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Pneumatic tourniquet work safety scale: A confirmatory factor analysis

Abstract

Objective: Although confirmatory factor analysis is an essential stage in validation of any instrument, the Pneumatic tourniquet work safety scale had not been subject to it. Accordingly, the present study aims to conduct a confirmatory factor analysis of the pneumatic tourniquet work safety scale.

Methods: This psychometric validation study was conducted in three university hospitals in the largest city in the south of Iran in 2024. The study population consisted of 300 operating room nurses in teaching hospitals who used pneumatic tourniquets. The 41-item Pneumatic tourniquet work safety scale, scored using a 5-point Likert scale, was completed by the operating room nurses who were selected by quota sampling. In the present study, to determine the validity and reliability of the scale, the researchers applied confirmatory factor analysis (CFA) and Cronbach's alpha, respectively.

Results: The total Cronbach's alpha of the scale was found to be 0.85. The CFA results validated the seven-subscale structure of the Pneumatic tourniquet work safety scale. These seven subscales are: 'testing the functioning of pneumatic tourniquets', 'contraindications for the use of pneumatic tourniquets', 'considerations on selecting the right cuff', safe application of pneumatic tourniquets before, during and after surgery, and 'record keeping and documentation'. The goodness-of-fit indexes of the factor analysis model of the scale were satisfactory and the value of the Cronbach's alpha confirmed the internal consistency of the items.

Conclusion: Given the satisfactory validity and reliability of the Pneumatic tourniquet work safety scale, administrators should consider adopting the scale as part of guidelines for application of pneumatic tourniquets. Drawing on credible, up-to-date scientific sources, the scale covers various aspects of application of pneumatic tourniquets and can enable all surgical team members to provide higher quality medical care.

Keywords: confirmatory factor analysis, nurses, operating room, pneumatic tourniquet

Introduction

Maintaining patient safety in the operating room is one of the primary concerns of the healthcare system[1]. The primary cause of medical errors in the operating room is the lack of professional healthcare providers and their insufficient competence to work in this environment[2]; furthermore, increasing use of technology in surgeries has escalated the complexity of medical procedures and, by extension, the likelihood of errors[3].

One of the devices used by surgeons to control bleeding, minimise hazards and improve patients' toleration of physiological effects is the pneumatic tourniquet equipped with internal pressure sensors and timers[4]. The United States of America Food and Drug Administration classifies pneumatic tourniquets as Class I medical devices[5]. Because of their safety, accuracy and reliability, pneumatic tourniquets have become very popular in operating rooms. Every day, over 15 000 surgical procedures worldwide are performed using a pneumatic tourniquet[6]. Yet, use of these devices is associated with certain complications, including systemic, cardiovascular, metabolic, thermal and neurological side effects; tissue ischemia; oedema and tourniquet pain syndrome[5]. To ensure patient safety, all surgical personnel must receive thorough instruction on pneumatic tourniquet operation and management[7]. Surgical staff serve as the first advocates and caregivers for patients in the operating room[2].

Studies have been conducted to identify the side effects and hazards of application of pneumatic tourniquets and suggest guidelines to avoid them[8–10]. A standardised, evidence-based assessment tool could significantly improve hazard identification and prevention strategies for pneumatic tourniquet applications, leading to fewer complications and better patient care[11]. Existing tools related to pneumatic tourniquet function primarily evaluate surgeons' knowledge[12–14]; however, pneumatic tourniquet operation is commonly also performed by other surgical team members. Therefore, a general scale for assessing the knowledge and performance of all surgical team members was necessary.

Accordingly, a recent methodological study designed to evaluate operating room personnel's observance of safety protocols in using pneumatic tourniquets has introduced a valid, comprehensive scale for measuring pneumatic tourniquet work safety. All the 41 items of this scale are scored positively on a 5-point Likert scale. The researchers measured the face, content and construct validities of the developed instrument. To test the reliability of the scale, the researchers measured the Cronbach's alpha of the instrument to determine its internal consistency. They used the test–retest method to measure the intraclass correlation of the results and determine the stability of the scale. The construct validity of the instrument was determined via exploratory factor analysis[11]. Exploratory factor analysis (EFA) was applied to determine the internal relationship between the variables and identify the categories of variables which had the most correlation with each other[15].

