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Developing and validating a scale to measure the risk of deep vein thrombosis (DVT) in patients who are candidates for surgery

Tayebeh Azarmehr [1], **Fereshte Sargolzaei** [2], **Mahboobe Doostkami** [3], **Mohammadreza Azizi** [4], **Najmeh Ghiami Keshtgar** [3*]

[1] Department of Operating Room, Faculty of Paramedicine, Zabol University of Medical Sciences, Zabol, Iran
[2] Department of Operating Room, Faculty of Nursery and Midwifery, Community Nursing Research Center, Zahedan University of Medical Sciences, Zahedan, Iran
[3] Department of Operating Room, Faculty of Nursery and Midwifery, Zahedan University of Medical Sciences, Zahedan, Iran
[4] Student Research Committee, Faculty of Nursery and Midwifery, Zahedan University of Medical Sciences, Zahedan, Iran

[*] **Corresponding author:** Najmeh Ghiami Keshtgar. Department of Operating Room, Faculty of Nursery and Midwifery, Zahedan University of Medical Sciences, Zahedan, Iran. **Email:** ghiamikeshtgar@gmail.com

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Abstract

Background: Deep vein thrombosis (DVT) is a prevalent and potentially fatal complication that can occur in patients following surgical procedures. It is crucial to identify risk factors in order to prevent DVT or intervene early.

Objectives: This study aimed to develop and validate a scale specifically designed to measure the risk of DVT in patients who are undergoing surgical procedures.

Methods: This study was conducted in 2022 within the hospitals situated in Zahedan city (Iran). The study encompassed a total of 120 patients who were deemed suitable for surgery. The selection of these patients was accomplished utilizing the available sampling technique. The assessment of these patients was executed employing the DVT risk assessment scale, which comprises three dimensions, 12 items, and 45 sub-items. The researchers examined the scale's validity using the content validity index (CVI), content validity ratio (CVR), and face validity, as well as reliability, which included internal consistency and measurement stability over time.

Results: A panel of 10 experts confirmed the scale's content and face validity. The total content index value for the scale was also calculated to be 0.94. Additionally, the content validity ratio for all the items exceeded the value of 0.62, ensuring that all the items were retained. Additionally, the scale demonstrated internal consistency with a Cronbach's alpha coefficient of 0.91. The mean risk of DVT is 22.88, indicating a moderate thrombosis risk.

Conclusion: The present study's findings indicate that the scale utilized to assess the risk of DVT in surgical candidates exhibits strong validity and reliability. Therefore, it can be effectively employed to measure the risk of DVT in patients scheduled for surgery who are referred to the operating room.

Keywords: Deep Vein Thrombosis, Validity, Reliability, Scale, Surgery.

Introduction

Deep vein thrombosis (DVT) is a prevalent and potentially fatal complication that can arise in patients following surgery. DVT occurs when a blood clot obstructs deep veins, typically in the leg, but it can also occur in brachial, mesenteric, and cerebral veins.[1] The annual incidence of DVT is approximately 1-2 cases per 1000 individuals.[2] Within the first month of developing DVT, the mortality rate exceeds 3%. This risk of death increases tenfold in patients who develop pulmonary embolism as a result of DVT.[3] DVT leads to significant complications, including chronic venous insufficiency and post-thrombotic venous thromboembolism (VTE) syndrome. Post-thrombotic syndrome affects 50% of patients within two years of experiencing DVT and manifests through symptoms such as leg pain, swelling, and, in some

instances, venous ulcers.[3] Globally, venous thromboembolism ranks as the third most common cause of death, following heart attacks and strokes.[4]

Furthermore, economic assessments have revealed that the healthcare system bears a significant financial burden due to the clinical complications associated with DVT in patients.[5] Various factors contribute to the incidence of DVT, such as lack of physical activity, extended hospitalization, traumatic events, coagulation disorders, pregnancy, the use of hormonal contraceptives, smoking, obesity, advancing age, and gender.[6]

