

Arrive: A retrospective registry of Indian patients with venous thromboembolism

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Abstract

Background and Aim: There is lack of substantial Indian data on venous thromboembolism (VTE). The aim of this study was to provide real-world information on patient characteristics, management strategies, clinical outcomes, and temporal trends in VTE. **Subjects and Methods:** Multicentre retrospective registry involving 549 medical records of patients with confirmed diagnosis of VTE (deep vein thrombosis [DVT] confirmed by Doppler ultrasonography; pulmonary embolism [PE] by computed tomography, pulmonary angiography and/or V/Q scan) from 2006 to 2010 at three Indian tertiary care hospitals. **Results:** Acute DVT without PE, acute DVT with PE, and PE alone were reported in 64% (352/549), 23% (124/549), and 13% (73/549) patients, respectively. Mean age was 47 (± 16) years, and 70% were males. H/o DVT (34%), surgery including orthopedic surgery (28%), trauma (16%), and immobilization >3 days (14%) were the most common risk factors for VTE. Hypertension (25%), diabetes (19%), and neurological disease (other than stroke) (8%) were the most common co-morbidities. Most (94%) were treated with heparin alone (82%) or fondaparinux (2%) for initial anticoagulation; low molecular weight heparin alone (5%) or warfarin/acenocoumarol (76%) for long-term anticoagulation. Anticoagulant treatment was stopped because of bleeding in 2% (9/515) patients. Mortality was 7% among patients diagnosed with VTE during hospital stay versus 1% in those hospitalized with diagnosed VTE. The annual incidence of DVT (\pm PE) increased from 2006 to 2010. **Conclusion:** Acute DVT alone was responsible for the substantial burden of VTE in Indian patients. Bleeding was not the limiting factor for anticoagulant treatment in most patients.

Keywords: Anticoagulants, deep vein thrombosis, pulmonary embolism, retrospective registry, venous thromboembolism

Access this article online

Website: www.ijccm.org

DOI: 10.4103/0972-5229.178178

Quick Response Code:



Introduction

Venous thromboembolism (VTE) comprising of deep vein thrombosis (DVT) and pulmonary embolism (PE) can result in significant mortality, morbidity, and healthcare expenditure.^[1] Approximately, one-third of patients with symptomatic VTE manifests PE, whereas

two-thirds manifest DVT alone.^[2] Both DVT and PE can be clinically silent (asymptomatic) and hence not suspected. If undiagnosed, asymptomatic VTE can lead to chronic venous disease or recurrent VTE and long-term debilitating sequelae such as postthrombotic syndrome and chronic thromboembolic pulmonary hypertension.^[3,4] VTE is not only disabling but also

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How to cite this article: Kamerkar DR, John MJ, Desai SC, Dsilva LC, Joglekar SJ. Arrive: A retrospective registry of Indian patients with venous thromboembolism. *Indian J Crit Care Med* 2016;20:150-8.

prolongs hospital stay and increases the cost of treatment. Along with myocardial infarction and arrhythmia (due to electrolyte imbalance), PE is one of the commonest causes of sudden unexplained deaths in hospitalized patients.^[5]

It is estimated that 20 million cases of lower extremity DVT occur in the USA alone.^[6] Routine postoperative venography has shown an incidence of 60% in patients undergoing orthopedic surgery.^[7] The prevailing notion that the incidence of VTE in Asians is less than that in the Western population has been disproved by recent studies.^[8,9] The incidence of postoperative DVT in Indian patients undergoing major lower limb surgery is as high (43.2% and 60% patients in the groups with and without prophylaxis, respectively) as seen in the Western world.^[10]

Given the growing burden of VTE in India and lack of substantial Indian data on characteristics of VTE patients, use of diagnostics tools, prophylaxis, treatment options, and clinical outcomes in VTE, there was a need to systematically collect such data.

The aim of this registry was to collect “real world” data on patient characteristics, clinical outcomes, predictors of mortality in acute DVT, management strategies and temporal trends in VTE. The intent was to collect and provide data that would reflect actual day-to-day clinical practice, rather than results of highly controlled clinical trials with restricted study populations and imposed experimental intervention.

Subjects and Methods

Institutional Ethics Committee approval was obtained before initiation of data collection. Consecutive medical records of inpatients and outpatients between January 2006 and December 2010, meeting eligibility criteria (confirmed diagnosis of acute or acute-on-chronic DVT by Doppler ultrasound scan and/or PE by chest computed tomography scan, pulmonary angiography or V/Q scan) were identified and collected from the general medical records and/or radiology departments at each of the three participating hospitals. Hospital data were used to obtain the total number of patients who were annually registered at the hospital from 2006 to 2010.