CFA is regarded as a 'gold standard' test of a measure's factor structure. CFA provides a more stringent test of the latent structure of a measure than does exploratory factor analysis, as it allows for the testing of specific hypotheses about data[16,17]. That is, it explicitly identifies whether the scale items are good measures of the underlying constructs or not[18]. Although CFA is an essential stage in validation of any instrument, the pneumatic tourniquet work safety scale had not been subject to it. Accordingly, the present study was conducted to implement CFA of the scale.

Methods

Study sample

This cross-sectional, psychometric validation study was conducted in three university hospitals in the largest city in the south of Iran in 2024. The sample was selected via quota sampling: after the teaching hospitals were designated as strata, the number of operating room nurses in each hospital was set as the proportion of each stratum. Sampling continued until the quota for each stratum was reached.

In the current study, 300 operating room nurses working in teaching hospitals who used pneumatic tourniquets participated in the CFA of the scale. Having 300 participants meant there was more than seven participants per item of the scale. The inclusion criteria were having at least an associate degree in operating room nursing, having at least six months' experience of practice in the operating room and being willing to participate in the study. The nurses who did not answer all the items on the scale were excluded.

Instrument

The scale comprises 41 items which address seven subscales – 'testing the functioning of pneumatic tourniquets' (5 items), 'contraindications for the use of pneumatic tourniquets' (4 items), 'considerations on selecting the right cuff (3 items), 'safe application of pneumatic tourniquets before surgery' (11 items), 'safe application of pneumatic tourniquets during surgery' (5 items), 'safe application of pneumatic tourniquets after surgery' (4 items) and 'record keeping and documentation' (9 items).

Subscale 1 (testing the functioning of pneumatic tourniquets) addresses tourniquet performance standards, including periodic calibration, cuff condition, connecting tubes, monitor and auditory alarms, device placement and disinfection procedures.

Subscale 2 (contraindications for the use of pneumatic tourniquets) covers conditions with which a tourniquet should not be used including nerve injuries, peripheral venous and blood circulation disorders and skin injuries.

Subscale 3 (considerations on selecting the right cuff) covers appropriate cuff selection based on limb shape, patient age and proper cuff length.

Subscale 4 (safe application of pneumatic tourniquets before surgery) focuses on proper cuff placement and application techniques, including tourniquet pressure adjustment before surgery and limb positioning for blood drainage (upper/lower extremity angles).

Subscale 5 (safe application of pneumatic tourniquets during surgery) addresses safety considerations, including the maximum tourniquet inflation time, checking for possible air leakage, patient physiological responses and the duration of cuff deflation during surgery.

Subscale 6 (safe application of pneumatic tourniquets after surgery) covers post-operative safety assessments such as monitoring vital signs, assessing distal pulses in the limb and evaluating the condition of skin after cuff deflation.

Subscale 7 (record keeping and documentation) pertains to the documentation principles in relation to the pneumatic tourniquet, including recording the device model and registration code, the type of cuff, site of the cuff, the type of padding under the cuff, the applied pressure, inflation and deflation times, limb perfusion status and the patient's skin condition[11].

The items are scored on a 5-point Likert scale, ranging from 'never' (scored as 1) to 'always' (scored as 5). The score range of the scale is between 41 and 205, with higher scores indicating better compliance with pneumatic tourniquet work safety standards (see supplement). In addition to the scale, participants were required to complete the demographic information questionnaire. The demographic questionnaire collected data on gender, age, marital status, educational level, work experience, employment type, experience of complications in using a pneumatic tourniquet and participation in tourniquet safety training workshops.

