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Original Article

Prevalence of venous thromboembolism risk factors and prophylactic adequacy among general surgical patients in a tertiary care hospital



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ABSTRACT

Introduction: Venous thromboembolism (VTE) is a disease manifested as deep vein thrombosis and pulmonary embolism. General surgical procedures are associated with significant risk of precipitating VTE, and despite the surging evidences, it is often overlooked. The study attempted at estimating the prevalence of VTE and bleeding risk factors coupled with the adequacy of thromboprophylaxis administered.

Methodology: The study spanning 1-year duration was executed through collection of data from patients older than 18 years, admitted to the general surgery department of a tertiary care hospital. The data were collected using internally validated data collection form and the appraisal of data was done using SPSS 18.

Results: Among the 400 subjects enrolled, number of patients in low, moderate, and high risk, as per the Caprini score, was 24%, 35%, and 41%, respectively, with the difference being significant with $p < 0.001$. Bleeding risk was positive in 28% subjects and 36% received any form of prophylaxis other than early ambulation. 28% subjects were identified to have received adequate thromboprophylaxis.

Conclusion: Although the prevalence of 41% individuals at high risk for VTE is comparable to the global prevalence of 41.5%, prophylactic adequacy of 28% was lower than the 33% observed globally. Meticulous planning coupled with operational interventions, such as institutional multidisciplinary thromboprophylactic team, can be an effective strategy at enhancing the prophylactic standards and thereby attaining optimal patient outcomes.

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1. Introduction

Thrombus comprising of platelets and fibrin is the terminal consequence of the blood coagulation pathway and helps perpetuate hemostasis. Despite its beneficial effect, it has the potential to dislodge from the site of injury and occlude blood vessels in other areas, producing a paradoxical effect.¹ Venous thromboembolism (VTE) is a disease that encompasses deep vein thrombosis (DVT) and pulmonary embolism (PE). With aptitude to produce significant morbidity and mortality, they jointly pose a global health concern. Oftentimes, VTE remains asymptomatic and underdiagnosed, culminating in chronic complications and truncated survival.

VTE is precipitated by several factors and humanity's comprehension on its probable association with surgical procedure is not novel. The patient at highest risk involves those undergoing major orthopedic procedures, where 50–60% patients have propensity to develop DVT.² Although the prophylaxis in orthopedic procedures is given due importance, risk associated with general surgical procedures has been consistently downgraded across the globe. A patient undergoing major surgical procedure has 20-fold risk enhancement for VTE and the risk is increased by 30% when there is absence of optimal prophylaxis.³ The risk associated with VTE in general surgery varies between 10 and 50% depending on the type of surgery and patient risk factors.⁴ Accurate estimation of thromboembolic risk is therefore quintessential and attempts have been made since 1970s for fabrication of several risk assessment models (RAMs) based on clinical and laboratory parameters. Despite profuse RAMs available, none provided a comprehensive guidance covering all patient groups.⁵

The increasing number of evidences accumulated through meta-analysis studies has led to the development of American College of Chest Physician (ACCP) 9th antithrombotic guidelines in 2013, which unlike its predecessor of 2008 has distinctively emphasized the relevance of risk stratification by addressing nonorthopedic surgical thromboprophylaxis in a separate section.^{6,7} The guideline advocates the use of Caprini score⁸ as an effective RAM to appraise individualized risk in general surgical candidates. Although it was not devised using meticulous statistical procedures, it is relatively easy to use and has been successful in discriminating different tiers of risk among surgical patients. It has also been validated using a large retrospective study comprising sample of general, vascular, and urological surgery patients.⁹ However, Caprini score has not been adequately validated in gynecological surgery subjects and the application of the same to this specific subgroup is unsubstantiated.

Although several studies have attempted to outline the distribution of VTE risk in surgical patients, very few have addressed the general surgical patients specifically. Estimation of prevalence of VTE and bleeding risk factors can assist healthcare practitioners contemplate on relevant issues with thromboprophylaxis in the specific population and meticulously plan strategies to tackle the same. The following study was aimed at assessing various VTE and bleeding risk factors prevalent in the population and the adequacy of prophylaxis provided in relevance to the ACCP 9th antithrombotic guidelines.