The collected information was verified against source documents. Data were managed with validated software “Oracle Clinical” (version 4.6, Oracle Health Sciences). Data were processed and analyzed using SAS (version 9.1, statistical analysis system). For the purpose of analysis, “acute-on-chronic” DVT was considered as “acute” DVT. Descriptive statistics were used to present patient characteristics, management strategies,

and clinical outcomes of patients. Annual incidence rates (95% CI) of VTE per 100,000 hospital registrations over a period of 5 years were reported for each site.

Fisher’s exact test was used to determine differences in the incidence of acute DVT (\pm PE) over the years 2006–2010. Cochran–Armitage trend test was used to examine the direction (positive or negative) of the trend.

As primary analyses were purely descriptive, no formal sample size calculations were done.

Results

A total of 949 medical records were reviewed. Information from 59% (556/949) records was captured for the registry. The remaining 41% (393/949) medical records were not included because they did not satisfy the inclusion criteria. Data from 99% (549/556) of the included records were analyzed. Data from seven patients were excluded as there was no radiologically confirmed diagnosis of PE.

A total of 64% (352/549) patients had acute DVT without PE, 23% (124/549) had acute DVT with PE, and 13% (73/549) had PE. Eighty-seven percent (476/549) of patients had acute DVT (\pm PE), and 36% (197/549) had PE (\pm acute DVT) [Figure 1].

A total of 21% (115/549) of patients visited the hospitals directly without being referred by a physician. The proportion of patients referred from different medical specialties is mentioned in Table 1.

Demographics and characteristics of venous thromboembolism patients

The demographic characteristics of the VTE patients are mentioned in Table 2.

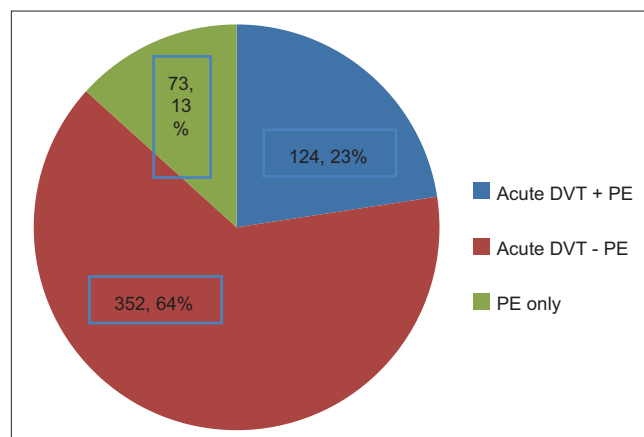


Figure 1: Overall distribution of venous thromboembolism patients (n = 549)

Risk factors for venous thromboembolism patients

A total of 182 patients had evidence of one risk factor, 126 had evidence of two risk factors, 70 had evidence of three risk factors and 31 had four or more risk factors

Table 1: Venous thromboembolism patients referred from different medical specialties (n=434)

Medical specialty	Patients, n (%)
Cardiologist	121 (27.9)
Family physician, general physician	95 (21.9)
Internist	69 (15.9)
General surgeon	27 (6.2)
Neurologist	19 (4.4)
Orthopedic surgeon	16 (3.7)
Oncologist	13 (2.9)
Chest physician	11 (2.5)
Nephrologist	11 (2.5)
Gynecologist	4 (0.9)
Other*	48 (11.1)

*Other includes referrals from the emergency department, a cardiothoracic surgeon, endocrinologist, gastroenterologist, hematologist, neurosurgeon, pediatric surgeon, plastic surgeon, rheumatologist, vascular surgeon or urologist, and specialty not specified

Table 2: Demographic characteristics of venous thromboembolism patients (n=549)

Characteristic	Patients
Age, mean (minimum-maximum), n (%)	46.9 (9 months-93 years)
Up to 39 years	188 (34.2)
40-59 years	239 (43.5)
60-74 years	93 (16.9)
≥75 years	29 (5.3)
Males, n (%)	384 (69.9)
BMI (kg/m ²), n (mean±(SD))	48 (27.9 (8.6))
Tobacco consumption, n (%)	
Yes	56 (10.2)
No	418 (76.1)
NK*	75 (13.7)
Smoker, n (%)	
Yes	39 (7.1)
No	449 (81.8)
NK*	61 (11.1)