CFA was then carried out to check whether the scale structure had appropriate goodness-of-fit indices. Assessment of model fit involves considering a number of indices of model fit. To evaluate model fit in CFA, researchers compare goodness-of-fit indices (GFIs) against fixed cut-off

values[19]. Traditional indices for assessing the fit of the model can be grouped into absolute fit indices and relative fit indices. Absolute fit indices measure the discrepancy between a statistical model and the data, whereas relative fit indices measure the discrepancy between two statistical models. Absolute fit indices consist of chi-square (χ2), goodness-of-fit Index (GFI), adjusted goodness-of-fit index (AGFI), root mean square error of approximation (RMSEA) and standardised root mean square residual (SRMR). Relative fit indices consist of Bollen's incremental fit index (IFI), comparative fit index (CFI) and Tucker-Lewis index (TLI)[20]. Researchers are advised to report more than one of the fit indices to support the fit of the hypothesised model[21]. Hu and Bentler[22] recommend SRMR and CFI. Schreiber et al.[23] prefer non-normed fit index (NNFI), CFI and RMSEA. Kline[24] recommends the two GFIs, CFI, RMSEA and SRMR.

In the current research, CFA was performed using LISREL software program version 8.8. The model fit was considered acceptable if the value of chi-square and chi-square divided by degrees of freedom (χ2/df) were less than 3. A GFI, AGFI, IFI, CFI and TLI of above 0.90 indicated good fit and above 0.80 indicated reasonable fit. An RMSEA of below 0.05 indicated good fit and between 0.05 and 0.08 indicated reasonable fit, and an SRMR of below 0.10 was considered good. A parsimony normed fit index (PNFI) and parsimony goodness-of-fit index (PGFI) of greater than 0.50 was considered good[21,22].

Reliability test

To determine the reliability of the scale, the researchers applied the methods for measuring internal consistency and stability.

Internal consistency

The internal consistency of the scale was measured by calculating Cronbach's alpha and the correlation between the even- and odd-numbered items. A Cronbach's alpha of between 0.7 and 0.8 indicates satisfactory internal consistency[25].

To measure the internal consistency of the scale, the researchers used a sample of 300 operating room nurses to determine the Cronbach's alpha of each subscale and of the whole scale.

Table 1: Distribution of demographic variables study participants (N = 300)

Variables		Frequency (%)
Gender	female	203 (67.7)
	male	97 (32.3)
Age	20–30 years	134 (44.7)
	31–40 years	120 (40.0)
	41–50 years	37 (12.3)
	> 50 years	9 (3.0)
Marital status	married	196 (65.3)
	single	104 (34.7)
Educational level	associate degree	21 (7.0)
	bachelor's degree	261 (87.0)
	master's degree	18 (6.0)
Work experience	0–3 years	87 (29.0)
	4–10 years	82 (27.3)
	11–15 years	58 (19.3)
	> 16	73 (24.3)
Employment type	temporary	64 (21.3)
	contractual	47 (15.7)
	permanent	189 (63.0)
Have encountered complications in using a pneumatic tourniquet	no	228 (76.0)
	yes	72 (24.0)
Have participated in training workshops on the safe use of pneumatic tourniquets	no	241 (80.3)
	yes	59 (19.6)

Test–retest reliability

The stability of the instrument was measured via the test–retest method. Accordingly, the scale was completed twice by 30 operating room nurses with an interval of two weeks. Next, the correlation between the two stages was measured using the intraclass correlation coefficient (ICC) index. A correlation of greater than 0.75 is considered as satisfactory[26].

Ethical considerations

The research plan was approved by the ethics committee of Shiraz University of Medical Sciences in Iran (Ethics code: IR.SUMS.NUMIMG.REC.1402.034, grant no: 28220). Prior to data collection, all necessary permissions were obtained from the teaching hospitals affiliated with the university. The researchers informed the participants of the purpose and content of the study and obtained written consent from all the participants before data collection. Participation was voluntary, and the participants were assured that they could withdraw from the study at any time for any reason. To ensure participant confidentiality, anonymous codes were used instead of participant names, and all data were stored in password-protected files. The research was carried out in accordance with relevant guidelines and regulations of the Declaration of Helsinki (as revised in Brazil in 2013).

