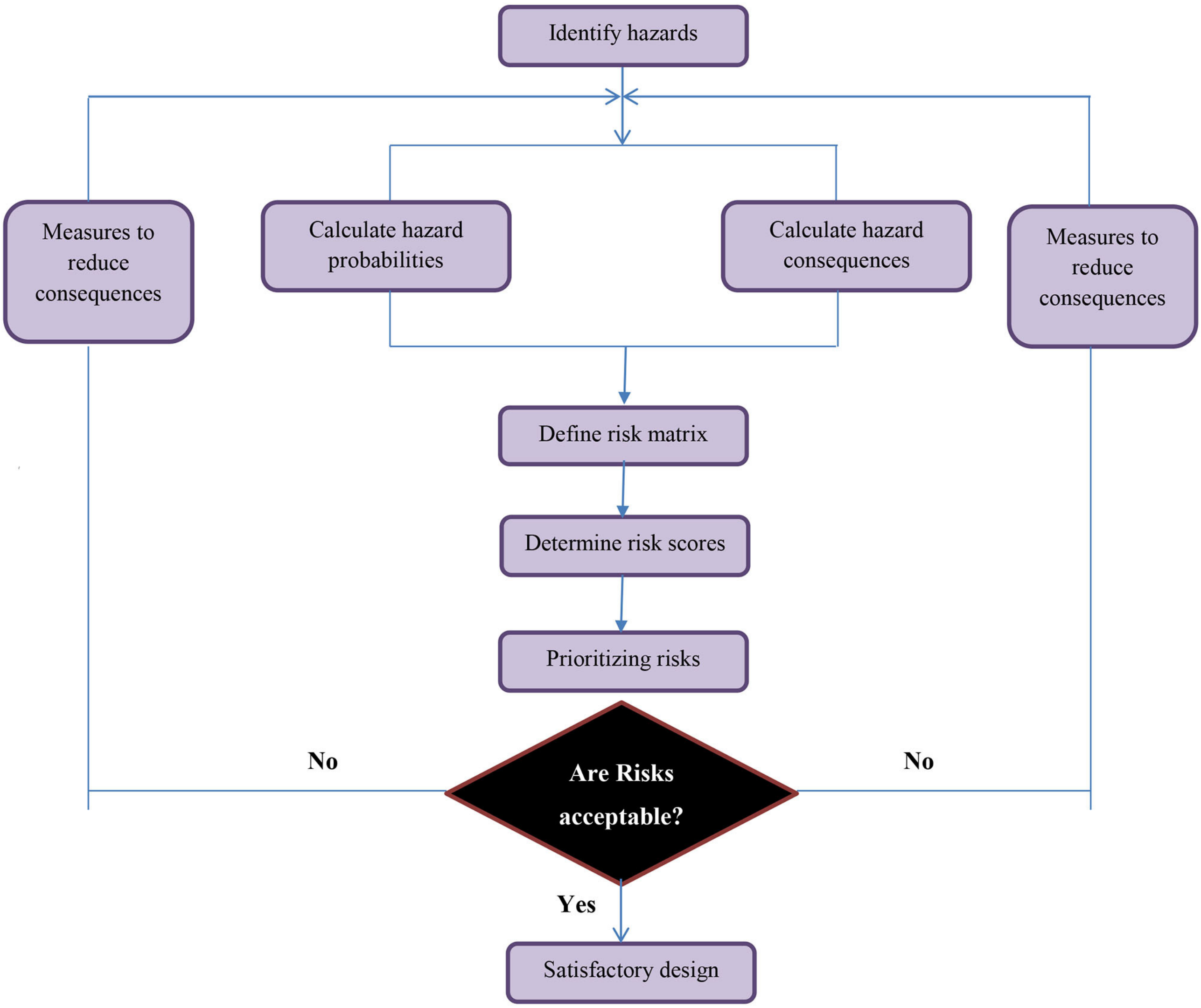

FIGURE 1 | Flowchart of the suggested methodology for risk assessment.

evaluating the risks posed by hazards, and managing the risks of hazards in the context of the university laboratory. This technique reviewed both quantitative and qualitative data regarding chemicals, environment, and activities associated with the specific processes, and judgments were confined to a particular laboratory process in isolation.

Recognition of potential risks and hazards in laboratory environments and activities was based on checklists, walk-through observation, and interviews with working individuals in laboratories. We developed a combined behavior-based and process-based checklists to conduct a broader risk assessment for identifying the risk level of work practices and mitigating the associated risks. The study tool was adopted from Laboratory Safety Guidance (OSHA), Occupational Hazard Datasheet (ILO), and the Princeton University Laboratory Safety Manual. The tool consisted of 131 items, which were used to assess working areas, emergency planning, required information and documentation, personal protective equipment, electrical hazards, chemical storage and use, flammable liquids, compressed gases, disposal of chemicals used in the lab, ventilation requirements, security, and training.

Collecting Information to Categorize Risk Factors

We identified and grouped chemical exposure and hazards according to their properties, work procedures, and occupational potential exposure scenarios by using frequency and work behavior in the laboratories studied.

Calculating Risk Levels

The laboratory hazard risk rating of a chemical was estimated by multiplying the severity of consequence value by the likelihood of incidence value. For this step, we assembled literature on hazard properties for each chemical from reliable resources to obtain a

TABLE 1 | Establishing a laboratory hazard and process matrix-based risk system with standard linear scaling (values 1–5) to determine the risk score.

Likelihood severity	1	2	3	4	5
1	1	2	3	4	5
2	2	4	6	8	10
3	3	6	9	12	15
4	4	8	12	16	20
5	5	10	15	20	25

Interpretation

Very low	1 - ≤5	Risk is acceptable and control measures is not necessary
Low	5.01 - ≤10	Risk is low and further studies needed in the future
Moderate	10.01 - ≤15	Risk is intermediate and control measures have to be done in the future
High	15.01 - ≤20	Risk is high and control measures have to be done as soon as possible
Very high	20.01 - ≤25	Risk is very high and control measures have to be done immediately

review of a clear understanding of the safety and health controls. The pieces of literature were reviewed for exposure limits and carcinogenicity of chemical substances as identified by the standards of American Conference of Governmental Industrial Hygienists (ACGIH), Immediately Dangerous to Life or Health Concentrations (IDLH) of toxic substances, and National Fire Protection Agency (NFPA) codes (17, 18).

We used an assessment matrix to conduct a comparative analysis concerning "the severity of consequence" and "the probability of incidence" to determine the risk rating for individual health, safety, and environmental hazards. Our estimates of hazard risk ratings were used to categorize risk into varying levels of risk by applying standard linear scaling. **Table 1** demonstrates the matrix of risk levels and expectations of responses required to improve safety and health in the laboratory (ISO 31000) (19).

Proposing Health, Safety, and Environmental Measures

The prevention and mitigation of health, safety, and environmental risk measures were proposed based on calculated risk scores.

TABLE 2 | Results of hazard analysis checklist based on work processes and behaviors evaluated in university chemical laboratories and verified frequency of compliance and non-compliance with health, safety, and environmental guidelines.

Laboratory environment and facilities	Compliance (%)	Non-compliance (%)
1. General work environment	59	41
2. Emergency planning	42	58
3. Required information and documentation	20	80
4. Personal protective equipment	25	75
5. Electrical hazards	56	44
6. Chemical storage	56	44
7. Flammable liquids	83	17
8. Compressed gases	87.5	12.5
9. Disposal system	NO*	100
10. Ventilation	83	17
11. Security	100	NO*
12. Training	17	83
13. Awareness	36	64

**Not Observed.*

RESULTS

In this study, we used a checklist to recognize potential risks and hazards in the laboratory settings. Health, safety, and environmental hazards associated with common chemical laboratory activities and workflow and the percentage of compliance and non-compliance with laboratory guidelines are shown in **Table 2**.

Our survey of laboratory activities showed that work with compressed gases and flammable liquids was in acceptable compliance with security considerations and safe work procedures. However, the above half of non-compliance was related to the preparation in emergency response situations, not using personal protective equipment, poor inappropriate chemical disposal, treatment of waste products, and awareness and training. The lack of written emergency action plans, chemical hygiene lab procedures, and Safety Data Sheet (SDS) were identified to contribute to operational risks in chemical laboratory activities. The unsafe acts by the lab staff related to waste effluent disposal management mainly included risk factors of improper disposal containment and methods for experiment waste. We observed a lack of compliance in emergency response plans that are mainly associated with inadequate knowledge of staff and students about how to identify the location of fire extinguishers, how to request emergency assistance, and how to communicate potential leak, fire, and explosion scenarios.

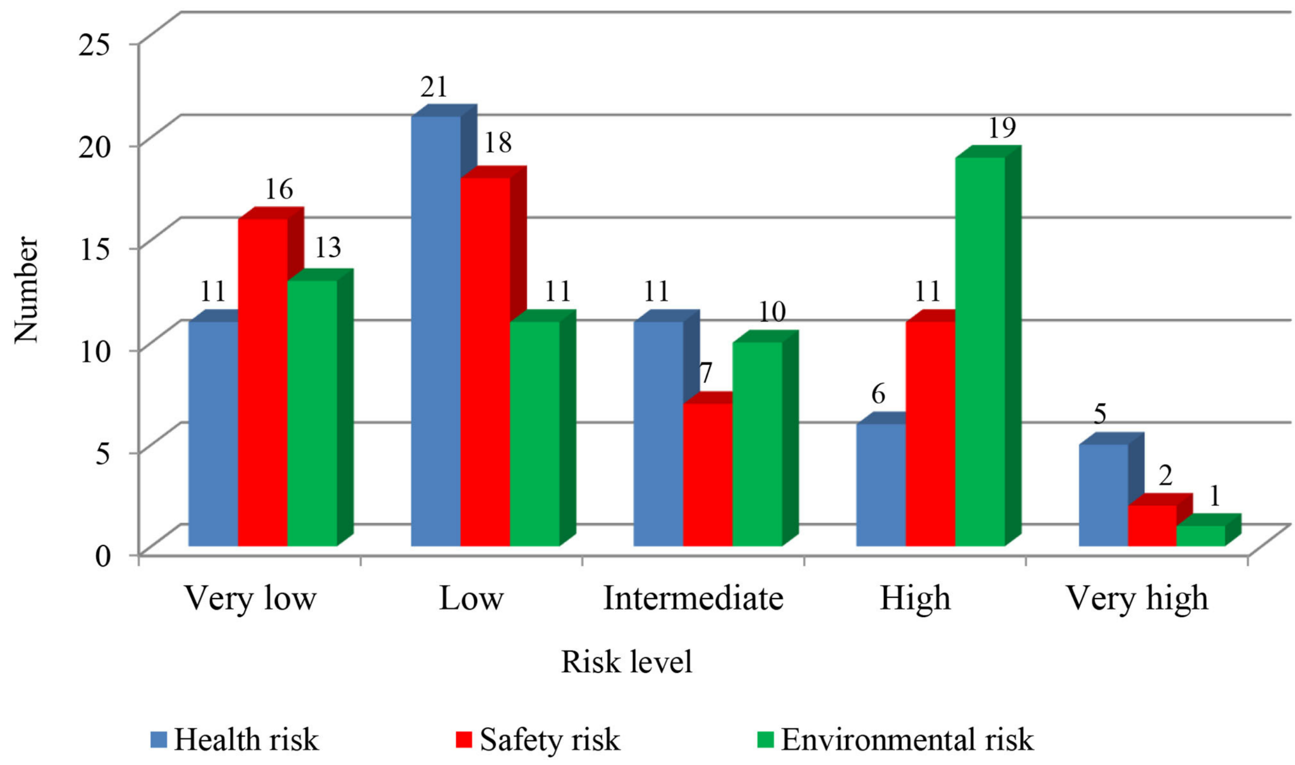

FIGURE 2 | Frequency of chemicals at estimated risk level classes in university laboratory activities.

The unsafe conditions, such as aging electrical cords and plugs and contact with incorrectly grounded devices, were identified to increase operational risks of instruments in laboratories. Additionally, obstructed fire alarm pull stations or inappropriate layout of fire extinguishers in the lab environments increases the reaction time in the occurrence of accidents. Almost all individuals involved in handling chemicals in the laboratories reported they had not received the proper chemical safety training. Our onsite observations showed the unsafe storage of chemicals, which may lead to leakage and increase the possibility of exposure and accidents or high potential for injuries and damages. Students and laboratory workers were more likely not to choose the safe course of action concerning the use of personal protective equipment. For example, a common unsafe act was working in university labs without wearing face and eye or respiratory protection. The absence of proper Protective Personal Equipment (PPE) leads to unsafe exposure and subsequent injury. Furthermore, in chemical laboratories, the users frequently violated safe work procedures during transporting or setting up the experiment or apparatus. We identified many facilities and experiments in compliance with environment, health, and safety codes for handling flammable liquids and compressed gases in chemical laboratories. However, any deviation from the intended experimental steps in laboratory operations could result in severe consequences. The survey evaluated comprehensive health, safety, and environmental hazards of 54 chemicals used in chemical laboratories (**Figure 2**).

The proposed class-based risk assessment involves five levels of classes. The fourth- and fifth-level classes characterize the main risk factors.

A total of 44 risk factors were predicted and recognized as the "high" or "very high" level assessment classes. Potential health hazards recognized at the "very high" level were more frequent when compared to safety and environmental hazards, respectively, accounting for 9.2, 3.7, and 1.8% of the total number of hazards at the "very high" level class. Moreover, the chemicals with the level of "high" risk contributed to a greater number of environmental hazards (35.2%) followed by safety hazards (20.4%) and health hazards (11.1%). The identified health, safety, and environmental hazards of chemicals at the intermediate level were, respectively, 20.4, 13, and 18.5% of the total number of third-level categories, implying that prevention and control actions are required to manage the risks. Additionally, the mean value of 29.7% of the assessed chemicals had very low and low health risk levels. These mean values for safety and environmental hazards were 31.5 and 22.3%, respectively.

Overall, using chemicals in laboratory operations produced a wide range of risk levels. Cyclohexane, Nitric acid, Sulfuric acid, Formaldehyde, and Sodium Hydroxide were classified as "very high" risk levels with a score estimated at 25, accounting for 9.3% of potential hazards to health. Many chemicals (35.2%) were classified at the "high" risk levels involved in environmental hazards. In contrast, few chemicals (1.8%) presented a "very high" risk level to the environment. **Table 3** demonstrates the

TABLE 3 | Health, safety, and environmental risk assessment matrix of common chemicals used in university laboratories.

Chemicals name	Environmental risk			Safety risk			Health risk		
	Probability	Severity	Risk score	Probability	Severity	Risk score	Probability	Severity	Risk score
Acetone	4	1	4	4	5	20	4	3	12
Acetic acid	4	4	16	3	4	12	4	3	12
Ethanol	5	3	15	5	5	25	5	3	15
Ammoniac	4	5	20	3	5	15	4	4	16
Benzene	3	3	9	4	4	16	3	5	15
Butanol	4	4	8	4	5	20	2	2	4
Chloroform	4	5	20	4	5	20	2	3	6
Cyclo hexanol	3	2	6	3	5	15	3	2	6
Hydrochloric acid	5	5	25	5	4	20	5	5	25
Hydrogen peroxide	4	4	16	4	3	12	4	4	16
Methanol	3	5	15	5	4	20	3	2	6
Nitric acid	5	4	20	4	4	16	5	5	25
Sulfuric acid	5	4	20	5	5	25	5	5	25
Di chloromethane	4	1	4	4	2	8	3	3	9
Di ethyl ether	3	3	9	4	5	20	3	2	6
Ethylene glycol	2	2	4	2	2	4	2	3	6
Formaldehyde	4	5	20	3	4	12	5	5	25
Isopropanol	3	3	9	4	4	16	3	2	6
Orto toluidine	1	5	5	2	4	8	1	4	4
Toluene	3	3	9	4	4	20	3	3	9
Carbon disulfide	4	3	12	4	5	20	3	4	12
Paraffin	4	1	4	1	2	2	2	2	4
Aluminum sulfate	4	4	16	1	3	3	3	3	9
Arsenic oxide	2	5	10	3	3	9	2	5	10
Barium chloride	2	5	10	1	2	2	2	3	6
Cadmium chloride	3	5	15	1	2	2	3	5	15
Iodine	4	5	20	2	2	4	5	4	20
Ferric sulfate	3	4	12	1	3	3	3	3	9
Ferric chloride	3	3	9	2	1	2	3	4	12
Ammonium carbonate	2	5	10	2	4	8	2	3	6
Ammonium chloride	2	2	4	2	1	2	2	3	6
Asbestos	4	4	8	2	4	8	1	5	5
Brome	2	5	10	3	3	9	2	4	8
Calcium carbonate	3	1	3	1	1	1	3	3	9
Calcium hydroxide	3	4	12	1	3	3	3	4	12
Magnesium oxide	2	5	10	1	2	2	2	3	6
Phenol	4	5	20	2	3	6	2	5	10
Manganese sulfate	4	5	20	1	2	2	2	4	8
Potassium hydroxide	5	4	20	3	3	9	5	4	20
Silver nitrate	3	5	15	2	3	6	3	4	12
Sodium azide	1	5	5	3	2	6	1	4	4
Sodium fluoride	3	5	15	2	2	4	3	4	12
Sodium hydroxide	5	4	20	3	3	9	5	5	25

(Continued)

TABLE 3 | Continued

Chemicals name	Environmental risk			Safety risk			Health risk		
	Probability	Severity	Risk score	Probability	Severity	Risk score	Probability	Severity	Risk score
Mercury	4	5	20	2	3	6	2	4	8
Potassium cyanide	4	5	20	3	4	12	2	4	8
Sodium cyanide	1	5	5	2	3	6	1	4	4
Potassium chromate	4	5	20	2	3	6	5	4	20
Tin chloride	4	5	20	2	3	6	4	4	16
Citric acid	2	2	4	1	2	2	2	2	4
Cobalt chloride	4	5	20	2	3	6	2	4	8
Lead acetate	1	5	5	2	2	4	1	3	3
Lead nitrate	1	5	5	2	4	8	1	4	4
Mercury chloride	4	5	20	3	5	15	1	5	5
Nitrate nickle	1	5	5	2	4	8	1	3	3

Very low – Acceptable risk.
Low – Further studies are needed in the future.
Moderate – Control measures have to be done in the future.
High – Control measures have to be done as soon as possible.
Very high – Control measures have to be done immediately.

potential health, safety, and environmental hazards of the studied chemicals and the relevant calculated risk scores.

Our risk assessment showed that 25.9% of the laboratory chemicals might be associated with heavy potential exposure as scored at 5 or 4. Moreover, more than half of the laboratory chemicals (25.9%) contributed to the high level of severity outcomes. The results demonstrated that Ethanol and Sulfuric acid presented a "very high" risk level (scored at 25) in safety risk assessment. Furthermore, 27.8 and 44.4% of chemicals were rated high scores of probability and severity, respectively, in the safety risk assessment. Hydrochloric acid was the only chemical that was ranked at the "very high" level in the environmental risk assessment, with a score estimated at 25.

DISCUSSIONS

This study assessed health, safety, and environmental risks in academic laboratories that use chemicals for educational and research activities. The variability of chemical use in academic laboratories might lead to various health, safety, and environmental risk factors. Our findings agree with prior research that suggested that educational and research laboratories of academic institutions need to assess their vulnerabilities and plan their own risk mitigation accordingly (20).

Our risk assessment indicated that the percentage of health hazards at the "very high" risk level was higher when compared to the safety and environmental hazards. Overall, the mean values of 13.6, 12.4, and 18.5% of the assessed chemicals were classified in "moderate" to "very high" categories of health, safety, and environmental hazards, respectively. Therefore, health and safety rules must be considered strictly as a priority by the people who work with chemicals in laboratories for reducing the risk of chemical-related diseases and accidents (21). In this study, the laboratory health and safety checklist showed that most non-compliance was linked to the chemical storage and training/awareness sections. The main faults in chemical storage were related to the labeling of cabinets to indicate chemical class and the labeling of chemical containers, particularly when chemicals are transferred from their original containers. Additionally, quantities of chemicals in storage were inconsistent with short-term needs of the assessed laboratories. All of these non-compliances in chemical storage may result in extensive fire or explosion in the laboratories of academic settings. Omidvari et al. found similar results in their study at Azad University in Iran, which reported fire risk and accidents in educational buildings, particularly in laboratories (22).

Due to the importance of training and awareness in reducing exposures, accidents, and injuries, all laboratory workers, such as faculty, staff, and students, should receive laboratory standard training. The training programs should involve chemical safety programs, chemical emergency action plans, and laboratory security plans. After holding the training courses, it should be ensured that the laboratory workers know who and when to use personal protective equipment, how to use emergency equipment, such as eyewashes and safety showers, where SDSs are kept, spill control procedures, emergency procedures, and chemical waste procedures. The previous studies recommended the periodic training courses for laboratory staff and approved the laboratory safety and security curriculum in most faculties in order to increase awareness, safety, and security culture among laboratory workers and allow them to distinguish what to do before, during, and after emergencies (9, 23–25).

Moreover, the general work environment, emergency planning, and required information for chemical laboratories were the other parts of the checklist that involved the highest numbers of non-compliance in this study. Not only allocating one room of the chemistry laboratory to a chemical warehouse has been increased the safety risk but also the layout of chemicals was not in accordance with safety principles and standards for practice. For instance, the chemical storage was not at "least 18 below the sprinkler head or at least 24" below the ceiling. In at least 2 laboratories, not considering the 5S principles for work environment and storage of materials, such as paper goods, plastic containers, boxes, and empty containers, that would fuel to the burning fire was major non-compliance violation. Additionally, the alternative exits, chemicals material safety data sheet (MSDS), safety instructions, Self-Contained Breathing Apparatus (SCBA), and required special security systems or controls to limit access were not available in the assessed laboratories. The lack of an emergency action plan was the other major fault in this study. The findings of this study and similar research studies provide useful information to plan and develop an emergency action plan for the prevention and mitigation of the emergencies and their harmful consequences in the laboratories of academic institutions (26–28). The prevention and mitigation measures should be prioritized for implementation in accordance with available funds and other resources. Prior studies reported low-cost interventions that might involve reducing major risks and their consequences. Planning a safe layout for gas cylinders or fire extinguishers, providing the SDS for all chemicals used in laboratories, using chemical labeling of cabinets and containers, and non-structural mitigation measures are recommended (29, 30).

