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Utilization and Decision-Making Accuracy on Antithrombotic Prophylaxis by Caprini and Padua Risk-Assessment Models for Predicting Venous Thromboembolism in Hospitalized Patients

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Abstract **Background:** Risk-Assessment Models may not accurately predict Venous Thromboembolism (VTE). This study prospectively assessed the use and decision-making accuracy of the Caprini and Padua risk-assessment models for antithrombotic prophylaxis in predicting VTE. **Methods:** Prospective study was conducted on 1075 Baghdad Teaching Hospital patients from December 1, 2022, until January 1, 2024. All patients and the subgroup examined for RAM discrimination using baseline medical and demographic data. Assessing Caprini and Padua scores' sensitivity and specificity. We analyze each score using the ROC curve and AUC. **Results:** The study observed 37 VTE cases. Individuals with VTE events had a significantly higher mean age (±SD) of 60.62 (15.8), p = 0.001. VTE occurs in 54% of acutely infected and/or rheumatologic patients P 0.002. Survival time and event-free period mean was 83.099 days (95% CI: 81.877-84.322) for patients without thromboprophylaxis and 74.085 days for those utilizing it. The Caprini RAM predicted VTE with 0.652 AUC, lower than Padua's 0.724. The Caprini RAM had 54.1% sensitivity and 61.7% specificity, whereas the Padua prediction score had 97.3% and 36.0%. **Conclusion:** The Caprini scores and Padua Prediction Score may improve hospital patients' thromboembolic risk classification compared to current practice.

Key Words Caprini scores, Padua Prediction Score, Risk-Assessment Models, Thromboembolism

INTRODUCTION

A major and sometimes deadly consequence in medical inpatients is venous thromboembolism (VTE), which includes both Pulmonary Embolism (PE) and Deep Venous Thrombosis (DVT) [1]. Reports indicate that 50%-75% of venous thromboembolism (VTE) events in inpatients arise in individuals receiving treatment for medical diseases, with a higher risk of fatal Pulmonary Embolism (PE) seen in medical patients compared to surgical patients [2,3]. Evidence unequivocally indicates that prophylaxis markedly decreases the occurrence of VTE and the majority of recommendations advocate for the administration of prophylaxis to medical inpatients at heightened risk of developing VTE, Nonetheless, the use of VTE prophylaxis in these individuals remains significantly underutilized [4,5]. Age, lack of movement and severe inflammatory illnesses are significant risk factors for the development of VTE upon hospitalization [6]. VCAM-1 is a cytokine-inducible endothelial cell adhesion molecule [7], its increased serum concentrations were found during the acute phase of Deep Vein Thrombosis (DVT) [8]. interleukin-10 (IL-10) is key regulator of immune homeostasis [9] and decreased in patients with idiopathic venous thrombosis [10]. Toll Like Receptors (TLRs) play a considerable role in the host defense against microorganism [11] and TLR3 might be involved in the inflammatory development of venous thrombosis [12]. A variety of VTE risk analysis models have been devised for the use of inpatient medical patients. Their limitations include an inadequate follow-up duration, an absence in prognostic validation, an application that is

restricted to high-risk categories and an excessive level of complexity [13]. The Padua Prediction Score (PPS) is a straightforward score of 11 criteria, developed and validated on a population consisting of all medical patients. individuals with an accumulated PPS of 4 or greater are at an increased risk of VTE for a period of 90 days and should thus get thromboprophylaxis throughout hospitalization [14]. The American College of Chest Physicians (ACCP) has recently endorsed the PPS as the best risk stratification instrument for non-surgical patients [15]. The Caprini RAM was initially designed for both surgical and medical patients [16]. Despite substantial data supporting its validity in surgical patients and the ACCP-9's recommendation for its use in assessing VTE risk in non-orthopedic surgery patients [15]; because to its categorical nature and ease of estimation, has been extensively accepted and has become increasingly popular for hospitalized medical patients [17]. However, it remains uncertain if this tool effectively predicts VTE or determines a risk threshold that would most likely benefit this population of patients from anticoagulation [18]. The objective of this research was to prospectively evaluate the use and decision-making accuracy of the Caprini and Padua risk-assessment models for antithrombotic prophylaxis in predicting venous thromboembolism in hospitalized patients, both during hospitalization and up to three months post-discharge.