Table 2: Model fit indices for CFA of the pneumatic tourniquet work safety scale

Fit index	Fitted model	Acceptable values	Great fit values
χ2	1905.74	–	–
df (p)	719 (<0.001)	–	–
χ2/df	2.65	<5	<3
RMSEA (90% CI)	0.074 (0.070–0.077)	<0.08	<0.05
GFI	0.92	>0.90	>0.95
IFI	0.89	>0.90	>0.95
TLI	0.91	>0.90	>0.95
CFI	0.86	>0.90	>0.95
AGFI	0.79	>0.90	>0.95
PNFI	0.86	>0.90	>0.95
SRMR	0.063	<0.08	<0.05
NFI	0.91	>0.90	>0.95
RFI	0.90	>0.90	>0.95

χ2 = chi-square, df = degrees of freedom, p = probability / significance level, RMSEA = root mean square error of approximation, CI = confidence interval, GFI = goodness-of-fit Index, IFI = Bollen's incremental fit index , TLI = Tucker-Lewis index, CFI = comparative fit index, AGFI = adjusted goodness-of-fit index, PNFI = parsimony normed fit index, SRMR = standardised root mean square residual, NFI = normed fit index, RFI = relative fit index.

Results

Demographic characteristics

The participants of the study consisted of 300 operating room nurses with the average age of 33.66 years. The majority of the nurses were female (67.7%), had a bachelor's degree (87.0%) and were permanent employees (63.0%) (Table 1).

Confirmatory factor analysis

The 41-item scale with seven subscales, as confirmed by exploratory factor analysis, was subject to a CFA model run in LISREL software version 8.8. The model fit of the 41-items is shown in Figure 1. Modification indices suggested correlations between certain items, and this error covariance was added to the model.

The CFA model with seven subscales and 41 items in LISREL yielded promising results in terms of construct validity. The fit indices, GFI, CFI, TLI and RMSEA, indicated a good fit of the model to the data. Overall, the index fit of the CFA model was acceptable. The index fit of the model was as follows: $\chi2 = 1905.74$ ($df = 719$, $P < 0.001$), $\chi2/df = 2.65$, RMSEA = 0.074 (90%CI = (0.070; 0.078), $P < 0.001$), SRMR=0.063, GFI = 0.925, IFI = 0.89, TLI = 0.91, CFI = 0.86, PGFI = 0.790, AGFI = 0.866, RFI=0.90, NFI=0.91 (Table 2).

The factor loadings of all the items were statistically significant, ranging from 0.30 to 0.99, suggesting a strong relationship between the items and their respective subscales. The standardised factor loadings further supported the distinctiveness of the subscales, with minimal cross-loading of items on multiple subscales.

The measurement model demonstrated satisfactory discriminant validity, as evidenced by the low correlations between the subscales and the high average variance values for each subscale. This suggests that the subscales are measuring distinct constructs.

Internal consistency was measured using Cronbach's alpha, and the overall alpha coefficient indicated high levels of internal consistency among the items. The test–retest reliability results further confirmed the questionnaire's stability and reproducibility.

The total Cronbach's alpha coefficient of the 41-item scale was 0.851. The Cronbach's alpha coefficients of the seven dimensions of the questionnaire ranged from 0.489 to 0.728. A split-half reliability (Spearman–Brown coefficient) of 0.741 further confirmed the internal consistency and reliability of the scale. Based on the results of test–retest reliability, the ICC of the 41-item scale was 0.851 ($p < 0.001$), and the ICCs of the subscales were 0.51 ($p < 0.001$), 0.69 ($p < 0.001$), 0.70 ($p = 0.010$), 0.59 ($p < 0.001$), 0.67 ($p = 0.010$), 0.56 ($p = 0.021$) and 0.69 ($p < 0.001$) respectively. The Pearson's correlation coefficient (r) of the 41-item scale was found to be 0.814. The Pearson's r of the subscales were 0.191, 0.341, 0.286, 0.132, 0.236, 0.357, and 0.294, respectively (Table3).

Discussion

The present study is a CFA of a comprehensive instrument designed to measure safety and work standards in the application of pneumatic tourniquets across all members of the surgical team. The results validated the instrument's validity and reliability, highlighting the significance of standardised practices for enhancing patient safety and improving outcomes in surgical procedures involving these devices.

