Retrospective Clinical Audit of Adherence to a Protocol for Prophylaxis of Venous Thromboembolism in Surgical Patients

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ABSTRACT

Background: Thromboprophylaxis after surgical procedures reduces the incidence of pulmonary embolism and deep vein thrombosis. In previous studies, adherence with recommended thromboprophylaxis guidelines has ranged from 13.3% to 94.0%.

Objective: This clinical audit was conducted to evaluate the rate of adherence to the venous thromboembolism prophylactic protocol for surgical patients at the authors' institution.

Methods: A chart review was conducted for surgical patients admitted from April 2005 to March 2006. Patients were included if they had undergone an elective surgical procedure, had been under general anesthesia for more than 45 min, had been admitted to hospital for more than 48 h, and were over 40 years old. Patients were excluded if they had been admitted for medical reasons, emergency surgery, or orthopedic surgery or if they had received anticoagulation before the surgery. Each patient's risk of venous thromboembolism was determined, and his or her thromboprophylaxis regimen was compared with the recommended regimen and assessed for adequacy.

Results: Thromboprophylaxis was used for 82 of the 100 surgical patients whose records were reviewed. However, only 29% of the patients had received adequate therapy as defined by the prophylaxis protocol. The major reason for inadequacy of thromboprophylaxis was inappropriate stratification of the patient's risk of venous thromboembolism.

Conclusion: Most surgical patients had received a thromboprophylactic regimen, but a large proportion of the patients received therapy that was suboptimal for their assessed level of risk. Provision of a checklist for assessing the risk of thrombosis and education of practitioners about risk stratification and the benefits of prophylaxis might improve adherence rates.

Key words: venous thromboembolism, thromboprophylaxis, surgical patients, compliance

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RÉSUMÉ

Historique : La thromboprophylaxie postchirurgicale réduit l'incidence d'embolie pulmonaire et de thrombose veineuse profonde. Dans des études antérieures, le taux d'observance des lignes directrices recommandées en thromboprophylaxie variait de 13,3 % à 94,0 %.

Objectif : Cette analyse clinique a été menée pour évaluer le taux d'observance du protocole de prophylaxie de la thromboembolie veineuse chez les patients opérés, dans l'établissement des auteurs.

Méthodes : Une analyse des dossiers médicaux des patients opérés entre avril 2005 et mars 2006 a été effectuée. Les patients étaient retenus aux fins d'analyse s'ils avaient subi une intervention chirurgicale non urgente, avaient reçu une anesthésie générale pendant plus de 45 minutes, avaient été hospitalisés pendant plus de 48 heures et étaient âgés de plus de 40 ans. Les patients n'étaient pas retenus s'ils avaient été hospitalisés pour des raisons médicales, pour une intervention chirurgicale urgente ou orthopédique, ou s'ils avaient reçu une anticoagulothérapie avant l'intervention. Le risque de thromboembolie veineuse a été évalué pour chaque patient et leur thromboprophylaxie a été comparée à la thromboprophylaxie recommandée pour déterminer si elle était adéquate.

Résultats : On a eu recours à la thromboprophylaxie chez 82 des 100 patients opérés dont les dossiers médicaux ont été analysés. Cependant, seulement 29 % de ces patients ont reçu une thromboprophylaxie adéquate telle que définie dans le protocole. La principale raison expliquant l'inadéquation de la thromboprophylaxie était la mauvaise stratification des risques de thromboembolie veineuse des patients.

Conclusion : La plupart des patients opérés ont reçu une thromboprophylaxie qui, chez une forte proportion d'entre eux, était sous-optimale selon le risque évalué. L'utilisation d'une liste de contrôle pour évaluer le risque de thrombose et la formation des praticiens sur la stratification du risque et les bienfaits de la prophylaxie pourraient faire augmenter les taux d'observance.

Mots clés : thromboembolie veineuse, thromboprophylaxie, patients opérés, observance

INTRODUCTION

Venous thromboembolism, a medical condition that encompasses pulmonary embolism and deep vein thrombosis,[1] is a major cause of morbidity, mortality, and resource expenditure.[2] Solid principles and scientific evidence support the use of prophylactic regimens to prevent this condition. First, because most hospital patients have at least one risk factor for venous thromboembolism (Table 1), the prevalence of this condition is high.[2] In the absence of thromboprophylaxis after surgery, the risk of pulmonary embolism ranges from 0.1% to 10% and that of deep vein thrombosis ranges from 2% to 80%.[3] Second, venous thromboembolism is associated with serious sequelae. For example, pulmonary embolism accounts for 10% of in-hospital deaths, whereas deep vein thrombosis may be associated with long-term morbidity such as post-thrombotic syndrome.[2] Finally, pooled analysis has demonstrated that thromboprophylaxis with heparin or low-molecular-weight heparin (LMWH) reduces the risk of deep vein thrombosis by up to 76%.[3] Although there is a risk of bleeding with any anticoagulant therapy, a previous meta-analysis showed little or no increase in the risk of a clinically significant bleeding episode with prophylactic doses.[4]

