Original Research Article

SAGE Open Medicine

SAGE Open Medicine
Volume 10: 1–7

DOI: 10.1177/20503121221079488
journals.sagepub.com/home/smo
SAGE

Incidence of thromboembolism and thromboprophylaxis in medical patients admitted to specialized hospital in Ethiopia using Padua prediction score

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Abstract

Introduction: Venous thromboembolism is a major cause of mortality and morbidity among hospitalized patients and thromboprophylaxis is one of the key strategies to reduce such events. We aimed to assess venous thromboembolism risk using Padua prediction score, thromboprophylaxis practice, and outcomes in hospitalized medical patients at Tibebe Ghion Specialized Hospital, Bahir Dar, Ethiopia.

Methods: A cross-sectional study was conducted among 219 patients admitted to Tibebe Ghion Specialized Hospital from 1 December 2018 to 31 May 2019. Data were collected from patients' medical records using a pre-tested data abstraction format to collect patients' clinical information and venous thromboembolism risk using the Padua prediction score. We used Statistical Package for the Social Sciences version 26 for data analysis. Descriptive statistics was used to summarize the findings, and binary logistic regression analysis was used to assess association between the variables of interest.

Results: Reduced mobility, recent trauma and/or surgery, heart and/or respiratory failure, and active cancer were the frequently identified venous thromboembolism risk factors. Based on Padua prediction score, 48.4% of patients were at high risk of developing venous thromboembolism. The venous thromboembolism prophylaxis was given only for 55 (25.1%) patients and 15 of them were at low risk of developing venous thromboembolism (<4 Padua score) and were ineligible for thromboprophylaxis. Fifteen (6.84%) patients developed venous thromboembolism events during their stay at the hospital and 80% of them were from high risk group. The odds of females to develop venous thromboembolism were more than 14 times higher (adjusted odds ratio = 14.51; 95% confidence interval: 2.52–83.39, p = 0.003) than males. Reduced mobility (adjusted odds ratio = 10.00; 95% confidence interval: 1.70–58.70), <1 month trauma and/or surgery (adjusted odds ratio = 18.93; 95% confidence interval: 2.30–155.56), active cancer (adjusted odds ratio = 6.00; 95% confidence interval: 1.05–34.27), chronic kidney diseases (adjusted odds ratio = 61.790; 95% confidence interval: 2.627–1453.602), and hypertension (adjusted odds ratio = 7.270; 95% confidence interval: 1.105–47.835) were significantly associated with the risk of developing venous thromboembolism.

Conclusion: Nearly half of the patients were at risk of developing venous thromboembolism. Underutilization of thromboprophylaxis and inappropriate use of prophylaxis were commonly seen in Tibebe Ghion Specialized Hospital.

Keywords

Venous thromboembolism, VTE risk, thromboprophylaxis, Padua prediction score, Ethiopia

Date received: 4 September 2021; accepted: 22 January 2022

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Introduction

Venous thromboembolism (VTE), which comprises deep vein thrombosis (DVT) and pulmonary embolism (PE), is the main antecedent of mortality and morbidity in hospitalized patients.[1] More than 25% of all VTE is related to hospitalization and 50%–75% of these cases happen in hospitalized medical patients,[2] and nearly one-fourth of the VTE events happen in the community.[3] Death because of PE is assumed to be high among medical inpatients.[4] The findings of the Medical Patients with Enoxaparin (MEDENOX) study indicated that the increased risk of VTE persists for up to 3 months after the initial presentation and recommended extended duration of thromboprophylaxis.[5] However, global audits have revealed that thromboprophylaxis prescribing practice by healthcare professionals for medical inpatients having VTE risk is low because of perceived fear of bleeding or lower risk of VTE against conveyed in the clinical trials.[6] A higher DVT rate was reported in medical patients who did not receive the prophylaxis.[7]

Prevention of VTE comprised pharmacological prophylaxis and non-pharmacologic prophylaxis such as compression stockings, leg elevation, sequential compression devices, ambulation, and vena cava filter.[8] The overall utilization of prophylaxis was not adequate in admitted patients, regardless of patient's VTE risk.[9] In a prospective observational study of 1180 medical inpatients, 39.7% were at high risk and VTE occurred in 11% of high-risk patient's versus 0.3% in low-risk patients.[10] Poor utilization of thromboprophylaxis in inpatients could be due to forgetting to consider the risk of DVT for every patient as most of the patients had multiple diagnoses and emphasis is given mostly to the patients' chief complaints and major diagnosis.[11]