In the domain of environmental risk assessment, 44.5% of chemicals were classified in "very low" and "low' risk levels, but 55.5% of them were ranked "intermediate" to "very high" risk degrees. The most important chemical environment-related hazard was waste disposal. The lack of an individual sewage system for laboratories and releasing chemicals into the urban sewage system can contaminate the underground water with hazardous chemicals. Previous studies assessed a high level of environmental risk in underground water reservoirs related to hazardous chemical effluents from academic laboratories (31, 32).

CONCLUSIONS

This chemical health, safety, and environmental risk assessment was developed and conducted according to the standards and guidelines set by the international occupational health and safety organizations. The applied approach revealed the significant risks associated with chemicals used at the university laboratories. The instrument developed for this study will be put into good use in helping health and safety engineers to identify and classify potential risks of laboratory operations to health, safety, and environment. Prevention and mitigation measures should be based on detailed risk assessment methods to minimize identified hazards and provide a safe environment to reduce and/or eliminate the occurrence of diseases and injury in laboratories.

Universities should provide training courses in the curriculum on health and safety in laboratories, particularly for new students at the first of each semester, and periodic similar training courses for faculty and staff plays a key role in increasing awareness and risk perception for considering significant risks at the laboratories. Furthermore, inspecting and assessing the laboratories and research facilities by standard laboratory checklists routinely and removing the non-compliance operations at the earliest time are essential in providing a safe work environment.

DATA AVAILABILITY STATEMENT

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

ETHICS STATEMENT

This study was approved by the Ethics Committee Review Board at Semnan university of Medical Sciences (IR.SEMUMS.REC.1398.131). All the participants signed a consent form and were informed on the purpose of the study prior to interview as per local protocol on research ethics.

AUTHOR CONTRIBUTIONS

AD: material preparation, conceptualization, methodology, investigation, writing—reviewing, and editing. MJ: material preparation, conceptualization, and data collection. FF: analysis, interpretation, first draft of the manuscript, conceptualization, and investigation. All authors contributed to the study conception, design, investigation, reviewed and commented on previous versions of the manuscript, and read and approved the final manuscript.

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Patient Acceptance and Intention to Use e-Consultations During the COVID-19 Pandemic in the Eastern Province of Saudi Arabia

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Background: Over the last decade, the use of digital technology has increased immeasurably and transformed both our personal and professional lives. The medical profession quickly embraced this development, especially after the spread of the COVID-19 pandemic. Medical consultations were transitioned to online settings as a substitute for face-to-face consultations. This exponential acceleration of the use of remote online consultations (e-consultations) was deemed necessary to respond to the impact of the global pandemic. This study identifies the factors that influence actual patient use and the intention to use e-consultations in Saudi Arabia.

Methods: A cross-sectional survey was distributed online via social media platforms targeting the population living in Saudi Arabia from August to December 2020. The questionnaire measured patient perceptions of and attitudes toward utilizing e-consultations using a validated questionnaire informed by the technology acceptance model (TAM). Analyses were performed in SPSS to identify the external factors that influence patients' actual use of e-consultations and to assess the TAM factors (usefulness, social influence, and ease of use) that influence the intention to use e-consultations across both actual users and never-users.

Results: A total of 150 participants completed the questionnaire; the average age was 38 years old, 85% of the participants were females, and 67% reported never using e-consultations. Additionally, motivation, trust, attitude, and social influence were significantly related to participants' intention to use e-consultations.

Conclusion: Participants' trust in and perception of the usefulness of e-consultations were significant factors in their intention to use e-consultation services. Policymakers' attention to those factors could play a role in increasing public acceptance and the use of e-consultations to improve distance medical care.

Keywords: e-consultations, TAM, COVID-19, trust, usefulness

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INTRODUCTION

For several decades, telemedicine has been adopted to provide healthcare services to those in need by ensuring that these services are reached virtually with high quality and efficiency (1–4). Telemedicine is usually used for specific purposes, such as treating and providing e-consultations for patients in rural areas, those with chronic illness, and elderly patients (2, 5). Moreover, in recent years, the use of e-consultations has shown similar outcomes to face-to-face consultations (5, 6). Healthcare management and delivery of care have undergone a transformational change to reduce crowding and distance treatable patients using e-consultations (7–10). Despite advances and uptake in telemedicine, geographical disparities exist, which have become more pronounced during COVID-19 (11). More importantly, user satisfaction and willingness to use e-services are among the essential elements for the success of healthcare policy aims and goals to incorporate technology into healthcare services (12, 13). This is also in line with the Ministry of Health 2030 vision and a new model of care in Saudi Arabia, where adapting technology in the delivery of care is one of the central goals to improve the quality and accessibility of care to the whole population (14). Several studies have been conducted to assess digital health in Saudi Arabia; however, these studies have focused on one e-service (phone calls) or certain health services (dermatology) or were conducted before the COVID-19 pandemic (15–17). This study adds to the literature by identifying the factors influencing actual use and intention to use e-consultations during and after the COVID-19 pandemic. Thus, it contributes important knowledge for policymakers aiming to improve digital health.

In the context of a global pandemic that affected all aspects of life, including hospital visits, and to control the spread of COVID-19, hospitals have restricted visits to only those with urgent conditions. Therefore, the exponential acceleration of the use of virtual services has been deemed necessary to respond to the impact of the pandemic. In particular, e-consultations are an excellent substitute for face-to-face consultations in many settings (16, 18). However, new methods of delivering health using technology could face some resistance due to factors related to trust in the system, lack of understanding its benefits, or digital illiteracy and the difficulty of use (2, 19–21). However, these studies have only assessed certain conditions (19, 20) or specific programs that are tailored to specific hospitals (18).

This study aims to understand the factors influencing the actual use of e-consultations during the COVID-19 pandemic in Saudi Arabia. It also assesses the factors that influence the intention to use e-consultations among the population. The use of e-consultations will ensure that healthcare services are accessible to all, reduce unnecessary hospital visits, and reduce long waiting times and crowding in hospitals. Exploring the factors influencing patients' use of e-consultations will help healthcare providers plan, improve, and sustain services to suit the users' needs (22). Additionally, the results of this study can be used as a baseline to monitor potential areas for improvement to increase the utilization of digital health.

METHODS

Study Design

This study used a cross-sectional quantitative design. Patient perception and attitude toward utilizing online consultations was measured using a validated questionnaire informed by the technology acceptance model (TAM) (20, 23). The TAM has two dimensions, perceived ease of use and perceived usefulness, which influence the intention to use, and which might predict actual usage behavior (24). In this study, e-consultations were defined as the use of any remote medical consultation method (e.g., video, text, voice, or all). Participant consent was acquired, and the definitions of terms were described at the beginning of the questionnaire.

As the native language in Saudi Arabia is Arabic, the questionnaire was distributed in two languages (Arabic and English). Both content validity and face validity were assessed for both versions of the questionnaire. The content validity of the questionnaire was assessed using an expert panel review. Arabic-speaking academic experts from Imam Abdulrahman Bin Faisal University (IAU) and physicians from King Fahd Teaching Hospital (KFTH) were invited to assess the content validity of the questionnaire. A total of 12 experts participated online between February and March 2020 to review both the English and Arabic versions and verify their semantic equivalence.

To assess face validity, a purposive sampling technique was used to sample 25 members of the target population. Face validity was determined via one-on-one interviews. To indicate maximum variation, potential participants were selected from different age groups, levels of education, and genders. The internal consistency reliability of the scale was tested using Cronbach's alpha, and the scale was found to be reliable (overall Cronbach's α ¼ 0.868). The reliability of specific domains within the scale was tested, and for all the domains, the Cronbach's α coefficients ranged from 0.756 to 0.905.

Recruitment Strategy

After the assessments of content and face validity were carried out, the online questionnaire was designed on Question Pro and distributed online via social media platforms, mainly WhatsApp and Twitter, using a convenience snowball sampling method. The inclusion criteria were being an adult aged 18 and above, living in Saudi Arabia, and speaking English or Arabic. The inclusion criteria were applied by adding questions related to age, language, and city of residency in Question Pro. The research team excluded respondents who did not meet the research criteria. Distributing the current study questionnaire via online channels was appropriate given both the aim of our research and the COVID-19 pandemic restrictions implemented during the data collection phase, which prohibited people from accessing hospitals, except in the case of emergencies. Recruitment was conducted from August to December 2020. Recall bias could have been introduced, as the data rely solely on the patient's recollection of their latest contact with an e-consultation service.

Study Size

The sample size was estimated to be a minimum of 384 in accordance with the following formula:

$$N = \frac{p\left(100 - p\right)\ \ z^2}{E^2}$$

where the $\boldsymbol{p} =$ population, which is estimated to be more than 1 million participants, $\boldsymbol{e} =$ margin of error is 0.5, and $\boldsymbol{t}$**-value** is 1.96 (25).

Abbreviations: TAM, Technology Acceptance Model; KFTH, King Fahd Teaching Hospital; IAU, Imam Abdulrahman Bin Faisal University.

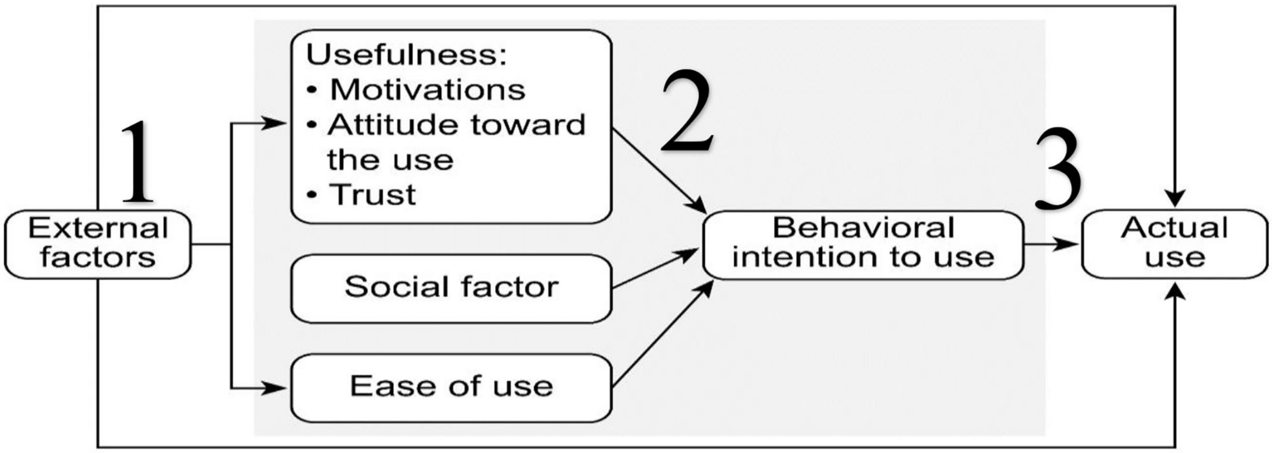

FIGURE 1 | Model of theory.

TABLE 1 | Study sample external factors.

Characteristics	N = 150	%
Age	Mean = 38	SD = 14
Gender		
Male	22	15.0
Female	128	85.0
Educational level		
Diploma and below	24	16
Bachelor	93	62
Postgraduate	33	22
Occupational level		
Government	59	39.0
Semigovernment	8	5.0
Private sector	23	15.0
Not employed	60	40.0
Monthly family income		
Less than 5,000 SR	10	7.0
From 5,001 to 10,000 SR	34	23.0
From 10,001 to 15,000 SR	34	23.0
From 15,001 to 20,000 SR	21	14.0
More than 20,000 SR	51	34.0
Do you suffer from any chronic diseases?		
Yes	35	23.0
No	115	77.0
Have you used e-consultations?		
Yes	67	45.0
No	83	55.0

Study Questionnaire

Following the TAM model (**Figure 1**), the questionnaire included 25 items reported on a satisfaction scale (ranging from 1 = strongly disagree to 5 = strongly agree) (**Appendix 1**). External variables included age (as a continuous variable) and gender, area of residence, education level, occupation type, monthly family income, and the existence of a chronic disease (all as categorical variables).

Statistical Analysis

The study analyses were performed in three stages. Stage 1: the external factors that influence the actual patient use of e-consultations were identified. These data were presented as descriptive and bivariate analyses. The external factors were patient social, economic, and clinical characteristics (categorical), and actual use of e-consultations was measured as "Yes" or "No." Descriptive tests included the calculation of percentages, and the bivariate analysis and the Chi square test were used. Stage 2: the TAM factors (usefulness, social influence, ease of use) that influence the intention to use e-consultations were assessed as continuous outcomes. The relations were compared using the Pearson correlation test. Stage 3: the relation between intention to use (continuous variable) and actual use (categorical variable) was assessed. Before such an analysis was conducted, a normality assessment was performed using Shapiro–Wilk (**Appendix 2**) to explore the TAM factors (usefulness, attitude, social influence, trust, intention to use, and ease of use) and found to be not normally distributed. Therefore, non-parametric tests were used in the analyses. The significant results were reported at the 95% confidence interval, and all the analyses were performed using SPSS version 27.

RESULTS

The questionnaire was completed by 150 participants, with a response rate of 75%. **Table 1** shows that the average age was 38 years old and 85% of the participants were females. The majority of the participants had a bachelor's degree (62%), worked in the government sector (39%), had a family monthly income that was more than SR20,000 (32%), and did not suffer from any chronic disease (82%). Most importantly, given the accelerated shift toward the use of e-consultations in the pandemic period, 45% reported actual use of e-consultations. There were no

TABLE 2 | The influence of external variables between actual e-consultation users and never-users.

Characteristics	Have you used e-consultations?						
	Yes		No		Chi²	df	*P*-value
	N = 67	%	*N* = 83	%			
Age*	40 (14)		37 (14)		0.147	1	0.701
Gender							
Yes	9	13.4	13	15.7			
No	58	86.6	70	84.3			
Educational level							
Diploma and below	11	16.4	13	15.7	0.311	2	0.856
Bachelor	40	59.7	53	63.9			
Postgraduate	16	23.9	17	20.5			
Occupational level							
Government	33	49.3	26	31.3	5.477	3	0.140
Semigovernment	3	4.5	5	6.0			
Private sector	10	14.9	13	15.7			
Not employed	21	31.3	39	47.0			
Monthly family income							
Less than 5,000 SR	2	3.0	8	9.6	5.315	4	0.256
From 5,001 to 10,000 SR	19	28.4	15	18.1			
From 10,001 to 15,000 SR	15	22.4	19	22.9			
From 15,001 to 20,000 SR	11	16.4	10	12.0			
More than 20,000 SR	20	29.9	31	37.3			
Do you suffer from any chronic diseases?							
Yes	17	25.4	18	21.7	0.282	1	0.596
No	50	74.6	65	78.3			

**Mean (SD).*

significant differences between the e-consultation users and non-users based on the study factors (age, gender, educational level, and family income) (**Table 2**).

Using the Pearson correlation test, we found that perceived usefulness factors, including motivation, trust, attitude, and social influence, were significantly associated with participants' intention to use e-consultations in the future (**Table 3**). In particular, participants with a higher level of perceived usefulness of e-consultations (Pearson 0.50, $p < 0.001$) and those with a higher trust score (Pearson 0.58, $p < 0.001$) reported a higher score for the intention to use e-consultations in the future. Ease of use had a minor non-significant relation with an intention to use e-consultations (Pearson −0.04, p 0.509).

As shown in **Table 4**, e-consultation actual users had higher scores for perceived usefulness (median = 50, IQR = 8) than actual non-users (median = 48, IQR = 7); $p = 0.014$. Similarly, e-consultation actual users reported a higher association between social influence and the ease of use that influenced such use ($P < 0.01$).

TABLE 3 | The relation between the TAM factors and the intention to use e-consultations among the total study population.

TAM factors	Intention to use *N* = 150	
	Pearson	*P*-value
Usefulness	0.497	<0.001
Motivation	0.142	0.034
Trust	0.580	<0.001
Attitude	0.281	<0.001
Social influence	0.192	0.004
Ease of use	−0.044	0.509

DISCUSSION

This article identifies the factors influencing the actual use of e-consultations during the pandemic in Saudi Arabia and assesses the TAM factors that influence the intention to use e-consultations among the population.

Saudi Arabia has allocated a very large budget to accelerate the implementation of electronic services in the healthcare sector. However, some authors have reported that the transition to electronic services in the Saudi health system was very slow (17, 26). However, since the COVID-19 pandemic, the Saudi health system has witnessed a significant boost in digitalizing health services (15). Thus, it was crucial to identify the factors that influence actual use and intention to use such services. This study provides baseline information regarding actual users of

TABLE 4 | TAM factors influencing the use of e-consultations among actual users and non-users.

TAM factors	Use of e-consultations				Mann–Whitney *U*-test	*P*-value
	Users ($N = 67$)		Non-users ($N = 83$)			
	Median (IQR)	Mean rank	Median (IQR)	Mean rank		
Perceived usefulness	50 (8)	83.11	48 (7)	69.36	2467.0	0.014
Motivation	12 (4)	77.68	12 (2)	73.74	2634.5	0.135
Trust	20 (5)	83.26	20 (3)	69.23	2471.0	0.057
Attitude	17 (3)	80.12	16 (2)	71.77	2260.5	<0.001
Social influence	10 (4)	81.70	9 (4)	70.49	2270.5	0.012
Ease of use	11 (5)	80.18	7 (4)	71.72	1391.0	<0.001
Intention to use	12 (3)	96.24	12 (1)	58.76	2365.0	0.002

e-consultations in the country. According to the literature, an increase in e-service utilization should ensure better access to care for all and achieve greater financial wealth and investment in the Saudi health sector (17, 22).

Further findings in the current study revealed that participants' trust in and perceived usefulness of e-consultation was significantly associated with their intention to use e-consultation services in the future. Many studies have found that trust in e-consultations is a major driving force for patients' adoption of e-consultation services (27, 28). Trust is a complex issue that might hinder the adoption of e-consultation because there is a lack of face-to-face interaction to promote patients' belief in doctors' reliability and ability to provide professional services (28). Thus, to enhance patients' trust in e-consultations, which will ultimately improve their adoption of e-consultations, research studies recommend fostering the social ties between patients and physicians (i.e., interpersonal trust) and the technological capabilities of the system that provides e-consultation services (i.e., technological trust) (28). This can be applied by establishing a robust review and a reporting system to allow the patients to report their satisfaction with the services offered during their e-consultations and thus enhance potential patient acceptance and adoption of the service (28). Additionally, eliminating the privacy and performance risks of e-consultation platforms will play a key role in enhancing patients' trust in e-consultations (28). The sharing of personal data through online platforms is a concern of users. Therefore, to ensure trust, it is important to use highly secured platforms for e-consultations and to provide health providers with adequate training on how to keep patients' data highly confidential during and after the e-consultation (29). Additionally, the standardization of telemedicine/e-consultations merits attention during and after COVID-19 (30).

Some studies have been conducted in Saudi Arabia to assess the uses of e-consultations, and they agreed that there was variation in the uses of e-health services, such as e-consultations, by region (17, 31–33). They found that people from western provinces had the lowest rate of using the Seha application as a type of consultation tool (32). However, the availability of e-services was found to be relatively high in western provinces of Saudi Arabia compared with other provinces (17). However, the uses of these services are lower than those in other provinces, as some of the published literature has found (33). This could be explained by the low awareness of online health services by the community of the western region, as suggested by another study (33). Western provinces have more rural areas, and previous literature has shown that people in rural areas are less likely to use e-services and prefer face-to-face communication with physicians (31, 34). The area of residence is an important factor among the study target population, as found in the literature; however, due to the disproportionality of respondents and limited sample size by area of residence, the current study could not draw any conclusion due to the high risk of selection bias.

Age could be a key factor in determining the rate of using services or telemedicine, and younger age groups might be more familiar with technology than older people. The difference in the mean age of users and non-users in the current study was very close; they were both between 37 and 40; however, users were from the older group. This is consistent with a previous study that found that although younger people are more aware of services such as the Seha application, they are less likely to use it than older people. The study concluded that the younger group might have good health and were less likely to use services (31). Additionally, for a more detailed comparison among the older population, it was found that people aged 30–39 had the highest odds of using 937 (a phone consultation service) than people aged 60 and older, especially if they had children (34). However, people aged above 60 might not be familiar with these services or they might not know how to use them. The reason for the discrepancies in the use of e-consultations by age group is still not clear. Further studies with qualitative analysis need to be conducted to identify the reasons for not using e-consultations among populations aged above 60.

An interesting finding in our study was that social influence, which another study referred to as the chances that the use of e-consultations would affect the way others think about the user (35), had a significant association with actual e-consultation use. This contradicts an earlier study that revealed that social risk is only a minor component of a perceived risk that hinders the adoption of e-consultation (24). One explanation of this contradiction is the unique culture of Saudi Arabia, where people pay significant attention to society and how others think of them

(36). Thus, it is especially important to raise awareness of e-consultation among the public in Saudi Arabia to help them understand its benefits and how it works. Some research studies have suggested that the most prominent reason for the lack of e-consultation use is that the public is not aware of the existence of such services (37, 38). With the improvement of awareness, the public will think it is a reasonable choice to use e-consultations and will not make a negative judgment about e-consultation use. In turn, these services will be used more effectively.