2. Materials and methods

The study spanning 1 year was carried out in the general surgical department of a private tertiary care hospital in Kerala. This cross-sectional study was conducted from February 2014 to January 2015 and enrolled subjects greater than 18 years of age, undergoing those surgical procedures, which are necessitated with inpatient admission. Pregnant patients, patients of non-Indian origin, those admitted solely for VTE treatment, or operated under local anesthesia were excluded from the study. Most of the local anesthesia procedures did not require admission and were performed on a day care basis. Ethical approval was obtained through written consent from the institutional ethical committee prior to enrollment of the first subject. Verbal as well as written consent was obtained either from the patients or relatives after duly informing them of the various aspects as mandated in the ICMR ethical guidelines.¹⁰ A total of 400 subjects were enrolled during the study period and their demographics along with surgical data were collected using an internally validated data collection form. Caprini score was utilized for stratifying the patients into low-, moderate-, and high-risk groups.⁸ Conditions, such as age 41–60 years, swollen legs, varicose veins, minor surgery, sepsis <1 month ago, history of inflammatory bowel disease, prior major surgery, abnormal pulmonary function, obesity (defined as BMI > 25 kg/m²), and other comorbidities (diabetes, hypertension, coronary artery disease, dyslipidemia), if present, were assigned 1 point each. 2 points were assigned for the presence of each of these conditions: age 61–74 years, laparoscopic surgery, major surgery (>45 min duration), history or presence of malignancy, bed confinement >3 days, and central venous access. Age >75 years and history of DVT were used to assign 3 points if present. Similarly, multiple trauma and lower limb fractures were assigned 5 points. The overall VTE risk score was assigned to each patient and was estimated through summation of the individual points assigned on the basis of presence of any of these mentioned conditions.

Conditions, such as active bleeding, prior major bleeding, known or untreated bleeding disorders, severe renal or hepatic failure, thrombocytopenia, acute stroke, uncontrolled systemic hypertension, concomitant use of anticoagulants, antiplatelet therapy, or thrombolytic drugs, were considered as risk factors for bleeding, as per the ACCP recommendations. Presence of these conditions was assumed as contraindications to administration of pharmacological prophylaxis. The thromboprophylactic therapy administered to each patient was scrutinized and compared against this guideline to estimate the compliance. The recommendations used for appraising the prophylactic compliance, as per the ACCP guidelines, have been summarized in [Table 1](#). Statistical analysis of the data was performed using SPSS 18.0 and the results were interpreted in terms of *p*-value with level of significance set at 0.05.

3. Results

An aggregate of 400 patients who met the predetermined criteria were enrolled in the study. Among the total sample,

Table 1 – ACCP recommended venous thromboembolism prophylaxis in nonorthopedic surgical patients.

Caprini score	Risk level	Prophylaxis regimen (without bleeding risk)	Prophylaxis regimen (with bleeding risk)
0	Very low	Early ambulation	
1–2	Low	Mechanical prophylaxis, preferably with IPC device	
3–4	Moderate	Any ONE of the following agents: <ul style="list-style-type: none"> • IPC device (min 20 h/day) or elastic stocking • Unfractionated Heparin 5000 U s.c. TID • Enoxaparin 40 mg s.c. OD • Fondaparinux 2.5 mg s.c. OD 	Mechanical prophylaxis preferably with IPC device
5 or more	High	Combination of the following agents: <ul style="list-style-type: none"> • IPC device (min 20 h/day) or elastic stocking + (any one of the following) <ul style="list-style-type: none"> • Unfractionated Heparin 5000U s.c. TID • Enoxaparin 40 mg s.c. OD • Fondaparinux 2.5 mg s.c. OD 	Mechanical prophylaxis, preferably with IPC device, until risk of bleeding diminishes and pharmacologic prophylaxis can be added

s.c., subcutaneous; OD, once-daily dosing; TID, thrice-daily dosing; IPC, intermittent pneumatic compression device.