*NK: Not known. SD: Standard deviation; BMI: Body mass index

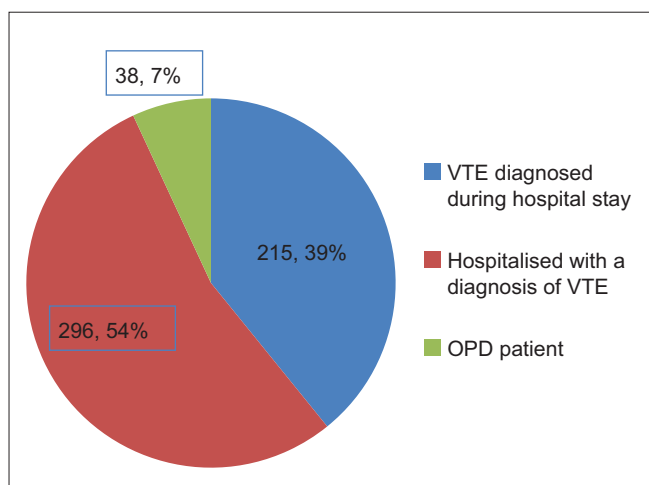


Figure 2: Place of detection of venous thromboembolism (n = 549)

recorded. Patients undergoing orthopedic surgery constituted 22% (33/152) of all surgical patients [Table 3].

Co-morbidities in venous thromboembolism patients

Based on a review of the available records, 157 patients had a single co-morbidity, 81 had two co-morbidities, 23 had three co-morbidities, and 16 had four or more co-morbidities. About 21% (114/549) of patients were “acutely medically ill” (myocardial infarction, heart failure, chronic obstructive pulmonary disease, ventilator dependency, sepsis, or pneumonia) [Table 4].

Clinical presentation of venous thromboembolism

Of the 476 patients with DVT, 2% (9) had upper extremity DVT, 97% (462) had lower extremity DVT and the site of DVT was not known in 5 patients. A total of 31% (143/462) patients had DVT in the right limb, 54% (249/462) in the left limb and 9% (41/462) in both limbs (site not known in 29 patients). Of the 462 patients with lower extremity DVT, 61% had proximal DVT, 13% had distal DVT, and 7% had proximal and distal DVT. A total of 39% (215/549) patients were diagnosed with VTE during their hospital stay, 54% (296/549) were admitted to hospital with a diagnosis of VTE, and 7% (38/549) were diagnosed and continued to be managed in the outpatient department [Figure 2]. The duration of hospitalization after diagnosis of VTE is shown in Table 5.

A smaller proportion of patients (15%; 81/549) was diagnosed with VTE during the postoperative period. Figure 3 shows the proportion of patients with VTE at different time points during the postoperative period. Of those diagnosed beyond 6 weeks, 21% (3/14) had orthopedic surgery (hip fracture surgery).

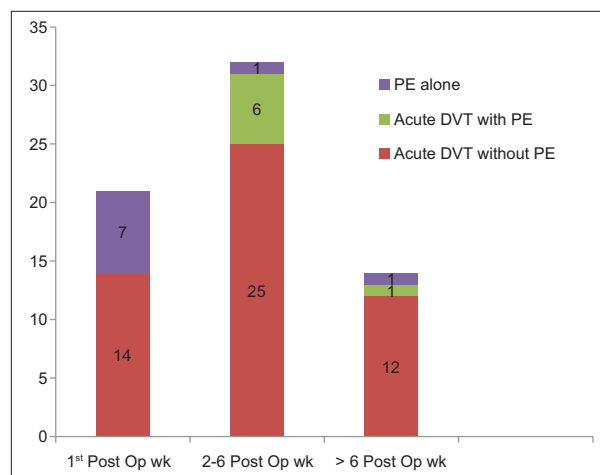


Figure 3: Diagnosis of venous thromboembolism during the postoperative period (n = 81)