LIMITATIONS

This is one of few studies to explore the use of e-services in the Saudi context. However, possible limitations include the study's reliance on participant reports of their e-consultation utilization. In future studies, it is recommended that the actual utilization of e-consultations be assessed using the hospital reporting system. In addition, the study used a convenient non-probability sampling technique. This technique was chosen due to the difficulty of visiting hospitals with the precautionary measures for COVID-19. Another limitation is the small sample size, which might not represent the Saudi population. The study aimed to target more than 384 participants. However, evidence from the literature stated that a sample size of more than 200 participants is considered good and could yield valid results (39). Finally, the majority of participants lived in the Eastern Province. This could hinder the generalizability of the study findings to all other regions in Saudi Arabia.

CONCLUSION

This study is unique in its use of a theoretical-based model to identify factors related to e-consultation use in Saudi Arabia. The study found that approximately 40% of study participants used e-Consultations during the period of rapid transition during the COVID-19 pandemic. Participants' trust in and perceived usefulness of e-consultations were significantly associated with their intention to use e-consultation services. Furthermore, the availability of e-services and awareness of using services could be affected by where users live. Policymakers' attention to those factors could play a role in increasing public acceptance and the use of e-consultations to improve distance medical care.

DATA AVAILABILITY STATEMENT

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

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Imam Abdulrhaman Bin Faisal University. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

ArA, BH, DA, and AfA contributed to the design and implementation of the research, the analysis of the results, and the writing of the manuscript. All authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2022.896546/full#supplementary-material

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The Relationship Between Nurses' Quality of Work-Life on Organizational Loyalty and Job Performance in Saudi Arabian Hospitals: A Cross-Sectional Study

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Purpose: The purpose of this study is to analyze the relationship between quality of work-life on the organizational loyalty and job performance in Saudi Arabia.

Methods: This study used a cross-sectional design for collecting the data related to the nurses' quality of work-life, organizational loyalty, and job performance from nursing staff in Saudi Arabian hospitals. Three questionnaires were used in this study, which includes Quality of Work Life Scale (QWLS), Organizational Commitment Questionnaire (OCQ), and Individual Work Performance Questionnaire (IWPQ). An online version of the survey questionnaire was generated using the Google survey, to which a link is generated for collecting data. At the end of the survey, 243 responses were received. After removing the incomplete responses, 209 responses were considered for the data analysis. The statistical techniques including *t*-tests and Pearson's correlation were used in the data analysis.

Results: Nurse managers reflected good quality of life, and high loyalty toward their employers, and also reflected good job performance levels. However, staff nurses reflected poor quality of work-life, organizational loyalty, and job performance. Training and development had strong positive correlation with continuance commitment ($r = 0.628$, $p < 0.01$). Job satisfaction and job security held strong positive correlation with task performance ($r = 0.601$, $p < 0.01$) and contextual performance ($r = 0.601$, $p < 0.01$).

Conclusion: Quality of work-life, organization loyalty, and job performance are positively correlated, and poor quality of work-life can negatively impact job performance and organizational loyalty of nurses.

Keywords: leadership, nurses' job performance, organizational loyalty, quality of work-life, Saudi

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INTRODUCTION

Saudi Arabia has been transforming its economy from an oil-based economy to knowledge-based economy through various initiatives in different sectors through vision 2030 and Saudization programs. As a result of which large structural and operational transformations are being taking place in different sectors (1, 2). One of the important approaches in this aspect is Saudization, which is aimed at empowering the Saudi nationals and increasing their participation in various industries in order to reduce the dependency on expatriates (3). Out of the 35 million population, 13.49 million are expatriate workers in Saudi Arabia (4).

Healthcare is one of the important areas of focus in vision 2030, aiming for rapid digitalization and structural transformation for achieving improved operational efficiency and sustainability. Nurses are the largest workforce in the healthcare sector, who are very important for effective functioning of healthcare as they are directly involved in taking care of the patients. Currently, there are 196,701 nurses working in various Saudi Arabian hospitals, out of which 112,317 nurses are non-Saudi, and only 42.9% of the total nursing work force includes Saudi citizens (5). Furthermore, the availability of nurses according to population needs is very low in Saudi Arabia (5.5 nurses per 1,000 population), compared to other countries like the UK (7.9 nurses per 1,000 population) and Switzerland (18 nurses per 1,000 population), but it reflects good proportion compared to its neighbors including Bahrain (2.4 nurses per 1,000 population) and the UAE (3.1 nurses per 1,000 population)0.5 (6, 7), Considering the projected nursing graduates in the next 2 years, there is a need for additional 185,722 expatriate nurses to achieve the target of having one nurse per 200 Saudi citizens (8) Given the current statistics, it is evident that there is a huge demand for nursing workforce in Saudi Arabia, and with limited local work force, the high dependency on expatriate nursing workforce still exists in the country.

Due to large expatriate workforce and limited Saudi citizens' participation, there are various challenges identified in the nursing work life and their job performance in Saudi Arabia. For instance, managing the diverse workforce can be challenging for the nurse managers. Furthermore, issues such as poor working conditions, limited opportunities, and poor image of nursing among Saudi citizens makes nursing profession least preferred among Saudis (9). In addition, due to the cultural influence, most of the Saudi women do not consider nursing as their career option (10, 11).

Focusing on the expatriate nurses, several issues such as poor living and working conditions, cultural differences, communication problems, complex social living conditions are affecting their work-life in the country (12), as a result of which their satisfaction levels and loyalty are decreasing. For instance, it was identified that many expatriate nurses initially come to Saudi Arabia even though the working and living conditions are poor, only to gain enough work experience, so that they can later move to the developed countries such as the US and the UK, where they can experience better work-life conditions (13). Therefore, there are various factors that affect both Saudi and non-Saudi nurses in relation to the quality of work-life and their satisfaction levels (14, 15).

Furthermore, sustainability, one of the main objectives of vision 2030 may not be achieved if there is a poor quality of work-life, job dissatisfaction, decreasing retention rates, poor loyalty, and poor job performance in nursing sector. As a part of Saudization, there is also a need to increase the attractiveness of nursing among the career options in Saudi Arabia. Therefore, there is an immediate need to assess various issues and the relationship between various influencing factors associated with nursing staff in Saudi Arabia.

LITERATURE REVIEW

Nurses' job satisfaction, which can be influenced by the quality of work-life was identified to be significantly correlated with commitment (16). Therefore, the poor quality of work conditions may affect the commitment or loyalty of nurses toward their organization. Furthermore, it was identified that the relationship between the nurses' quality of work-life and turnover intention was partially mediated by organization loyalty, as quality of work-life is significantly influences organizational loyalty (17). The previous studies (18, 19) have identified that work-related issues such as lack of managerial effort to improve the work environment of nurses, seeking perfectionism, support from the ward manager, salary, the relationship at work with other nurses, communication, relationship with team members, and the fairness of shift work between nurses can significantly affect the loyalty and job performance of nurses in Saudi Arabian hospitals. Communication between nurses and between nurses and patients plays an important role in improving the quality of work life, and communication issues were identified to be significantly correlated with the nurses' dissatisfaction (15). Lower satisfaction levels among the nurses may lead to decreased organization loyalty, while higher satisfaction levels may lead to increased job performance (16), whereas, improved job performance is positively correlated with organizational commitment (17). Furthermore, lower satisfaction levels may result in increased turnover intentions, indicating poor organizational loyalty (17). Moreover, the poor quality of work life such as high stress levels can adversely affect the nurses' job performance (20). Although the previous studies have identified relationships between organizational commitment and quality of work life; work stress and job performance, the relationship between the quality of work life, organizational loyalty, and job performance was not investigated. In this context, this study aims to analyze the relationship between quality of work-life on the organizational loyalty and job performance (as shown in **Figure 1**) in Saudi Arabia using following hypothesis.

H1: Nurses' Quality of work life is positively correlated with organizational loyalty.

H2: Nurses' Quality of work life is positively correlated with job performance.

MATERIALS AND METHODS

This study used a cross-sectional design for collecting the data related to nurses' quality of work life, organizational loyalty, and job performance from nursing staff in Saudi Arabian hospitals.

Survey Instruments

Three questionnaires were used in this study, which include Quality of Work Life Scale (QWLS) (21), Organizational Commitment Questionnaire (OCQ) (22), and Individual Work Performance Questionnaire (IWPQ)0.2 (4). The quality of work

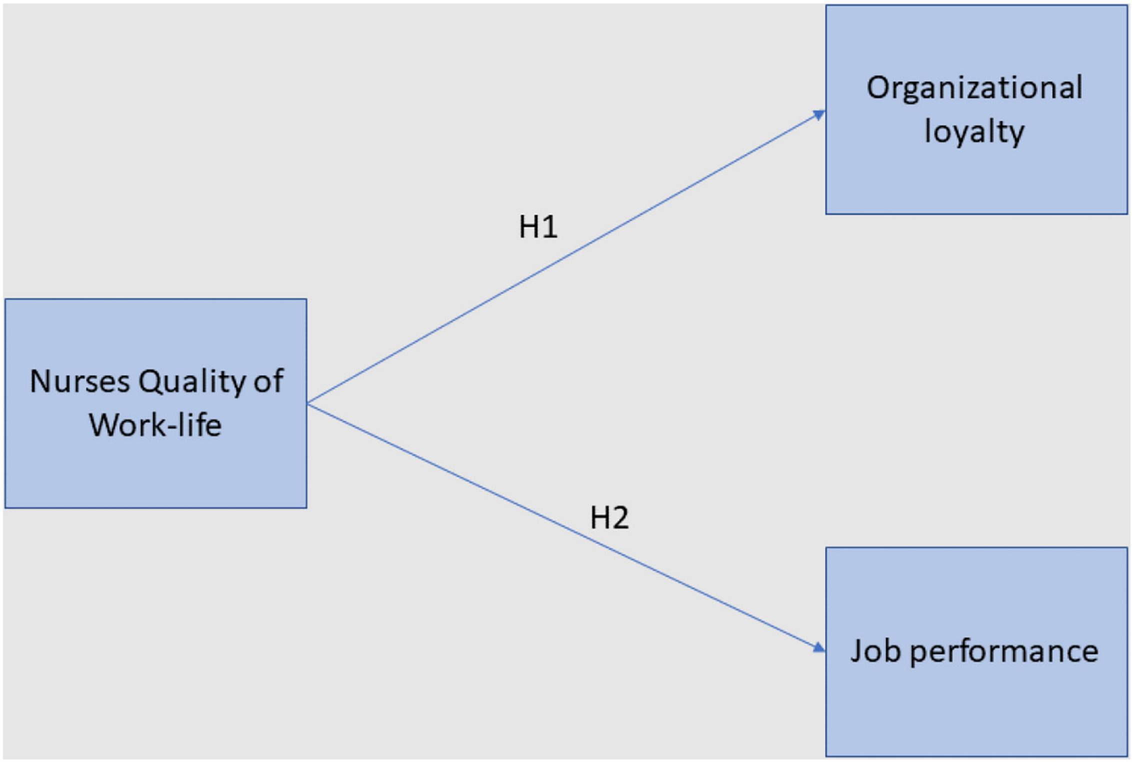
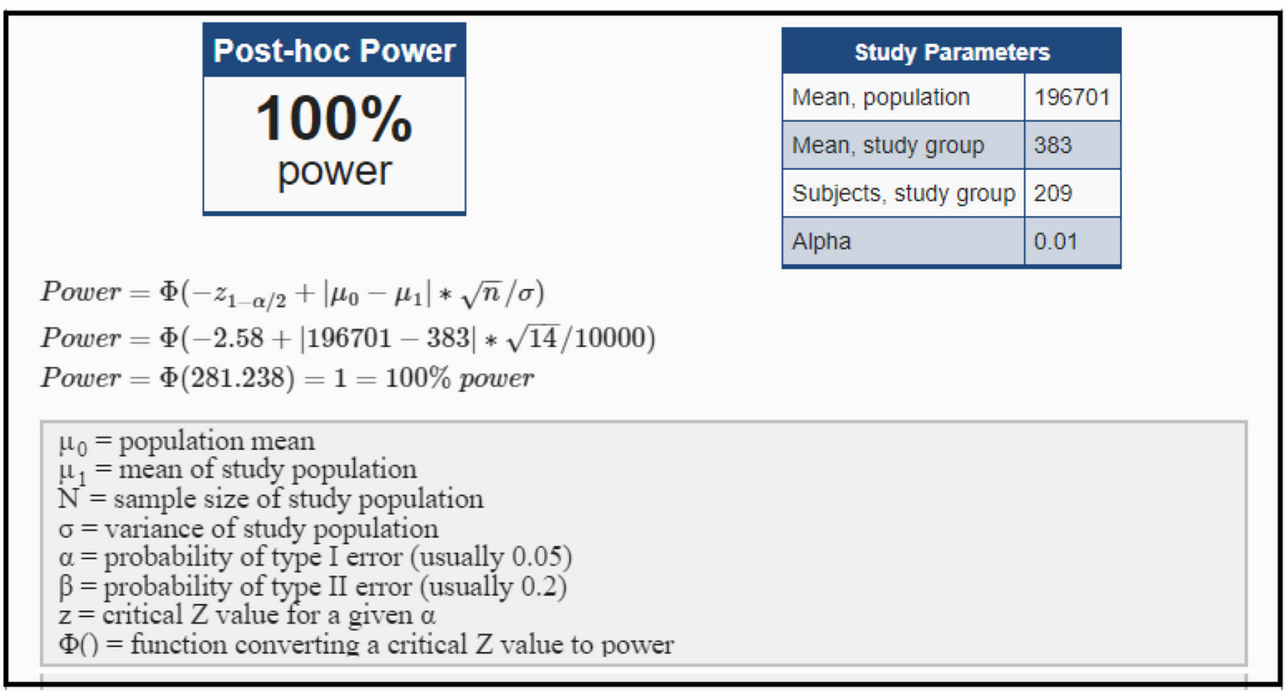


FIGURE 1 | Study model.



Post-hoc Power

100% power

Study Parameters	
Mean, population	196701
Mean, study group	383
Subjects, study group	209
Alpha	0.01

$$Power = \Phi(-z_{1-\alpha/2} + |\mu_0 - \mu_1| * \sqrt{n}/\sigma)$$
$$Power = \Phi(-2.58 + |196701 - 383| * \sqrt{14}/10000)$$
$$Power = \Phi(281.238) = 1 = 100\%\ power$$

μ_0 = population mean
μ_1 = mean of study population
N = sample size of study population
σ = variance of study population
α = probability of type I error (usually 0.05)
β = probability of type II error (usually 0.2)
z = critical Z value for a given α
$\Phi()$ = function converting a critical Z value to power

FIGURE 2 | *Post-hoc* power analysis.

life is a multi-dimensional construct, and QWLS includes nine different components which can effectively cover various aspects that may influence the nurses' quality of work life. The organizational commitment is a factor that can reflect organizational loyalty in terms of their affective, continuance, and normative commitments, which are included in OCQ, making it one of the effective and efficient instruments for assessing the commitment and loyalty factors. Similarly, IWPQ includes three contexts: task performance, contextual performance, and counterproductive performance, which can be aptly applied in the context of nursing job. Considering the relevance and applicability, the three scales such as QWLS, OCQ, and IWPQ are used for measuring quality of work life, organizational loyalty, and job performance, respectively. All the three questionnaires were embedded into a single main questionnaire. Accordingly, the main questionnaire is divided into four parts. First part focuses on the collecting participants' demographic information. Second part of the questionnaire includes 50 items from QWLS, which need to be rated on a five-point Likert scale (1: Strongly disagree; 2: Disagree; 3: Neutral; 4: Agree; 5: Strongly agree). Items one to six focus on work environment; items seven to thirteen focus on organization culture and climate; items 14–19 focus on relation and cooperation; items 20–23 focus on training and development; items 24–28 focus on compensation and rewards; items 29–33 focus on facilities; items 34–41 focus on job satisfaction and job security; items 42–47 focus on autonomy on work; and items 48–50 focus on adequacy of resources.

Third part of the questionnaire includes 18 items, measured on a 7-point Likert scale (($SD = 0$) strongly disagree; ($MD = 1$) moderately disagree; ($LD = 2$) slightly disagree; ($O = 3$) neither disagree nor agree; ($LA = 4$) slightly agree; ($MA = 5$) moderately agree; ($SA = 6$) strongly agree) related to organizational commitment adapted from OCQ. These are further categorized into affective commitment (items 1–6), continuance commitment (items 7–12), and normative commitment (items 13–18).

Fourth part of the questionnaire includes 47 items related to job performance, measured on a 5-point Likert scale (($N = 0$) never; ($R = 1$) rarely; ($S = 2$) sometimes; ($O = 3$) often; ($VO = 5$) very often. These are further categorized into four sections. The first section focuses on task performance and includes 13 items; second section focuses on contextual performance and includes 16 items; third section focuses on adaptive performance and includes eight items; and fourth section focuses on Counterproductive work behavior, which includes 10 items.

A pilot study was conducted with 27 nurses, and the analysis of pilot study results resulted in achieving the Cronbach's alpha of 0.83 (>0.70) indicating good internal reliability and consistency (23). An online version of the survey questionnaire was generated using the Google survey, to which a link is generated for collecting data.

Sampling and Participants

As the survey is targeted at nursing managers and nurses working in Saudi Arabian hospitals, the survey link is forwarded to HR administrators of 68 hospitals which include public and private hospitals. Considering 196,701 nurses working in Saudi Arabia, estimated sample was calculated using the Cochran's formula (24), at 95% *CI* and 5% of Margin of error, giving an estimated sample of 383 participants. The survey link was active from 1st December 2021 to 22nd January 2022, and at the end of the survey, 243 responses were received. After removing the incomplete responses, 209 responses were considered for the data analysis. Considering the population (196,701), with a study group of 383 nurses and considered sample of 209, the *post hoc* power analysis resulted in 100% power as shown in **Figure 2**.

TABLE 1 | Participants' demographic information.

Demographic characteristics	*N*	Relative frequency
Gender		
Male	54	25.8%
Female	155	74.2%
Education		
Diploma	55	26.3%
Bachelor's degree	128	61.2%
Master's degree	23	11%
Doctorate	3	1.4%
Age (years)		
20–29	48	22.9%
30–39	108	51.7%
40–49	42	20.1%
50–59	11	5.3%
>59	0	0%
Work experience		
≤3 years	30	14.3%
3–5 years	32	15.3%
6–10 years	79	37.8%
>10 years	68	32.5%
Role		
Nurse manager	21	10.1%
Nurse	188	89.9%
Nationality		
Saudi	93	44.4%
Non-Saudi	116	54.6%

Data Analysis

Various statistical techniques including *t*-tests (to identify significant differences between groups), and Pearson's correlation (to identify relationships between factors) were used. Missing data were removed in order to avoid any bias in analyzing the results.

Ethical Considerations

Participants were fully informed about the study and informed consent was taken prior to the participation. The anonymity of the participants is protected and the survey data are securely stored ensuring privacy and security. The ethical approval for the study was received from Ministry of Health, Saudi Arabia.

TABLE 2 | Nurse managers' and staff nurses' perceptions of quality of work life.

	Nurse managers		Nurses		*T*	*P*
	Mean	SD	Mean	SD		
Work environment	4.10	1.25	3.24	1.78	2.1,533	0.0,325*
Organization culture and climate	3.89	1.11	3.10	1.64	2.1,507	0.0,327*
Relation and cooperation	4.20	1.73	3.35	1.77	2.0,917	0.0,377*
Training and development	4.46	1.86	3.24	1.45	3.5,479	0.0,005*
Compensation and rewards	3.94	1.42	3.10	1.32	2.7,450	0.0,066*
Facilities	3.96	1.33	3.12	1.96	1.9,132	0.0,571
Job satisfaction and job security	4.15	1.88	3.13	1.74	2.5,274	0.0,122*
Autonomy of work	3.88	1.07	2.97	1.81	2.2,572	0.0,250*
Adequacy of resources	4.48	1.46	3.15	1.94	3.0,441	0.0,026*

**Statistically significant difference.*

TABLE 3 | Nurse managers' and staff nurses' perceptions of organizational loyalty.

	Nurse managers		Nurses		*T*	*P*
	Mean	SD	Mean	SD		
Affective commitment	3.51	1.44	2.59	1.64	2.4,656	0.0,145*
Continuance commitment	4.67	1.78	2.50	1.93	4.9,224	0.0,001*
Normative commitment	4.64	1.37	2.56	1.86	4.9,714	0.0,001*

**Statistically significant difference.*

TABLE 4 | Nurse managers' and staff nurses' perceptions of job performance.

	Nurse managers		Nurses		*t*	*P*
	Mean	SD	Mean	SD		
Task performance	2.83	1.52	2.25	1.02	2.3,374	0.0,204*
Contextual performance	3.63	1.41	2.36	1.19	4.5,249	0.0,001*
Adaptive performance	3.67	1.69	2.53	1.24	3.8,399	0.0,002*
Counterproductive work behavior	1.61	0.43	1.22	0.63	2.7,628	0.0,062*

**Statistically significant difference.*

RESULTS

As shown in **Table 1**, the majority of the participants were women representing 74.2% of the total participants indicating higher female nursing workforce in Saudi Arabia. Among the total participants, 54.6% were expatriates and 44.4% were Saudi nurses representing higher participation of expatriates in Saudi Arabian hospitals. Furthermore, 10.1% of the participants were nurse managers and 89.9% staff nurses. The majority of the participants were young represented by 22.9% aged between 20 and 29 years, and 51.7% participants aged between 30 and 39 years. About 20.9% participants were aged between 40 and 49 years, followed by 5.3% of participants aged between 50 and 59 years. No participants were identified who were aged more than 59 years. The majority of the participants were qualified in Bachelor's degree in nursing (61.2%), followed by diploma in nursing (26.3%), master's degree in nursing (11%), and Ph.D. in nursing (1.4%). Focusing on the work experience, the majority of the participants had more than 6 years of work experience, represented by 37.8% having work experience between 6 and 10 years, and 32.5% participants having more than 10 years of work experience. In addition, 15.3% participants had 3–5 years of work experience, followed by 14.3% participants having 3 or <3 years of work experience.

