Original Article

A prospective study on risk assessment and prophylaxis of venous thromboembolism in general surgery patients

Nita Bharti[1], Anil Luther[2], Michael Deodhar[3], Amit Mahajan[2], Rajesh Kumar[4]

[1]Department of CTVS, All India Institute of Medical Sciences (AIIMS), New Delhi, Delhi, India, [2]Department of General Surgery, Christian Medical College and Hospital (CMC), Ludhiana, Punjab, India, [3]Department of General Surgery, Christian Medical College and Hospital (CMC), Vellore, Tamilnadu, India, [4]Department of Nephrology and Renal Transplant Medicine, V.M.M.C. and Safdarjung Hospital, New Delhi, Delhi, India

Abstract

Aims and Objective: To evaluate the patients at risk of venous thromboembolism (VTE) based on Caprini VTE risk assessment scale and the effect of implementation of this scale on the use of thromboprophylaxis. **Materials and Methods:** A prospective study was conducted, including patients who underwent major elective surgical procedures. Demographic details were noted, and VTE prophylaxis offered if needed. According to the VTE risk assessment scale, patients were categorised into very low-, low-, moderate-, and high-risk categories. The data were analysed statistically. **Results:** A total of 500 patients (women = 259; men = 241) were enrolled in this study. Of them, eight women and nine men developed VTE ($P = 0.691$). The maximum number of patients who developed VTE belonged to 61–70 years group ($n = 7$). According to VTE risk assessment, 61 patients were categorised as low-risk, 217 patients as moderate-risk, and 222 patients were categorised as high-risk. A significant ($P < 0.0005$) correlation was found between body mass index (BMI) and VTE development. In obese patients with BMI >25, 14 patients developed VTE. Out of total, 329 patients received prophylaxis for deep vein thrombosis. Of 284 patients who received pharmacologic prophylaxis, only three developed VTE ($P = 0.002$). Of 145 patients who received mechanical prophylaxis, 75 had high risk and none of them developed VTE. Four patients had mortality, and a significant ($P = 0.022$) correlation was found between mortality and VTE development. **Conclusion:** According to Caprini risk assessment scale, the prophylaxis for VTE was effective in patients undergoing major elective general surgery, resulting in significant lowering of morbidity and mortality.

Keywords: Caprini risk assessment, general surgery patients, prophylaxis of thromboembolism, venous thromboembolism

Introduction

Venous thromboembolism (VTE) consisting of deep vein thrombosis (DVT) and pulmonary embolism (PE) is a major healthcare problem which results in significant morbidity and mortality.[1] The incidence of VTE is increasing globally, especially after the coronavirus disease 2019 (COVID-19) pandemic situation. Patients with severe COVID-19 symptoms are at high risk of VTE, arterial thrombosis, and thrombo-embolic complications.[2] A recent Indian retrospective study showed 66% of patients with acute DVT, and the most common age group with high incidence of DVT was between 41 and 60 years.[3]

Increased risk of VTE is observed in patients with hospitalisation, joint fixation, and long-term travel.[4] Other commonly reported risk factors are age, obesity, hypertension, oral contraceptive use, hormonal treatment, and previous DVT.[5] A multi-national cross-sectional study showed that 61% surgical patients and 45% medical patients were at risk for VTE.[6]

Address for correspondence: Dr. Nita Bharti, Post MCh-Senior Resident, Department of CTVS, All India Institute of Medical Sciences (AIIMS), New Delhi - 110 029, Delhi, India.
E-mail: bhartinita80@gmail.com

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Co-morbidities associated with VTE are hypertension, heart failure, diabetes, and congestive heart failure.[7] The American College of Chest Physicians (ACCP) recommends evidence-based management of anti-coagulant therapy in different hospital settings.[8] Evaluation of Caprini score and venous clinical severity score were found to be significant predictors for post-operative DVT.[5]

Cases of general surgery/any surgical patients in India are dealt at all the primary levels in various surgical departments like general surgery, obs and gynae, neurosurgery, CTVS, and oncosurgery patients. This article emphasises that DVT prophylaxis is necessary and beneficial to prevent VTE in the post-operative period. The same thing applied to bed-ridden patients due to co-morbidities.