Table 3: Risk factors for venous thromboembolism

Risk factor	VTE patients (n=549), n (%)	Acute DVT without PE (n=352), n (%)	Acute DVT complicated with PE (n=124), n (%)	Patients with PE alone (n=73), n (%)
Past history of DVT	189 (34.4) [§]	123 (34.9) [§]	65 (52.4)	1 (1.4)
Past history of PE	46 (8.4)**	5 (1.4)	30 (24.2)	11 (15.1)**
Family history of VTE	4 (0.7)	4 (1.1)	0	0
Total hip replacement	2 (0.4)	2 (0.6)	0	0
Total knee replacement	1 (0.2)	0	0	1 (1.4)
Hip fracture surgery	14 (2.6)	10 (2.8)	2 (1.6)	2 (2.7)
Other orthopedic surgery*	16 (2.9)	14 (4.0)**	1 (0.8)	1 (1.4)
Surgery [†]	119 (22)**	91 (26)	16 (13)	12 (16)
Immobilization for >3 days	76 (13.8) [§]	54 (15.3) [§]	11 (8.9)	11 (15.1)
Received blood transfusion	34 (6.2) [§]	30 (8.5) [§]	3 (2.4)	1 (1.4)
Cancer [‡]	38 (7)	30 (9)**	3 (2)	4 (5)
Ongoing radiation therapy for cancer	3 (0.5)	3 (0.9)	0	0
Ongoing chemotherapy for cancer	16 (2.9)	14 (4)	1 (0.8)	1 (1.4)
Trauma	89 (16.2) [§]	59 (16.8) [§]	19 (15.3)	11 (15.1)
Hormone replacement therapy	0	0	0	0
Pregnancy/postpartum	11 (2)	7 (2)	1 (1)	3 (4)
Hormonal contraceptives	2 (0.4)	0	1 (0.8)	1 (1.4)
Long distance travel including air travel	5 (0.9)	3 (0.9)	2 (1.6)	0
Varicose veins	59 (10.7)	43 (12.2)	15 (12.1)	1 (1.4)
Intravenous drug abuse	0	0	0	0
Indwelling central venous catheter	32 (5.8) [§]	21 (6.0) [§]	4 (3.2)	7 (9.6)
Thrombophilia	42 (7.7) [§]	18 (5.1) [§]	22 (17.7)	2 (2.7)
Elevated homocysteine level	53 (9.7)	25 (7.1)	20 (16.1)	8 (11.0)

*Other orthopedic surgery includes surgery other than TKR, THR and hip fracture surgery (significance value is mentioned for all orthopaedic surgeries together); [†]Surgery includes gastrointestinal, cardiovascular, obstetrics/gynaecological, general. Genito-urinary, neurological, oncology and bariatric surgeries; [‡]Cancer includes gastrointestinal, genito-urinary, lung, breast, blood/lymphatic cancers; [§]P<0.0001; ^{||}P<0.005; ^{**}P<0.05. DVT: Deep vein thrombosis; VTE: Venous thromboembolism; PE: Pulmonary embolism; TKR: Total knee replacement; THR: Total hip replacement

Table 4: Co-morbidities in venous thromboembolism patients

Co-morbidity	VTE patients (n=549), n (%)	Acute DVT without PE (n=352), n (%)	Acute DVT complicated with PE (n=124), n (%)	Patients with PE alone (n=73), n (%)
Hypertension	135 (24.6)	86 (24.4)	30 (24.2)	19 (26.0)
Diabetes mellitus	105 (19.1)	70 (19.9)	18 (14.5)	17 (23.3)
Neurological disease (other than stroke)	45 (8.2)	34 (9.7)	7 (5.6)	4 (5.5)
Stroke	29 (5.3)	23 (6.5)	1 (0.8)	5 (6.8)
Myocardial infarction	38 (6.9)	23 (6.5)	9 (7.3)	6 (8.2)
Heart failure	12 (2.2)	9 (2.6)	3 (2.4)	0
COPD	11 (2.0)	7 (2.0)	0	4 (5.5)
Ventilator dependent	18 (3.3)	8 (2.3)	2 (1.6)	8 (11.0)
Sepsis	16 (2.9)	11 (3.1)	2 (1.6)	3 (4.1)
Obesity	31 (5.6)	11 (3.1)	14 (11.3)	6 (8.2)
Pneumonia	19 (3.5)	9 (2.6)	5 (4.0)	5 (6.8)
Inflammatory bowel disease	1 (0.2)	0	1 (0.8)	0
Severe dehydration	3 (0.5)	3 (0.9)	0	0

DVT: Deep vein thrombosis; VTE: Venous thromboembolism; PE: Pulmonary embolism; COPD: Chronic obstructive pulmonary disease

The most common (73%) symptom was "swelling of the limb" among patients with VTE [Table 6].

Management strategies for venous thromboembolism patients

Diagnostic tools for venous thromboembolism

In merely 4% of all the patients, DVT was also confirmed by venography. PE was confirmed by pulmonary angiography in 27% of all the patients [Table 7].

Anticoagulant treatment in venous thromboembolism

A total of 94% (515/549) of patients were recommended anticoagulants. Heparin (low molecular weight

heparin [LMWH]/unfractionated heparin [UFH] alone, a combination of heparin (LMWH/UFH) and oral anticoagulant (warfarin), and fondaparinux sodium alone were recommended to 82% (420/515), 13% (66/515), and 2% (12/515) patients, respectively as initial anticoagulation. The rest of patients were recommended streptokinase, urokinase, or tissue plasminogen activator.

Five percent (25/515) of patients were recommended LMWH alone, and 76% (393/515) were recommended either warfarin or acenocoumarol alone for long-term anticoagulation.