METHODS

Study Design

We designed prospective cohort research with completely blinded evaluation of events. The study aimed to evaluate which RAM can differentiate between participated medical patients at the highest and lowest risk of VTE and to reveal the application of appropriate thromboprophylaxis in high-risk patients during hospitalization provides enduring prevention of thromboembolic complications. Participant enrollment and follow up began in December 2022 and completed in January 2024.

Study Setting

The research recruited participants consisting of all successive patients referred to the Internal Medicine wards of Baghdad Teaching Hospital, Medical City Complex in Baghdad, Iraq.

Eligibility Criteria

Participants were eligible for this research provided they were not on full-dose anticoagulant drugs, had no restrictions to pharmacological prophylaxis (such as recent or continuing severe bleeding, a level of platelets below 100×10^{9} L, or creatinine elimination rate below 30 mL min^{-1}) and were neither pregnant nor younger than 18 years of age. Participants were required to provide written informed permission to engage in the research.

VTE Risk Assessment

Participants' demographic data, including age, gender, Body Mass Index (BMI) and Padua risk-assessment model and Caprini RAM parameters, were retrieved from medical files. Further management factors and diagnosing indicators related to VTE have been obtained as well. Every people's overall VTE risk score and related risk level were evaluated. The results of these factors were limited to the paperwork most directly related to the time of admission. The ACCP criteria were followed in the categorization of the PPS [19].

Outcomes

The screener assessed the use of thromboprophylaxis over admission. Attending doctors were not informed of their patients' VTE risk. Thromboprophylaxis was considered sufficient if initiated within 48 hours after hospital admission and included the daily dose of a minimum of 15,000 U of unfractionated heparin or 4,000 U of enoxaparin. All final events were evaluated by an unbiased assessment committee, whose members were blind to the patients' risk factors and thromboprophylaxis usage. The main objective of the research was to evaluate the risk of VTE complications in high-risk patients who got appropriate prophylaxis vs those who did not, over the 3-month follow-up period.

Sample Size

A cohort of 1,075 people was enrolled. The sample size was determined using an approach for calculating one single proportion. Z denotes the standard normal variable at a 95% confidence level (1.96), p signifies the anticipated population percentage of 50%, assuming an infinite population size, with a margin of error of 5%:

$$n = \frac{z^2 \times \hat{p}(1-\hat{p})}{\varepsilon^2}$$

Statistical Analysis

The entire set of data was processed using SPSS, version 23.0 for Windows. GraphPad Prism version 8 for Windows (GraphPad Software, Inc., California, USA) was used to generate a visual representation of the information. Draw.io is free online diagram software employed for making flowcharts. The Chi-square test was used to ascertain significant relationships between VTE and other factors. An independent sample t-test was used to ascertain significant differences RAMs scores between VTE and non-VTE groups. A two-by-two table was developed to calculate the diagnostic precision, specificity and sensitivity of the Caprini and Padua scores. DeLong's test is employed to demonstrate that the AUCs of two models are statistically substantially different. A ROC curve integrates sensitivity and (1 - specificity) across several decision thresholds. The Kaplan-Meier curve visually illustrates the survival rate, with time depicted on the x-axis and survival rate on the y-axis. The trapezoidal rule is used to compute the area under the curve (AUC) of a ROC graph. A p-value of less than 0.05 was deemed to be significant.