A survey in Togo has found that only 16% of anesthetists and surgeons considered that VTE is common in their country as in western countries.[12] The lack of implementation of evidence-based guidelines for VTE prophylaxis among risky medical patients may be due to confusion regarding the assessment of VTE risk, a lack of awareness of VTE risk, or a strong fear of major bleeding.[13] VTE recurs frequently and this had significantly worse disease severity and poorer quality of life than patients without prior VTE, indicating that burden of illness is more severe in such patients.[14] The cost of drugs in low-income countries may have a detrimental effect on the prescription of VTE prophylaxis and patients' adherence to the prophylaxis.[15] Former studies have revealed that costs for the management of a recurrent VTE event were greater than those for the management of a first VTE event.[16] Similarly, an inpatient VTE incident study evaluating 2147 patients found that the median cost of VTE events was US$3131 per DVT, US$6424 per PE, and US$6678 per DVT + PE event.[17] Hospitalized patients were at increased risk to develop VTE when compared to patients in the community.[18,19] But, both DVT and PE are preventable in medical inpatients by using appropriate VTE prophylaxis.[20] Findings from a global survey indicated that 84% of hospitals were described as using a risk assessment tool for VTE and 68% showed it was mandatory, whereas only 8.8% had national guidelines justifying the use of VTE risk assessment.[21] A systematic review and meta-analysis showed that from 50.5% of patients with an indication to thromboprophylaxis, 54.5% had received adequate thromboprophylaxis, and bleeding, thrombocytopenia, and renal/hepatic failure were commonly specified contraindications to thromboprophylaxis.[22] Hence, we aimed to assess VTE risk, thromboprophylaxis practice, and outcomes using the Padua prediction score (PPS) in hospitalized medical patients at Tibebe Ghion Specialized Hospital (TGSH).

Materials and methods

Study area

The study was carried out at TGSH, Bahir Dar, Ethiopia. It is a tertiary teaching hospital that is affiliated to Bahir Dar University with 500 beds, out of which 72 are reserved for medical adult patients. The hospital served as a referral center in Amhara Region and gives emergency, inpatient, and outpatient services.

Study design and period

A retrospective cross-sectional study was conducted among medical patients admitted to TGSH from 1 December 2018 to 31 May 2019.

Inclusion and exclusion criteria

All patients (age $\geqslant$18 years old) with complete documentation, who were admitted to medical wards of the hospital during the study period, and hospitalized for $>$48 h were included in the study. However, patients admitted with established VTE and on treatment were excluded from our study.

Sample size and sampling method

The sample size of this study was determined by single population formula. The rate of VTE prophylaxis utilization (first outcome measurement) of 40% and prevalence of VTE in hospitalized medical patients (second outcome measurement) of 5.5% were reported from similar pervious study in Ethiopia.[23] Considering assumptions of 95% confidence interval (CI), level of precision 5% with addition of a 10% non-response rate in both scenarios, sample size of 406 and 80 was obtained, respectively. The sample size calculated using the first outcome measurement was larger than that of second outcome measurement and accordingly sample size of 406 was taken. Consequently, 406 patients' charts were included for retrospective review by systematic random

Table 1. Sociodemographic and clinical characteristics of patients admitted to medical wards of TGSH.

Sociodemographic and clinical profile		N (%)
Sex	Male	112 (51.1)
	Female	107 (48.9)
Age (in years)	18–39	87 (39.7)
	40–59	68 (31.1)
	60–74	38 (17.4)
	⩾75	26 (11.9)
Reason for admission to hospital	Congestive heart failure	59 (26.9)
	Anemia	45 (20.5)
	Retroviral infection	19 (8.7)
	Hypertension	14 (6.4)
	Hematologic malignancy	5 (2.3)
	Diabetes mellitus	17 (7.8)
	Others[a]	27 (12.3)
Duration of hospital stay (in days)	⩽7	125 (57.3)
	8–15	66 (30.1)
	16–30	20 (9.1)
	31–90	4 (1.8)
	⩾91	4 (1.8)

TGSH: Tibebe Ghion Specialized Hospital.
[a]Others: chronic kidney disease, acute kidney injury, and respiratory infections.

sampling method. Finally, we reviewed 219 patients' charts that fulfilled the inclusion criteria during the 6-month admission period and included in final analysis.