Despite strong evidence supporting thromboprophylaxis and the existence of clinical guidelines to direct the practitioner, studies evaluating the adequacy of and adherence to guidelines for prophylaxis of venous thromboembolism after surgery have shown suboptimal utilization of anticoagulation.[5-10] For surgical patients, adherence to recommended guidelines varies widely (from 13.3% to 94%).[5-10] The most common reasons for poor adherence were lack of knowledge needed to appropriately stratify the patient's risk or lack of prescription of a thromboprophylactic regimen.[11]

In 2000, a patient died because of postoperative pulmonary embolism at the authors' institution, the Vancouver Island Health Authority—South Island (VIHA-SI), located in Victoria, British Columbia. The death was thought to have occurred secondary to a lack of thromboprophylaxis. This event prompted development of a preprinted prophylactic protocol for venous thromboembolism, which was included on surgical order forms. The protocol was based on the thromboprophylaxis guidelines of the American College of Chest Physicians (ACCP).[2] Deviations from the ACCP guidelines were based on practicality and availability of thromboprophylactic agents at the VIHA-SI and included use of sequential compression devices instead of graduated compression stockings or intermittent pneumatic compression devices. Before implementation, the protocol was reviewed by a member of the ACCP expert panel for thromboprophylaxis. The VIHA-SI's recommended thromboprophylactic regimen for each risk level is given in Table 2.

After development of the thromboprophylactic protocol, a quality assurance audit was conducted. The objective of this clinical audit was to determine the rate of adherence to the prophylactic protocol for surgical patients.

Table 1. Risk Factors for Venous Thromboembolism*

Surgery
Trauma (major or lower extremity)
Immobility, paresis
Malignancy
Cancer therapy
Previous venous thromboembolism
Age > 40 years
Pregnancy or postpartum period
Estrogen-containing oral contraception
Hormone replacement therapy
Selective estrogen receptor modulators
Myocardial infarction
Heart or respiratory failure
Inflammatory bowel disease
Nephrotic syndrome
Myeloproliferative disorders
Paroxysmal nocturnal hemoglobinuria
Obesity
Smoking
Varicose veins
Central venous catheterization
Inherited or acquired thrombophilia
Antiphospholipid antibody syndrome

*Adapted, with permission of the publisher, from Geerts WH et al.[2] *Chest* 2004;126(3 Suppl):338S-400S.

METHODS

A chart review was conducted for patients who underwent surgical procedures at 2 tertiary acute care hospitals within VIHA-SI from April 2005 to March 2006. The primary outcome of the audit was the rate of adherence to the prophylactic protocol for these surgical patients. Secondary outcomes were the rate of documented in-hospital venous thromboembolism, the rate of hemorrhage, and the percentage of charts with sufficient data to allow risk stratification.

The audit included patients who underwent an elective surgical procedure, who had been under general anesthesia for more than 45 min, who had been admitted to hospital for more than 48 h after the surgery, and who were at least 40 years of age. Patients were excluded if they had been admitted for medical reasons or for emergency surgery, if they had undergone

Table 2. Classification of Risk* and Recommended Thromboprophylactic Regimens at the Vancouver Island Health Authority—South Island

Level of Risk	Recommended Regimen
Low risk	
Uncomplicated minor surgery in patients < 40 years of age with no clinical risk factors (see Table 1)	No specific measures Early ambulation
Moderate risk	
Any surgery (major or minor) in patients 40–60 years of age with no additional risk factors Major surgery in patients < 40 years of age with no additional risk factors Minor surgery in patients with one or more risk factors	Heparin 5000 units SC q12h ***or*** Sequential compression device (if patient has risk of bleeding)
High risk	
Major surgery in patients > 60 years of age without additional risk factors Major surgery in patients 40–60 years of age who have additional risk factors Patients with myocardial infarction, medical patients with one or more risk factors	Heparin 5000 units SC q8h ***or*** LMWH† ***or*** Sequential compression device (if patient has risk of bleeding)
Highest risk	
Major surgery in patients > 40 years of age with prior deep vein thrombosis, prior pulmonary embolism, malignant disease, or hypercoagulable state Major surgery in patients > 60 years of age with additional risk factors Patients undergoing elective major orthopedic surgery of the lower extremity or receiving treatment for hip fracture, stroke, multiple trauma, or spinal cord injury	LMWH† ***or*** Warfarin ***or*** Adjusted-dose IV heparin ***or*** Sequential compression device ***and*** either LMWH† or heparin SC

LMWH = low-molecular-weight heparin.
*Adapted, with permission of the publisher, from Geerts WH et al.[2] *Chest* 2004;126(3 Suppl):338S-400S.
†For low-molecular-weight heparin (tinzaparin), if weight < 50 kg, give 3500 units SC daily; if weight 50–70 kg, give 4500 units SC daily; if weight 71–90 kg, give 6000 units SC daily; if weight > 90 kg, give 7500 units SC daily.

orthopedic surgery, or if they had received anticoagulation before surgery.