The prime measure for prevention of VTE is use of pharmacologic, mechanical, or a combination of both types of prophylaxis. One of the previous studies evaluating usage of pharmacological thromboprophylaxis for prevention of VTE showed that it was administered to 35% of patients, of which around 47% were intensive care unit (ICU) patients and 7% were post-surgical patients, which shows very low usage.[9] Therefore, it is needed to improve the patient safety practice to prevent the long-term complication and increase the survival rate using thromboprophylaxis. It helps to reduce the incidence of VTE and is recommended for routine use.[10] The aim of the present study was to evaluate the patients at risk of VTE based on Caprini VTE risk assessment scale and the effect of implementation of this scale on the use of thromboprophylaxis.

Materials and Methods

A prospective study was conducted for a period of one year, which included patients of either sex and aged >18 years who underwent major elective surgical procedures in the Department of General Surgery, Christian Medical College, Ludhiana, India. Patients admitted with the diagnosis of DVT or VTE and for minor surgical procedures were excluded from the study. The Institutional Ethics Committee approved the study protocol. The study was conducted in accordance with the approved protocol and International Conference on Harmonization-Good Clinical Practice. Written informed consent was obtained from all patients before enrolling into the study.

All patients undergoing major elective surgery were assessed within 24 h of admission prior to surgery. Demographic details were noted, and VTE prophylaxis was offered if needed. According to the VTE risk assessment scale,[11] patients were categorised into very low-, low-, moderate-, and high-risk categories. Additionally, details of mortality were also collected.

Statistical analysis

Categorical variables were presented in number and percentages. Normality of data was tested by Kolmogorov–Smirnov test. Quantitative variables were compared using analysis of variance (ANOVA)/Kruskal Wallis test (when the data sets were not normally distributed) between the groups. Qualitative variables were compared using Chi-square test/Fisher's exact test. The data were assessed using Statistical Package for Social Science (SPSS) version 21.0. A P value of < 0.05 was considered as statistically significant.

Results

A total of 500 patients were enrolled in the study. Out of 259 women, eight patients developed VTE, while nine patients from 241 men developed VTE ($P = 0.691$). The highest number of patients belonged to the age group of 51–60 years ($n = 134$), but the maximum number of patients who developed VTE belonged to 61–70 years group ($n = 7$). According to VTE risk assessment, 61 patients were categorised as low-risk, 217 patients as moderate-risk, and 222 patients were categorised as high-risk. Out of total women, 133 patients had high risk of VTE, followed by 102 with moderate risk and 24 with low risk. Categorisation according to age group showed that the greater number of patients with low, moderate, and high risk of VTE was in the range of 21–40, 31–60, and 41–70 years of age, respectively. Of the total patients, 17 had VTE (14 had DVT and three had PE), 11 had high-risk, five had moderate-risk, and one had low-risk ($P = 0.223$). Of 14 patients with DVT, eight had high risk, five had moderate risk, and only one had low risk. However, all patients with PE had high risk. There was no significant ($P > 0.05$) correlation between type of VTE development and risk assessment [Table 1].

Among the patients with high risk of VTE, the majority ($n = 6$) of them belonged to the age group of 61–70 years. However, VTE development was not found among patients with 18–40 and >80 years. Equal numbers of patients with VTE development in 31–80 years were found in patients of the moderate-risk group. On the other hand, only one patient with low risk developed VTE in the age group of 31 and 40 years [Table 2]. Out of 259 women, eight patients developed VTE, and of 241 men, nine patients developed VTE. Correlation of gender with VTE risk assessment showed the majority of the women ($n = 133$) were having high risk of VTE development, followed by moderate ($n = 102$) and low-risk ($n = 24$) assessment. Among 241 men, 115 had moderate risk, followed by 89 men with high risk and 37 with low risk. In patients with high risk of VTE development, six men and five women developed VTE. Among patients with moderate risk, three men and two women developed VTE. Only one woman with low risk had developed VTE. However, the correlation was not statistically significant.

A significant ($P < 0.0005$) correlation was found between body mass index (BMI) and VTE development. In obese patients with BMI >25, 14 patients developed VTE, while in non-obese patients with BMI ≤25, only three of them had VTE [Table 1]. Among three patients with VTE and BMI ≤25, two patients had low risk and one had moderate risk of VTE. However, among 14 patients with VTE and BMI >25, nine of them had high risk,