Data collection, management, quality assurance, and analysis

A data collection instrument was designed to capture sociodemographic profiles (age, sex), VTE risk assessment, contraindication, thromboprophylaxis, and VTE-related patient outcomes and used to collect data from patients' charts. The Padua risk assessement model (RAM) was used for assessing VTE risk assessment in our study.[11] The VTE events were identified as recorded by attending physicians on medical charts of patients. The data were collected by two interns and the principal investigator after 1-day training was provided. A pre-test was conducted on 5% of the study population for checking data collection; instrument clarity, simplicity, understandability, and necessary modification were made to it before actual data collection.

Statistical analysis

We used Statistical Package for the Social Sciences (SPSS) version 26 for analyzing data. Descriptive statistics were used to analyze relevant socio-demographic and clinical characteristics, and logistic regression analysis was carried out to assess the association between dependent and independent variables. Significant association was declared at p-value < 0.05.

Ethical approval

Ethical clearance was secured from the Ethical Review Committee of College of Medicine and Health Sciences of Bahir Dar University (Approval Number: 00232//2020). Every effort was made to maintain the confidentiality of study participants in this study, and data are analyzed in aggregate.

Results

Sociodemographic and clinical characteristics

Out of 219 patients, 51.1% were male. The mean (± SD) age of the participants in years was 46.40 (± 18.64 SD). The maximum hospital stay was 57 days with a mean of 9.5 days. Major reasons for hospitalization were due to congestive heart failure (26.9%), anemia (20.5%), and stroke (15.5%) (Table 1).

The most frequently identified VTE risk factors were acute infection/and rheumatologic disorder (76.7%) and reduced mobility (41.1%). All risk factors based on Padua RAM are shown in Table 2.

VTE Risk stratification based on Padua RAM and thromboprophylaxis

In our study, 48.4% of study participants were at high risk of developing VTE (⩾4 Padua risk score). The maximum and minimum total Padua risk scores were 8 and 1, respectively, with a mean score of 2.2 (Table 3).

Table 2. VTE risk factors of medical patients hospitalized to medical wards of TGSH based on Padua risk score stratification.

VTE Risk factors and Padua score		N (%)
1-point risk factor	Acute infection and rheumatologic disorder	168 (76.7)
	Heart and/or respiratory failure	47 (21.5)
	Acute myocardial infarction or ischemic stroke	28 (12.8)
	Elderly age ⩾ 70	30 (13.7)
2-point risk factor	Recent (<1 month) trauma and/or surgery	10 (4.6)
3-point risk factor	Reduced mobility	90 (41.1)
	Active cancer	23 (10.5)
	Previous VTE (excluding superficial venous thrombosis)	3 (1.4)

VTE: venous thromboembolism; TGSH: Tibebe Ghion Specialized Hospital.

Table 3. VTE risk stratification, thromboprophylaxis, and VTE outcomes in patients admitted to medical wards of TGSH.

Total risk score	Risk stratification	N (%)	Prophylaxis not provided N (%)	Prophylaxis provided N (%)	VTE Developed N (%)
0–3	Low risk	113 (51.6)	98 (86.7)	15 (15.3)	3 (2.6)
⩾4	High risk	106 (48.4)	66 (62.3)	40 (37.7)	12 (11.3)
Total		219 (100)	164 (74.9)	55 (25.1)	15 (6.8)

VTE: venous thromboembolism; TGSH: Tibebe Ghion Specialized Hospital.

Table 4. Thromboprophylaxis used in hospitalized medical patient at TGSH.

Thromboprophylaxis Used	N (%)
Unfractionated heparin 7500 IU SC BID	46 (21)
Unfractionated heparin 5000 IU SC TID	1 (0.4)
Aspirin 81 mg per oral daily	8 (3.7)
No prophylaxis given	164 (74.9)

TGSH: Tibebe Ghion Specialized Hospital.

VTE prophylaxis was given for 55 (25.1%) patients and 15 of them were at low risk of developing VTE (<4 Padua score) and were ineligible for thromboprophylaxis. In the remaining 26 patients from a high-risk group, thromboprophylaxis was not prescribed. Heparin 7500 IU SC BID/day was the most widely used prophylaxis regimen in the studied population (Table 4).