DVT can be attributed to various factors, with surgery being a significant cause. Within the surgical setting, several factors contribute to the risk of developing DVT, including the type and duration of the procedure, the method of anesthesia, bleeding, positioning, the use of tourniquets, and blood transfusions. Certain surgical specialties, such as orthopedics (particularly total hip/knee replacement surgery and hip fracture surgery), gynecology, abdominal surgery, and neurosurgery, have a higher incidence of DVT.[7]

It is crucial to assess the risk factors for DVT before, during, and after surgery in order to implement appropriate preventive and therapeutic measures.[8] By taking preventive measures in patients who are at a high risk of DVT, the complications and mortality associated with this condition can be significantly reduced. These preventive measures should ideally be initiated 24 hours prior to the surgery.[9]

For patients who are candidates for surgery, preventive treatments for DVT can include both pharmaceutical and non-pharmacological methods. In patients with a low risk of DVT, early movement within the first 24 hours after surgery and leg exercises can be effective preventive measures. For patients with a moderate risk, the use of elastic bandages may be recommended. In high-risk patients, the use of pneumatic compression stockings and drug treatments is often employed as preventive measures.[10]

It is crucial to identify risk factors for DVT in order to prevent it or intervene early. Therefore, it is important to identify DVT risk factors at the beginning of a patient's admission to the operating room and take preventive measures accordingly. While there are various scales available to identify DVT risk factors and prevent them in hospital departments, there is currently no scale specifically developed for identifying patients at risk of DVT in the operating room. Given that DVT is a potential complication of surgical procedures, it is essential for operating room technologists to utilize a unique scale to identify DVT risk factors in this setting. Considering that DVT poses a threat to patient safety, healthcare center managers should plan accordingly to assess and prevent the risk of DVT in the operating room. Additionally, due to the significant increase in the number and types of surgeries, as well as the associated risk of DVT, it is necessary to implement a DVT risk assessment scale specifically for the operating room.

Objectives

This study aimed to develop and authenticate a measurement scale that can effectively assess the risk of DVT in patients who are undergoing surgery.

Methods

This study is a methodological investigation conducted in Zahedan city, located in the southeast region of Iran, during the months of September and October in the year 2022. The statistical population for this study consisted of surgical candidate patients who were referred to the operating rooms of teaching hospitals in the aforementioned city. A total of 120 patients who met the study's inclusion criteria were selected using the available sampling method. The inclusion criteria required the patients to be candidates for surgery, provide their consent for cooperation, and be above the age of 18. The exclusion criterion was the patient's unwillingness to cooperate.

In order to develop the scale, an extensive study was conducted using various sources, including 300 medical files of patients who experienced DVT after surgery from 2013 to 2022. Reliable sources, surgery guidelines, and related articles were also consulted. Expert opinions were sought to create a comprehensive list of factors that contribute to the occurrence of DVT in surgical patients. These factors were then categorized into three dimensions: preoperative, intraoperative, and postoperative. The initial

scale consisted of 12 items, divided into three main dimensions: preoperative risk factors (n=5), intraoperative risk factors (n=5), and postoperative risk factors (n=2). Each item was scored using the Likert scale. A score of 0–10 indicated low risk, 10–23 indicated moderate risk, and a score of 23 or higher indicated a high risk of DVT. Once the initial items were compiled, the scale underwent examination for content validity, face validity, and reliability, including internal consistency and measurement stability over time.

The scale's content validity was assessed both qualitatively and quantitatively. For this study, a total of 10 experts from various departments, including surgery, medicine, biostatistics, the operating room, and nursing (excluding the research team), were selected to evaluate the content quality. The experts were briefed about the test objectives and were asked to carefully review each item, providing their opinions and suggestions for improvement. This evaluation process considered the use of appropriate language, proper placement of items within the dimensions, suitable scoring, and examination of the questions' writing. Based on the feedback received, the items were revised, and necessary corrections were implemented. A list of the initial scale items was compiled, consisting of 12 items across three dimensions: before surgery (24 sub-items), during surgery (15 sub-items), and after surgery (6 sub-items).

To assess the face validity of the scale, experts utilized the criteria of face validity, logicality, appropriateness, and readability of the items. Additionally, the scale was distributed to a group of 10 operating room experts (the target group) for their evaluation of the clarity and comprehensibility of the items. Subsequently, necessary modifications were implemented in the items based on the feedback and recommendations received.

