ARTICLE

A Retrospective Evaluation of Adherence to Guidelines for Prevention of Thromboembolic Events in General Medical Inpatients

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ABSTRACT

Background: Venous thromboembolism is a frequently occurring disorder associated with significant morbidity, mortality, and resource expenditure. Although most venous thromboembolic incidents occur in medical patients, standardized protocols for thromboprophylaxis in such patients have not been implemented at the authors' institutions.

Objective: To compare institutional thromboprophylactic practices for medical patients with current guidelines.

Methods: A chart review was performed for patients admitted to the medical wards of 2 university-affiliated hospitals over a 7-month period. Patients were included if they had one major risk factor and/or at least 2 minor risk factors for venous thromboembolism. The primary endpoint was the rate of thromboprophylaxis during hospital admission.

Results: A total of 131 subjects were included in the analysis. The rate of thromboprophylaxis was 21%, was similar in subjects with and without major or minor contraindications to pharmacologic prophylaxis, and did not differ by age. Two patients, both of whom received thromboprophylaxis, experienced a venous thromboembolic event. In patients who received thromboprophylaxis, unfractionated heparin was the most common agent. Of patients who received thromboprophylaxis, approximately 7% experienced a minor bleed and 7% experienced a major bleed.

Conclusions: Among medical patients at the authors' institutions with risk factors for venous thromboembolism, a small proportion received thromboprophylaxis, which reflects poor adherence to current guidelines. The low rate of prophylaxis was not explained by contraindications to prophylaxis or the age of the subjects.

Key words: venous thromboembolism, thromboprophylaxis, medical patients

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ABSTRACT

Historique : La thromboembolie veineuse est une affection fréquente qui entraîne de la morbidité, de la mortalité et des dépenses en ressources significatives. Bien que la plupart des accidents thromboemboliques veineux surviennent chez les patients admis aux services de médecine, des protocoles de thromboprophylaxie standardisés pour de tels patients n'ont pas été mis en œuvre dans les établissements où sont rattachés les auteurs.

Objectif : Comparer les pratiques de thromboprophylaxie utilisées chez les patients admis aux services de médecine dans ces établissements à celles des lignes directrices actuelles.

Méthodes : On a évalué les dossiers médicaux des patients admis aux unités de médecine de deux hôpitaux universitaires sur une période de sept mois. Les patients étaient retenus s'ils présentaient un facteur de risque principal et (ou) au moins deux facteurs de risque secondaires de thromboembolie veineuse. Le critère d'évaluation primaire était le taux de thromboprophylaxie durant le séjour à l'hôpital.

Résultats : Au total, 131 sujets ont été inclus dans l'analyse. Le taux de thromboprophylaxie a été de 21 %, et était semblable que les sujets aient eu ou non des contre-indications mineures ou majeures de la prophylaxie médicamenteuse, et ne différait pas selon l'âge. Deux patients, qui ont tous deux reçu une thromboprophylaxie, ont eu un accident thromboembolique veineux. Chez les patients qui ont reçu une thromboprophylaxie, l'héparine non fractionnée était l'agent le plus souvent utilisé. Parmi les patients qui ont reçu une thromboprophylaxie, environ 7 % ont eu des saignements mineurs et 7 % des saignements majeurs.

Conclusions : Une faible proportion des patients admis aux services de médecine dans les établissements où sont rattachés les auteurs et présentant un risque de thromboembolie veineuse ont reçu une thromboprophylaxie, ce qui reflète une timide adhésion aux lignes directrices actuelles. Le faible taux de prophylaxie ne pouvait être expliqué par des contre-indications de la prophylaxie ou l'âge des sujets.