Analyzing the results related to the quality of work-life, the mean for all categories were identified to be between 3.0 and 3.44, indicating average-good conditions. Furthermore, differences between the nurse managers and staff nurses' perceptions of quality of work-life were presented in **Table 2**. The findings revealed that significant differences existed between the nurse managers and staff nurses in relation to all categories of quality of work-life, except facilities. Nurse managers perceived all categories of work-life aspects to be better compared to staff nurses, who perceived them to be average or poor.

TABLE 5 | Correlations between Quality of Work Life Scale (QWLS) subscales, Organizational Commitment Questionnaire (OCQ), and Individual Work Performance Questionnaire (IWPQ) subscale using the Pearson product-moment.

	Affective commitment	Continuance commitment	Normative commitment	Task performance	Contextual performance	Adaptive performance	Counter productive work behavior
Work environment	0.435**	0.583**	0.514**	0.450**	0.433**	0.396**	0.010**
Organization culture and climate	0.480**	0.477**	0.570**	0.446**	0.463**	0.405**	0.039**
Relation and cooperation	0.474**	0.590**	0.598**	0.378**	0.470**	0.348**	–0.009**
Training and development	0.446**	0.628**	0.598**	0.358**	0.446**	0.420**	0.322**
Compensation and rewards	0.502**	0.612**	0.601**	0.421**	0.548**	0.520**	0.238**
Facilities	0.463**	0.608**	0.568**	0.381**	0.511**	0.586**	0.219**
Job satisfaction and job security	0.517**	0.627**	0.569**	0.601**	0.606**	0.592**	0.183**
Autonomy of work	0.607**	0.573**	0.759**	0.618**	0.640**	0.715**	–0.002**
Adequacy of resources	0.449**	0.786**	0.906**	0.571**	0.753**	0.861**	–0.023**

***Correlation is significant at the 0.01 level (2-tailed).*

The overall results relating to organizational loyalty reflected poor levels, which can be analyzed from low mean ratings for affective commitment (Mean = 2.68, *SD* = 1.83), continuance commitment (Mean = 2.72, *SD* = 1.64), and normative commitment (Mean = 2.77, *SD* = 1.29). **Table 3** presents the difference of opinions between staff nurses and nurse managers. The statistically significant differences were observed between nurse managers and staff nurses in all types of commitments. While nurse managers reflected greater loyalty, nurses reflected low levels of loyalty. Continuance commitment (Mean = 4.67, *SD* = 1.78) and normative commitment (Mean = 4.64, *SD* = 1.37) were high among nurse managers compared to affective commitment (Mean = 3.51, *SD* = 1.44). Among nurses all types of commitment were identified to be similar which can be analyzed from mean ratings: affective commitment (Mean = 2.59, *SD* = 1.64), continuance commitment (Mean = 2.50, *SD* = 1.93), and normative commitment (Mean = 2.56, *SD* = 1.86).

Similarly, the results related to job performance were also identified to be poor in relation to all sub-categories such as task performance (Mean = 2.3, *SD* = 1.41), contextual performance (Mean = 2.49, *SD* = 1.39), adaptive performance (Mean = 2.65, *SD* = 1.62), and counterproductive work behavior (Mean = 1.26). In similar to organizational loyalty, statistically significant differences were observed among nurse managers and staff nurses in relation to all sub-categories of job performance as shown in **Table 4**. Contextual (Mean = 3.63, *SD* = 1.41) and adaptive (Mean = 3.67, *SD* = 1.69) performances were rated to be high by nurse managers; while staff nurses rated all types of performances to be poor. Interestingly, counterproductive work behavior was rated to be very poor by both nurse managers and nurses although differences existed between both groups.

Table 5 presents Pearson correlation coefficients between the sub-scales of QWLS, and OCQ and IWPQ, reflecting significant correlations at 99% confidence interval. Strong positive correlations were observed between various sub-scales. Training and development had strong positive correlation with continuance commitment ($r = 0.628$, $p < 0.01$). Compensation and rewards held strong positive correlation with continuance commitment ($r = 0.612$, $p < 0.01$) and normative commitment ($r = 0.601$, $p < 0.01$). Autonomy of work held strong positive correlation with affective commitment ($r = 0.607$, $p < 0.01$) and normative commitment ($r = 0.759$, $p < 0.01$). Adequacy of resources held strong positive correlation with continuance commitment ($r = 0.786$, $p < 0.01$) and normative commitment ($r = 0.906$, $p < 0.01$). Based on the findings (**Table 5**), it can be observed ('*r*' value <0.5 for most of the relations) that nurses' quality of life moderately correlated with organizational loyalty, reflecting the hypothesis (H1) to be false.

In relation to the relationship between quality of work-life and job performance, both positive and negative correlations were identified. The job satisfaction and job security held strong positive correlation with task performance ($r = 0.601$, $p < 0.01$) and contextual performance ($r = 0.601$, $p < 0.01$). Autonomy of work held strong positive correlation with task performance ($r = 0.618$, $p < 0.01$), contextual performance ($r = 0.640$, $p < 0.01$), and adaptive performance ($r = 0.715$, $p < 0.01$). Adequacy of resources held strong positive correlation with contextual performance ($r = 0.753$, $p < 0.01$) and adaptive performance ($r = 0.861$, $p < 0.01$). Negative correlations were identified between QWL sub-classes such as relation and cooperation, autonomy of work, adequacy of resources, and job performance sub-class including counterproductive work behavior. Based on the findings (**Table 5**), it can be observed ('*r*' value < 0.5 for most of the relations) that nurses' quality of life moderately correlated with job performance, reflecting the hypothesis (H2) to be false.

DISCUSSION

The main findings revealed that the overall quality of work-life and organizational loyalty was very poor. The job performance reflected the average performance levels of the participants. In all the aspects such as quality of work-life, organizational loyalty, and job performance, statistically significant differences were observed between the nurse managers and staff nurses. Nurse managers reflected good quality of life, and high loyalty toward their employers, and also reflected good job performance levels. However, staff nurses reflected poor quality of work-life, organizational loyalty, and job performance. As nurse managers are less involved in direct care operations because of the main focus on nursing management, it is possible that their work-life, loyalty, and performance may be different from that of staff nurses. Furthermore, differences in types of work and high salaries of nurse managers may lead to more loyalty compared to staff nurses. Similarly, high commitment levels of nurse managers were identified in a similar study (25), when compared to the commitment levels of staff nurses.

Considering the quality of work-life of nurses, several studies (26–32) have indicated poor quality of work life levels in similar with the findings in this study. Aspects identified in this study such as training and development, relationship between team members, job satisfaction, and work environment were identified to be more influencing factors related to the quality of work-life in similar to the previous study in Saudi Arabia (26). In relation to organizational loyalty, poor levels of commitment were identified in the previous studies (13, 25), which can be related with the low levels of quality of work-life analyzed from the findings in this study and also previous studies (26–32). Task performance, which can be analyzed from the performance of given basic nursing tasks in terms of quality and quantity, was identified to be reasonable among the nurse managers and nurses. Contextual performance (characterized by behaviors that support the organizational, social, and psychological environment in which the technical core must function) and adaptive performance (the extent to which an individual adapts to changes in the work role or environment) were identified to be high for managers and low for nurses. Behaviors such as demonstrating effort, facilitating peer and team performance, cooperating, and communicating, reflecting contextual performance are mostly reflected in nurse managers as they need to coordinate with all team members, and it might be the reason why nurse managers rated it to be high compared to staff nurses. Similarly, nurse managers are held with the responsibility to implement changes, as a result they need to be more adaptive so that they can enforce the changes on team members, and it may be the reason why nurse managers rated adaptive performance to be high compared to staff nurses. Counter-productive behaviors (negative behaviors that affect work/tasks/activities) were rated to be low by both nurse managers and nurses. Similar findings in relation to job performance can be observed from the previous studies (33–37), reflecting that job performance is often linked with work-life quality.

Accordingly, counterproductive behavior is negatively correlated with different work-life subscales such as relations and cooperation, autonomy of work, and resources adequacy, and reflected a weak positive correlation with all other sub-scales of work-life subscales. However, the significant positive correlations were established between quality of work life and job performance, such as task, contextual, and adaptive performance. Job satisfaction, autonomy of work, and resource adequacy reflected more strong correlations with task, contextual, and adaptive performance; and all types of commitment. As identified in the previous studies (12, 14, 15, 26, 38), job satisfaction, one of the important 'quality of work-life' subscale was identified to be significantly influencing job performance and organization loyalty. Thus, it can be analyzed and concluded that quality of work-life can moderately influence the organization loyalty and job performance of the nurses in Saudi Arabia, based on the hypothesis analysis.

Overall, this study has both theoretical and practical implications. Theoretically, it contributes to the literature, addressing the research gaps in nursing research in Saudi Arabia. Although the factors, organizational loyalty, job performance, and quality of work-life of nurses were addressed in different research separately, no efforts were taken in linking these factors and assessing the relationship between them (39, 40). This study addresses the above issue. Secondly, it has practical implications as it provides valuable findings in relation to quality of work life, organization loyalty, and commitment, which can help decision-makers in improving the nurses' work-life (as the results revealed average quality of work life, poor commitment, and job performance, especially among nurses but not nurse managers) and their performance by taking necessary measures such as deploying transformational leadership styles, providing support and training, increasing pay, rewards, etc., to attract more committed nursing employees as an approach toward achieving vision 2030 objectives.

However, there are few limitations in this study. Firstly, the sample identified in this study is lower than the estimated sample; therefore, results should be generalized with care. Secondly, as there was no prior study identified investigating the three factors: quality of work-life organizational loyalty, and job performances of nurses, the discussion is limited with comparison with studies focusing either one or two considered factors. Thirdly, the study is limited to the nursing staff in Saudi Arabia; therefore, the generalization of results, especially in other similar countries should be done with care. These limitations can be addressed in future studies. Future studies can focus on analyzing the relationship between these three factors in other countries, and may include more diverse and higher sample population in order to generalize the results, and address the issue of limited research in this area. In addition, multiple relationships between other factors such as satisfaction, turnover intentions, commitment, and attitudes may be included in future studies.

CONCLUSION

The purpose of this study is to analyze the relationship between quality of work-life on the organizational loyalty and job performance in Saudi Arabia, thereby addressing the research gaps identified in this area. Findings have revealed that Quality of work-life is moderately correlated with organization loyalty and job performance. Poor quality of work-life can negatively impact job performance and organizational loyalty of nurses. Considering the fast-changing work-life of nurses being influenced by various factors, it may be assumed that they may be under stress, which may significantly affect their work-life. This in turn can influence organizational loyalty and job performance, affecting the overall healthcare services. Therefore, it is important that the measures need to be developed for addressing the issues in nurses' quality of work-life, thereby improving the job performance and loyalty. However, further studies are needed to establish clear a relationship between these factors in various contexts.

DATA AVAILABILITY STATEMENT

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

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Ministry of Health.

AUTHOR CONTRIBUTIONS

The author confirms being the sole contributor of this work and has approved it for publication.

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UV protection properties of workwear fabrics coated with TiO_2 nanoparticles

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The main purpose of this study was to evaluate the ultraviolet protective factor (UPF) of fabrics coated with TiO2 nanoparticles made using an *in-situ* synthesis method and more accurately assess the intrinsic properties of the textile. The cotton-polyester twill fabric (70–30%) (246.67 g/m2) was coated *in-situ* with TiO2 nanoparticles. *In-situ* coating is conducted in 4 steps; washing the fabrics, preparation of nanoparticles, injecting the nanoparticles into fabrics, and drying the fabric after coating. The scanning electron microscope (SEM) and X-ray diffraction (XRD), FTIR spectrometer, dynamic light scattering (DLS) and UV-Vis spectrophotometer were used to analyse the data of the coating and UPF results. Also, four standards such as ASTM D737, ISIRI 8332, ISIRI 4199, and ISIRI 567 were used for analyzing the intrinsic properties of a textile. The results of SEM, XRD and DLS altogether confirmed the *in-situ* formation of nanoparticles onto textile fibers. Moreover, the UPF value of the uncoated and coated fabrics was 3.67 and 55.82, respectively. It was shown that the *in-situ* deposition of TiO2 nanoparticles on fabric can provide adequate protection against UVR. Also, the results of analyzing the intrinsic properties of the textile showed that there were no significant differences in the intrinsic properties between the coated and uncoated fabrics. Based on the results, it can be concluded that the UV protective properties of workwear fabrics can be improved by coating TiO2 nanoparticles on them without any effect on the cooling effect of perspiration evaporation.

KEYWORDS

TiO2, nanoparticles, UPF, *in-situ*, textile

Introduction

The incidence of skin cancer has been rising at an alarming rate over the past few decades due to overexposure to ultraviolet radiation (1). As a result, UV-induced skin damage has become an urgent health challenge (2–4). Accordingly, different strategies have been introduced to protect the skin against ultraviolet radiation which include using sunscreen, avoiding the sun at its highest intensities, and wearing clothing that effectively covers the skin surface. Outdoor workers such as farm workers, mine workers, bricklayers, construction workers, etc., are exposed to UV radiation, more frequently and for longer periods than people working indoors. The clothing worn by them is considered the most important personal protective equipment, preventing cuts and lacerations as well as contact with chemicals. Their clothing can protect their body from radiant heat and harmful rays (2, 4). Also, welders, furnace operators (steel industry and foundries), and even laboratory technicians (for UV disinfection) are exposed to ultraviolet light (5, 6). Wearing protective clothing is the cheapest and easiest way to limit UV exposure. However, intrinsic properties of textiles such as physical structure and chemical composition, low absorption, and UV–induced vulnerability of textiles can affect their UV-blocking properties. Therefore, the UV-blocking properties of the textile should be optimized. In other words, improvement of the Ultraviolet Protection Factor (UPF) is required to change the physical and chemical properties of textiles (7).

Fabrics generally have a UPF rating of 15–50, allowing only 2.5% of the sun's UV rays to pass through and any fabric that allows <2 percent UV transmission is labeled UPF 50+. Researchers have used different coatings as UV protectors for producing textile fibers. Chemical additives used as UV protectors can become toxic and degraded by sunlight (8, 9). Moreover, the preparation of these protectors often involves several steps as well as the use of hazardous chemicals. Hence, advanced protective coatings should be prepared and modified (10). Given that the properties imparted to textiles using conventional methods often do not have permanent effects and loss of function may occur after repeated washing, while the modifications made to the textile structure using nanotechnology and nanofibers are more stable and can improve the durability of textiles, the use of nanotechnology in the textile industry is increasingly attracting worldwide attention due to the existing interests (11). Nanomaterials such as metal oxide nanoparticles can impart UV blocking properties to textiles (12).

Loading the nanoparticles with UV blocking properties onto nanofibers can have a significant effect on the UV blocking properties of the textile. Nanoparticles are more efficient in blocking UV light than larger particles. Metal oxide nanoparticles such as titanium dioxide (TiO_2), zinc oxide, selenium dioxide, and aluminum dioxide have been used for this purpose, among which nano-TiO_2 is one of the best choices due to its cost-effectiveness, and simplicity, low toxicity, and high surface energy (13). Studies have shown that titanium provides UV protection via an absorption mechanism (14). For instance, Attia et al. (15) coated cotton/polyester (65/35%) fabric with TiO_2 and ZnO nanoparticles (20 nm), and the results showed that UPF in treated fabrics was significantly enhanced and achieved more than six fold. Also, Hasan et al. coated aramid fabrics with silver nanoparticles to assess the antibacterial effects of nanoparticles. Results revealed that the fabrics have demonstrated excellent antibacterial action with more than 99% bacterial reduction efficiency against both Escherichia coli (E. coli) and Staphylococcus aureus (S. aureus) (16). At the end, Mondal showed in a review article that several nanomaterials such as ZnO, TiO_2, and Carbon nanotube were used in several studies. Also, cotton fabrics were the most used materials to study UPF (17).

Given the vast numbers of outdoor workers and their prolonged exposure to the sun, designing UV-protective textiles is essential since the intrinsic properties of textiles such as physical structure and chemical composition, low absorption, and UV– induced vulnerability of textiles can affect their UV-blocking properties. Therefore, the present study aimed to evaluate the UPF of fabrics coated with TiO_2 nanoparticles made using an *in-situ* synthesis method and more accurately assess the intrinsic properties of the textile (such as air permeability, abrasion resistance, wrap resistance and surface wetting resistance).

Materials and methods

Chemical substances and fabric properties

Chemical substances including Titanium isopropoxide (TTIP) (284.22 g/mol, $C1_2H_28O4Ti$) (Merck No. 821895), ethanol 99.99%, and sodium hydroxide were purchased from Shimi Parsian Co Tehran, Iran. Also, the cotton-polyester twill fabric (blend ratio: 70/30%) (246.67 g/m^2) was provided by Yazd Baf Co, Yazd, Iran. To remove the interference effects of dying on the UPF value, the fabric was purchased from the factory before being dyed. The cotton-polyester twill fabric was used since it is the most common workwear fabric in Iran.

Synthesis of TiO_2 nanoparticles on the fabric

TiO_2 nanoparticles were *In-situ* synthesized on cotton fabrics as described as the fabric samples in cuts of 4 × 4 cm were washed with ethanol inside a shaker and then again rinsed in distilled water and dried in an oven at 80°C. Next, a 4.2 mol/L NaOH solution was used for nanoparticle preparation, and the mixture was then subjected to ultrasonic cleaning in an ultrasonic bath (PARSONIC 2600s, Ac 220v/50 Hz) for 15 min. Also, 1 ml of pure ethanol and 4.5 ml of TTIP, and 1 ml of pure ethanol were withdrawn with a 10 ml syringe, respectively. The solution inside the syringe was then added dropwise to the solution containing the fabric in the ultrasonic bath and subjected to the ultrasonic cleaning for 5 h. The fabric samples were then washed three times in distilled water and dried in an oven at 80°C for 2 h.

Structural properties

The morphological structure of the textiles was investigated using a scanning electron microscope (SEM) and energy-dispersive X-ray spectroscopy system (EXD) (XL30, supplied by Philips Healthcare, the Netherlands) and a Philips PW-1510 diffractometer (PW 1510) before and after direct *in-situ* modification of cotton fabric using TiO_2 nanoparticles. The samples were placed on the SEM stub and coated with gold. Image Analysis Software was used after x-ray diffraction imaging, morphological analysis, and particle size analysis. An FTIR spectrometer (Tensor 27, Bruker, Ettlingen, Germany) was used to analyze the chemical composition of synthesized TiO_2 nanoparticles and the amount of metal loaded, and a dynamic light scattering analyzer (Microtrac MRB's NANOTRAC Wave, USA) was used to analyze TiO_2 nanoparticle size. The energy-dispersive X-ray spectroscopy system, attached to the same microscope, was also used for elemental analysis. The structure of the *In-situ*-modified fabric samples was identified *via* X-ray diffraction (XRD) analysis at room temperature using an X-ray diffractometer (Panalytical X'PERT PRO) with a Cu Kα anode operating at 40 kV and 50 mA and $\lambda = 1.5406$). Diffraction data were collected over the 2θ range of 10–50° with a step size of 0.02 ° and a scan speed of 1 s. The use of these instruments as well as how to do it is designed and implemented based on previous studies (18–21).

UV protection

The UV transmittance spectra (280–400 nm) of the textile were measured at a distance of 5 nm using a spectrophotometer (Varian Cary 100, Australia) (22). The UPF, UV-A (315-400) protection factor, and the UV-B (280-315) protection factor were evaluated using AS/NZ 4399:1996 and equation 1. Three replicated measurements were carried out for each sample and an average value was reported (22). According to the AS/NZ 4399: 1996 standard, the spectral intensity of radiation proportional to that of the solar spectrum (S_λ) in the spectrophotometer was proportional to any wavelength from 290 nm (4–10 × 767/0 $W.m^{-2}.nm^{-1}$) to 400 nm (180/1 $W.m^{-2}.nm^{-1}$).

Equation 1 (22).

$$UPF = \frac{\int_{280}^{400} E_\lambda S_\lambda d_\lambda}{\int_{280}^{400} E_\lambda S_\lambda d_\lambda T_\lambda} \quad (1)$$

Where:

E_λ: Relative efficiency of the radiation source.
S_λ; Initial spectrum of the radiation source (W.m-2. nm-1).
d_λ: Bandwidth (nm).
T_λ: The amount of light transmitted.

Intrinsic properties of the manufactured textiles

The intrinsic properties of fabrics contribute to their performance, resistance, and heat transfer, so the effect of nanoparticles, applied as a coating, on these properties should be investigated. The properties examined in this study include:

1- Air permeability: the rate of airflow passed through the pores. This property, which indicates the fabric's resistance to sweating-induced evaporative cooling, was tested *via* ASTM D737 method using the TF164E Air Permeability Apparatus (23).

2- Abrasion resistance: the ability to resist wearing and indicates the cut resistance. This property was estimated using ISIRI 8332 standard (24).

3- Wrap resistance: resistance to tensile force and indicates fabric's strength against tearing. This property was evaluated using ISIRI 4199 (25).

4- Surface wetting resistance: the penetration of water through the fabric or the resistance to wetting. It was measured using ISIRI 567 (26).