RESULTS

Of the 2541 eligible patients, 1466 were eliminated due to the diagnosis of VTE at admission, anticoagulation at admission, hospitalization for less than three days, refusal to participate, or lack of consent. In all, 1075 individuals were enrolled for this research, of whom 37 were identified as having VTE at the completion of the study period, whereas 1038 were without VTE (Figure 1). Table 1 presents the primary demographic and medical characteristics of the research participants. Findings from this research indicated that the age of individuals with VTE events is considerably greater than that of event-free individuals, with a mean age (±SD) of 60.62 (15.8), p = 0.001. Persons with acute infections and/or rheumatologic problems experience VTE episodes in 54% of total cases, with a significance level of P 0.002. The study outcomes indicated that people with myocardial infarction

Table 1: Primary demographic and medical characteristics of the research participants

Variables		Events		p-value
		No	Yes	
Gender	Male	438	12	0.155
Age (Years)	Mean (±SD)	52.95 (17.7)	60.62 (15.8)	0.001
BMI ≥25	Frequency (%)	178 (17.1)	7 (18.9)	0.824
Congestive heart failure	Frequency (%)	30 (2.89)	0 (0)	0.621
Sepsis	Frequency (%)	25 (2.4)	0 (0)	0.412
Pneumonia	Frequency (%)	99 (9.53)	1 (2.70)	0.246
Acute infection and/or rheumatologic disorders	Frequency (%)	310 (29.86)	20 (54)	0.002
Stroke	Frequency (%)	10 (9.6)	0 (0)	0.703
Varicose vein	Frequency (%)	0 (0)	0 (0)	NA
Major surgery	Frequency (%)	102 (9.82)	3 (8.1)	0.504
Current central venous access	Frequency (%)	34 (3.27)	1 (2.70)	0.659
Current swollen legs	Frequency (%)	36(3.46)	4 (10.8)	0.045
History of DVT/PE	Frequency (%)	192 (18.49)	18 (48.6)	0.0001
Family history of thrombosis	Frequency (%)	20 (1.92)	0 (0)	0.493
Mobility (Patient confined to bed >72 hours)	Frequency (%)	523 (51.2)	18 (48.6)	0.442
Myocardial infraction	Frequency (%)	310 (29.86)	20 (54)	0.002
Chronic obstructive pulmonary disease	Frequency (%)	23 (2.21)	2 (5.4)	0.211
Present or previous malignancy	Frequency (%)	29 (2.79)	1 (2.7)	0.724
Ongoing hormonal treatment	Frequency (%)	22 (2.11)	3 (8.1)	0.051
Already known thrombophilic condition	Frequency (%)	152 (14.6)	13 (35.13)	0.002
Type of prophylaxis	No prophylaxis	793 (76.39)	22 (59.45)	0.036
	LMWH	106 (10.2)	4 (10.8)	
	UFH	139 (13.39)	11 (29.7)	