Table 1: VTE development and risk assessment according to gender, BMI, VTE prophylaxis, pharmacological, mechanical, and combined prophylaxis

	n (%)	VTE development	*P*	VTE Risk Assessment			*P*
				Low (*n*=61)	Moderate (*n*=217)	High (*n*=222)	
Age Group							
18-20	9 (1.80)	-	0.076	5 (55.56)	3 (33.33)	1 (11.11)	-
21-30	51 (10.20)	-		22 (43.14)	26 (50.98)	3 (5.88)	
31-40	86 (17.20)	2 (11.76)		34 (39.53)	43 (50.00)	9 (10.47)	
41-50	97 (19.40)	2 (11.76)		-	48 (49.48)	49 (50.52)	
51-60	134 (26.80)	3 (17.65)		-	59 (44.03)	75 (55.97)	
61-70	90 (18.00)	7 (41.18)		-	30 (33.33)	60 (66.67)	
71-80	30 (6.00)	3 (17.65)		-	8 (26.67)	22 (73.33)	
>80	3 (0.60)	-		-	-	3 (100.00)	
Total	500 (100)	17 (100.00)		61 (12.20)	217 (43.40)	222 (44.40)	
BMI							
≤25	357	3 (0.84)	<0.0005	54 (88.52)	162 (74.65)	141 (63.51)	<0.0005
>25	143	14 (9.79)		7 (11.48)	55 (25.35)	81 (36.49)	
VTE prophylaxis (any type)							
Yes	329 (65.8)	3 (17.65)	<0.0005	28 (45.90)	136 (62.67)	165 (74.32)	<0.0005
No	171 (34.2)	14 (82.35)		33 (54.10)	81 (37.33)	57 (25.68)	
Pharmacological prophylaxis							
Yes	284 (56.80)	3 (17.65)	<0.002	21 (34.43)	118 (54.38)	145 (65.32)	<0.0005
No	216 (43.20)	14 (82.35)		40 (65.57)	99 (45.62)	77 (34.68)	
Mechanical prophylaxis							
Yes	145 (29.00)	-	0.005	13 (21.31)	57 (26.27)	75 (33.78)	0.082
No	355 (71.00)	17 (100.00)		48 (78.69)	160 (73.73)	147 (66.22)	
Combined prophylaxis (mechanical and pharmacological)							
Yes	100 (20.00)	-	0.031	6 (9.84)	39 (17.97)	55 (24.77)	0.022
No	400 (80.00)	17 (100.00)		55 (90.16)	178 (82.03)	167 (75.23)	

BMI=Body mass index, VTE=Venous thromboembolism. Data mentioned as *n* (%)

Table 2: VTE development in high-risk, moderate-risk, and low-risk groups according to age distribution

Age group	Total no of patients (High risk)	VTE development	Total no of patients (Moderate risk)	VTE development	Total no of patients (Low score)	VTE development
18-20	1	-	3	-	5	-
21-30	3	-	26	-	22	-
31-40	9	-	43	1 (2.33)	34	1 (2.94)
41-50	49	1 (2.04)	48	1 (2.08)	-	-
51-60	75	2 (2.67)	59	1 (1.69)	-	-
61-70	60	6 (10.00)	30	1 (3.33)	-	-
71-80	22	2 (9.09)	8	1 (12.50)	-	-
>80	3	-	-	-	-	-
Total	222	11 (4.95)	217	5 (2.30)	61	1 (0.63)

VTE=Venous thromboembolism. Data mentioned as *n* or *n* (%)

four had moderate risk, and one had low risk of VTE. These results were not statistically significant.

Out of total patients, 329 received prophylaxis for DVT. Of 329 patients, the majority of them had significantly (n = 165, $P < 0.0005$) high risk, followed by moderate risk (n = 136) and low risk (n = 28). Of 165 patients who received VTE prophylaxis with high risk, only three developed VTE ($P < 0.0005$). However, of 57 who did not receive VTE prophylaxis, eight patients with high risk, five with moderate risk, and one with low risk developed VTE. Of 284 patients who received pharmacologic prophylaxis, only three developed VTE (P = 0.002). Among these patients, 145 had high risk, 118 had moderate risk, and 21 had low risk of VTE ($P < 0.0005$). Of 145 patients with high risk, three of them developed VTE. However, of 216 who did not receive pharmacologic prophylaxis, eight patients with high risk, five with moderate risk, and one with low-risk developed VTE.