The quantitative calculation of content validity involved the utilization of two measures: the content validity index (CVI) and the content validity ratio (CVR). To determine the CVR, experts were tasked with categorizing each question into three parts of the Likert spectrum: necessary, useful but not necessary, and not necessary. Subsequently, the content's validity ratio was assessed using the Lavache method, based on the CVR formula. The resulting index value ranges from -1 to +1. It is important to note that the Lawshe method sets a minimum acceptable CVR value of 0.62 based on the participation of 10 experts in the study.

To calculate the CVI, experts were tasked with assessing the relevance of each item using a four-part spectrum: irrelevant, requiring major revision, relevant but needing revision, and completely relevant. The number of experts who chose options 3 and 4 is then divided by the total number of experts. If the final result is less than 0.7, the item is discarded. If it falls between 0.7 and 0.79, it should be revised. And if it is greater than 0.79, it is considered acceptable.

After establishing the scale and confirming its validity, the reliability of the scale was evaluated using Cronbach's alpha coefficient (to measure internal consistency of the questions) and Pearson's correlation coefficient (to assess consistency between the questions). Additionally, the reliability of the scale was checked using the simultaneous observation method. To do this, 20 patients were chosen, and the scale was completed by two observers simultaneously. In order to further assess reliability using Cronbach's alpha coefficient, a pilot study was conducted with 120 patients who were candidates for surgery.

Statistical analysis

The continuous variables were expressed as the mean±SD, and the categorical variables were presented as a percentage and frequency. All statistical analyses were performed with SPSS (version 16.0, SPSS Inc, Chicago, IL, USA). A “P-value” less than 0.05 was considered significant.

Ethical considerations

The study was carried out in compliance with the Declaration of Helsinki. The code of ethics was obtained from Zahedan University of Medical Sciences, IR.ZAUMS.REC.1401.156. We obtained the necessary permission to access the operating rooms. A detailed explanation of the study's objectives and methods was presented and informed written consent was received.

Results

The findings indicate that out of the 120 patients, 58.33% were male and 41.66% were female. The mean age of the

patients was 45.7±3.8 years, and the mean length of stay in the ICU before surgery was 3±2 days.

All 12 items on the scale had content index values greater than 0.85. The total content index value for the scale was also calculated to be 0.94. Additionally, the content validity ratio for all the items exceeded the value of 0.62 presented in the Lawsche table, ensuring that all the items were retained [Table 1].

In terms of the scale's reliability, the correlation coefficient (r) values were found to be greater than 0.75, indicating a high level of measurement stability for both the overall scale and each individual dimension. Additionally, the Cronbach's alpha values, which assess the internal consistency of the scale within each dimension, were deemed acceptable according to Table 2.

Table 3 presents the distribution of risk factors and scores of the DVT risk assessment scale in patients eligible for surgery, encompassing the preoperative, intraoperative, and postoperative periods. The mean risk of DVT is 22.88, indicating a moderate thrombosis risk.

Table 1. Content validity index (CVI) and content validity ratio (CVR) of scale items

Dimensions	Items	CVI	CVR
Before surgery	Gender	1	0.85
	Activity/Mobility	1	0.71
	BMI	0.91	0.85
	Age	0.91	0.79
	Underlying disease	1	0.85
During surgery	position	0.95	0.79
	Type of surgery	1	0.72
	Tissue retraction and stretching	0.85	0.86
	Duration of tourniquet use	0.92	0.89
	Blood transfusion	1	0.86
After surgery	the operation length	1	0.79
	Bleeding	0.92	0.73

Table-2. The values of correlation coefficient and Cronbach's alpha coefficient of the scale

Dimensions	Cronbach's alpha coefficient	Correlation coefficient (r)
Before surgery	0.73	0.75
During surgery	0.70	0.83
After surgery	0.70	0.80
Total	0.91	0.85