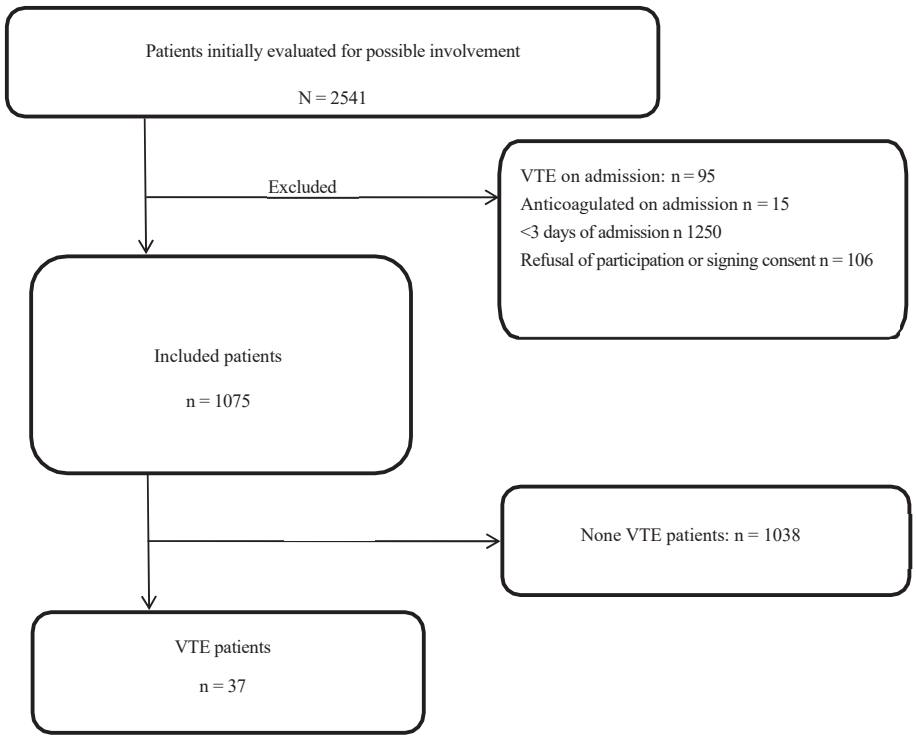

Figure 1: Flowchart of patients' enrollment

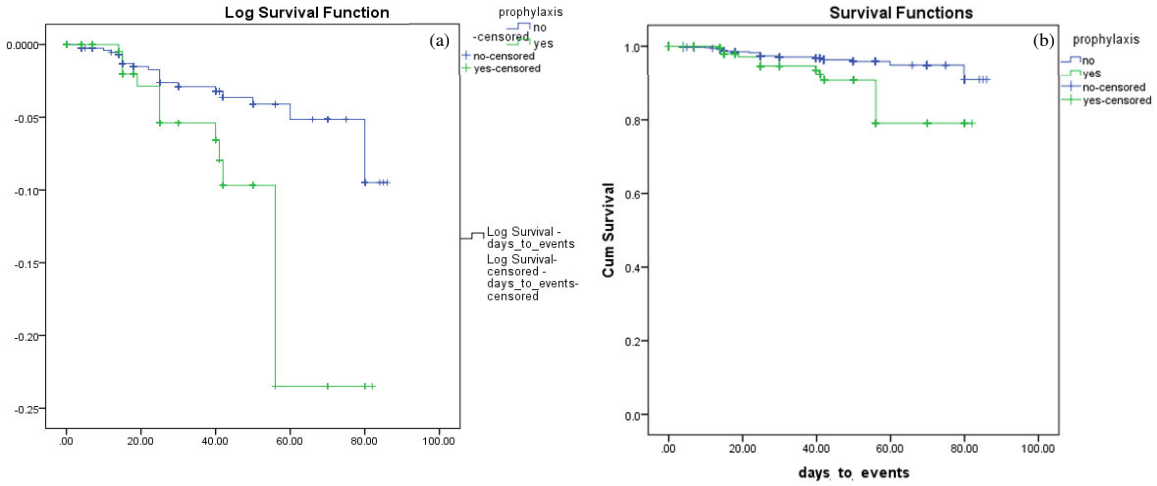

Figure 2 (a-b): Kaplan-Meier event-free probability for all medical inpatients, (a) Survival function and (b) Log survival function