Since the factor loadings of items 3, 5, 16 and 19 were less than 0.35, those items were omitted. All the items whose factor loadings were greater than 0.35 and were more related to the scale were retained. Although items with factor loadings less than 0.35 should typically be removed to enhance scale validity, modifications (e.g. item removal) in this study were grounded in theoretical rationale, not solely statistical criteria, to avoid exploratory bias. To preserve content coverage and construct representation, items with low factor loadings were further evaluated by an expert panel.

Item 3 referred to placement of the device and was recommended for removal by the expert panel. The panel determined that its content was not consistently applicable in all clinical environments, since operating rooms use centralised tourniquet systems lacking these features; therefore, the expert panel recommended its removal.

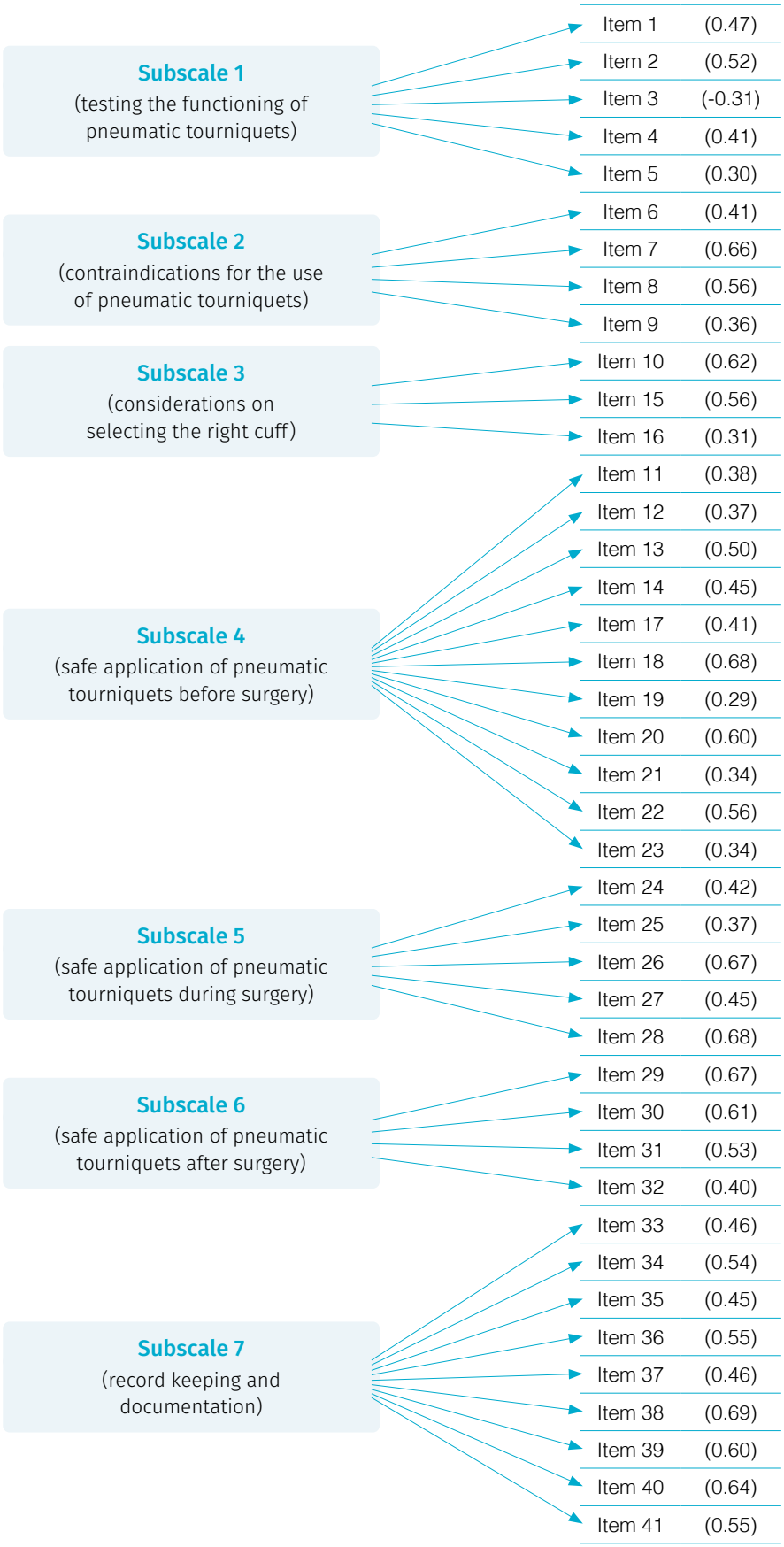

Figure 1: Path diagram of CFA of the pneumatic tourniquet work safety scale

Item 5 pertained to disinfecting reusable cuffs. Given their infrequent use in operating rooms and conceptual overlap with Item 2, which covers checking the tourniquet cuff, this item was also removed based on the panel's consensus.

Item 16, about where on the limb the cuff was fastened, was eliminated due to its alignment with items related to selecting appropriate cuff sizes

Item 19, addressing tourniquet pressure confirmation, was redundant with items 23 and 24, about setting tourniquet pressure and maximum inflation duration, and thus removed.

The deleted items were either redundant, specific to certain operating room setups, or peripheral to the core construct. Therefore, their removal is unlikely to compromise the scale's content coverage.

The CFA results demonstrated a strong fit for the proposed measurement model, indicating that the 41 items on the work safety scale reliably measured distinct yet related constructs. Robust factor loadings supported the theoretical foundation of the scale, in line with the existing literature on pneumatic devices. This validates the scale's ability to reflect the multifaceted aspects of application of pneumatic tourniquets, including safety, effectiveness and user experience.

The model identified seven key factors or subscales that emerged from the data. These factors show that a comprehensive evaluation of pneumatic tourniquets should address user interaction and effectiveness of training, which can ultimately enhance patient safety. The first subscale addresses the protocols for testing the functioning of pneumatic tourniquets. These protocols are intended to increase the lifetime and efficacy of these medical devices.