Mots clés : thromboembolie veineuse, thromboprophylaxie, patients admis aux services de médecine

INTRODUCTION

Venous thromboembolism (VTE) is a frequently occurring disorder encompassing deep venous thrombosis (DVT) and the more serious complication of pulmonary embolism. It is associated with significant morbidity, mortality, and resource expenditure.[1] Most venous thromboembolic incidents occur in medical patients,[1] and hospital admission itself has been shown in some studies to explain the majority of these events.[2] Autopsy series have shown that pulmonary embolism was the cause of 4% to 11% of deaths in hospital patients, but only 1 in 4 of these patients had recently undergone surgery.[3,4] Using venography, large randomized trials have identified VTE in 5% to 15% of medical inpatients receiving no prophylactic therapy.[5,6] The incidence may be higher among patients with specific conditions such as myocardial infarction, ischemic stroke, acute spinal cord injury, and trauma.[1,7]

Identification and classification of patients with risk factors for VTE may aid clinicians in choosing appropriate antithrombotic therapy, in determining the duration of therapy for secondary prevention, and in determining the need for primary prevention in relatives with hereditary coagulation defects. For example, nearly all hospital patients have 1 high-risk factor for VTE, and 80% of these patients have at least 3 risk factors.[8] Anderson and Spencer have identified and stratified risk factors for VTE,[9] and these are reflected in the current American College of Chest Physicians (ACCP) thromboprophylaxis guidelines.[1] It is believed that the presence of multiple risk factors has a cumulative effect on the risk of VTE.[10] A recent analysis of patients in a large clinical trial found that the presence of an acute infectious disease, age older than 75 years, cancer, and a history of VTE were independent risk factors for VTE.[11]

Although it has been suggested that only patients with more than one risk factor for VTE should receive prophylaxis,[10] a method of risk stratification leading to appropriate initiation of thromboprophylactic therapy has not yet been validated or accepted in practice.[12] Furthermore, high-quality randomized trials comparing antithrombotic therapy with placebo have failed to demonstrate the efficacy of thromboprophylaxis in reducing symptomatic DVT, pulmonary embolism, and death.[5,6]

Primarily on the basis of reductions in nonclinical endpoints, such as venographically or ultrasonographically detected VTE, observed with heparin and low-molecular-weight heparin (LMWH), the ACCP has, since 2001, recommended the following: "In acutely ill medical patients who have been admitted to the hospital with congestive heart failure or severe respiratory disease, or who are confined to bed and have one or more additional risk factors, including active cancer, previous VTE, sepsis, acute neurologic disease, or inflammatory bowel disease, we recommend prophylaxis with LDUH [low dose unfractionated heparin] or LMWH"[1] and that "every hospital develop a formal strategy that addresses the prevention of thromboembolic complications. This should generally be in the form of a written thromboprophylaxis policy."[1,13] At the authors' institution, there is a standardized protocol for the use of heparin and warfarin in the treatment of VTE and preprinted orders for LMWH for DVT prophylaxis in patients with acute spinal cord injury and various surgical populations; however, a standardized protocol is lacking for thromboprophylaxis in nonsurgical patients. Furthermore, a review of institutional thromboprophylactic practices for medical patients and a comparison with current guidelines have not previously been conducted. The objective of this study, therefore, was to assess and compare local institutional practice with current ACCP recommendations.

METHODS

A chart review was conducted for patients admitted between January 1 and July 31, 2003, to the units for acute medical care, subacute medical care, and acute care of the elderly in 2 university-affiliated acute care hospitals. Computer-generated random number sets were used to select subjects for screening from a larger cohort of patients deemed potentially eligible on the basis of admission unit and date. Only patients admitted directly to the target units from outpatient or residential care settings were eligible.

The subjects' charts were reviewed for presence of risk factors for VTE according to available guidelines. Hence, patients were included if a review of the health record revealed 1 documented major risk factor and/or at least 2 documented minor risk factors for VTE. Risk factors and their stratification were based on published evidence and guidelines (Table 1).[1,9,10] Any risk factor not specifically described as a major risk factor in the literature was considered a minor risk factor. Exclusion criteria included surgery or lower-extremity plaster cast within 3 weeks before admission, length of stay less than 5 days, and existing anticoagulation therapy for any reason at the time of admission.