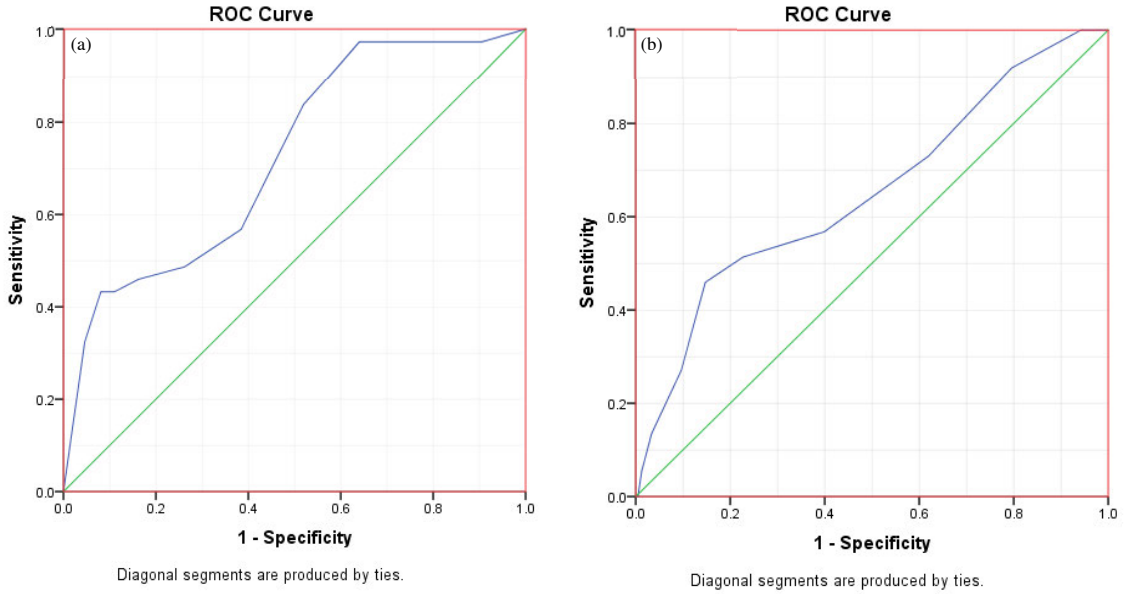

Figure 3: ROC curves for all medical inpatients of the Caprini RAM and PPS. (A) the AUC of the ROC curve of the PPS was 0.724 (B) the AUC of the ROC curve of the Caprini RAM 0.652

experience venous thromboembolism instances in 54% of total cases, with a significance level of p = 0.002. Individuals with mobility impairments (patients confined to bed for over 72 hours) have venous thromboembolism episodes in around fifty percent of all cases associated with these conditions. p = 0.442. Individuals without prophylaxis have VTE events in roughly 59.45% of cases while patients receiving LMWH exhibit a decreased incidence of VTE compared to those on UFH, with rates of 4 (10.8%) vs 11 (29.7%), p = 0.036.

Means duration for Survival Time and events free period was 83.099 days with 95% Confidence Interval of (81.877-84.322) days for patients without thromboprophylaxis and 74.085 days with 95% Confidence Interval (70.245-77.924) days for those taking pharmacological thromboprophylaxis, the overall mean duration 81.895 days with 95% Confidence Interval of (80.564-83.225), p-value 0.003, as seen in Figure 2.

To validate the results, we analyzed the ROC curves of the Caprini RAM and Padua prediction scores in patients with and without VTE during and after hospitalization. Thus, 1075 individuals were included in the analysis. The Caprini RAM had an AUC of 0.652 for predicting VTE, lower than the Padua prediction score of 0.724. The research found that the Caprini RAM had a sensitivity of 54.1% and a specificity of 61.7%, whereas the Padua prediction score had a sensitivity and specificity of 97.3% and 36.0%, respectively as presented in Table 2 and Figure 3.

Padua's mean score of 4.740 was significantly higher than Caprini's score of 4.335 (p-value <0.0001, 95% confidence interval 0.1764 to 0.6329, Difference between means ± SEM 0.4047 ± 0.1164), as shown in Figure 4.