The validation of the instrument is consistent with the existing literature on safety practices by surgical teams. For instance, studies by Urban et al.[27] and von Vogelsang et al.[28] emphasise the role of standardised protocols and team communication in improving surgical outcomes. The results of the present study show how these elements interact and contribute to overall safety in the specific context of pneumatic tourniquet application.

The findings of the current study are consistent with those of Pevec et al.[29], who conducted a similar CFA of surgical instrument safety standards. They identified comparable dimensions, including 'user proficiency' and 'compliance with protocols,' indicating a consensus on the guidelines for safe medical device usage. Similarly, Khazaei et al.[30] assessed work standards in emergency medical equipment and found that training and efficiency directly influenced outcomes, further underscoring the importance of comprehensive training programs.

The validated Pneumatic tourniquet work safety scale can be used as a vital tool by clinical facilities seeking to enhance the performance of their personnel and safety of pneumatic tourniquets. By addressing the identified factors from the analysis, healthcare organisations can develop training curricula that emphasise critical skills and knowledge essential for effective use of these devices. This is particularly pertinent given that several studies have shown that insufficient user training is a leading cause of incidents involving pneumatic tourniquets[26,27].

Moreover, hospitals could use these findings to establish performance protocols and quality improvement initiatives, fostering an environment of ongoing assessment and refinement. The establishment of a feedback mechanism wherein healthcare professionals can report their experiences with using pneumatic tourniquets could further inform updates to training materials and operational protocols[31].

Given the satisfactory validity and reliability of the Pneumatic tourniquets work safety scale, administrators should consider adopting the scale as part of guidelines for using pneumatic tourniquets. By setting clear work standards, healthcare organisations can help mitigate risks associated with using pneumatic tourniquets. On a similar note, a study by Garner et al.[32] advocates a more robust regulatory framework surrounding use of medical devices to ensure consistent safety and efficacy.

The principles underlying the development of a work safety scale for pneumatic tourniquets may apply to other medical devices and technologies.