Discussion

The aim of this study was to validate the risk assessment scale for DVT in patients undergoing surgery. The findings indicated that this scale can effectively assess the risk of DVT in surgical candidates who are scheduled for the operating room. The scale consisted of 3 dimensions and 12 items. The findings showed that the scale had good content validity, as certified by experts, and no parameters were eliminated. Furthermore, the reliability coefficients of the two observers revealed no significant variation in their scores, indicating that the scale exhibits good reliability. There is ongoing discussion surrounding the risk factors associated with DVT in various patient populations. The identification of specific risk factors and the accurate assessment of complications related to specialized procedures have allowed for more precise patient selection. VTE, which encompasses DVT and pulmonary embolism (PE), is considered one of the most severe complications across all medical specialties.[1] Multiple methods exist for evaluating the risk of VTE. Kucher et al., developed a risk classification technique and studied its application in patients for 90 days after hospital discharge. They identified several factors as the most prevalent risk factors, including cancer, previous history of VTE, hypercoagulability, major surgery, age, obesity, sedentary lifestyle, hormone replacement therapy, and oral contraceptives.[2] Furthermore, according to Caprini's study, venous stasis is also observed in general surgery cases. In fact, the degree of venous distension can reach up to 22-28% in patients undergoing general anesthesia and surgery and up to 57% in those who receive 1 liter of saline infusion during the surgical procedure.[3] Other studies have shown similar findings, indicating that factors like obesity have a significant impact on the risk of VTE by increasing venous stasis and reducing venous return.[4] Additionally, VTE is more prevalent in women compared to men.[5] However, Heit et al., found that BMI cannot be regarded as an independent risk factor for VTE.[6]

Several researchers have identified patients who are at risk for VTE using different risk stratification methods.[3] However, despite being identified as high-risk, these patients were not prescribed thromboprophylaxis. Zakai et al., investigated three VTE risk assessment models

utilizing inpatient medical records.[7] Similarly, Osborne et al., recommended the routine use of evidence-based guidelines for VTE risk assessment in patients undergoing abdominal or pelvic surgery.[8]

Table 3. Risk factors and scores of DVT risk assessment scale in surgical candidate patients

Risk factors before surgery		**N (%)**
Gender	Male	70 (58.33)
	Female	50 (41.66)
Mobility	Mobility without movement restriction, has partial movement restriction	1 (0.83)
	Requires partial mobility aids	5 (4.1)
	Requires full mobility equipment	3 (2.5)
BMI	<30	15 (12.5)
	30-35	95 (79.16)
	35<	10 (8.33)
Age	<39	30 (25.01)
	40-59	70 (58.33)
	60<	20 (16.66)
Underlying disease	Cardiovascular disease, respiratory disease	1 (0.83)
	Peripheral vascular disease including varicose veins	3 (2.5)
	Blood pressure above 80/120	20 (16.66)
	Diabetes	6 (5.01)
	Splint or plaster in the lower limb	1 (0.83)
	Acute or treated cancer	5 (4.16)
	Pregnancy/birth in the last 6 months	40 (33.33)
	Multiple trauma	1 (0.83)
	History of surgery in the last 12 weeks	1 (0.83)
	History of VTE	
	Coagulation disorders	
	Use of hormonal drugs (including contraceptives)	25 (20.83)
	Smoking	10 (8.33)
Risk factors during surgery		
Position	Supine position - Prone	90 (75.01)
	Lateral	10 (8.33)
	Reverse Trendelenburg-Lithotomy-Semi-reclining	20 (16.66)
Type of surgery	eye surgery - neurosurgery	30 (25.01)
	Abdominal surgery	50 (41.66)
	Surgery on the pelvis or lower limb	40 (33.33)
Tissue retraction and stretching	<1 hr	30 (25.01)
	1-2	55 (45.83)
	>2 hr	35 (29.16)
The duration of using the tourniquet	30 min	10 (8.33)
	30-60 min	40 (33.33)
	>60 min	70 (58.33)
Blood transfusion	1 unit	1 (0.83)
	2	10 (8.33)
	3	-
Risk factors after surgery		
The duration of the operation	Up 30 min	1 (0.83)
	30-60 min	34 (28.33)
	>60 min	85 (70.83)
Bleeding	200 cc	30 (25.01)
	200-400 cc	20 (16.66)
	>400 cc	70 (58.33)