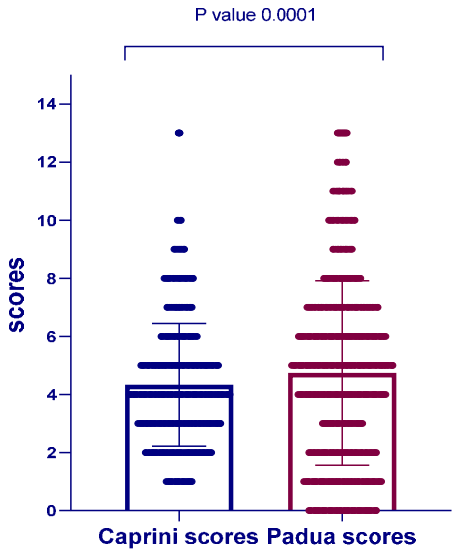

Figure 4: Mean score of the two employed RAM

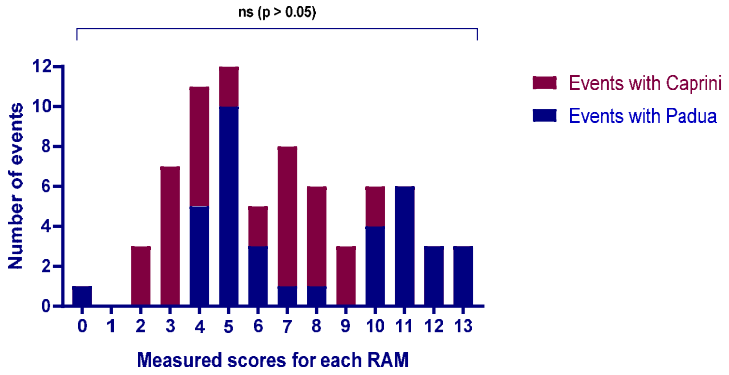

Figure 5: Venous thromboembolisms events distribution among per each score of the risk assessment models

Table 2: The predictive validity of the Caprini RAM and Padua prediction scores among inpatients

Diagnostic accuracy	Caprini score	p-value	Padua score	p-value
Sensitivity	54.1%	0.041	97.3%	0.0001
Specificity	61.7%		36.0%	
False positive	38.3%		64.0%	
False negative	45.9%		2.7%	
Area Under the Curve (AUC)	0.652		0.724	

Table 3. Accuracy of given prophylaxis relative to assessed individual risk of VTE development

Variables			Prophylaxis		Total	p-value
			No	Yes		
Caprini scores	Low risk	Count	566	91	657	0.001
		%	69.4%	35.0%	61.1%	
	High risk	Count	249	169	418	
		%	30.6%	65.0%	38.9%	
Padua score	Low risk	Count	345	30	375	0.001
		%	42.3%	11.5%	34.9%	
	High risk	Count	470	230	700	
		%	57.7%	88.5%	65.1%	

There was no significant difference in the frequency and occurrence of events per score between the two risk assessment models. The mean number of events was 2.643, with a difference of 0.000 ± 1.049 (95% confidence interval -2.157 to 2.157), as shown in Figure 5.

Among those identified as high risk for developing VTE based on Caprini scores, 30.6% did not get pharmacological prophylaxis; while within the group classified as high risk according to Padua scores, 57.7% did not receive pharmacological prophylaxis as presented in Table 3.