Results and discussion

Properties of the fabrics coated with TiO_2 nanoparticles

Coating thickness was determined by gravimetric analysis. The results showed that the weight of the fabric was 0.4297 g before coating and 0.4745 g after coating, so 10.42% of TiO_2 nanoparticles had been coated on the surface of the fabric. Micrographs and EDX analysis as well as SEM images confirmed the *in-situ* formation of nanoparticles onto the textile fibers (Figure 1). Ti signals observed in EDX analysis patterns of the fabric modified with TiO_2 nanoparticles were recorded. The diameter of TiO_2 nanoparticles on the textile fibers was measured using the DLS method. The nanoparticle average diameter determined by DLS was found to be 98.15 nm (Figure 2). Dense TiO_2 nanoparticles were observed on the fabric, indicating the effect of the chemical composition of the

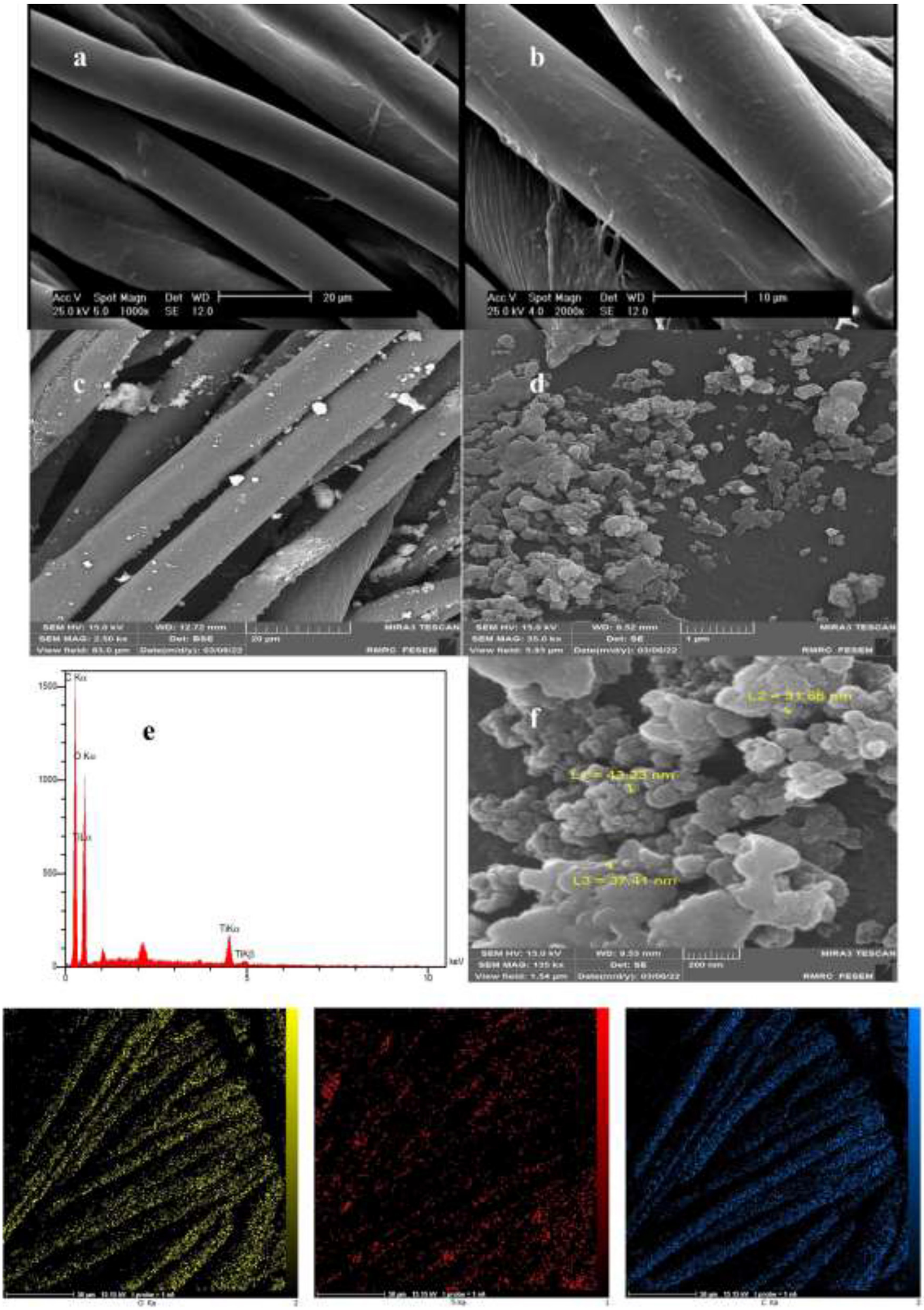

FIGURE 1
EDX and SEM analysis of TiO_2 nanoparticles coating: **(a,b)** Imaging of the uncoated fabric with image sizes of 20 and 10 µm. **(c,d,f)** Imaging of TiO_2 -coated fabric with image sizes of 20, 1 µm, and 500 nm. **(e)** EDX spectra of the agents coated onto the fabric surface.

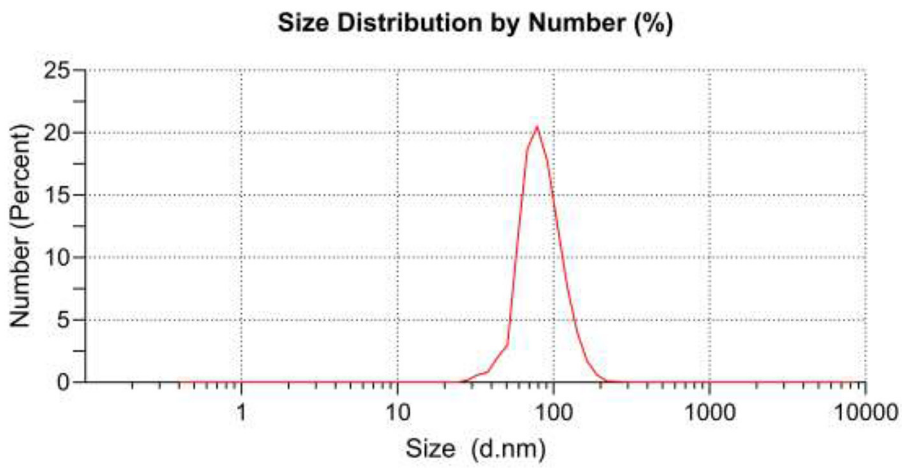

FIGURE 2
Size distribution of TiO_2 nanoparticles obtained by DLS.

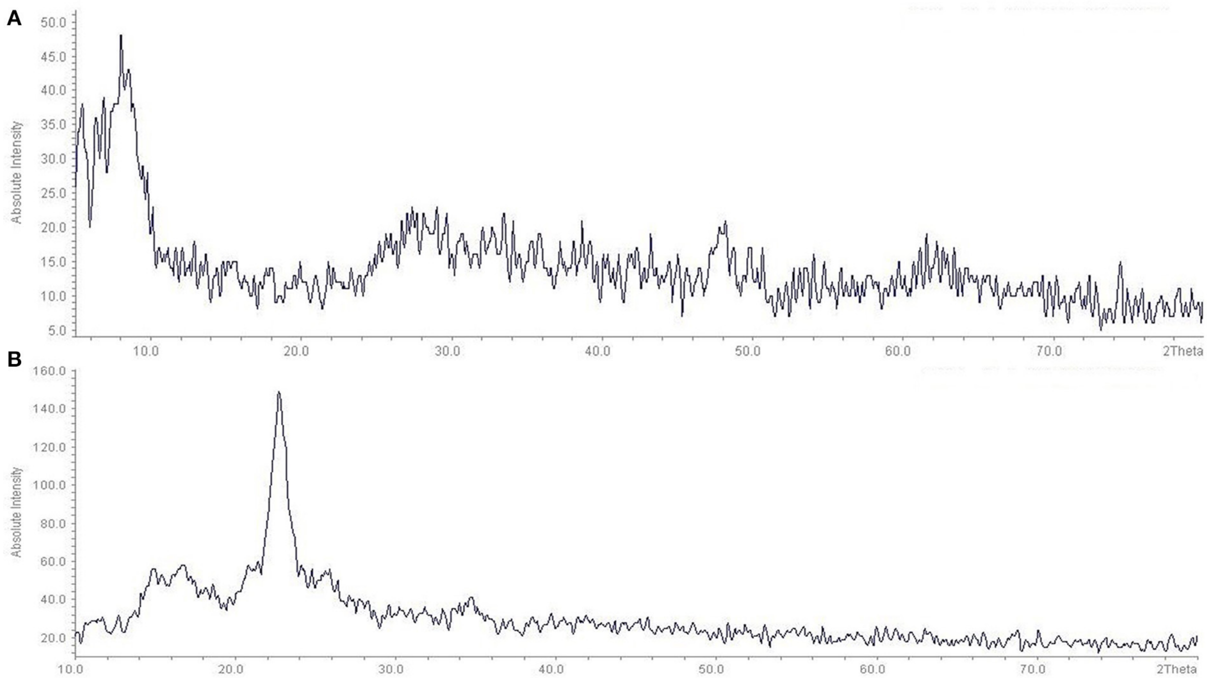

FIGURE 3
XRD patterns of pure TiO_2 Nanopowder and fabric coated with TiO_2 nanoparticles: **(A)** Pure TiO_2 Nanopowder, **(B)** fabric coated with TiO_2 nanoparticles.

fabric on the nature of the prepared TiO_2 nanoparticles (27, 28). The EDX spectra revealed the presence of C, O, and Ti on the surface of cotton fabrics.

The XRD analysis confirmed the *in-situ* synthesis of the TiO_2 on the fabric surface (Figure 3). As can be seen, the diffraction peaks were located at 5.45, 6.90, 8.08, and 29.37°. Also, consistent with previous studies, after surface modification, some 2θ peaks (base peaks) of the TiO_2 nanoparticles were located at 16.74, 22.75, and 34.70° according to the TiO_2 nanoparticles (29). The results of the SEM, XRD, FTIR, DLS of the present study are similar to the results of other studies (30–32).

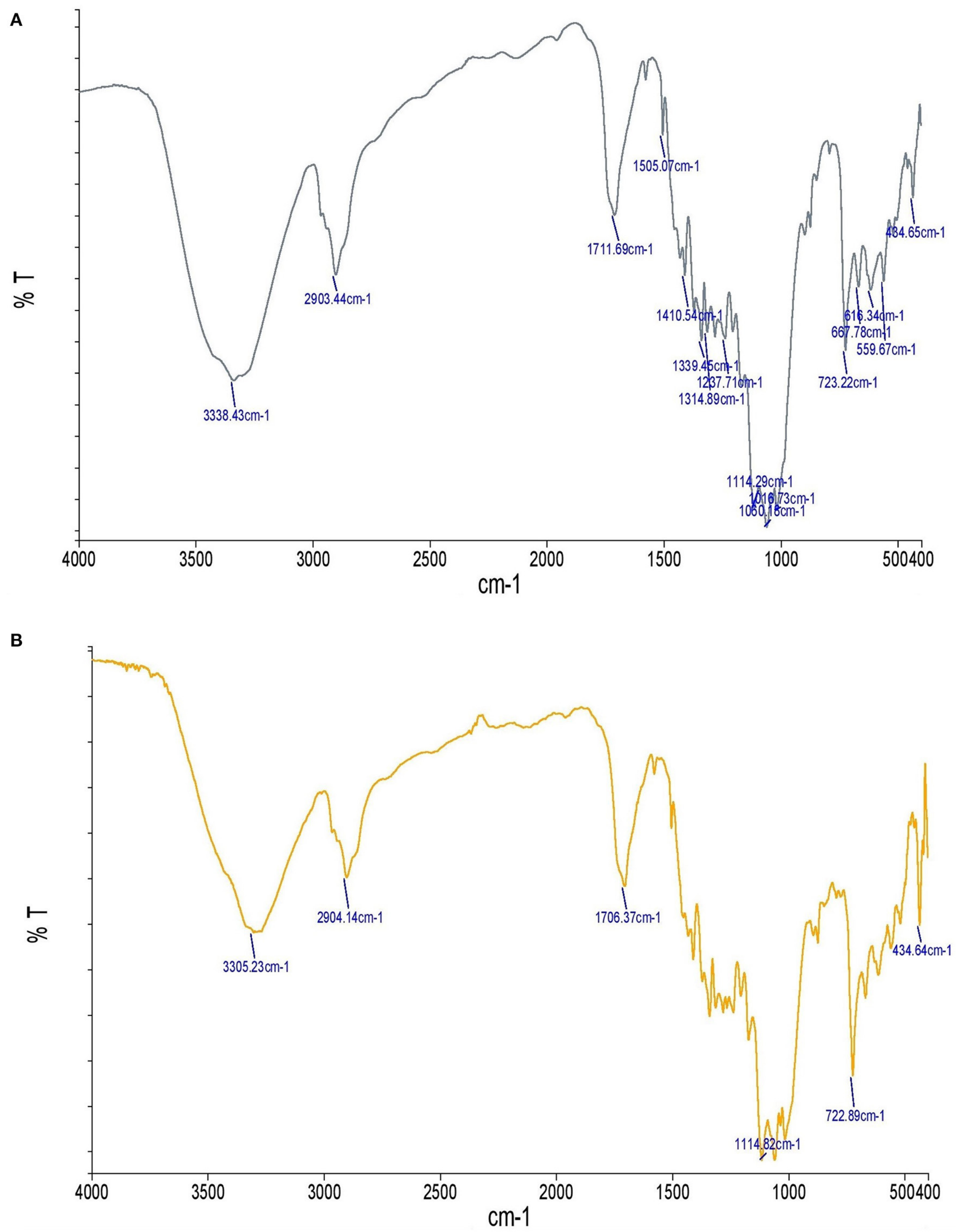

FIGURE 4
FTIR spectra of uncoated fabric compared with the fabric coated with TiO_2 nanoparticles: **(A)** Uncoated fabric, **(B)** fabric coated with TiO_2 nanoparticles.

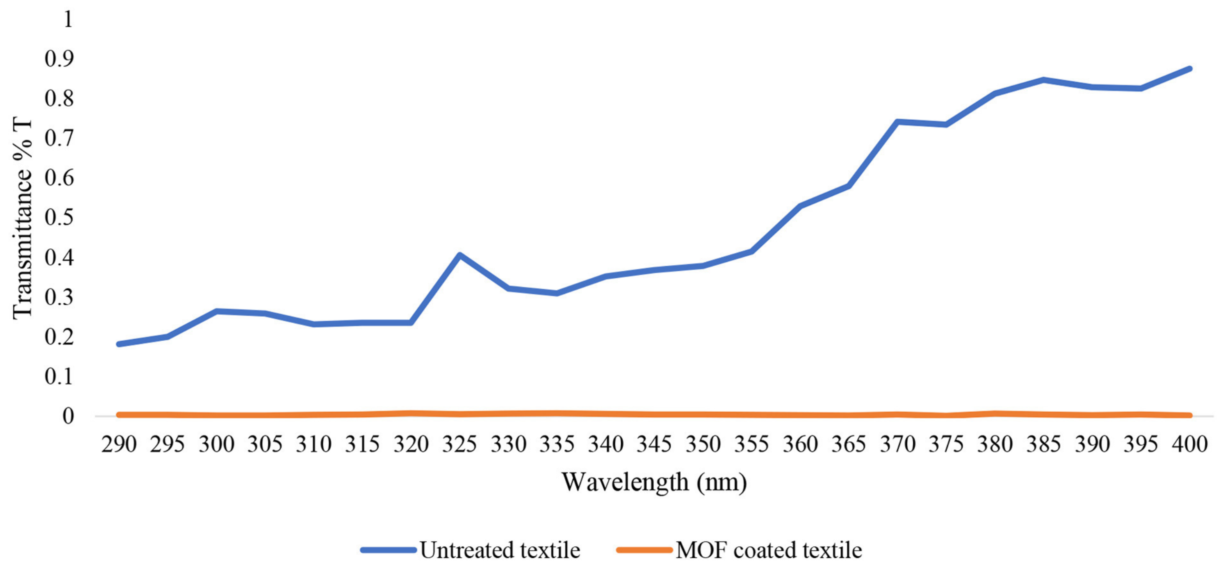

FIGURE 5
UVR transmittance property of uncoated fabrics and fabrics coated with TiO_2 nanoparticles according to AS/NZS 4399 Sun Protective Clothing standard.

TABLE 1 Comparison of uncoated and coated textile with TiO_2 nanoparticle in terms of intrinsic properties of the textile.

Textiles	Intrinsic properties of the textile							
	Warp resistance N), Mean (SD)	*P*-value*	Air Permeability (ml/cm^2/s), Mean (SD)	*P*-value	Abrasion resistance (kg), Mean (SD)	*P*-value	Surface wetting resistance (g), Mean (SD)	*P*-value
Uncoated	16.19 (3.96)	0.10	21 (1.58)	0.073	204 (1.16)	0.317	0.47 (0.01)	0.317
Coated with TiO_2	16.32 (1.62)		18.80 (1.64)		501.66 (1.15)		0.67 (0.01)	

*Mann-Whitney Test.

The chemical composition of the fabric was investigated using FTIR before and after the *in-situ* formation of the TiO_2 nanoparticles (Figure 4). Note the broad peak at 3,305 cm-1 due to the O–H stretch. The broad peak around 2,904 cm-1 also resulted from the C-H stretch. Despite the CH groups of cellulose, the symmetric and asymmetric stretching peaks were not separated as sharp peaks. The peak near 1,706 cm-1 can be attributed to the absorption of water molecules. The broad absorption bands at 434 cm-1 and 722 cm-1 were caused by the bending vibrations of the Ti-O and -O-Ti-O groups, and the peak observed at 1,114 cm-1 was due to the bending vibration of Ti-O-Ti. The vibration bands observed at 1,300–4,000 cm-1 can be attributed to the chemical and/or physical co-adsorption of the H_2O and CO_2 molecules. Therefore, it can be concluded that the fabrics were well coated with the TiO_2 nanoparticles. These results are consistent with other studies on TiO_2 nanoparticles (29, 33–37).

UPF values

The UPF of uncoated and coated fabric by measuring the transfer rate (T) for UVR and its spectral results is shown in Figure 5. According to the results, the UPF value of the uncoated fabrics calculated *via* Equation 1 was 3.67 and the UPF value of fabrics coated with TiO_2 nanoparticles was 55.82, indicating the strong UV blocking ability of the coated fabrics. It was confirmed that the *in-situ* deposition of TiO_2 nanoparticles on fabric can provide adequate protection against UVR.

According to the Australian/New Zealand Standard and the British standard (22), uncoated fabrics with UPF $<$ 20 have insufficient UV protection. After direct *in-situ* modification, the fabrics reached UPF $>$ 50 and could be classified in the excellent UV protection category according to the mentioned standard. Other studies have also shown that TiO_2 nanoparticles coated on fabric can provide adequate protection against UVR (38, 39). Moreover, previous studies have revealed the enhancement of

UV absorption in the TiO_2 nanoparticles formed on cotton fabrics. The cotton fabrics loaded with dense layers of the TiO_2 nanoparticles exhibited greater UPF values after a longer deposition period (40). Alebeid et al. also showed that the TiO_2 nanoparticles can block UV more efficiently compared with dyes, implying that dye is not a reliable indicator of the UV protection provided by dyed fabrics (41–43).

Some studies have shown lower UPF values and this difference can be due to fiber type. For example, Kathirvelu et al. found that 100% cotton fabrics coated with the TiO_2 had UPF values lower than the adopted standard and it cannot be classified in the excellent "UV protection category. However, cotton and polyester blended fabrics treated with the TiO_2 nanoparticles exhibited higher UPF values and woven fabrics made of polyester-cotton blend yarns showed better UV absorption properties compared to other fabrics (44). Consistent with other studies, the present study indicated that coating fabrics with TiO_2 nanoparticles can significantly increase UPF values and improve anti-ultraviolet performance. The difference in the anti-ultraviolet performance can be attributed to different concentrations of the TiO_2 nanoparticles and increasing the concentration of TiO_2 nanoparticles can increase the UV protection capacity of the fabric (45). In addition, according to studies, the increase in UPF values can be attributed to the natural UV absorption properties of TiO_2 and can be explained by the band theory of solids. The TiO_2 is a semiconductor with a wide bandgap (3.2 eV) between the low energy valance band and the high energy conduction band. When the TiO2 is activated with light waves of energy greater than its bandgap, the electrons will absorb UV light due to its wide bandgap; that is why the TiO_2 can protect against ultraviolet radiation (46).

Many studies have investigated the UV-blocking capacity of TiO_2 nanoparticles and have shown that the *in-situ* synthesis of TiO_2 nanoparticles on the fabric surface can lead to UV protection capacity, confirming that *in-situ* deposition of TiO_2 nanoparticles on fabric can provide good to excellent UV protection (28, 29).

Structural properties of the fabric

The present study compared the fabric coated with the TiO_2 nanoparticle and the uncoated fabric to investigate the effect of coating on the intrinsic properties of the fabric, including wrap resistance, air permeability, abrasion resistance, and surface wetting resistance. Wrap resistance and abrasion resistance indicate the ability of fabric in various conditions and environments. Also, air permeability and surface wetting resistance refer to the rate of airflow and moisture transfer through the fabric, respectively. This can affect the sweat absorption and comfort properties of the fabric. The results showed no significant difference in the intrinsic properties between the coated and uncoated fabrics, implying that coating the fabric with the TiO_2 nanoparticles had no effect on the intrinsic properties of the fabric and caused no reduction in its resistance, air permeability, and the cooling effect of perspiration evaporation (Table 1). This lack of difference shows that coating the fabrics with the TiO_2 nanoparticles did not affect their intrinsic properties and the heat and air transfer capacities of the modified fabric were similar to those of the uncoated fabric. Also, the modified fabric had sufficient resistance to withstand work environments. Few studies have investigated the intrinsic properties of the fabric after coating it with the TiO_2 nanoparticles and the majority of studies conducted in this field aimed to make fabrics waterproof. No study has been conducted to design workwear fabrics with high UPF values without imposing changes to their intrinsic properties. However, previous studies have also shown that hydrophilicity is also an important property that refers to absorbing moisture vapor and can add to the comfort properties of fabric (47, 48).