The median duration of initial anticoagulation was 5 days while that of long-term anticoagulation was 180 days (6 months).

Anticoagulants were needed to be stopped because of bleeding in only 2% (9/515) patients.

Clinical outcomes in VTE patients are mentioned in Tables 8 and 9.

Annual incidence of acute deep venous thrombosis including the trend over a period of 5 years

The annual incidence of acute DVT (\pm PE) increased from 2006 to 2010 at all the three sites [Figure 4]. However, a formal site-wise statistical analysis could not be performed to analyse trends in the incidence rates in acute DVT (\pm PE) and PE alone as there were zero observations in some instances.

Table 5: Duration of hospitalization after diagnosis of venous thromboembolism

Diagnosis of VTE	VTE patients	Acute DVT without PE	Acute DVT complicated with PE	Patients with PE alone
VTE diagnosed while patient was in the hospital	n=211	n=112	n=44	n=55
Mean (minimum-maximum)	9 (0-50)	9.6 (0-50)	8 (1-38)	8.4 (1-34)
Patient was admitted into hospital with a diagnosis of VTE	n=182	n=113	n=59	n=10
Mean (minimum-maximum)	7.6 (1-30)	8.2 (1-30)	6.5 (1-22)	7.7 (1-21)

DVT: Deep vein thrombosis; VTE: Venous thromboembolism; PE: Pulmonary embolism

Table 6: Symptoms in venous thromboembolism patients

Symptom	VTE patients (n=504), n (%)	Acute DVT without PE (n=320), n (%)	Acute DVT complicated with PE (n=117), n (%)	Patients with PE alone (n=67), n (%)
Swelling of limb	366 (72.6)	286 (89.4)	71 (60.7)	9 (13.4)
Extremity discomfort	257 (51)	196 (61.3)	58 (49.6)	3 (4.5)
Discoloration of limb	43 (8.5)	38 (11.9)	5 (4.3)	0
Erythema of limb	38 (7.5)	36 (11.3)	2 (1.7)	0
Dyspnoea	189 (37.5)	49 (15.3)	86 (73.5)	54 (80.6)
Chest pain	77 (15.3)	19 (5.9)	35 (29.9)	23 (34.3)
Cough	67 (13.3)	15 (4.7)	26 (22.2)	26 (38.8)
Syncope	13 (2.6)	0	6 (5.1)	7 (10.4)
Fever	26 (5.7)	11 (3.4)	9 (7.7)	6 (8.9)

DVT: Deep vein thrombosis; VTE: Venous thromboembolism; PE: Pulmonary embolism

Table 7: Diagnostic tools

Test	VTE patients (n=549), n (%)	Acute DVT without PE (n=352), n (%)	Acute DVT complicated with PE (n=124), n (%)	Patients with PE alone (n=73), n (%)
Venography for DVT	20 (3.6)	14 (4)	5 (4)	1* (1.4)
CT scan for PE	41 (7.5)	2 (0.6) [†]	20 (16.1)	19 (26.0)
V/Q scan for PE	51 (9.3)	12 (3.4) [†]	25 (20.2)	14 (19.2)
Pulmonary angiography for PE [‡]	150 (27.3)	23 (6.5) [†]	84 (67.7)	43 (58.9)

*Venography was done to exclude a diagnosis of associated PE; [†]CT scan, V/Q scan and pulmonary angiography were done to exclude PE; [‡]CT pulmonary angiography. DVT: Deep vein thrombosis; VTE: Venous thromboembolism; PE: Pulmonary embolism; CT: Computed tomography

Discussion

To our knowledge, this is the first multicenter, retrospective registry in India involving patients with VTE that reflect real-world clinical practice.

In contrast with the Western data in which VTE is predominantly a disease of older age,^[11] 44% patients in our study were between 40 and 59 years of age while 34% were below 40 years, particularly those with PE. In a study from North India, 80% of PE patients were below 50 years.^[12] Men constituted 70% of our registry, more than those reported from Vellore registry (48%),^[13] but similar to those reported in the ENDORSE (Epidemiologic

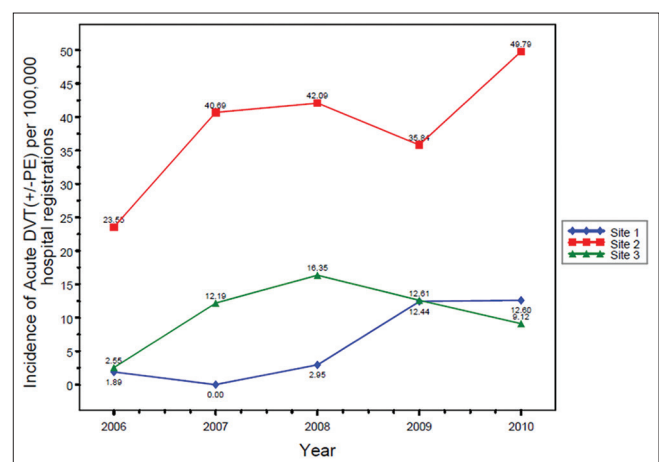


Figure 4: Incidence of acute deep vein thrombosis (with or without pulmonary embolism) over a 5 years period (2006–2010) at three sites