The primary endpoint was the rate of thromboprophylaxis during the hospital stay. Use of subcutaneously administered heparin, LMWH, warfarin, intermittent

Table 1. Major and Minor Risk Factors for Venous Thromboembolism[1,9,10] Used in a Comparison of Institutional Practices and Current Guidelines

Major Risk Factors	Minor Risk Factors
Acute spinal cord injury	Infection
Acute myocardial infarction	Thrombophilic disorder
Trauma, including hip or leg fracture	Documented obesity
Malignancy	Central venous lines
Chronic obstructive pulmonary disease	Acute burn
Other chronic lung disease	Varicose veins
Congestive heart failure	Oral contraceptive therapy
Ischemic stroke	Hormone replacement therapy
Major trauma	Tamoxifen or raloxifene therapy
Previous venous thromboembolism	Current pregnancy or a history of 3 or more pregnancies

pneumatic compression, or compression stockings were considered as evidence of the primary endpoint being met. Secondary endpoints were the frequency, type, and duration of prophylaxis administered, the incidence and outcomes of VTE events, and the frequency and types of adverse reactions to prophylaxis (documented heparin-induced thrombocytopenia [HIT], major bleed, or minor bleed). HIT was defined as (1) documented diagnosis of HIT; (2) 50% fall from preheparin level in platelet count, or platelet nadir between 20 x 10^9/L and 100 x 10^9/L, with a clear onset between 5 and 10 days after heparin exposure (or less than 1 day if there had been previous heparin exposure within the past 100 days); (3) the occurrence of one or more HIT-associated clinical events (thrombosis or skin lesions at heparin injection sites, skin necrosis, or acute systemic reaction after administration of a heparin bolus) and detection of HIT antibodies in patient serum or plasma; or (4) fall in platelet count with no other evident cause.[14] Major bleeding was defined as overt bleeding resulting in death; a bleed in a retroperitoneal, intracranial, or intraocular location; a drop in hemoglobin of at least 3 g/dL; or the requirement for transfusion of 2 or more units of blood.[15] Minor bleeding was defined as any clinically important bleeding that did not qualify as a major bleed, for example, epistaxis, ecchymosis, hematoma, or macroscopic hematuria. Other secondary endpoints were the incidence and type of contraindications to chemoprophylaxis.

Contraindications, classified as relative or absolute, were based on current product monographs for warfarin, unfractionated heparin, and the LMWHs.[16]

The sample size of 130 subjects was based on available investigator resources and time. Characteristics of patients and their hospital stay related to the primary and secondary endpoints were collected by one of the investigators (K.P.) according to a standardized data collection protocol, to minimize interindividual variability. Any uncertainty encountered during data collection was handled by group discussion to establish consensus about the data. Chi-square tests were used to evaluate relationships between use of thromboprophylaxis and presence of absolute and relative contraindications. Unadjusted univariate odds ratios were calculated to evaluate associations between receipt of thromboprophylaxis and risk factors and contraindications. Data analysis was performed using SPSS version 11.0 (SPSS Inc, Chicago, Illinois).

RESULTS

Screening of 246 patient charts yielded the required cohort of 131 patients. The mean age of the subjects was 74 years (range 27 to 96 years), 56 (43%) were female, and the median length of stay on the target units was 20 days (range 5 to 144 days).

Thromboprophylaxis was used for 27 (21%) of the patients during their hospital stay, and the median duration of therapy was 12.5 days. The mean age of patients who received prophylaxis and those who did not was identical. The frequency and type of major and minor risk factors for VTE are listed in Table 2. The only risk factor that was significantly associated with thromboprophylaxis use was previous VTE (odds ratio 13 [95% confidence interval 1.3 to 129]). Two patients (2%) experienced a clinically evident venous thromboembolic event: one case of pulmonary embolism was diagnosed with spiral computed tomography, and one case of DVT was diagnosed with combined doppler ultrasonography and D-dimer testing. Both of these patients were receiving thromboprophylaxis at the time the clinical suspicion arose (one was receiving long-term warfarin therapy, and one had been using compression stockings for 24