According to the findings of the study, it is recommended that physicians conduct a risk evaluation for patients prior to any elective surgical procedure. To enhance prevention and subsequent evaluation, it would be more beneficial to utilize a meticulously designed risk assessment scale to measure the risk of VTE. Consequently, patients identified as having a high risk of VTE should be provided with suitable counseling for preventive assessment and post-surgical follow-up in order to minimize the likelihood of VTE.[9] Bahl et al.'s research utilized a retrospective VTE risk scoring method based on the Caprini model. Their findings demonstrate that this approach is cost-effective and can serve as a valuable tool for assessing adherence to VTE prevention guidelines in general surgery, vascular, and urology patients.[10] In another study, Yasui et al., used logistic regression analysis to identify characteristics that might predict the development of DVT/PE in colorectal cancer patients after laparoscopic surgery.[11] Furthermore, another study developed a prediction rule for classifying PTS risk in patients with DVT. This user-friendly clinical prediction rule accurately identifies individuals at high risk of developing PTS within 24 months, enabling them to receive targeted training or therapeutic interventions to mitigate the risk.[12]

Research was carried out to develop and authenticate a forecast model for assessing the likelihood of PE in DVT patients, considering their medical history, clinical symptoms, physical symptoms, and electrocardiogram signs. The findings indicated that the newly developed predictive model, aimed at identifying DVT patients with varying risks of PE, could potentially serve as a valuable tool in quickly estimating the probability of PE before receiving conclusive test results, thereby expediting emergency management procedures. Furthermore, having knowledge of the estimated event rate is crucial in making informed clinical decisions concerning anticoagulation therapy for patients with venous thromboembolism.[13]

A meta-analysis of nine trials, including 14,963 cancer patients with VTE, found that the Ottawa score is a valid measure for predicting recurrent VTE within the first six months of anticoagulation therapy. The Ottawa score, specifically designed for this purpose, effectively stratifies patients based on their risk of developing venous thromboembolism.[14] However, a study revealed contrasting findings regarding the effectiveness of the Caprini evaluation scale, a method used to assess DVT. This scale was found to be time-consuming and prone to errors if not completed accurately by a trained specialist.[15] Furthermore, Trihan et al., found that the Wells score, used to assess DVT risk in hospitalized patients on anticoagulant treatment, had poor performance and low inter-physician reliability.[16] However, in 2021, researchers utilized a model to evaluate the likelihood of VTE in patients undergoing urologic surgery. The findings demonstrated that, due to the difficulty of diagnosing venous thromboembolism and physicians' tendency to underestimate its risk, objective and practical risk assessment models such as the Caprini score are valuable tools in guiding the implementation of thromboprophylaxis.[17] Nemeth et al., conducted a study to examine the predictive capabilities of environmental and genetic risk factors, as well as coagulation marker levels, following knee arthroscopy. They integrated these factors into a predictive model known as L-TRiP (ascopy), which proved to be effective. However, they emphasized the necessity of a larger validation study to validate these results.[18]

Conclusions

The evaluation of the DVT risk assessment scale was conducted in the current investigation. This scale consisted of 3 dimensions, 12 items, and 45 sub-items. Our study findings indicated that, given the significance of DVT assessment based on prior research, it has the potential to serve as a valuable tool for surgical candidates who visit the operating room.

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Competing interests

The authors declare that they have no competing interests.

Abbreviations

Deep vein thrombosis: DVT; Pulmonary embolism: PE;

Content Validity Index: CVI; Content Validity Ratio: CVR; Venous Thromboembolism: VTE.

Authors' contributions

All authors read and approved the final manuscript. All authors take responsibility for the integrity of the data and the accuracy of the data analysis.

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Availability of data and materials

The data used in this study are available from the corresponding author on request.

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki. Institutional Review Board approval (IR.ZAUMS.REC.1401.156) was obtained. This study did not interfere with the process of diagnosis and treatment of patients and all participants signed an informed consent form.

Consent for publication

By submitting this document, the authors declare their consent for the final accepted version of the manuscript to be considered for publication.

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