Table 3: Standardised factor loadings and reliability indices for the model

	Item	Standardised factor loading	Cronbach's alpha	Spearman-Brown coefficient	ICC	r
Subscale 1	Item 1	0.51	0.489	0.441	0.51	0.191
	Item 2	0.62				
	Item 3	0.48				
	Item 4	-0.33				
	Item 5	0.31				
Subscale 2	Item 6	0.46	0.722	0.59	0.69*	0.341*
	Item 7	0.88				
	Item 8	0.63				
	Item 9	0.38				
Subscale 3	Item 10	0.81	0.53	0.378	0.70*	0.286
	Item 15	0.69				
	Item 16	0.32				
Subscale 4	Item 11	0.41	0.637	0.573	0.59*	0.132
	Item 12	0.39				
	Item 13	0.53				
	Item 14	0.51				
	Item 17	0.44				
	Item 18	0.85				
	Item 19	0.32				
	Item 20	0.76				
	Item 21	0.38				
	Item 22	0.67				
	Item 23	0.35				
Subscale 5	Item 24	0.44	0.56	0.574	0.67*	0.236
	Item 25	0.39				
	Item 26	0.92				
	Item 27	0.53				
	Item 28	0.95				
Subscale 6	Item 29	0.93	0.69	0.511	0.56*	0.357*
	Item 30	0.83				
	Item 31	0.62				
	Item 32	0.42				
Subscale 7	Item 33	0.51	0.72	0.641	0.69*	0.294
	Item 34	0.63				
	Item 35	0.49				
	Item 36	0.66				
	Item 37	0.54				
	Item 38	0.91				
	Item 39	0.78				
	Item 40	0.83				
	Item 41	0.69				

* p-value < 0.05

ICC = intraclass correlation coefficient, *r* = Pearson's correlation coefficient

Future research may explore cross-disciplinary applications of the CFA model to develop similar scales for devices used in other medical fields, e.g. orthopaedic surgeries and emergency medicine. This could facilitate a broader understanding of application standards and user competency across diverse clinical contexts.

The present CFA offers a critical framework for evaluating healthcare professionals' compliance with pneumatic tourniquet work safety standards, combining theoretical constructs with practical application. The findings support the appropriate fitting of the collected data with the developed scale, making it suitable for use in operating rooms to assess surgical teams' knowledge and application of pneumatic tourniquet safety standards. Evaluation of the performance of operating room personnel using this scale can inform targeted training initiatives, ensuring that all the team members are equipped with the latest knowledge and skills necessary for safe application of pneumatic tourniquets. Drawing on credible, up-to-date scientific sources, the scale covers various aspects of application of pneumatic tourniquets and can enable all surgical team members to provide higher quality medical care. Furthermore, this scale can assist other researchers and medical centre administrators to identify existing risk factors, ultimately leading to the creation of educational programs or the implementation of new policies intended to mitigate or eliminate those risks.

Limitations and future research

The scale in the present study was designed based on the perspectives of experts in Iran, and the CFA was also conducted in Iranian hospitals. Therefore, the results may not be generalisable to all populations. However, the researchers developed the items of this scale through a comprehensive and extensive literature review, incorporating international sources. Thus, it appears that this scale has the potential for applicability in other populations as well. Nevertheless, future studies are recommended to validate this tool in different settings to identify potential cultural differences. Besides, the removal of four items in this study was based on low factor loadings and the consensus of the expert panel. However, since the strength of CFA lies in testing measurement invariance across different populations, future studies could assess whether the factor structure generalises to other contexts.

Conclusion

The developed scale can be used for training, safety performance evaluation and standardisation in the operating room. This study highlights the importance of pneumatic tourniquet safety dimensions for operating room students, surgical residents, surgeons, clinical educators and faculty members. Integrating the identified components of this scale into the theoretical and clinical curricula of operating room students and surgical residents is strongly recommended. Furthermore, clinical administrators and policymakers can use the safety dimensions outlined in this scale to design targeted workshops and training programs for nurses and surgeons. Additionally, this tool can be employed to monitor operating room nurses' performance for safety audits.

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

All authors had full access to the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. CT was responsible for the study conceptualisation and performed the data curation. CT and HF performed the investigation and methodology. CT, MR and GS supervised the study. CT, HF, MR and GS were responsible for data collection and analysis. CT, HF, MR and GS led the writing of the manuscript. All authors helped to review and edit the manuscript.

Conflict of interest and funding statement

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