In our study, 15 (6.84%) patients developed VTE events and 80% of them were from high VTE risk groups (Table 3) and it occurred in patients who stayed in the hospital for 7 days and above. All patients who developed VTE did not receive thromboprophylaxis and then they received treatment regimens for VTE management. Thromboprophylaxis was given inappropriately for 15 patients although they did not fulfill the criteria for prophylaxis, that is, at low risk of developing VTE. Prophylaxis was continued until mobility returned to an anticipated level or when the patient was discharged from the hospital whichever was sooner in the study participants. In 66 (30.13%) study participants, who were in a high-risk group, VTE outcomes and VTE prophylaxis administration status were not documented in the study setting. In addition, four patients with absolute contraindications received prophylaxis without considering the hurts.

Contraindications to pharmacological prophylaxis

In this study, 18 patients had one or more contraindications to thromboprophylaxis due to high bleeding (61.11%), gastrointestinal bleed within the last 3 months (16.67%), significant thrombocytopenia <50,000/cell (11.11%), and severe peripheral artery disease (11.11%).

Factors associated with VTE development in studied participants

All variables with a p-value ⩽0.25 in bivariate analysis were taken to a multivariable model to control for all possible confounders. Accordingly, the odds of females to develop VTE were 14.51 times higher (95% CI (2.52–83.39), p = 0.003) than males. Reduced mobility adjusted odds ratio (AOR) = 10.00 (95% CI (1.70–58.70)), <1 month trauma and/or surgery AOR = 18.93 (95% CI (2.30–155.56)), active

Table 5. Factors associated with VTE development in TGSH.

Variables	Category	COR (95% CI)	AOR (95% CI)	p-value
Sex	Female	4.59 (1.26–16.75)	14.51 (2.52–83.39)	0.003
	Male	1.00		
Age in years	⩾60	9.6 (2.62–35.24)	17.78 (2.88–109.95)	0.002
	<60	1.00		
Reduced mobility	Yes	6.46 (1.79–23.62)	9.99 (1.70–58.70)	0.011
	No	1.00		
Recent (<1 month) trauma and/or surgery	Yes	7.04 (1.61–30.68)	18.93 (2.30–155.56)	0.006
	No	1.00		
Chronic kidney disease	Yes	7.69 (1.287–45.97)	61.79 (2.63–1453.60)	0.010
	No	1.00		
Active cancer	Yes	3.54 (1.03–12.21)	5.999 (1.05–34.28)	0.044
	No	1.00		
Hypertension	Yes	3.94 (1.24–12.53)	7.270 (1.11–47.84)	0.039
	No	1.00		

COR: crude odds ratio; AOR: adjusted odds ratio; CI: confidence interval; TGSH: Tibebe Ghion Specialized Hospital.

cancer AOR = 6.00 (95% CI (1.05–34.27)), chronic kidney diseases AOR = 61.790 (95% CI (2.627–1453.602)), and hypertension AOR = 7.270 (95% CI (1.105–47.835)) were independent predictors for VTE incidents in this study (Table 5). The c-index for the prediction of VTE using Padua model was 0.7 (95% CI: 0·54–0·80), which revealed good discrimination characteristics.

Discussion

In line with other studies reported from Ethiopia,[23,24] in the present study, the most common risk factors for VTE were acute infection/and rheumatologic disorder (76.7%), reduced mobility (41.1%), having heart and /or respiratory failure (21.5%), elderly age ⩾70 years (13.7%), active cancer (10.5%), and acute myocardial infarction or ischemic stroke (12.8%).

Nearly half (48.4%) of admitted patients were at a high risk of VTE that requires pharmacological thromboprophylaxis. Similarly, another study from Ethiopia reported that about 47.6% of medical inpatients had a significant DVT risk.[24] However, in our study, thromboprophylaxis was given to only 25.1% of patients and 6.84% of them received it without having risk or they were at lower risk which doesn't mandate thromboprophylaxis and four patients were given pharmacologic prophylaxis despite the patients had absolute contraindication. There were 26 patients from high-risk group who did not get prophylaxis which may be due to ineligibility and/or contraindication, the fear of risk of bleeding and failure of prescribing them even for legible patients by prescribers. In the studied hospital, pharmacological prophylaxis was continued until mobility returned to an anticipated level or when the patient was discharged from the hospital whichever was sooner.