Table 2. Risk Factors for Venous Thromboembolism (VTE) in Study Patients

Risk Factor	No. (%) of Patients*			OR (95%CI)
	All Patients (*n* = 131)	Received Prophylaxis (*n* = 27)	No Prophylaxis (*n* = 104)	
Major				
Acute myocardial infarction	13 (10)	4 (15)	9 (9)	1.8 (0.51–6.5)
Fracture, including hip or leg fracture	13 (10)	0 (0)	13 (13)	0.13 (0.0–2.4)
Malignancy	38 (29)	4 (15)	34 (33)	0.36 (0.11–1.1)
COPD or lung disease	32 (24)	7 (26)	25 (24)	1.1 (0.41–2.9)
CHF or other heart failure	42 (32)	9 (33)	33 (32)	1.1 (0.43–2.7)
Ischemic stroke	21 (16)	7 (26)	14 (13)	2.2 (0.80–6.3)
Major trauma	1 (1)	1 (4)	0 (0)	12 (0.47–299)
Previous VTE	4 (3)	3 (11)	1 (1)	13 (1.3–129)
Minor				
Infection	52 (40)	14 (52)	38 (37)	1.8 (0.80–4.4)
Obesity	3 (2)	1 (4)	2 (2)	2.0 (0.17–22)
Pregnancy or history of 3 or more pregnancies	1 (1)	1 (4)	0 (0)	12 (0.47–299)
Central venous lines	1 (1)	1 (4)	0 (0)	12 (0.47–299)
Varicose veins	2 (2)	0 (0)	2 (2)	0.75 (0.04–16)
Decreased mobility or prolonged immobilization	8 (6)	2 (7)	6 (6)	1.3 (0.25–6.9)

OR = odds ratio, CI = confidence interval, COPD = chronic obstructive pulmonary disease, CHF = congestive heart failure.
*Because each patient could have more than one risk factor, the column entries do not sum to the *n* value in the corresponding heading.

Table 3. Contraindications to Pharmacologic Thromboprophylaxis

Contraindication*	No. (%) of Patients		*p* Value†
	Received Prophylaxis (*n* = 27)	No Prophylaxis (*n* = 104)	
Absolute	5 (19)	23 (22)	0.89
Relative only	22 (81)	78 (75)	0.65

*Some patients had both absolute and relative contradictions.
†χ^2 test.

days), and both patients recovered without sequelae. Among patients who received thromboprophylaxis, unfractionated heparin (5000 units subcutaneously twice daily) was the most common agent (for 20/27 patients [74%]), followed by warfarin to a target international normalized ratio of 2–3 (3 patients [11%]) intermittent pneumatic compression (3 patients [11%]), and enoxaparin (30 mg subcutaneously twice daily) (1 patient [4%]). All subjects receiving warfarin were getting this drug for other conditions diagnosed while in hospital and were considered to have adequate VTE prophylaxis. Among patients who received thromboprophylaxis, 2 (7%) experienced a minor bleed (receiving enoxaparin and warfarin, respectively) and 2 (7%) experienced a major bleed (receiving heparin and warfarin, respectively). Two patients (7%) who were not receiving thromboprophylaxis had minor bleeding.

There were a variety of contraindications to pharmacologic prophylaxis among patients who received some type of thromboprophylaxis and those who did not (Tables 3 and 4), and the incidence of thromboprophylaxis was not influenced by the presence of these contraindications (p = 0.89 for absolute contraindications, p = 0.65 for relative contraindications; χ^2 test). The number of subjects with an indication for prophylaxis and no absolute contraindications was 103 (79%). Twenty-two of these (21%) received prophylaxis.

DISCUSSION

The majority of medical inpatients at risk for VTE events did not receive prophylaxis during the study period. In particular, use of thromboprophylaxis in the subgroup of patients with an indication for and no contraindications to antithrombotic drug therapy differed