DISCUSSION

The Caprini and Padua Risk Assessment Models are essential instruments for identifying individuals susceptible to venous thromboembolism in various therapeutic contexts [20,21]. The Caprini model is mostly used to assist patients having surgery, while the Padua model was developed specifically for medical situations [22]. The two approaches have significant benefits and drawbacks and the one chosen should be decided by the individual's socioeconomic and clinical situation [23,24]. Despite the fact that a large proportion of people in hospitals are at elevated risk for subsequent episodes of VTE, thromboprophylaxis has not been properly used [25,26]. Consequently, the most trustworthy and effective preventative strategy for VTE has become a significant unresolved inquiry [27-30]. The Padua RAM surpassed the Caprini RAM in terms of sensitivity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV), contradicting previous study that claimed the Caprini RAM was superior at prediction. This discrepancy is also inconsistent with findings by Trabulsi *et al.* [17] in a study conducted in Saudi Arabia, which demonstrated that the Caprini RAM outperformed the Padua RAM in sensitivity, PPV and NPV, aligning with earlier research asserting the Caprini RAM's superior predictive accuracy. Risk factors such as advanced age, severe infections and/or rheumatologic disorders, a prior history of Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE) and pre-existing thrombophilic diseases were significantly more common in VTE patients compared to non-VTE cases, according to the current study. Kupelian *et al.* [31] and Alabdulkarim *et al.* [32] reached similar findings. A multitude of research has shown Caprini RAM's efficacy in surgical patients. Over fifteen thousand persons undergoing surgery were studied by Geerts *et al.* [33] and Khalid *et al.* [34] and they discovered a strong correlation between the Caprini score and the incidence of postoperative VTE. In a second study, Obi *et al.* [35] evaluated the Caprini Risk Assessment Model in 3,955 individuals undergoing general surgery. The results demonstrated that those with higher Caprini scores had a heightened risk of postoperative venous thromboembolism. Mrad *et al.* [36] shown in their extensive research that the Caprini Model more accurately predicts postoperative venous thromboembolism occurrences in high-risk plastic surgery patients than the American Society of Anesthesiologists grading system.

The potential to obtain solid conclusions on the efficacy differences between the Caprini and Padua models is hindered by the absence of a direct comparison investigation that particularly analyzes PPV [37]. The positive predictive value of a RAM indicates the percentage of individuals identified as high risk who subsequently develop venous thromboembolism [38]. In their study of medical patients in hospitals, Wen et al. discovered that the Padua model was 91.3% sensitive. Although the statistics show that the Padua model successfully finds true positives, the predictive power of its positive predictions is contingent upon the prevalence of VTE in the particular group that was examined. The Caprini model has also shown promise in predicting VTE risk in evaluations, however there is a dearth of detailed evidence about PPV [39]. Higher Caprini scores were linked to an increased frequency of postoperative VTE, according to Obi *et al.* [35] assessment of the Caprini model in surgically treated individuals. Unfortunately, there was no documentation of any direct comparisons between PPV and the Padua model. The new group had a much lower incidence of VTE (3.4% on average) compared to previous studies of those admitted with medical conditions (10 to 15%) [40]. Heit *et al.* [41] established that the overall incidence rate of VTE in a sample of patients was 960.5 per 10,000 person-years within hospitalized persons, but it was much lower at 7.1 per 10,000 person-years among residents. Recent Italian longitudinal observational research conducted in medical wards revealed that 0.4% of consecutively admitted severely unwell patients acquired proximal deep vein thrombosis throughout their hospital stay [42].

This study has some limitations that must be acknowledged. The regular evaluation of hospitalized individuals for asymptomatic venous thromboembolism (VTE) is not conducted at our institution. Consequently, we may have inadequately represented the occurrence of VTE among some control patients, particularly those categorized as high risk. Future prospective studies should focus on hemorrhagic outcomes during thromboprophylaxis. Thirdly, we did not link our results with the tumor-associated VTE RAMs; hence, the validity of the RAMs may not be comprehensively evaluated in cancer patients. Fourthly, our study was not a multicenter.

CONCLUSIONS

In conclusion, our findings indicate that the Caprini scores and Padua Prediction Score may enhance the categorization of thromboembolic potential in patients receiving medical care in hospitals relative to standard practice. Nonetheless, its validity requires appropriate verification and validation from further extensive prospective investigations. Furthermore, it has to be proved if knowledge of the potential utility of this RAM may lead to an increased incidence of clinicians adopting appropriate thromboprophylaxis for their patients.

Conflicts of Interest

The authors declare there are no conflicts of interest.

Funding

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Conflicts of Interest

The authors declare there are no conflicts of interest.

Ethical Approval

Ethical authorization was obtained from the Ethical Review Committee of Al-Rasheed University on January 2, 2022 (Approval Number: RUCPD30112201). All measures were used to preserve the anonymity of research participants and the data are examined individually.

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