Conclusion

The present study aimed to evaluate the UPF (ultraviolet protective factor) of fabrics coated with the TiO_2 nanoparticles made using an *in-situ* synthesis method and more accurately assess the intrinsic properties of the textile. The results showed that the textile coated with the TiO_2 nanoparticle had greater UPF values than the uncoated textile and also the intrinsic properties of the coated fabric did not change significantly. Based on the results, it can be concluded that the UV protective properties of workwear fabrics can be improved by coating the TiO_2 nanoparticles on them without any effect on the cooling effect of perspiration evaporation. However, the production of workwear fabrics requires further research. Future studies can evaluate the cytotoxicity and antibacterial properties of the TiO_2 nanoparticles to ensure that the TiO_2 coating of fabrics has no adverse effects on human skin.

Data availability statement

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

Ethics statement

Ethical approval for this study was obtained from School of Public Health and Neuroscience Research Center, Shahid Beheshti University of Medical Sciences (IR.SBMU.PHNS.REC.1400.045).

Author contributions

SF was the leader of study and edited the final manuscript. HR and AK gathered data and performed laboratory experiments and were a major contributor in writing the manuscript. MM analyzed laboratory experiments about fabrics and was a major contributor in writing the manuscript. SK analyzed nanomaterials laboratory experiments and was a major contributor in writing the manuscript. All authors read and approved the final manuscript. 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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Emphasis on heat strain to the ocular surface: A functional and clinical study of a modified goggle

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Purpose: The limitations of conventional goggles have caused immense inconvenience, and even damage, to the physical and mental health of healthcare workers. Hence, this study aimed to build a modified goggle (MG) with better physical performance. The temperature-humidity index (THI) was used as an indicator to investigate the impact of goggle-related heat strain on the ocular surface.

Methods: The basic functions of antifog, anti-ultraviolet (UV), and anti-blue-light radiation capabilities were evaluated. Furthermore, the clinical impact on noninvasive keratography tear film break-up time (NIKBUT), intraocular pressure, central corneal thickness, Schirmer test I, and the Dry Eye-related Quality of life Score (DEQS) were assessed in 40 healthcare workers by comparing MG with standard goggles (SG). The relationships between THI and the above parameters were explored.

Results: MG had a significantly longer antifog time than SG (212.75 ± 23.95 vs. 138.35 ± 5.54 min, $p < 0.05$), stronger antiultraviolet ability at 400 nm (99.99 vs. 45.55%), and optimal anti-blue-light performance at 440 nm (33.32 vs. 13.31%). Tear film stability after wearing the goggle was significantly worse than that before wearing them ($p < 0.05$). Both goggles achieved moderate to strong heat strain, with a THI of >80 at all timepoints. The MG group showed lower THI and DEQS and higher NIKBUT than the SG group ($p < 0.05$). THI was significantly correlated with DEQS, NIKBUT, and real fogging time ($r = 0.876$, −0.532, −0.406; *all* $p < 0.05$).

Conclusion: Wearing goggles for a long time may cause heat strain to the eyes, thereby leading to eye discomfort and changes in the microenvironment of the ocular surface. Our MG exhibited better antifog, antiultraviolet, and optimal anti-blue-light performance and lower heat strain than SG, thus making it ideally suited for healthcare workers.

KEYWORDS

goggles, healthcare worker (HCW), heat strain, antifog, blue light

Introduction

Globally, as of July 18, 2022, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has infected more than 559 million individuals and caused more than 6 million deaths (1). Although vaccines are available worldwide, their effectiveness needs to be further evaluated because of the continuous mutations in the virus (2). The use of personal protective equipment (PPE) remains the best method for preventing infection.

Goggles, which are eye protection devices, are of great importance in reducing the infection rate among healthcare workers (HCWs) (3). The physical barrier effect of goggles is better than that of face shields, which is especially important because evidence that COVID-19 can be transmitted through the eyes is emerging (4, 5). However, in the real world, with the sudden appearance of the epidemic, many countries have encountered a shortage of goggles and have faced problems related to their low function (6). The limitations of conventional goggles have posed immense inconvenience, and even damage, to the physical and mental health of HCWs. The goggles face issues, such as fogging (6), pressure damage (7, 8), and radiation risks (9, 10), and cause severe discomfort (11) (Figure 1). Medical goggle standards that can help in overcoming the above constraints and preventing the spread of highly infectious pathogens that expose the HCWs to potential risks are lacking.

Heat strain refers to a series of reactions in the organisms to the thermal environment. A recent article stated that many factors exist in the human thermal environment, including environmental factors (temperature, humidity, wind velocity, and solar radiation), task-dependent factors (e.g., metabolic rate and clothing), and individual factors (e.g., age, sex, body mass, morphology, and aerobic fitness). These factors cause heat strain to the cardiovascular system, central nervous system, and skeletal muscle function and result in fatigue development (12). During COVID-19, there has been a high prevalence of heat strain among HCWs because of wearing PPE, which has resulted in heat-related physical symptoms, including thirst, fatigue, sweating, uncomfortable warmth, and reduced work performance (13). However, the effect of heat strain on the eyes has not yet been studied.

Goggles cause systemic heat strain and directly affect the eyes. Previous studies have shown that brief (approximately 10 min) exposure to the high temperature (45°C–55°C)–humidity environment of goggles can effectively warm the outer eyelids and is effective against meibomian gland dysfunction (14). However, whether routine continuous (≥4 h) exposure of the eyes to the high temperature–humidity of the goggles causes heat strain and affects the function of the ocular surface and whether the subjective symptoms are related to the environment inside the goggles need to be explored.

This study aimed to create a modified goggle (MG) that has the potential to overcome the shortcomings of the standard goggles (SG) and explore the impact of heat strain on the ocular surface. A technical introduction regarding the fabrication of MG and the results of the function and cross-sectional clinical study compared with the SG from the 3M company are provided, along with a discussion based on the design considerations.

Methods

Study design and participants

Our MG is composed of a specially designed silicone body and a lens with improved technology. The silicone body contained four virus-proof air filters and a one-way valve

FIGURE 1
Photographs from news media reports in China indicate that goggles fogging and PPE-related pressure injuries were prominent among HCWs.

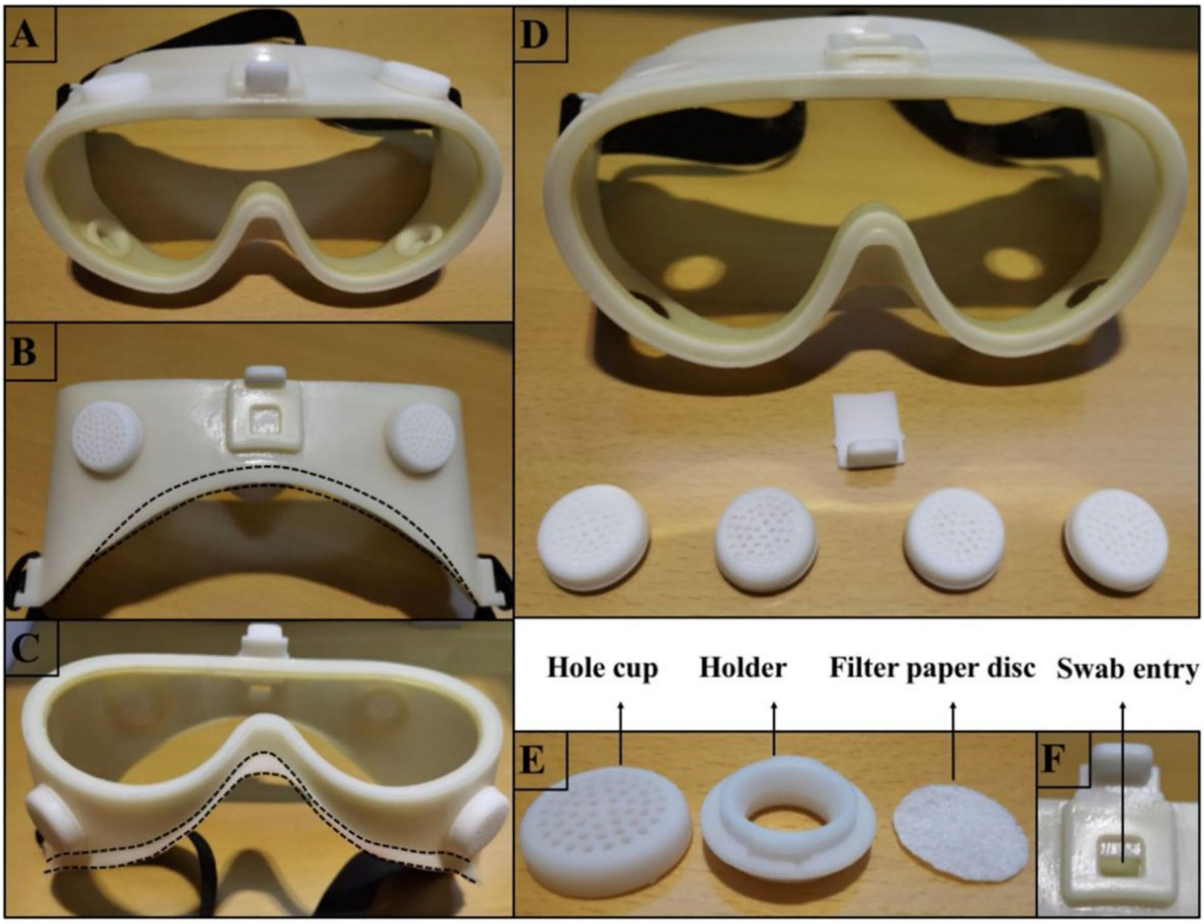

FIGURE 2
Photographs depicting how the MG was fabricated. **(A)** Shows the front view of the MG. **(B,C)** Illustrate the top and bottom views of the MG, respectively, and the dotted line indicates how the silicone portion fits the face. **(D)** Illustrates the decomposed portion of the MG, which includes 4 filters and a one-way valve. **(E)** Illustrates the decomposed portion of the filter, including the hole cup, holder, and filter-paper disc. **(F)** Illustrates the valve open state when the swab can be inserted into the goggle to fix an urgent tickle or dry the eyes without removing the goggles.

(Figure 2). The air filter comprised a holder, filter paper disc, and hole cup. The filter paper disc was removed from the qualified face mask. The lens provided by Actif Polarizers Technology was qualified for anti-fog, optimal anti-blue light radiation, and anti-ultraviolet radiation functions. SG (AF1621, 3M), which claims to be anti-fog and 99% anti-UV, was used to compare the performances of MG.

HCWs at Tongji Hospital affiliated with Tongji University were invited to participate in this study. Those with a completely normal ophthalmological assessment under a slit-lamp microscope (YZ5T, 66 Vision Technology, China) and related routine eye examinations were eligible to participate in the study. The exclusion criteria were a history of systemic or intraocular inflammatory diseases, including dry eye diseases, myopia with −1.00 D or lower, and systemic or topical therapies in the last 6 months that could have modified the ocular surface. Those with a history of contact lens use and myopia were asked to remove the lens or glass for a week before the test. After enrolment, the participants were assigned the goggle *via* a random number generated by "MS Excel," with 20 participants in each group. For each subject, the fit of the goggles was carefully checked to ensure that it did not confound the results. Once the goggles were comfortable and optimally fitted, the timer was set to 240 min. The HCWs operated computers for 2 h and read books for another 2 h in one room without participating in other tasks. If the goggles were removed halfway, the subject was withdrawn from the study. The participants provided informed consent before the study, and it was approved by the Medical Ethical Committee of Tongji Hospital affiliated with Tongji

University. The study adhered to the tenets of the Declaration of Helsinki.

Function tests

The function tests included antiultraviolet, anti-blue-light, and simulated antifog capabilities before wearing. ***Antiultraviolet and anti-blue-light capability:*** The capability to resist ultraviolet and blue radiations was tested using spectral transmittance experiments that reflect the loss of light at different wavelengths through objects. Two types of goggles were tested through an independent professional agency with a UV spectrometer (SDR1911, Speedre Technology Co. Ltd, China) from 190 to 1,100 nm in 1 nm step. The goggles were positioned carefully over the entrance optics of the spectrometer. The scans were repeated at least three times, and the average value was calculated. All data were converted into line charts. ***Antifog capability:*** To evaluate the antifog capability, both simulation and real-scene tests were adopted. The simulation test was modified from GB/T31726-2015 (15). The protocol was to quickly place the two types of goggles on the mouth of a beaker containing distilled water at a temperature of 85 ± 2°C and then transfer them to the nearest printed eye chart paper after 60 s. The same region was observed within 5 s, and photographs were taken to record the degree of fogging under the same circumstance. The real-scene test was conducted during the subsequent clinical test. After wearing the goggles, the participants were requested to record the real fogging time (r-FT), which signifies the duration from no fog to the fog covering the whole lens and negatively impacting the work.

Clinical tests

An open recruitment strategy was used, with an online link that was distributed to our professional WeChat official account of the Tongji Eye Department. Participants who met the inclusion and exclusion criteria were allowed to provide basic information, including age and sex. Clinical tests, including intraocular pressure (IOP), measured using a non-contact tonometer (NT-510, NIDEK, Japan), central corneal thickness (CCT) using an anterior segment optical correlation tomography (Visante^{TM}, ZEISS, Germany), median noninvasive keratography tear film break-up time (NIKBUT) using a Keratograph (5M, OCULUS, German), and Schirmer test I (STI) using a tear filter strip (Jingming, China), were performed in the right eyes of the 40 participants before and after wearing the random goggles for 4 h. IOP, CCT, and NIKBUT were repeated three times, and the average value was calculated. All participants completed the test in the same working environment (temperature, 27°C; relative humidity, 50%) and performed the same activities. Data on the subjective symptoms were collected using the Dry Eye-related Quality of life Score (DEQS) questionnaire, with 15 questions every 30 min at 30, 60, 90, 120, 150, 180, 210, and 240 min. The results were used to assess not only the degree of bothersome eye symptoms but also the impact on daily life (16). The score for each item ranged from 0 to 4 points. The higher the score, the more serious are the symptoms. Temperature and relative humidity inside the goggles were recorded during the test using a mini temperature-humidity calculator (ABS-8845, DELI, China) for 30 min, along with the DEQS questionnaire. The temperature–humidity index (THI), which combines temperature and humidity as a single value, was calculated using the following formula (17):

$$THI = (1.8\times T + 32) - [(0.55 - 0.0055 \times RH) + (1.8 \times T - 26)],$$

The correlations between THI and the above parameters were further studied.

Statistical analyses

Statistical analyses were performed using the SPSS software (version 20.0; IBM, Armonk, NY, USA). The data were checked for normality using the Shapiro–Wilk test. Means with standard deviations (SD) or medians [interquartile ranges] were used to record the descriptive variables, whereas counts and percentages were used for categorical variables. The age and sex differences between the two groups were calculated using an independent sample *t*-test and chi-square test, respectively. One-way repeat measures ANOVA was used to compare the differences in THI and DEQS between the MG and SG groups at all timepoints. Differences in IOP, CCT, NIKBUT, and STI between and within groups were evaluated using an independent sample *t*-test or paired *t*-test. The r-FT between the two groups was compared using an independent sample *t*-test. Pearson or Spearman correlation coefficients were used to determine the correlation between THI, temperature, and humidity and DEQS, IOP, CCT, NIKBUT, STI, and r-FT. Statistical significance was set at $p < 0.05$.

Results

Antifog test

In the simulation test, when the two kinds of goggles were placed on the cup where the hot water vapor overflowed, the SG fogged immediately and the eye chart became blurred and illegible, whereas the chart under the MG was clearly visible, as shown in Figure 3. In the real scene test, r-FTs of the 40 HCWs wearing SG and MG were 138.35 ± 5.54 min and 212.75

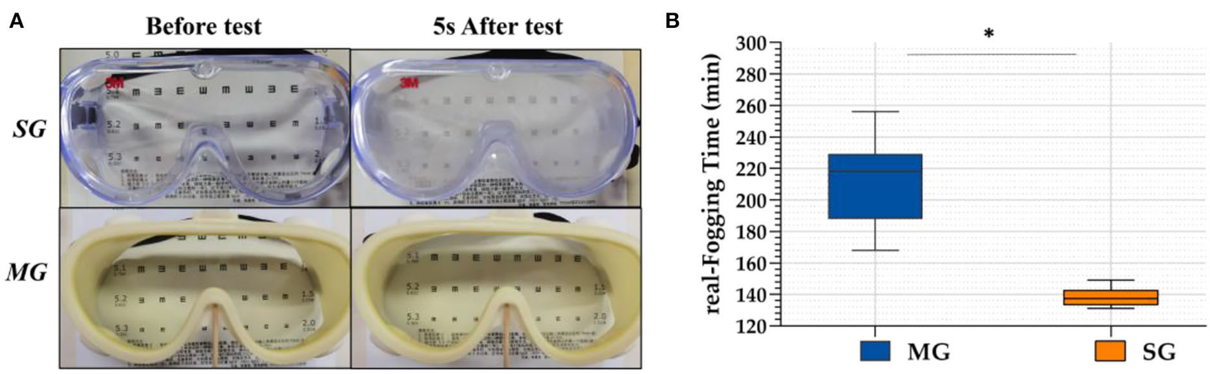

FIGURE 3
Antifog capability in simulated test **(A)** and real scene test **(B)**. *$p < 0.05$.

± 23.95 min, respectively. Statistically significant differences were observed between the SG and MG ($t = 5.497$, $p < 0.05$) groups.

Ultraviolet and blue-light transmittance test

As clearly demonstrated in Figure 4, the light transmittance of the MG was only 0.1% in the ultraviolet band (200–400 nm), whereas that of the SG increased rapidly after 365 nm, reaching 54.45% at 400 nm. The light transmittance of the MG in the blue light band (400–500 nm) was significantly lower than that of the SG. MG reached 66.68% at 440 nm, whereas SG reached 86.69% at the same wavelength.

Subject characteristics

The mean age of the MG group was 28.65 ± 3.54 years and that of the SG group was 29.90 ± 3.68 years. There were eight men participants (40.00%) in the MG group and seven (35.00%) in the SG group. There were no significant differences between the two groups ($t = -1.094$, $p = 0.281$; $\chi^2 = 0.107$, $p = 0.744$).

Ocular surface index

The four parameters were recorded before and after the test and analyzed, as shown in Table 1. In both the MG and SG groups, the m-NIKBUT was significantly lower than the baseline ($t = 6.516$, $t = 9.463$; both $p < 0.05$). The STI was significantly higher than the baseline ($t = -3.416$, $p < 0.05$) in the SG group but not in the MG group ($t = -1.360$, $p = 0.182$). There were no differences in any of the parameters between the groups before the test. After the test, no differences were observed in IOP, CCT, and STI between the groups, but a difference was seen in NIKBUT ($t = 5.172$, $p < 0.05$).

Dry eye-related quality of life score

A total of 320 questionnaires were obtained from the 40 HCWs. DEQS values increased with the increase in goggle wearing time (MG-$F = 127.91$, $p < 0.05$; SG-$F = 81.23$, $p < 0.05$). Goggle types and timepoints had no interaction ($F = 2.245$, $p = 0.11$). The MG group attained significantly lower DEQS values at all timepoints than the SG group ($F = 31.05$, $p < 0.05$).

The results of the DEQS completed by all the participants at 240 min are shown in Table 2. The items of painful or sore eyes, ocular fatigue, blurred vision when watching something, problems with eyes when reading, problems with eyes when watching television or looking at a computer or cell phone, and eye symptoms affect work showed relatively high scores in both groups. Furthermore, painful or sore eyes, ocular fatigue, problems with eyes when watching television or looking at a computer or cell phone, feeling distracted because of eye symptoms, and eye symptoms affect work showed significant differences between the MG and SG groups (*all* $p < 0.05$).

Temperature–humidity index and correlations

The average temperature, relative humidity, and THI of the two groups at each timepoint are shown in Figure 5. THI values increased with the increase in goggle-wearing time (MG-F =

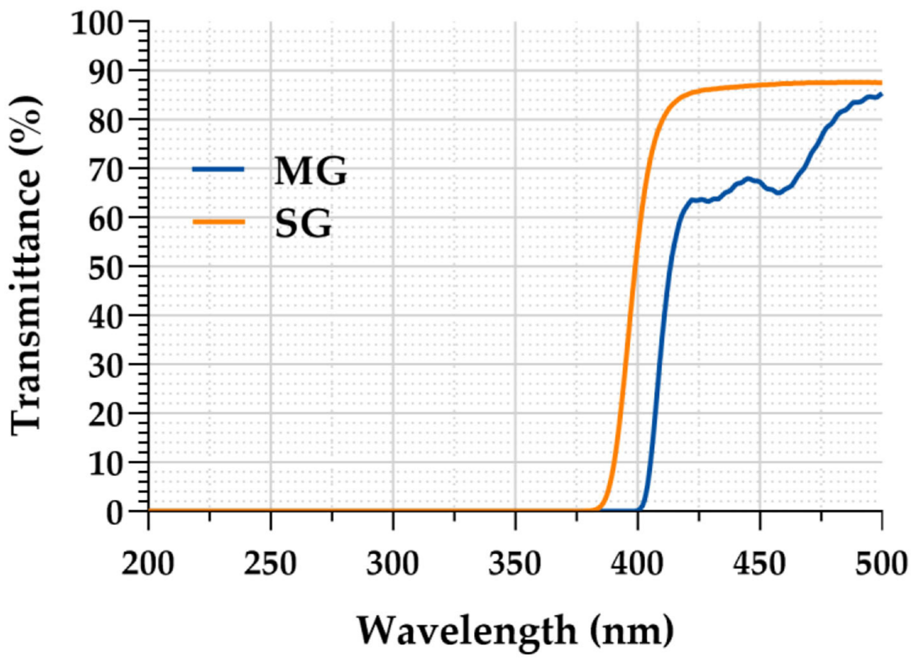

FIGURE 4
Anti-ultraviolet and blue-light capability in light transmittance test.

TABLE 1 Ocular surface index before and after tests between MG group and SG group.