Of total patients, 271 patients received low-molecular-weight heparin (LMWH), and 216 patients did not receive anti-coagulants and 13 received unfractionated heparin. Of 145 patients who received mechanical prophylaxis (elastic stocking), 75 had high risk, followed by 57 with moderate risk and 13 with low risk (P = 0.082). None of these patients developed VTE. However,

of 17 patients who did not receive mechanical prophylaxis and developed VTE, 11 had high risk, five had moderate risk, and one had low risk. Similarly, 100 patients received combined prophylaxis (mechanical and pharmacological) and none of them developed VTE ($P = 0.031$). Of 100 patients, 55 of them had high risk, 39 had moderate risk, and six had low risk ($P = 0.022$). Of 17 patients who did not receive combined prophylaxis and had developed VTE, 11 had high risk of VTE, five had moderate risk, and only one had low risk ($P = 0.139$).

Out of total patients, only 17 patients developed clinical features of VTE at discharge. Amongst them, 11 had high risk of VTE, five had moderate risk, and one had low risk ($P = 0.223$). Only 15 patients underwent radiological diagnostic test, 14 underwent Doppler ultrasonography, two any other test (D-dimer), and one underwent CT pulmonary angiography test. Among ten patients with prolonged hospital stay, eight had high risk and two had moderate risk ($P = 0.066$). Four patients had mortality, two of them due to PE and another two due to unknown causes. All four patients with mortality had high risk of VTE ($P = 0.080$). A significant ($P = 0.022$) correlation was found between mortality and VTE development.

Discussion

In spite of the availability of guidelines and the availability of safe and effective prophylactic agents, appropriate thromboprophylaxis is not being offered to large numbers of surgical patients. The present prospective study emphasises to ensure appropriate prophylaxis as per ACCP guidelines in all general surgery patients undergoing elective major surgery to reduce the incidence of VTE (PE, DVT) and mortality.

The major findings from the present were as follows: The majority of patients who developed VTE were in the age group of 61–70 years and 44.44% patients were categorised as high risk as per VTE risk assessment. The majority of patients received pharmacological, mechanical, or both types of prophylaxis ($n = 329$). Of 284 patients who received pharmacological prophylaxis, only three developed VTE ($P = 0.002$). Of 145 patients who received mechanical prophylaxis, 75 had high risk and none of them developed VTE. Four patients had mortality, and a significant ($P = 0.022$) correlation was found between mortality and VTE development.

In the present study, the majority of patients who developed VTE were in the age group of 61–70 years (41.18%), 71–80 (17.65%) and, 51–60 (17.65%) years, which shows that patients who developed VTE were above 50 years. Similarly, The Atherosclerosis Risk in Communities (ARIC) and Cardiovascular Health Study (CHS) studies found that risk of VTE relatively increased with advancing age and concluded that at least one in 12 middle-aged adults develop VTE in their lifetime.[12] In the present study, the incidence of VTE was slightly higher in men than in women (3.73% vs. 3.09%) with a similar trend seen in high-risk (6.74% vs. 3.76%) and moderate-risk groups (2.61% vs. 1.96%), where the percentage of men was higher. However, a population-based study by Naess *et al.*[13] showed the incidence of VTE to some extent higher in women than in men. Evidence suggests higher occurrence in women of childbearing age (16–44 years) compared with men of a similar age, although prevalence in individuals aged >45 years is usually higher in men.[14] A Danish study showed that this higher incidence in men is mediated by body height.[15]

A case-control study of 732 patients showed that obesity was associated with a 6.2-fold higher risk for VTE that was the highest in patients aged >50 years and those belonging to classes II and III of obesity.[16]A similar trend was observed in the present study.

The ENDORSE study evaluated VTE risk and prophylaxis in all hospital patients ≥18 years of age admitted to a surgical ward in 358 hospitals from 32 different countries. Amongst 30,827 surgical patients, 64.4% were assessed to be at risk for VTE according to ACCP guidelines, 2004. However, only 58.5% of at-risk surgical patients received ACCP-recommended VTE prophylaxis. In Indian patients enrolled in the ENDORSE study, only 16.3% of at-risk surgical patients received adequate prophylaxis.[17] In 2009, a study done by Pandey A *et al.*[18] in developing countries showed that 75% of patients had the highest risk for DVT and PE; only 12.5% had DVT prophylaxis within the first 2 days of admission. The present study also correlates that despite availability of guideline and effective prophylactic agents, appropriate thromboprophylaxis is not being offered to a large number of surgical patients.