63% ($n = 252$) were males and the remaining were females demonstrating a significant difference in gender distribution with $p < 0.001$. The mean age of the total sample was determined at 50.09 ± 16.52 years. Mean age of male population was estimated to be 51.44 ± 11.15 years and that of females as 47.61 ± 17.48 years. The difference in age distribution with respect to gender was found to be significant with $p = 0.011$. Majority of the subjects were found to belong to the age group of 41–60 years (43%) with the least (7%) in age group >74 years (Table 2). The distribution of males and females in different age groups was found to be significantly different with $p = 0.045$.

The average height and weight of the population was determined as 1.67 ± 0.07 m and 65.69 ± 10.2 kg, respectively. The average BMI of the sample was found to be 23.4 ± 3.5 kg/m² and the average length of hospital stay was estimated as 7.81 ± 3.22 days. 4% ($n = 16$) of the subjects were underweight, 68% ($n = 272$) had normal weight, and the remaining 28% ($n = 112$) were obese.

Major surgery defined as procedures lasting >45 min using general anesthesia was the most prevalent procedure encompassing 52% ($n = 208$) of the subjects. 20% ($n = 80$) underwent laparoscopic surgery and the remaining 28% (112) had minor surgery. The average duration of procedures was computed as 1 h 21 min \pm 59 min. 44% ($n = 176$) underwent the procedure under spinal anesthesia contrasting with 56% ($n = 224$), who had general anesthesia, and the difference was significant with $p = 0.019$.

The average Caprini score of the enrolled subjects was computed as 4.26 ± 2.52 points. The number of patients in low, moderate, and high risk, as per the Caprini score, was 24%, 35%, and 41%, respectively, with the difference being significant with $p < 0.001$. 29% of the patients on evaluation were found to have bleeding risk factors with the most prevalent being hepatic dysfunction encompassing 12% of the total subjects (Fig. 1). The bleeding risk was found to be 8.3%, 37.14%, and 34.14% among low-, moderate-, and high-risk patients, respectively, with the difference among groups proving to be significant with $p < 0.0001$. An extremely significant correlation was computed between Caprini

score and number of risk factors with Pearson correlation coefficient of 0.849. Similar correlation was found between age and Caprini score with Pearson correlation coefficient of 0.456. However, correlation was also estimated with bleeding risk factor and age yielding coefficient of 0.503.

Mobilization was used as sole strategy of prophylaxis in 64% subjects, whereas, at least some sort of prophylaxis using mechanical and pharmacological modalities was done in the remaining cases. Among them, mechanical prophylaxis was administered to 14% patients, which comprised 5% subjects receiving elastic compression stocking and 9% receiving sequential compression device. Pharmacological prophylaxis was relied for prophylaxis in 14% patients and consisted of 11% receiving enoxaparin and the remaining 3% receiving low-dose unfractionated heparin. Combination of both mechanical and pharmacological prophylaxes was used only in 8% of the patients. On comparing and contrasting the prophylactic strategies with the standard guideline, it was estimated that only 28% of the patients received optimal prophylaxis. Prophylactic compliance with ACCP 9th guideline in each risk category is represented in Fig. 2. Noncompliance with standard prophylaxis was appraised as 65.52% among patients without bleeding risk and 74.65% among patients having positive bleeding risk. The difference was found to be nonsignificant, with $p = 0.065$.

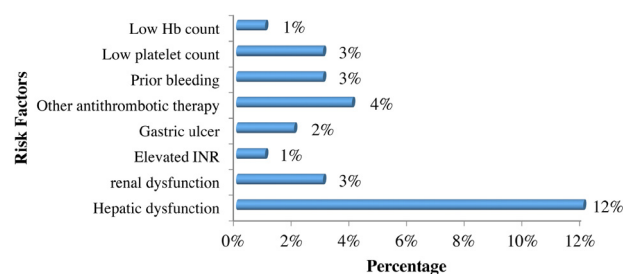
**Fig. 1 – Histogram representing frequency distribution of bleeding risk factors.**

Table 2 – Patient risk factors for VTE and surgical procedure distribution.