Group		IOP (mmHg)	CCT (um)	NIKBUT (s)	STI (mm)
MG	Before	15.24 ± 1.69	523.60 ± 13.67	12.86 ± 1.07	13.94 ± 2.34
	After	14.70 ± 1.89	531.30 ± 13.31	10.54 ± 1.18*	14.84 ± 1.81
SG	Before	15.22 ± 1.60	529.50 ± 21.09	13.44 ± 1.92	13.27 ± 2.12
	After	14.86 ± 1.86	530.95 ± 21.99	8.43 ± 1.38*	15.41 ± 1.83*
After-*p* value		0.789	0.952	<0.05	0.324

*The parameter was significantly different from the baseline.
IOP is short for intraocular pressure; CCT is short for central corneal thickness, NIKBUT is short for noninvasive keratography tear film break-up time; STI is short for Schirmer test I.

179.95, $p < 0.05$; SG-$F = 123.32$, $p < 0.05$) and were >80 at all timepoints. Goggle types and timepoints had no interaction ($F = 2.20$, $p = 0.129$). The MG group attained significantly lower THI at all timepoints than the SG group ($F = 21.07$, $p < 0.05$).

The relationships and coefficients among THI, temperature, humidity and the above parameters are described in Table 3. The results demonstrated that THI had a stronger correlation with DEQS than temperature or humidity. THI was also negatively related to NIKBUT and r-FT.

Discussion

Increasing evidence supports the possibility of virus transmission through the ocular surface (4, 5). Therefore, the use of goggles as a physical barrier is recommended for HCWs. However, there are no unified medical goggle standards at home or abroad. Low functional goggles have caused great trouble and resulted in injury to HCWs during the epidemic and have also been responsible for more potentially unknown damage. The recommended performances of medical goggles have been reviewed in our previous study (18).

In this study, an MG with antifog, antiultraviolet, and optimal anti-blue-light radiation capabilities was introduced and evaluated *via* function and clinical tests. To the best of our knowledge, this is the first study to propose that goggle-related heat strain acts on the ocular surface (Figure 6). The standard antifog and antiultraviolet goggles manufactured by the 3M company were selected as a control, which makes the research convincing and representative.

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TABLE 2 Results of DEQS items at 240 min-timepoint analysis in MG and SG groups.

Item	MG		SG	
	Average	Proportion	Average	Proportion
Bothersome ocular symptoms				
Foreign body sensation	1.0	4.72%	1.0	3.65%
Dry sensation in eyes	0.3	1.42%	0.3	1.15%
*Painful or sore eyes	2.2	10.38%	2.7	10.36%
*Ocular fatigue	1.9	8.73%	3.1	11.90%
Heavy sensation in eyelids	1.2	5.66%	1.3	4.99%
Redness in eyes	0.3	1.42%	0.2	1.92%
Impact on daily life				
Difficulty opening eyes	0.8	3.54%	0.3	4.80%
Blurred vision when watching something	2.3	10.61%	2.5	9.40%
Sensitivity to bright light	1.5	7.08%	1.4	5.18%
Problems with eyes when reading	2.3	10.61%	2.6	9.79%
*Problems with eyes when watching television or looking at a computer or cell phone	1.9	8.73%	2.6	9.79%
*Feeling distracted because of eye symptoms	1.7	8.02%	2.3	8.64%
*Eye symptoms affect work	1.8	8.49%	2.7	10.17%
Not feeling like going out because of eye symptoms	1.1	5.19%	0.6	2.30%
Feeling depressed because of eye symptoms	1.2	5.42%	1.6	5.95%

*The corresponding parameters showed statistical differences between groups.

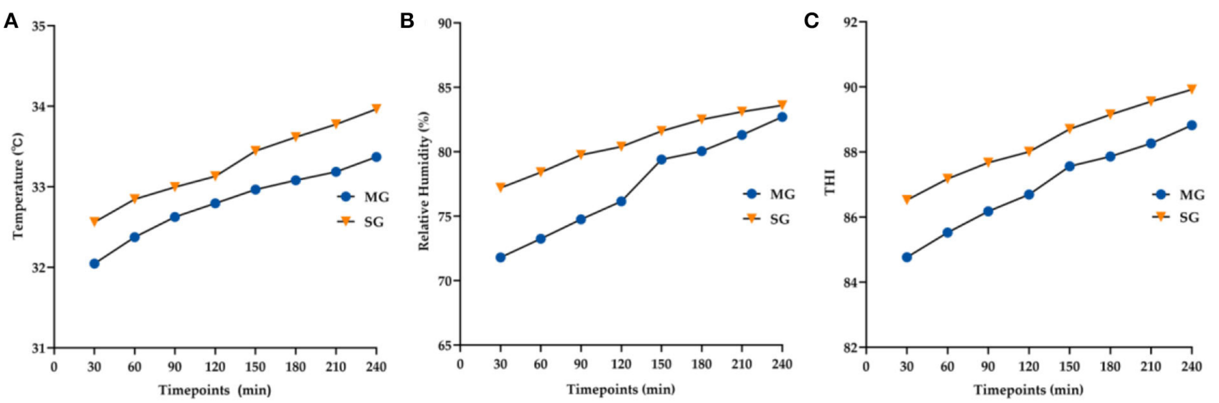

FIGURE 5
Changes in the average temperature **(A)**, relative humidity **(B)**, and THI **(C)** at all time points between the two groups.

In the function tests, the r-FT of MG was 212.75 ± 23.95 min, which was 1.5 times longer than that of SG, mainly due to the specific manufacturing process of the lenses and the optimized main body design that lower both temperature and humidity. Kumar et al. stated that detergent-based surfactant is a low-cost technique that controls the fogging of goggles and provides a longer duration of clear visibility (69.3 ± 8.16 min) than antifog polyethylene terephthalate films and filtered vents (19). However, detergent-based surfactants cause frequent eye irritation and slightly distort the vision if the soap is not properly wiped (20). Bhardwaj et al. opined that a simple solution to the fogging problems is to avoid airflow *via* the application of Micropore^{TM} or other paper-based adhesive tapes to the upper margin of the mask and the skin (21). However, all these methods have limited antifog effects and involve complicated steps. Our research proved that not only should the antifog capacity of the lens be optimized but also the temperature and humidity inside the goggles must be simultaneously reduced.

It is well known that wearing goggles for a short time (no more than 20 min) can increase the humidity around the eyelids, thereby reducing the symptoms of dry eye disease and meibomian gland dysfunction (14, 22). However, whether exposure to relatively high humidity and temperature for a long time (more than 4 h, the normal shift time) affects the ocular surface has not yet been examined. Research has shown that extended exposure to temperatures >25°C along with high humidity can cause heat strain to the human body, especially the cardiovascular, central nervous, and skeletal muscle systems, and result in fatigue development (12, 17). Environmental factors (temperature, humidity, wind velocity, and solar radiation), task-dependent factors (e.g., metabolic rate and clothing), and individual factors (e.g., age, sex, body mass, morphology, and aerobic fitness) are involved in heat strain (12). Air movement inside the goggles is low, the indoor solar radiation is effectively blocked, and the work intensity and clothing were controlled by the test. Hence, THI (a formula involving only temperature and humidity) was selected to measure the heat strain inside the goggles rather than other usual indicators, such as the universal thermal climate index and predicted heat strain. The THI was initially developed to quantify the discomfort felt by a human during the summer and was later extended to estimate the heat stress on livestock (23, 24). Unexpectedly, it was found that during the 4 h of wearing the goggles, the eyes were exposed to a moderate to strong heat strain ($80 \leq THI \leq 89$) at all time points

TABLE 3 Relationships and coefficients between the parameters and THI, temperature, humidity.

Coefficients	THI	Temperature	Humidity
DEQS	0.876*	0.740*	0.807*
IOP	−0.218	−0.221	0.119
CCT	0.161	0.223	−0.094
NIKBUT	−0.532*	−0.461*	−0.267
STI	0.276	0.271	−0.069
r-FT	−0.406*	−0.368*	−0.204

*The corresponding parameters showed significant statistical relationships.

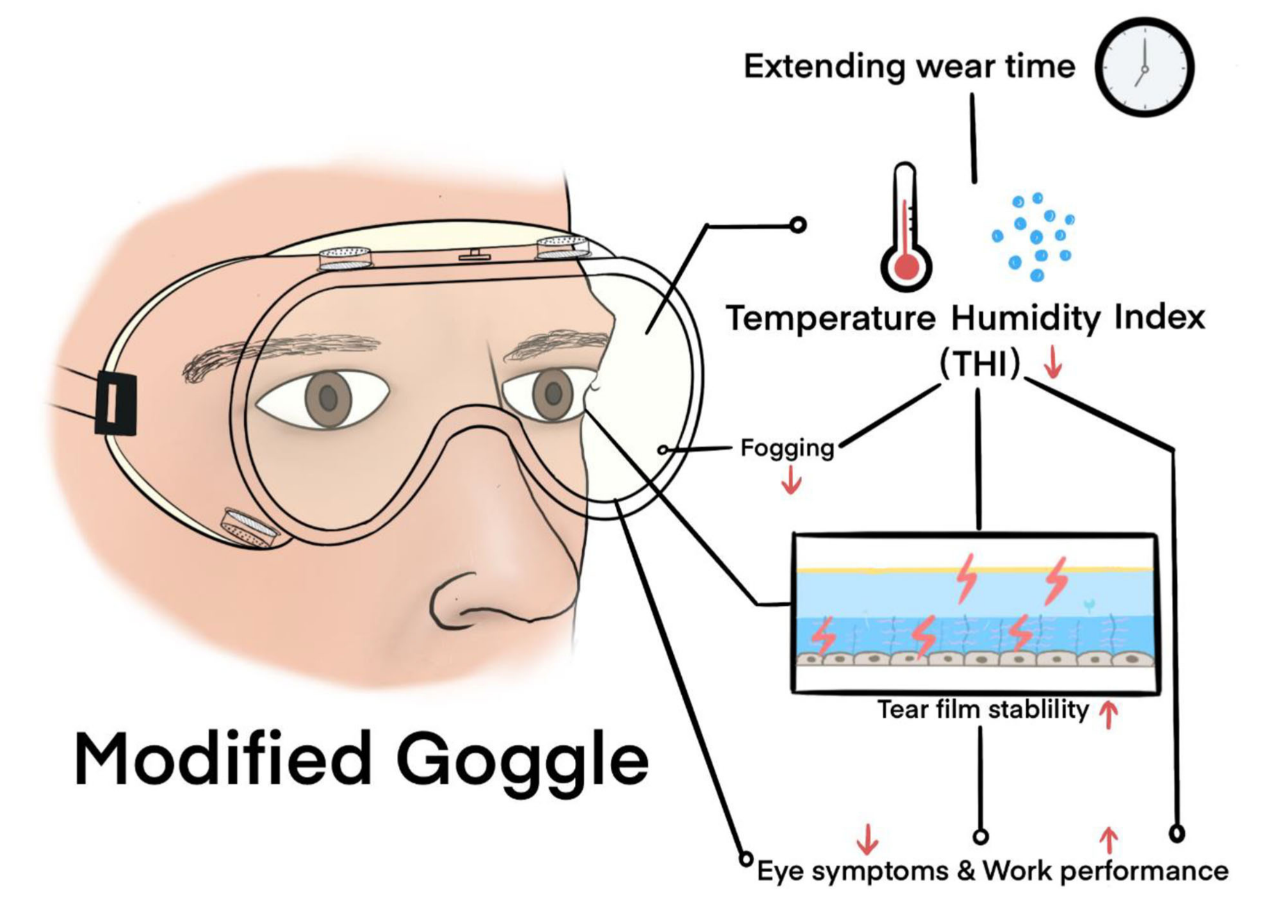

FIGURE 6
The possible clinical mechanisms of heat strain to the eye and preferable effect of MG.

and that THI increased gradually with the extension of wearing time to a very strong strain (>89).

The DEQS was used to evaluate the subjective symptoms of the participants. Although the ocular surface disease index is widely used to diagnose and evaluate the symptom severity, it does not fully cover the effect on the lives of the subjects (16). Therefore, the DEQS questionnaire was selected. Bongers et al. observed that HCWs experienced approximately 25 times greater heat strain symptoms while performing medical duties with PPE (93% of HCWs) than that without PPE (30% HCWs) (13). The reported heat strain symptoms include thirst, fatigue, (excessive) sweating, and uncomfortable warmth. Their effects are slower work performance and less accurate execution of work activities (25). According to the results of our questionnaire, painful or sore eyes and ocular fatigue were the main eye symptoms. Others included the impact of blurred vision when watching something, problems with eyes when reading, problems with eyes when watching television or looking at a computer or cell phone, and eye symptoms affecting work. Our study revealed that the alterations in DEQS were significantly related to THI, with an r_p value of 0.876. This finding suggests that heat strain causes eye and eye-related systemic symptoms. The MG group showed significantly lower DEQS and THI than the SG group at all time points, which is indicative of a superior wearing experience.

To further study the effect of heat strain on ocular surface function, the ocular surfaces of the 40 participants who wore goggles for four consecutive hours were clinically evaluated. IOP and CCTs did not reveal any significant intergroup differences. However, a significant decrease in NIKBUT occurred in each group, which agrees with the results of Vera et al. (26). Tear film breakup results from the linear thinning of the tear film between blinks, which may be due to the flow of tears in three directions: outward (i.e., evaporation), the inward flow of water into the corneal epithelium, and tangential flow along the surface of the epithelium (27). The normal reference value for human central corneal temperature is $32.6 \pm 0.70^{\circ}$C (28). In our study, the temperature inside the goggles exceeded the critical value after wearing them for 30–60 min, which might have led to the evaporation of tears on the ocular surface and the instability of the tear film. Correlation analysis further confirmed that NIKBUT showed a significant negative correlation with THI and temperature. Although there was no significant correlation between high humidity (>70%) and the decrease in NIKBUT, the following direct or indirect evidence revealed that appropriate humidity was necessary to tear film stability. First, a previous study demonstrated that the humidity decreases by 5% in 1 h when the temperature remains unchanged and that the tear film rupture time is significantly shortened (29). Second, the tear film remained stable when the temperature exceeded this value in summer and the humidity was 30–60%. In addition, the STI was found to increase significantly in only the SG group, but no significant correlation with THI was seen. Hence, it was speculated that ocular fatigue caused by heat strain or pungent odor resulted in lacrimal reflex secretion. The sample size needs to be further increased. In general, the results showed that wearing the goggles for 4 h affected the microenvironment of the ocular surface. The MG showed a better subjective feeling, which could be attributed to fewer changes in ocular surface functions caused by the heat strain.

The pressure on the face also affects comfort and is highly related to the material of the skin-contact surface. The silicone rubber, which is more skin-friendly and has a lower coefficient of friction than polyethylene, was used (30). The one-way valve that allows the HCWs to use a sterile cotton swab to tickle without removing the goggles is an important humanized design.

Finally, ultraviolet and blue light are often overlooked in medical settings. The use of ultraviolet light for disinfection is quite common and harms the eye and the surrounding skin (8–10). Many electronic devices transmit blue light (420–460 nm), which harms the oculus (31). Compared with the SG, the MG exhibited a stronger blocking performance of ultraviolet and blue-light radiation, thereby preventing potential damage to the eyes. Our previous study confirmed that shielding approximately 30% of the blue light can improve the accommodation of the human eye and ocular fatigue (32, 33). The data from the MG group showed that the scores for painful or sore eyes, ocular fatigue, problems with eyes when watching television or looking at a computer or cell phone, and eye symptoms affecting work were significantly lower than those of the SG group, which could also be attributed to the optimal anti-blue-light performance of the lens.

In conclusion, the MG showed improvements in several aspects compared with the SG, but some problems still exist. For example, (I) the antivirus capability is hard to test; (II) the main body of the goggles should be transparent to expand the field of view; (III) lack of objective examinations, such as *in vivo* confocal microscopy, to detect the morphologic changes in all kinds of cells under heat strain; (IV) in the real environment, the shortage of medical staff increases the continuous working hours and the activity associated with heavy tasks, thus leading to a greater degree of heat strain to the eye than that reported in this study; (V) the humidity and temperature inside the goggle need to be decreased further to relieve heat strain; (VI) the molecular mechanism of heat strain on the ocular surface needs further elucidation.

The findings from this study establish that the MG exhibits better antifog, antiultraviolet, and optimal anti-blue-light performance and lower heat strain than the SG. The heat strain to the eyes of HCWs caused by the wearing of goggles for a long time in medical settings cannot be ignored. Optimizing the goggles and formulating medical goggle standards are, hence, required.

Data availability statement

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

Ethics statement

The studies involving human participants were reviewed and approved by the Medical Ethical Committee of Tongji Hospital affiliated to Tongji University. The patients/participants provided their written informed consent to participate in this study.

Author contributions

This work is the result of collaboration with JW and PW. YB and LZ: conception and review. JS and XL: clinical operation. YS: methodology, formal analysis, and writing. YB: funding acquisition. 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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Hearing loss and its associated factors among metal workshop workers at Gondar city, Northwest Ethiopia

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Introduction: Noise-induced hearing loss is a permanent sensorineural deficiency, which is caused by exposure to excessive noise sound. Although noise-induced hearing loss due to industrialization is a main public health problem in Ethiopia, studies on the prevalence and associated factors of hearing loss are scarce.

Objectives: This study aimed to assess the prevalence and associated factors of hearing loss among workers at a metal workshop in Gondar city, Northwest Ethiopia.

Methods: A cross-sectional study was employed among 300 participants using a stratified sampling technique. Data were collected using an interviewer-administered questionnaire. Bivariable and multivariable logistic regressions were conducted. In the multivariable logistic regression model, adjusted odds ratios (AOR) with a 95% confidence interval (CI) and a $p < 0.05$ were computed to determine the level of significance.

Results: The prevalence of hearing loss among metal workshop workers was 30.7% [95% CI: (25.7, 35.7)]. Age between 30 and 44 years [AOR = 2.9; 95% CI: 1.2, 7.1], age between 45 and 65 years [AOR = 3.8; 95% CI (1.5, 9.5)], cigarette smoking [AOR = 2.3; 95% CI: 1.2, 4.5], working area noise level >85 dB [AOR = 2.2; 95% CI: 1.1, 6.5], working experience of 6–10 years [AOR = 1.8; 95% CI: 1.4, 6.0], working experience >10 years [AOR = 3.5; 95% CI: 1.3, 4.3], and using ear protection devices [AOR = 0.3; 95% CI: 0.1, 0.6] were significantly associated with hearing loss.

Conclusion: The prevalence of hearing loss was considerably high. This study revealed that advanced age, cigarette smoking, increased working area noise level, and working experiences were found to increase the odds of having hearing loss. Therefore, it is important to emphasize metal workshop workers that are at high risk of hearing loss and develop preventive strategies to reduce the burden of this problem. Besides, minimizing working area noise levels, proper utilization of ear protection devices, and creating awareness about the impact of hearing loss are recommended.

KEYWORDS

hearing loss, metalworkers, associated factors, Gondar city, audiometer

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Introduction

Hearing loss is defined as if an individual has a threshold level of ≥25 dBA at the frequencies 250, 500, 1,000, 2,000, 4,000, and 8,000 Hz (1). Noise-induced hearing loss (NIHL) is a permanent sensorineural deficiency, which is caused by exposure to excessive noise sound (2). Hearing impairment due to occupational noise exposure is an important public health concern throughout the world (3, 4). Indeed, exposure to various sound sources including metal industries, nightclubs, bars, cinemas, concerts, and live sporting events increases the likelihood of developing hearing loss (5).

Previous studies have confirmed that exposure to a noise level of more than 85 dB can lead to an increased risk of hearing loss (6). Interestingly, mechanical damage to the cochlea is the main pathological change, which occurs as the result of the high intensity of noise. The hair cells in the organ of Corti are directly affected by the high intensity of continuous sound causing the constriction of cochlear blood vessels. This leads to a decrease in the flow of blood to the cochlea and causes ischemia and hypoxia of hair cells (7, 8).

Globally, about 16% of disabling hearing loss in adults is due to occupational-related noise (3). Studies conducted in the United States revealed that about 33% of workers are potentially affected by occupational noise-induced hearing loss (9). In Canada, 35% of metal workshop workers experienced noise-induced hearing loss (10) and in Japan, 61.5% of participants experienced this problem (11). Noise-induced hearing loss due to excessive noise levels was high in different countries, for instance, it was 30.4% in Nepal (12), 35.0% in Jordan (13), and 38% in a study conducted in Saudi Arabia (14). Noise-induced hearing loss in Botswana accounts for 78% of all metal workshop workers (15). In Sudan, about 62.5, 10, and 12.5% of metal workers develop noise-induced hearing loss in the bilateral ear, right, and left ear, respectively (16). Hearing loss is the 4th main root cause of disability, with an estimated yearly cost of ≥750 billion dollars (17).

Workplace noise exposure shows a significant financial and health impact on individuals and society levels (18, 19). It has also a major psychosocial impact on individuals' daily life. Furthermore, several studies showed that individuals with hearing loss are prone to social isolation, impaired communication with coworkers and family, decreased ability to monitor the work environment, decreased self-esteem, and loss of productivity (16, 20).

Based on previous studies, factors that are associated with hearing loss include occupational noise in the workplace (21), duration of exposure and intensity of working area noise level (22), cigarette smoking (23), age (24), the use of ototoxic medicines (e.g., aminoglycosides), head injury, and chronic ear infection (25, 26). Different studies revealed that minimizing working area noise levels, use of ear protective devices, and creating awareness about the consequence of hearing loss for employers were important means to minimize the risk of acquiring occupational noise-induced hearing loss (3, 27).

Nowadays, hearing loss due to industrialization is a main public health problem in Sub-Saharan Africa, particularly in Ethiopia (12). Although the number of metal workshops in Ethiopia have increased to meet the rising demand for different infrastructures, the level of occupational noise exposure is still not clear. Besides, studies showing the prevalence of hearing loss among metal workshop workers are scarce. Therefore, this study aimed to determine the prevalence of hearing loss and its associated factors among metal workers in Gondar city.