Table 4. Frequency of Contraindications to Pharmacologic Thromboprophylaxis

Contraindications	No. (%) of Patients*			OR (95%CI)
	All Patients (*n* = 131)	Received Prophylaxis (*n* = 27)	No Prophylaxis (*n* = 104)	
Absolute (*n* = 28)				
Severe active bleeding	14 (11)	2 (7)	12 (12)	0.61 (0.13–2.9)
Suspected intracranial hemorrhage	1 (1)	0 (0)	1 (1)	1.2 (0.05–32)
Leukemia	2 (2)	0 (0)	2 (2)	0.75 (0.03–16)
Aneurysm	1 (1)	0 (0)	1 (1)	1.2 (0.05–32)
Polyarthritis	2 (2)	1 (4)	1 (1)	4.0 (0.24–65)
Diverticulitis	1 (1)	0 (0)	1 (1)	1.2 (0.05–32)
Severe uncontrolled or malignant hypertension (SBP > 180 mm Hg and/or DBP > 110 mm Hg)	1 (1)	0 (0)	1 (1)	1.2 (0.05–32)
Pericarditis or pericardial effusion	1 (1)	1 (4)	0 (0)	12 (0.50–299)
Visceral carcinoma	5 (4)	1 (4)	4 (4)	0.96 (0.10–9.0)
Relative (*n* = 129)				
Age > 60 years	109 (83)	24 (89)	85 (82)	1.8 (0.50–6.6)
Acute infection	51 (39)	13 (48)	38 (37)	1.6 (0.70–3.8)
Concomitant treatment with platelet inhibitors	19 (15)	5 (19)	14 (13)	1.5 (0.48–4.5)
Malignancy	24 (18)	2 (7)	22 (21)	0.30 (0.07–1.4)
Renal insufficiency (CrCl < 50 mL/min)	13 (10)	2 (7)	11 (11)	0.70 (0.14–3.3)

OR = odds ratio, CI = confidence interval, SBP = systolic blood pressure, DBP = diastolic blood pressure, CrCl = creatinine clearance.

significantly from that recommended by the ACCP. Possible reasons for inadequate therapy include clinicians' concern about adverse effects such as hemorrhage, a primary focus on the underlying disease, a lack of awareness of consensus guidelines, and a belief that the risk of VTE is too low to consider prophylaxis.[1,17,18] An additional reason may be clinicians' knowledge that there is a paucity of evidence that prophylaxis reduces clinical endpoints and hence rejection of the guidelines.

Our finding that a minority of eligible medical patients received thrombopropylaxis is consistent with similar evaluations conducted elsewhere.[19-22] Although educational interventions may be effective for increasing the rate of prophylaxis among eligible patients,[19] the absence of randomized controlled trials supporting the efficacy of such therapy in terms of reduction in symptomatic DVT, pulmonary embolism, or death makes it difficult to justify the resources, expense, and toxic effects associated with more widespread use of pharmacologic prophylaxis.

Clinicians' perceptions of the risks and benefits of VTE prophylaxis are not well documented; therefore, identifying which of these factors plays the greatest role in determining thromboprophylactic therapy is especially difficult to ascertain. The role of relative contraindications to pharmacologic prophylaxis in clinical decision-making is also unknown, as the frequency of relative contraindications was similar among patients who did and did not receive thromboprophylaxis. Although all relative contraindications listed in drug product monographs were considered in this study, the risk to benefit ratio of chemoprophylaxis is probably more important than the presence of relative contraindications alone.

The main limitations of this study were its relatively small sample size and its reliance on clinically documented data. In addition to the usual limitations of retrospective studies, the use of mechanical thromboprophylaxis may have been underdocumented in this study. Finally, the rate of symptomatic VTE was too low to compare with previous reports among medical patients receiving and not receiving prophylaxis. This is probably due to the small sample size used, given that trials with thousands of patients have estimated this incidence to be less than 1%.[5]

Among medical patients at the authors' institution with risk factors for VTE, a small proportion received thromboprophylaxis, reflecting poor adherence to current guidelines. The low rate of prophylaxis was not explained by the presence of contraindications to prophylaxis, since the frequency of absolute and relative contraindications was similar among patients who did and did not receive prophylaxis. Unfortunately, the best available evidence suggests that antithrombotic therapy does not reduce the incidence of clinically meaningful VTE (symptomatic VDT, pulmonary embolism, death, duration of hospital stay), making efforts to increase utilization of thromboprophylaxis in general medical inpatients difficult to justify.

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