Risk factor for DVT	Frequency (number of patients)	Percentage (%)
<i>1 point Caprini score risk factors</i>		
Age 41–60 years	172	43
Swollen legs	12	3
Varicose veins	12	3
Minor surgery	112	28
Sepsis <1month	60	15
History of IBD	4	1
Prior major surgery	12	3
Abnormal pulmonary function	36	9
Obesity		
Other risk factors	160	40
<i>2 point Caprini score risk factors</i>		
Age 61–74 years	76	19
Laparoscopic surgery	80	20
Major surgery	208	52
Malignancy present/previous	44	11
Bed confinement >3 days	20	5
Central venous access	4	1
<i>3 point Caprini score risk factors</i>		
Age >75 years	28	7
History of DVT	4	1
<i>5 point Caprini score risk factors</i>		
Multiple trauma	4	1
Hip/pelvis/leg fracture	8	2
<i>Surgical procedure</i>		
Drainage and debridement	68	17.0
Cholecystectomy	52	13.0
Appendectomy	48	12.0
Hernia repair	48	12.0
Exploratory laparotomy	28	7.0
Gastrectomy	16	4.0
Hemorrhoidectomy	16	4.0
Lords dilation	16	4.0
Thyroidectomy	16	4.0
Colostomy	12	3.0
Limb amputation	12	3.0
Mastectomy	12	3.0
Diagnostic laparoscopy	8	2.0
Fasciotomy	8	2.0
Fistulectomy	8	2.0
Anastomosis resection	4	1.0
Colectomy	4	1.0
Diaphragm repair	4	1.0
Orchiectomy	4	1.0
Proctectomy	4	1.0
Sclerotherapy	4	1.0
Skin grafting	4	1.0
Tracheostomy	4	1.0

4. Discussion

In this study, we assessed the prevalence of various risk factors among the general surgical patients of a tertiary care hospital for a period of 1 year. Since admissions in inpatient general surgical department are usually made for patients requiring surgery or necessity of surgery is evaluated, each

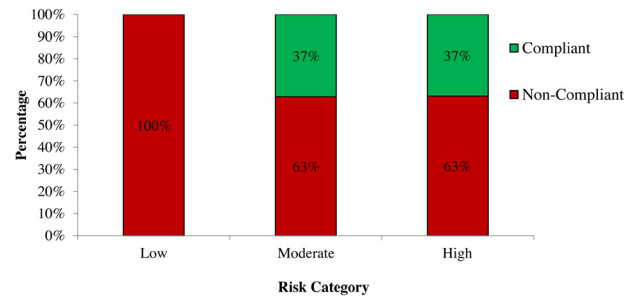


Fig. 2 – Compliance of prophylactic compliance to ACCP 9th guideline in each risk category.

patient will, therefore, have at least a minor risk for VTE, as per the Caprini score.

The majority in the subject pool were men, similar to most other similar studies with male dominance, and thus reducing the risk factor in this population associated with use of hormone preparations, such as oral contraceptives and hormone replacement therapies. There was found to be extremely significant correlation between the number of risk factors and Caprini score indicating that rather than single dominant risk factors, presence of multiple minor factors was responsible for the overall score. Although several RAMs are available to estimate the risk of VTE, selection of an improper one can underestimate the patient's risk and culminate in inadequate thromboprophylaxis. Many surgeons tend to perceive only obesity, immobilization, malignancy, and prior VTE as potential threats and tend to overlook the minor factors. These factors although may seem unsubstantial individually, they may pose serious threats to the patients in combination with underlying genetic deficiencies, which are rarely screened for in India.

The data demonstrated correlation between age and overall Caprini score, which necessitated more stringent monitoring of elderly patients. However, the situation is further complicated by the increase in bleeding risk factors with age, as evident from the correlation between the two.