Materials and methods

Study setting, design, and period

A cross-sectional study was conducted among workers at a metal workshop in Gondar city from March to May 2021. Gondar is one of the historical cities in the country and is located in the Central Gondar Zone of the Amhara National Regional State. It is far around 750 km from Addis Ababa, the capital city of Ethiopia. Based on the Gondar city trade and industry office report, a total of 409 employees are found in 46 metal workshops.

Population

All metal factory workers at Gondar city were the source of population. All metal workshop workers who are presented in the study area during the study period were included in the study population.

Eligibility criteria

All adult metal workshop workers whose age is ≥18 years and working in the metal factory at least for 6 months were eligible to participate in the study.

Sample size determination and sampling procedure

The sample size of the study was determined using a single population proportion formula by considering: the confidence level (95%), the margin of error = 5%, and the prevalence of hearing loss = 28.2% taken from the previous study done in Nigeria (28) since no previous similar study done in Ethiopia. By adding a 5% non-response rate, the required sample size was 328. A stratified random sampling technique was performed to select the study participants. All metal workshops were stratified by the working area noise level. A total of 328 metal workshop workers were selected by using a simple random technique in all-metal workshops after proportion allocation was made.

Study variables

The dependent variable *for this study was* hearing loss (yes/no). Socio-demographic factors such as sex, age, educational status, marital status, and monthly income were assessed. Behavioral and working area-related behaviors like cigarette smoking, alcohol intake, utilization of hearing protection devices (earmuff, and earplugs), work experience, duration of exposure, the intensity of exposure, leisure-time noise exposure, and working area noise level were also assessed.

Operational definitions

Metal workshop workers

Those workers who were making metal welding, cutting, and reshaping to create useful objects.

Hearing loss

It was diagnosed if an individual has a threshold level of ≥25 dBA at the frequencies 250, 500, 1,000, 2,000, 4,000, and 8,000 Hz as measured by an audiometer test (5).

Working area noise levels

Workers who are exposed to ≥85 dB are at higher risk of developing hearing loss.

Cigarette smoking

Metal workshop workers who reported smoking at least for 6 months.

Alcohol consumption

Participants who drunk any alcohol at least 1 time per day for 1 year.

Data collection tools and procedures

Data on socio-demographic and behavioral factors like age, sex, marital status, educational status, income, cigarette smoking, and alcohol consumption were collected by interviewing the metal workshop workers using structured interviewer-administered questionnaires. The questionnaire was initially developed in English, translated into the local language (Amharic), and then translated back into English by experts who are fluent in both languages. Participants were interviewed by four Bsc nurses under the supervision of a principal investigator. Two types of instruments used for measuring sound levels were the sound level meter (model, SL-5868I) (in the recording of the noise levels in several metal workshops) and the pure-tone audiometer (to evaluate the hearing threshold of participants).

Physical measurements

Working area noise level measurement

The environment noise (working area noise level) was measured in work stations using the sound level meter (model, SL-5868I) with a measurement range between 25 and 130 dB. In this study, the sound level meter was calibrated before and after each use and workplace noise level measurements were taken on slow response. The device was placed at an approximate distance of at least 1 m from the noise source. The audiologist holds the device by facing the microphone toward the noise source and observed the measurement on the liquid crystal display. The working area noise level was measured as an average value of 5 measurements hourly throughout working times for 8 h since the production process was inconsistent, and 8-h time-weighted average was taken. Lastly, the mean working area noise level of 8-h time-weighted average on five different days was taken for each working area (29).

Audiometric measurements

Pure-tone audiometer calibration was done daily using supposedly normal people with normal hearing prior to any audiological evaluation of the participants. All audiometric tests were done in a quiet room with a background noise level of 36–40 dB before the workers entered their work stations to avoid the effects of temporary threshold shifts, due to continuous noise exposure inside the working area. Participants were advised of a planned audiometric test, therefore, they can have a "quiet time" or "acoustic rest" of ideally 16 h before the audiometric test (30). The participants were thoroughly instructed about the test and asked to sit still and not to talk. Earphones were placed on the participant's ears. The earphones are connected to the machine that will deliver the tones and different sounds of speech to the participant's ear. Participants were familiarized with the signal before threshold determination by presenting a signal of sufficient intensity to evoke a clear response. The right and left ears of participants were tested consequently by adjusting the audiometer machine. Then, participants were asked to press the pointer of the audiometer when they heard the sound and the audiologist records the hearing threshold level in dB at a frequency of 250, 500, 1,000, 2,000, 4,000, and 8,000 HZ. Three consecutive audiometric measurements were performed before the workers entered their workstations. The average audiometric measurement of the three consecutive records was analyzed. Finally, hearing loss was diagnosed if an individual has a threshold level of ≥25 dBA at the frequencies 250, 500, 1,000, 2,000, 4,000, and 8,000 Hz (5).

Anthropometric measurements

The height of metal workshop workers was measured with calibrated height measuring steel attached to the beam balance in a standing upright position with bare feet. Participants' weight was also measured using a calibrated weight scale and recorded accurately to 100 g. Body mass index was calculated based on the result of anthropometric measurements and it was categorized as underweight (<18.5 kg/m^2), normal (18.5–24.99 kg/m^2), overweight (25–29.99 kg/m^2), and obese (≥30 kg/m^2).

Data quality control

To ensure data quality, 2-day training was given for data collectors. Pretesting of the questionnaire was done with 5% of metal workshop workers at Dabat town to ensure its validity. Daily close supervision of the data collectors was made by the principal investigator during the data collection period. The data were checked for completeness and consistency before entry.

Data processing and analysis

After data collection, data were entered into Epi data 4.6 and then exported into Statistical Package for Social Sciences (SPSS) version 25 software for analysis. Descriptive statistics (mean, median, frequency, percentage, interquartile range) were used to summarize the characteristics of the study population through tables and charts. The normality of continuous data was checked by the Shapiro-Wilk test ($p = 0.001$). The Hosmer–Lemeshow test was done to assess model goodness-of-fit ($p \geq 0.05$). Independent variables having a $p \leq 0.2$ in bi-variable analyses were included in the multivariable analysis to control confounders in binary logistic regression models. An odds ratio (OR) at a 95% confidence interval (CI) was determined to see the strength of association between the independent variables and outcome variables. Factors with a $p \leq 0.05$ in the multi-variable regression model were considered statistically significant.

Results

Socio-demographic and anthropometric characteristics

A total of 300 metalworkers participated in this study with a response rate of 91.5%. A majority (94.4%) of study participants were males. The median age of the participants was 35 years with an interquartile range of 16. Nearly 47% of study participants were unmarried. Regarding educational status, about one-third (35.3%) of participants were diplomas and above. A majority (92.4%) of the participants had a normal body mass index (Table 1).

Behavioral and work-related characteristics

About one-third (34.7%) of the participants were smokers. One-third (34%) of the participants had more than 10 years of working experience. Among the total metal workers, about 57.3% of participants have not used ear protection devices and nearly half (52%) of the participants were exposed to noise levels >85 dB (Table 2).

Prevalence of hearing loss among metal workers

In this study, the prevalence of hearing loss among metalworkers was found to be 30.7% (95% CI: 25.7, 35.7). In addition, 23.7% of participants had bilateral hearing loss, whereas 7% had unilateral hearing loss (3.7% right ear, and 3.3% left ear) (Figure 1). Regarding the degree of hearing loss, about 17, 11, and 2.7% of participants had a mild, moderate, and severe form of hearing loss, respectively (Figure 2).

Factors associated with hearing loss

In the bivariable analysis: work experience, working area noise level, age, cigarette smoking, alcohol intake, listening to music, and use of ear protection devices were significantly associated with hearing loss. However, in multivariable binary logistic regression analysis: only age, working experience, use of ear protection devices, smoking, and working area noise level were identified as statistically significant risk factors for hearing loss (Table 3).

Metal workshop workers in the age group between 45 and 65 years were 3.8 times more likely to develop hearing loss when compared to those in the age group between 18 and 29 years (AOR = 3.8; 95% CI: 1.5, 9.5). Similarly, the likelihood of hearing loss among metal workshop workers in the age group between 30 and 44 years was 2.9 times higher compared to those in the age group between 18 and 29 years (AOR = 2.9; 95% CI: 1.2, 7.1). Participants who had more than 10 years of working experience were 3.5 times more likely to have a hearing loss than those participants who had 1–5 years (AOR = 3.5; 95% CI: 1.3, 4.3). Participants with working experience of between 6 and 10 years were 1.8 times higher to have hearing loss as compared to those participants between 1 and 5 years [AOR = 1.8; 95% CI: (1.4, 6.0)]. Participants who used ear protection devices were 70% less likely to develop hearing loss as compared to those who

TABLE 1 Socio-demographic and anthropometric characteristics of study participants among metal workers in Gondar city, Northwest Ethiopia, 2021.

Variables	Category	Frequency	Percentage
Sex	Male	283	94.3
	Female	17	5.7
Age in years	18–29	103	34.4
	30–44	106	35.3
	45–65	91	30.3
Average monthly income (Ethiopian birr)	<1,500	17	6
	1,500–2,000	27	9
	2,001–3,200	120	40
	>3,200	136	45
Marital status	Single	139	46.3
	Married	125	41.7
	Divorced	20	7
	Widow	16	5
Educational levels	Illiterate	18	6
	Primary school	83	27.7
	Secondary school	93	31
	Diploma and above	106	35.3
BMI(kg/m^2)	<18.5	3	1
	18.5–24.9	277	92.4
	25–29.5	20	6.6

TABLE 2 Behavioral and work-related characteristics of study participants among metal workers in Gondar city, Northwest Ethiopia, 2021.

Variables	Category	Frequency	Percentage
Previous working experience	Military	37	12.3
	Mining	50	16.7
	Construction	15	5
	Garage	46	15.3
	Others*	152	50.7
Current working experience (in years)	1–5	107	36
	6–10	90	30
	>10	102	34
Music listing with earphones	Yes	101	33.7
	No	199	66.3
Working area noise level (dB)	<85	143	47.3
	≥85	157	52.7
Alcohol consumption	Yes	117	39
	No	183	61
Smoking cigarette	Yes	107	34.7
	No	193	65.3
Use of ear protection devices	Yes	127	42.7
	No	173	57.3

*Students, merchants, farmers.

did not use ear protection devices (AOR = 0.3; 95% CI: 0.1, 0.6). Metalworkers who were exposed to a working area noise level of more than 85 dB had 2.2-fold higher odds of hearing loss than those who were exposed to <85 dB (AOR = 2.2; 95% CI: 1.1, 6.5). A smoker had a 2.3 times higher chance of developing hearing loss as compared to non-smokers (AOR = 2.3; 95% CI: 1.2, 4.5) (Table 3).

Discussion

The purpose of the present study was to assess the prevalence of hearing loss among metal workshop workers and its associated factors in Gondar city. In this study, the overall prevalence of hearing loss was 30.7% (95% CI: 25.7, 35.7). This finding is similar to previous studies done in Nepal (30.4%) (12), Rwanda (35%) (31), and Nigeria (26%) (32). This might be due to the similarity of the study design used and the working-related characteristics of participants. However, the values obtained as results of this study are lower than other studies conducted in Malaysia (73.3%) (33), Thailand (40%) (34), Tanzania (48%) (5), and Zimbabwe (37%) (35). The possible reason for this difference might be due to variation in working area noise level, type, and the number of machines used. This finding is higher than previous studies done in Gondar (20.7%) (36) and Addis Ababa, Ethiopia (22%) (37). The possible reason for the difference between the current study and a study conducted in Gondar might be due to the discrepancy in methods used (the use of audiometer tests in our study may have increased the burden of hearing loss) and study population (since the previous studies were conducted among metal and woodwork workers). Besides, the difference between the present study and Addis Ababa could be attributed to the difference in the operational definition of hearing loss (>30 dBA at 4,000 Hz audiometric result in Addis Ababa but ≥25 dBA in our study) and study area. The current finding was also higher than the 2013 WHO global report (15%) (38). This could be due to the variations in noise exposure levels and the implementation of occupational health and safety measures that protect against hearing loss (39).

The present study showed that 23.7% of participants had bilateral hearing loss, whereas 7% had unilateral hearing loss (3.7% right ear and 3.3% left ear). The prevalence of bilateral hearing loss in the current finding is lower than the similar

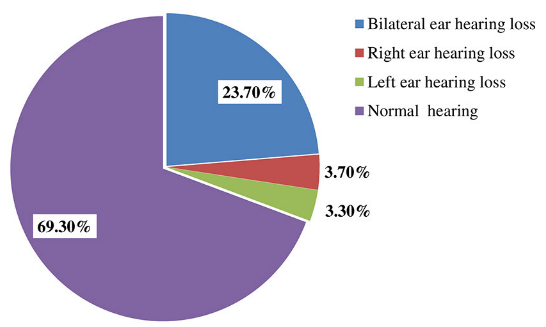

FIGURE 1
The prevalence of hearing loss according to types among metalworkers in Gondar city, Northwest, Ethiopia.

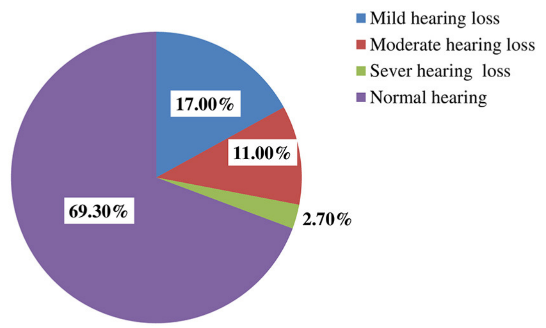

FIGURE 2
The prevalence of hearing loss according to the degree of severity among metalworkers in Gondar city, Northwest, Ethiopia.

findings of a study done in Sudan (62.5%) (40). In both studies, the right ear was more affected than the left ear. The reason for this could be that most of the study participants were right-handed workers whose right ear is closer to the noise source, and hence, received more sound energy, which leads to the possibility of right ear hearing loss (41). This might be also due to noise shielding in the right ear, unequal recovery after excessive noise sound exposure, and unequal sensitivity of both ears and direction of noise exposure.

In this study, factors such as age, working experience, cigarette smoking, and working area noise level were positively associated with hearing loss. However, the use of ear protection devices was negatively associated with hearing loss. The current study revealed that metal workshop workers in the age group between 30 and 44 years and 45 and 65 years were more likely to develop hearing loss when compared to those in the age group between 18 and 29 years. This finding is consistent with the previous studies (24, 34, 42–44). This could be due to the aging effect, which impacts the cochlea of the inner ear in which self-regeneration ability is impaired. As a result, a loss or damage of hair cells could be irreversible and causes permanent hearing loss (38). Moreover, hearing loss might be associated with the primary degeneration of outer hair cells, spiral ganglion cells, and nerve fibers during aging (45).

The finding of this study indicated that participants with a working experience of 6–10 years and above 10 years had a higher chance of developing hearing loss than those participants between 1 and 5 years. This is supported by previous literature done elsewhere (5, 10, 12, 32, 37). The possible reason could be chronic exposure to noise that causes direct mechanical damage to hair cells in the cochlea of the inner ear, which may lead to the generation of toxic free radicals, and eventually result in necrotic and apoptosis cell death (46, 47). However, a study done in Thailand showed that working experience was not significantly associated with hearing loss (34). The possible explanation for this variation could be attributed to the fact that the majority of participants in Thailand were young laborers with a short period of working experience. Additionally, there is also a variation in the implementation of health and occupational safety measures that protect against hearing loss during working hours (48).

The present study indicated that exposure to working area noise levels was associated with hearing loss. Metalworkers who were exposed to the noise level of $\geq$85 dB had higher odds of hearing loss than those who were exposed to <85 dB. Similar findings were found in other studies (5, 21, 34, 35, 37, 49–51). This might be due to the direct mechanical damage and degeneration of hairy cells of the organ of Corti *via* excessive sound (38).

According to the current study, participants who used ear protection devices were less likely to develop hearing loss than their counterparts. This is in line with the previous studies done elsewhere (10, 34, 41, 49). This might be due to the protective effect of ear protection devices that minimize the incoming sound reaching the inner ear (34).

Furthermore, the result of this study showed that the odds of having hearing loss were higher among cigarette smokers than non-smokers. This is supported by the previous studies conducted in Brazil, Japan, and Nepal (12, 22, 23, 42). This might be because cigarette burning releases chemicals including toluene, styrene, and xylene, which have the potential to cause an ototoxic effect on hair cells. In addition, carbon monoxide released from burning cigarettes reduces cochlear blood oxygen levels as it makes the dissociation of oxygen from hemoglobin difficult and leads to hair cell hypoxia and degeneration (11).

The strength of this study was that data were collected from various metalworking areas (Multicenter) allowing us to generalize the findings to all metal workshop workers in Gondar city. This study has some limitations: First, the study did not show the cause and effect relationship since it is a cross-sectional study design. Second, the study did not address extra working significant exposure. Furthermore, the study will be a base for future investigators to perform better study designs like

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TABLE 3 Factors associated with hearing loss among metal workshop workers in Gondar city, Northwest Ethiopia, 2021.

Variables	Category	Hearing loss		COR (95% CI)	AOR (95%CI)
		Yes	No		
Age in years	18–29	11 (10.7%)	92 (89.3%)	1	1
	30–44	29 (27.4%)	77 (72.6%)	3.2 (1.5, 6.7)	2.9 (1.2, 7.1)*
	45–65	52 (52.1%)	39 (42.9%)	11.2(5.3, 23.6)	3.8 (1.5, 9.5)*
Current working experience (years)	1–5	12 (13%)	96 (88.9%)	1	1
	6–10	29 (31.5%)	61 (67.8%)	3.8 (1.8, 8.8)	1.8 (1.4, 6.0)*
	>10	51 (55.4%)	51 (38.2%)	8.0 (4.1, 18.5)	3.5 (1.3, 4.3)**
Music listing with, earphone	Listener	50 (54.3%)	82 (39.4%)	1.8 (1.1, 3.0)	0.8 (0.4, 1.6)
	Non-listener	42 (37.9%)	126 (62.1%)	1	–
Working area noise level (dB)	<85	17 (11.9%)	126 (88.1%)	1	–
	≥85	75 (47.8%)	82 (52.2%)	6.7 (3.7, 12.9)	2.2 (1.1, 6.5)*
Cigarette smoking	Smoker	62 (57.9%)	45 (42.1%)	10.6 (4.4, 22)	2.26 (1.1,4.5)*
	Non-smoker	30 (15.5%)	163 (84.5%)	1	1
Ear protection devices	Used	16 (12.6%)	111 (87.4%)	0.6 (0.3, 0.9)	0.3 (0.1, 0.6)*
	Not used	76 (43.9%)	97 (56.1%)	1	1
Alcohol consumption	Drunker	50 (37%)	85 (63%)	1.72 (1.1, 2.8)	1.23 (0.9, 4.5)
	Non-drunker	42 (25. 5%)	123 (74.5%)	1	1

1= reference category, Hosmer Lemshow = 0.27, $^{*}p \leq 0.05$, $^{**}p \leq 0.001$.

prospective cohort and experimental studies in this setting to bring findings with better validity.

Conclusion

The prevalence of hearing loss among metal workshop workers in Gondar city was relatively high. The study indicated that advanced age, cigarette smoking, high working area noise level, and prolonged working experience were found to increase the odds of having hearing loss among metalworkers. Therefore, it is important to emphasize metal workshop workers that are at high risk of hearing loss and develop preventive strategies to reduce the burden of this problem. This study recommends the proper utilization of ear protection devices. Besides minimizing working area noise levels, proper utilization of ear protection devices and creating awareness about the impact of hearing loss are also recommended.

Data availability statement

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

Ethics statement

The studies involving human participants were reviewed and approved by School of Medicine Ethical Review Committee, College of Medicine and Health Sciences, University of Gondar. The patients/participants provided their written informed consent to participate in this study.

Author contributions

DA and MM conceived and designed the study, participated in the data collection process, analyzed data, and wrote the manuscript. BM and AA participated in data analysis, drafting of the manuscript, and advising the whole research paper and also were involved in the interpretation of the data and contributed to manuscript preparation. All authors read and approved the final manuscript.

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Conflict of interest

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

The reviewer BF declared a shared affiliation with the authors DA, MM, AA, and BM to the handling editor at the time of review.

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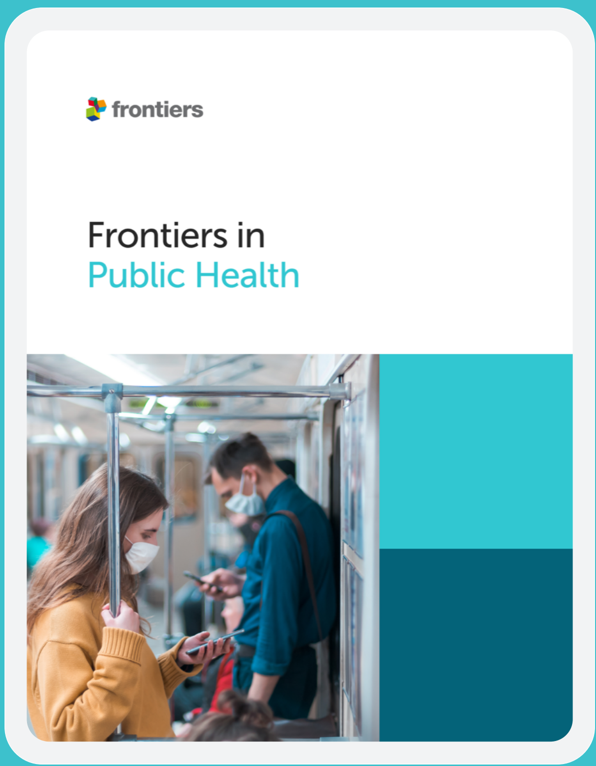

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