Table 8: Clinical outcomes in patients diagnosed with venous thromboembolism during hospital stay

Clinical outcome	VTE patients (n=215), n (%)	Acute DVT without PE (n=116), n (%)	Acute DVT complicated with PE (n=44), n (%)	Patients with PE alone (n=55), n (%)
Discharged from hospital				
Yes	203 (94.4)	106 (91.4)	43 (97.7)	54 (98.2)
No	12 (5.6)	10 (8.6)	1 (2.3)	1 (1.8)
Shifted to ICU				
Yes	105 (48.8)	29 (25)	30 (68.2)	46 (83.6)
No	97 (45.1)	76 (65.5)	13 (29.5)	8 (14.5)
Not known	13 (6.0)	11 (9.5)	1 (2.3)	1 (1.8)
Readmitted to hospital				
Yes	12 (5.6)	8 (6.9)	3 (6.8)	1 (1.8)
No	54 (25.1)	47 (40.5)	3 (6.8)	4 (7.3)
Not known	142 (66.0)	55 (47.4)	38 (86.4)	49 (89.1)
Not applicable	7 (3.3)	6 (5.2)	0	1 (1.8)
Death during hospital stay				
Yes	16 (7.4)	13 (11.2)	2 (4.5)	1 (1.8)
No	199 (92.6)	103 (88.8)	42 (95.5)	54 (98.2)

DVT: Deep vein thrombosis; VTE: Venous thromboembolism; PE: Pulmonary embolism; ICU: Intensive Care Unit

Table 9: Clinical outcomes in patients admitted to hospital with a diagnosis of venous thromboembolism

Clinical outcome	VTE patients (n=296), n (%)	Acute DVT without PE (n=199), n (%)	Acute DVT complicated with PE (n=79), n (%)	Patients with PE alone (n=18), n (%)
Discharged from hospital				
Yes	292 (98.6)	195 (98)	79 (100)	18 (100)
No	3 (1)	3 (1.5)	0	0
Not known	1 (0.3)	1 (0.5)	0	0
Shifted to ICU				
Yes	103 (34.8)	50 (25.1)	44 (55.7)	9 (50)
No	189 (63.9)	146 (73.4)	35 (44.3)	8 (44.4)
Not known	4 (1.4)	3 (1.5)	0	1 (5.6)
Readmitted to hospital				
Yes	21 (7.1)	12 (6)	7 (8.9)	2 (11.1)
No	41 (13.9)	38 (19.1)	2 (2.5)	1 (5.6)
Not known	234 (79.1)	149 (74.9)	70 (88.6)	15 (83.3)
Death during hospital stay				
Yes	3 (1.0)	3 (1.5)	0	0
No	292 (98.6)	195 (98)	79 (100)	18 (100)
Not known	1 (0.3)	1 (0.5)	0	0

DVT: Deep vein thrombosis; VTE: Venous thromboembolism; PE: Pulmonary embolism; ICU: Intensive Care Unit

International Day for the Evaluation of Patients at Risk for VTE in the Acute Hospital Care Setting) study (69%).^[14] One of the reasons for this could be significantly high levels of homocysteine (thrombophilia marker) in males as compared to females as reported in an Indian study.^[15] Fewer Indian women use oral contraceptives and postmenopausal hormone replacement therapy, which are known to be risk factors for thrombosis. This is supported by the fact that only 1% of women in this registry reported the use of oral contraceptives, and none reported use of hormonal replacement therapy.

A total of 28% of the overall referrals were from cardiologists. The majority (82%) of the referrals were from medical rather than surgical (15%) specialties as against a referral rate of 93% from surgeons at Vellore.^[13] Our finding complements that from the ENDORSE study^[14] in which 55% of the medical patients at risk

of VTE had cardiovascular disease. Majority (53%) of patients in our study had co-morbid cardiovascular disease including diabetes mellitus; it is possible that these patients visited a cardiologist for their cardiovascular ailment (s) and were then referred by the cardiologist to vascular disease specialist (investigator). DVT without PE was mostly referred by family/general physicians. Most (89%) of these patients had swelling of the (lower) limb. It is possible that these patients may not have felt the need to visit a specialist for a symptom like "swelling of limb," instead visited their family physician. It is very encouraging to know that family physicians suspected DVT in these situations and referred the patient to a specialist.