This may be attributed to the decline in hepatic function with increasing age, which prevents the use of pharmacological prophylactic measures in this age group. Elderly patients should therefore be given adequate duration of mechanical prophylaxis unless contraindicated, and monitoring should be done at regular intervals to ensure compliance.

The study revealed that 41% patients were at high risk for developing VTE. The prevalence was lower than the estimation made through ENDORSE study by Pinjala et al.,¹¹ where 61.3% surgical patients were at-risk. However, the later study had also encompassed orthopedic surgical patients, which may have increased the prevalence. The global surgical risk, as estimated by Cohen et al.,¹² accounted to 41.5% in surgical patients and was comparable with the present study. In the Indian subset ENDORSE study, the proportion of surgical candidates provided with any kind of prophylaxis was determined as 18.5%, of whom, 16.3% met the ACCP recommended adequacy. It was observed in the current study that 36% of the surgical patients were given at least some

prophylactic therapy and 28% in this group received adequate prophylaxis. Although these ratios were higher than the Indian study, global ENDORSE study had estimated a greater prophylaxis administration of 50.2% and up to 33% satisfying adequacy criteria. European countries like Germany, Spain, and Switzerland in contrast have been successful in achieving appropriate prophylaxis rates of 92%, 82%, and 81%, respectively.^{13–15} Such high rates have been achieved through incorporation of computerized reminder systems in practice, which is currently available in very few hospitals across India. Another noteworthy finding is the complete noncompliance estimated in low-risk patients. As per the ACCP recommendation, low-risk patients should be administered mechanical prophylaxis preferably with sequential compression device, which has not been practiced here. A recent study found that despite timely ambulation, patients were still at risk of VTE, and this risk was substantially reduced with mechanical or pharmacological prophylaxis. Therefore, patient ambulation or mobility should not be used as a reason to discontinue, or restrict, prophylaxis during hospitalization.¹⁶

The major factor restraining the utilization of optimal prophylaxis could be the lack of update with current guidelines. ACCP 9th guideline is more comprehensive than its prior edition on which most surgeons rely to design prophylaxis. Inadequacy may also be attributed to lack of individualization of thromboprophylaxis. Patient discomfort associated with mechanical prophylaxis, which mandate 20 h continuous compression of the calf region, is also another probable factor restraining surgeons from giving prophylaxis to low-risk patients. Bleeding risk factor was positive in 28% of the subjects and should not be considered as a curtailing component as the guideline clearly states the type of prophylaxis to be utilized in such a situation. The surgeon was not apprehensive of the bleeding risk factors with prophylactic doses of anticoagulants, especially enoxaparin, as the incidence of adversities was perceived to be extremely low. This is evident from the absence of any significant difference between noncompliance among patients with and without bleeding risk. However, surgeons must exercise caution while considering pharmacological prophylaxis in patients with underlying bleeding risk, and should adhere to the guideline to avoid adversities.

Formation of multidisciplinary thromboprophylaxis teams comprising of physicians, clinical pharmacists, and nursing staff can be a viable option to enhance the prophylactic strategies in a country like India, where reliance on computerized reminder system is not feasible across all settings. The surgical nurse can make a detailed patient interview to evaluate the VTE and bleeding risks in line with the standard guidelines. The individualized score can then be communicated to the clinical pharmacists, who, after weighing the risk and benefits of pharmacological versus mechanical prophylaxis, can make detailed recommendation to the physicians on thromboprophylaxis for each surgical candidate.

5. Conclusions

The study triumphed in estimating the prevalence of risk factors associated with VTE in the study setting. Hepatic

dysfunction was the most prevalent bleeding risk factor and its association with increasing age presents a potential complication in administering proper prophylaxis. Physicians should restrain from using early ambulation as the sole prophylactic strategy. The thromboprophylaxis adequacy, although comparable to global estimates, still has scope for enhancement through meticulous planning and appropriate interventions.

Conflicts of interest

The authors have none to declare.

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