According to Gould MK *et al.*, mechanical prophylaxis is recommended in low- and moderate-risk groups. The pharmacological prophylaxis is recommended for the moderate-risk group alone and for the high-risk group along with mechanical prophylaxis.[11] One meta-analysis of 18 randomised trials done by Sachdeva A *et al.*[19] in 2010 in surgical patients reported that the use of graduated compressive stocking alone was more effective than no prophylaxis in the prevention of DVT. The largest meta-analysis, done by Ho KM *et al.*[20] in 2013, which included data on 16,164 patients enrolled in 70 trials, reported that an intermittent pneumatic device was more effective than no prophylaxis in reducing DVT. Similarly, in the present study, there was less incidence of VTE in patients who got mechanical prophylaxis in each risk group.

In the present study, the patients who did not receive pharmacological prophylaxis in high- (10.39%), moderate- (5.05%), and low-risk (2.50%) groups developed VTE. However, of the patients who received prophylaxis, only 2.07% developed VTE in the high-risk group, but those in moderate- and low-risk groups showed an absence of VTE, indicating the effectiveness of pharmacological prophylaxis. Similarly, a study done by Kwon S *et al.* in 2011 showed fewer adverse events (4.2% vs. 2.5%, $P = 0.002$), deaths (2.5% vs. 1.6%, $P = 0.03$), and incidences of VTE (1.8% vs. 1.1%, $P = 0.04$) in those who received pharmacologic prophylaxis.[21] A meta-analysis of

seven RCTs with 1728 participants by Felder S *et al.*[22] assessed the efficacy and safety of prolonged thromboprophylaxis with LMWH after abdominal or pelvic surgery. The findings of this study demonstrated that continued thromboprophylaxis with LMWH significantly lowered the risk of VTE compared to thromboprophylaxis during hospital admission only. Also, there was no rise in bleeding complications or mortality after the surgery. Likewise, in the present study, most patients (95.42%) received LMWH as a pharmacological prophylaxis.

According to Gould MK *et al.*, both mechanical and pharmacological prophylaxes are recommended for the high-risk group.[11] In the present study, patients who did not receive combined prophylaxis, particularly in the high-risk group and moderate risk group, developed VTE. In patients who received prophylaxis, none of them developed VTE in the high-risk group. These data proved the effectiveness of combined prophylaxis in the high-risk group. Another meta-analysis of 11 studies, including 7431 patients, compared intermittent pneumatic compression with pharmacologic prophylaxis. The use of combined modalities reduced significantly the incidences of symptomatic PE (from about 3–1%) and DVT (from about 4–1%). Compared with pharmacologic prophylaxis alone, the use of combined modalities significantly reduced the incidence of DVT (4.21–0.65%).[23] The present study showed results in accordance with the above-mentioned studies.

A study done by Poley RA *et al.*[24] in 2014 showed that compressive ultrasound has been proven to be highly sensitive and specific modality for recognition of lower-extremity DVT. The stand-alone sensitivity and specificity of limited-compression ultrasound were found to be 91% and 97%, respectively. In the present study, Doppler ultrasonography was the single mode of diagnostic test for all the suspected patients with DVT and diagnostic in 100% clinically suspected cases.

A prospective study done by Lucena J *et al.*[25] reported that approximately 25% of patients showed sudden-unexpected death as the first manifestation of PE, while Lee AD *et al.*[26] reported mortality of 13.5% in patients with PE. In the present study, out of three confirmed cases of PE, two had sudden death, while in two cases, the cause of death was inconclusive. In the present study, the mortality rate was 0.8% and all of them were in the high-risk group. A study done by Geerts *et al.*[27] in 2004 showed that the incidence of fatal PE in the absence of prophylaxis was estimated to be 0.1–0.8% in patients undergoing elective general surgery, while in the present study, the incidence of fatal PE in elective general surgery patients was 0.4%. A study in Asian population reported by Yeo DX *et al.*[28] showed that the rate of DVT in general surgery patients was between 0 and 7.4%. In the present study, this rate was 2.8%, thus indicating the need and importance of appropriate thromboprophylaxis post surgery.

To keep it in routine practice of primary care physicians, this article reinforces the practice of DVT prophylaxis in the post-operative period and bed-ridden patients with co-morbidities. Strengths of this study include a prospective design with a large population size with VTE. The study was limited with participants from a single centre from India, so results may not be generalisable to other races or geographical locations.

Conclusion

In conclusion, according to Caprini risk assessment scale, the prophylaxis for VTE is effective in patients undergoing major elective general surgery. The patients who are in the low- to high-risk group should get mechanical or pharmacological prophylaxis or both as per standard guidelines. This will reduce the incidence of DVT and PE, thereby reducing the morbidity and mortality significantly.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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