Patients with a history of VTE are about 8 times more likely to develop a new episode during a subsequent high-risk period compared with patients without a

history of DVT or PE.^[16] Prior history of DVT was the most (34%) common risk factor in patients who had only DVT, whereas past history of PE, trauma, and immobilization for more than 3 days were the most common risk factors in patients who had only PE. Patients undergoing orthopedic surgery constituted 22% (33/152) of all surgical patients. Six percent patients received blood transfusion while 5% patients had obstetrics/gynecological surgeries. Our results (major lower limb surgery as a risk factor in 3% patients) appear to be consistent with those reported in the ENDORSE study, which reported DVT in 4.4% patients undergoing major lower limb surgery.^[14] Other studies from India have reported a DVT incidence rate ranging from 8% to 20% in major lower limb surgery.^[17,18] Malignancy has been reported as a risk factor in 31% patients.^[13] However, in our study, only 7% of patients had malignancy as a predisposing factor. Among the malignancies, genitourinary cancer had the highest incidence (45%).

Hypertension (25%) was the most common co-morbidity followed by diabetes mellitus (19%) in this patient population. In addition, obesity (11%) was a common risk factor in DVT complicated by PE. Our findings support an Asian (Korean) study that demonstrated prevalence of the metabolic syndrome in 48% patients with VTE.^[19] Co-morbid neurological disease (other than stroke) and ventilator dependency were also commonly found in patients with DVT (10%) and PE (11%) respectively. Both these conditions immobilize patients for prolonged periods of time, predisposing them to VTE. About 21% of patients were acutely medically ill.

Venography and pulmonary angiography are the gold standard for diagnosis of DVT and PE respectively.^[20] In our study, venography was used in just 4% patients and pulmonary angiography in less than one-third of the patients. Perhaps the relatively high cost of these tests and limited availability of such procedures may be the limiting factors. Doppler ultrasonography still remains the widespread diagnostic modality for detecting VTE in India.

Overall, most (93%) patients were managed as inpatients (39% diagnosed with VTE during hospital stay and 54% admitted to hospital with a diagnosis of VTE). PE was mostly (75%) diagnosed during hospital stay. A mean duration of hospitalization of 7–9 days after diagnosis of VTE is supported by published data.^[21] In selected low-risk patients, outpatient treatment of DVT and PE may be considered.^[22–24] This approach was observed in a small proportion (7%) of patients who were managed on an outpatient basis, nearly all (97%) of whom had only DVT.

The reported prevalence of postsurgical VTE in our study (15%) was half of that (30%) reported in Vellore registry.^[13] This could be explained by higher referral rate from surgeons at Vellore compared to that of our sites. Most (40%; 32/81) DVT cases were diagnosed between 2 and 6 postoperative weeks, but PE in most cases (70%; 7/10) was diagnosed during the first postoperative week. We notice that acute DVT complicated by PE was less (6%; 7/124) frequently diagnosed during the postoperative period as against 18% (64/352) and 14% (10/73) of acute DVT alone and PE alone, respectively.

Anticoagulants are the mainstay of treatment for VTE. The use and duration of anticoagulants in our registry appears to be consistent with the American College of Chest Physicians treatment guidelines,^[25] which recommend at least 5 days of initial anticoagulation with parenteral anticoagulation (LMWH, fondaparinux, intravenous UFH, or subcutaneous UFH) and at least 3 months of long-term anticoagulation treatment with Vitamin K antagonist.

Bleeding is the most serious complication of anticoagulation treatment and is a major concern for clinicians particularly as the patient's age advances. In this registry, anticoagulant treatment was needed to be stopped because of bleeding in only 2% of the study population. The prospective REITE registry has reported a rate of 3% for major/fatal bleeds.^[26] Thus, the fear of bleeding complications, which decreases the use of anticoagulant treatment, appears to be minimal.

Almost all (97%) hospitalized patients were discharged from hospital. DVT complicated by PE (60%) and PE alone (75%) were more frequently shifted to Intensive Care Unit than those who had DVT alone (25%). Similar to published data in which hospital readmission rate for VTE was 5% for primary and 14% for secondary diagnosis,^[27] we report a hospital readmission rate of 6%; however we do not know the cause for readmission.

Overall 4% of hospitalized patients died. The death rate was 7% among those diagnosed with VTE during hospital stay as against a rate of 1% among those who were hospitalized with a diagnosis of VTE. Over 90% of patients treated on an outpatient basis obtained symptomatic relief with treatment. In our study, the hospital discharge rate (97%) was more than triple and death rate was a quarter of that reported by Pandey *et al.*^[28] (hospital discharge rate 31% and death rate 16%) at a university hospital in Delhi.