In comparison with our finding, slightly higher thromboprophylaxis rate (39.3%) was documented in Saudi Arabia study.[25] Underutilization of prophylaxis was shown in several studies including the ENDORSE study (a multinational cross-sectional survey) which reported 39.5% of thromboprophylaxis rate.[13] Higher rates of thromboprophylaxis (90%) were seen in Canadian multicenter study, but only 16% received appropriate thromboprophylaxis.[26] The MEDENOX trial which compared patients received enoxaparin with placebo reported that the incidence of VTE was significantly reduced among the enoxaparin 40 mg group (5.5%) compared to the placebo group (14.9%).[27] In the same way, Barbar et al.[11] documented the importance of prophylaxis in reducing the incidence of VTE among high VTE risk patients (Padua score ⩾ 4) (2.2%) compared with who hadn't received thromboprophylaxis (11%). Lower rates of utilizing prophylaxis in our study might be due to physicians might perceiving low incidence of VTE in these groups of patient population, failure to recognize high-risk patients, familiarity with published recommendations, and fear of bleeding from anticoagulation.

In the present study, the incidence of VTE events was 6.84% which is higher than that of the Israel's study (0.24%),[28] but almost similar to the other study conducted in Ethiopia (5.5%).[23] The high incidence of VTE in our study compared to the study reported in Israel could be linked to failure to assess risk factors and lower rate of utilization of thromboprophylaxis for eligible patients.

Reduced mobility, recent trauma (<1 month) and/or surgery, active cancer, being female, chronic kidney diseases, and hypertension were found to be independent predictors of VTE development. In line with our study, another study done at public medical college in Pakistan[29] described reduced mobility (54.7%, $p < 0.005$) and advancing age (41.17%, $p < 0.005$) are independent risk factors of VTE. Hospitalized

medical patients symbolize a population with varied susceptibility to VTE for which risk assessment is needed before starting thromboprophylaxis.[30] Even though the use of thromboprophylaxis is recommended for acutely ill medical patients at increased risk VTE, it remains unclear which RAM should be routinely used to identify at-risk patients requiring thromboprophylaxis. Risk stratification remains an ongoing problem because existing RAMs might not effectively classify risk groups.[31]

A systematic review done in 2017 showed that existing RAMs (e.g. 4-Element RAM, Caprini RAM, a full logistic model, Geneva risk score, IMPROVE-RAM, Kucher Model, a "Multivariable Model," and PPS) to assess the need of thromboprophylaxis in acutely ill medical patients are challenging to compare and none fulfills the criteria of an ideal RAM.[32] However, the appropriateness of thromboprophylaxis may be improved by using one of the validated RAMs. Whereas in other study, the addition of D-dimer into the IMPROVE VTE risk assessment model improves risk stratification in hospitalized medically ill patients who took thromboprophylaxis.[33]

Limitations

Since we used data from chart review, some necessary data (like body mass index, undocumented VTE, and its risk factors) were not found on patients' medical charts. Another limitation was we did not include enough patients in accordance with the sample size calculation to achieve the expected power. It was difficult to assess other non-pharmacologic alternatives like leg elevation and early ambulation since it was not documented on patients' charts. We couldn't collect data on the bleeding rates in this study population as such information were not documented in patients' charts. In addition, since only small number of VTE events had occurred, it might be difficult to measure association accurately.

Conclusion

Nearly half of the patients were at risk of developing VTE, but there was underutilization of thromboprophylaxis in medical patients admitted at TGSH. There was also inappropriate use of prophylaxis in ineligible study participants, that is, in low risk and patients' contraindication to the thromboprophylaxis. The hospital shall design quality improvement strategy to improve VTE risk assessment and prophylaxis prescribing by using validated tool by embedding it in patients' charts for better assessment and deciding on VTE prophylaxis.

Acknowledgements

The authors would like to acknowledge Tibebe Ghion Specialized Hospital for facilitating this study.

Author contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising, or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Data sharing statement

The original dataset supporting the finding of the present study will be available from the corresponding author upon a reasonable request.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

Ethical approval and consent to participate

Ethical clearance was obtained from the Ethical Review Committee of Bahir Dar University, College of Medicine and Health Sciences (Approval Number: 00232//2020), and permission to access patient charts was obtained from the hospital clinical service director and internal medicine department. Information obtained from the data collected during the study was only handled by the research team.

Informed consent

Informed consent was not sought for the present study because we collected data retrospectively from patients' charts. Hence, as we have not interviewed patients, there was no need to obtain informed consent. This was waived by Institutional Review Board of College of Medicine and Health Science Bahir Dar University with approval number: 00232//2020 (dated 22 May 2020).

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Supplemental material

Supplemental material for this article is available online.

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