Our data show a significant increase in acute DVT (\pm PE) from 2006 to 2010. This can be explained by the increased awareness of VTE in India as well as the advent of better diagnostic modalities, such as duplex ultrasonography becoming more readily available and accepted. Although there was no significant change in the number of PE cases from 2006 to 2010, the burden of PE is almost double (13% of all VTE) of 7%, rate reported at Christian Medical College, Vellore during a 10-year period from 1996 to 2005.^[13] Our finding is consistent with a study from North India that reported a 16% incidence of PE in adult medical autopsies.^[12]

This study has the expected limitations of any retrospective review including the availability of complete records for all patients, although a robust review of the data on medical charts was conducted. Controlling for bias and confounders is difficult as there is no randomization and no blinding. Follow-up data of patients after hospital discharge were not available. In cases of death, the exact cause of death was not mentioned on medical records. Further, the clinic charts reviewed in this study included a mix of those from Vascular Surgery and Hematology Departments, limiting the generalizability of the study results. Despite these limitations, this study provides large amount of useful information in a short span of time on patient characteristics, clinical outcomes, management strategies, and temporal trends in VTE, based on "real world" data that reflect actual day-to-day clinical practice over a period of 5 years across three sites in India. We believe that this information will serve as a guide in the optimal implementation of VTE prophylaxis and treatment, to improve patient outcomes and to decrease the occurrence of VTE in India.

Conclusion

Real world data reflecting actual day-to-day clinical practice in VTE over a period of 5 years across three sites in India showed that VTE is not uncommon in Indian patients and that acute DVT was responsible for the substantial burden of VTE. Bleeding was not the limiting factor for anticoagulant treatment in most patients. We believe that this information will serve as a guide in the optimal implementation of VTE prophylaxis and treatment, to improve patient outcomes and to decrease the occurrence of VTE in India.

Acknowledgments

This study was funded by GlaxoSmithKline Pharmaceuticals, Mumbai, Maharashtra, India. All listed

authors meet the criteria for authorship set forth by the International Committee for Medical Journal Editors. The authors wish to acknowledge Dr. Ramakrishna Pinjala (Department of Vascular Surgery, Nizam's Institute of Medical Sciences, Hyderabad - 500 082, Telangana, India) and Dr. Rajiv Parakh (Division of Peripheral Vascular and Endovascular Sciences, Medanta - The Medicity, New Delhi, India) for their inputs in developing the study protocol, Dr. Jeroze Dalal for operational oversight to the study, Ms. Samuda Kanakapura for monitoring the conduct of the study and Dr. Sujay Kulkarni for critical review and assistance during the development of this manuscript. Dr. Jeroze Dalal, Ms. Samuda Kanakapura, and Dr. Sujay Kulkarni are full-time employees of GlaxoSmithKline Pharmaceuticals Limited.

Financial support and sponsorship

This study was funded by GlaxoSmithKline Pharmaceuticals, Mumbai, Maharashtra, India.

Conflicts of interest

Dr. Liesel C. Dsilva is and Dr. Sadhna J. Joglekar was full-time employee of GlaxoSmithKline Pharmaceuticals Limited.

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Notice

Dear ISCCM members,

Greetings from ISCCM office!

We have been celebrating ISCCM Day every year with a theme. The theme of ISCCM Day for this year is "Patient Safety in the ICU".

Poster is a good method for making doctors and lay people aware of Patient safety in the ICU. Taking the opportunity of the ISCCM day celebration, we are announcing a Poster competition on "Patient Safety in the ICU".

Top 2 posters will receive a citation from society and prize of Rs 10,000 and Rs 7,500 respectively.

Instructions for submission of Poster on "Patient Safety in the ICU"

1. Ensure that poster is catered to Indian setup
2. It should be original and not copied from somewhere else
3. Should be in poster format
4. Words allowed-up to 100 maximum
5. Should be in English

Last day for submission is 10th September 2016 and it should be emailed to Dr. Vijaya Patil, Secretary ISCCM and Chairman, ISCCM Day Committee, ISCCM at vijayapatil@yahoo.com

We welcome any other suggestions from our members.

With warm regards

Dr. Atul Kulkarni
President - ISCCM

Dr. Kapil Zirpe
President - Elect, ISCCM

Dr. Pradip Kumar Bhattacharya
General Secretary ISCCM

Dr. Vijaya Patil
Secretary ISCCM, Chairman,
ISCCM Day Committee, ISCCM