A list of patients who had undergone 1 of 5 types of surgery (general surgery, cardiac surgery, abdominal vascular surgery, prostatectomy, or major urological procedure) and who met the inclusion criteria was generated by the hospital's Clinical Information Department. An arbitrary sample of 100 patients, with equal representation from each surgical area if possible, was selected for the audit by means of computer-generated random number sets. Upon application of the exclusion criteria, 25 of the 100 randomly selected patients were excluded, and another 25 patients were randomly selected from the lists to meet the predefined audit quota of 100 patients. The hospital's Clinical Research Ethics Board waived the requirement for ethics approval because the study was a retrospective quality assurance audit that did not affect patient care or therapy.

To minimize inconsistencies in data abstraction and to eliminate inter-reviewer variability, one investigator (C.L.) was responsible for extracting all of the data and stratifying patients' risk of venous thromboembolism. A standardized data collection form was used to record patient demographic characteristics, risk factors (Table 1), the prophylactic regimen ordered for the patient, the prophylactic regimen received by the patient, and the occurrence of documented in-hospital venous thromboembolism or hemorrhage. Hemorrhage was classified as major or minor. Major hemorrhage was defined as bleeding for which re-operation or transfusion was required. Minor hemorrhage was any bleeding that could not be categorized as major hemorrhage. Hemorrhage was considered to be associated with the thromboprophylaxis if the hemorrhage occurred after the surgery and was assessed as excessive or if the prescribed thromboprophylaxis was discontinued as a result of the hemorrhage.

Each patient's risk of venous thromboembolism was stratified into 1 of 4 levels (Table 2) on the basis of type of surgery, age, and recorded risk factors.[2] Surgery was classified as major or minor. Major surgery involved opening one of the major body cavities (abdomen, chest, or skull), which would stress the vital organs.[12] All

other procedures were defined as minor. Among the recorded risk factors, obesity can be determined from weight and height; therefore, the data for this risk factor were considered adequate if the component data were present in the chart, even if obesity was not explicitly recorded. If the patient's risk could not be determined, the chart data were considered inadequate, and the patient was excluded from the final analysis.

Once a patient's risk had been determined, his or her prophylactic regimen was compared with the recommended thromboprophylaxis for that risk level (Table 2) to assess adequacy of therapy. Therapy was considered adequate if the following conditions were met: prophylactic regimen used was the same type, the same dose (for subcutanous administration of heparin, 5000 units; for LMWH, correct dose based on documented weight), and the same frequency as recommended for the assessed level of risk; prophylaxis was started within 24 h after the surgery; and the duration of prophylaxis was at least 7 days, until hospital discharge, or until the patient was ambulatory. Patients were considered ambulatory if they were able to walk independently in the hallways. For patients who received inadequate thromboprophylaxis, the data were assessed to formulate potential reasons for inadequacy of therapy.

RESULTS

Data for 100 patients meeting the inclusion criteria (and not excluded by the exclusion criteria) were reviewed: 20 patients each in the vascular, general, and cardiac surgery groups, 18 patients who had undergone prostatectomy, and 22 patients who had undergone major urological surgery. The mean age of patients was 68 years (range 40 to 87 years), and 74% were men. The mean length of the hospital stay was 6.9 days (range 2 to 30 days). The mean number of risk factors per patient was 3. The most common risk factors, aside from surgery and age over 40 years, were malignancy (25%), obesity (24%), and central venous catheterization (19%). Seventy-four of the patients had undergone major surgery.

Thromboprophylaxis was used for 82% of the patients (Table 3). However, only 29% of the patients had received therapy that corresponded to their risk of venous thromboembolism. Failure to appropriately stratify a patient's risk accounted for 58% (41/71) of those receiving inadequate therapy (Table 4). All of these patients had an anticoagulation regimen appropriate for a risk level lower than their assessed risk. No patients received a thromboprophylactic regimen appropriate for a risk level higher than their assessed risk.

Secondary outcomes were also considered. Two patients experienced clinically evident venous thromboembolism during their hospital stay. The first of these patients experienced pulmonary embolism after a prostatectomy, which prolonged the hospital stay from about 4 days to 30 days. According to the chart review, the patient had not received any thromboprophylaxis after the surgical procedure. The second patient experienced deep vein thrombosis after a major urological procedure. This patient had received thromboprophylaxis; however, it did not correspond to the regimen recommended in the prophylaxis protocol, as the patient's risk had been stratified to a lower level than what the chart information alone might have indicated. This patient's hospital stay was prolonged from approximately 4 days to 11 days. In both of these cases, it is important to recognize that the treating clinicians might have taken into consideration other factors that were not apparent in the chart. Minor hemorrhage (not requiring re-operation or transfusion) was reported for 7% of the patients (Table 3). Despite

Table 3. Outcomes of Clinical Audit of Adherence to Protocol for Prophylaxis of Venous Thromboembolism

Outcome	Type of Surgery; No. (%) of Patients					
	Overall (*n* = 100)	General (*n* = 20)	Cardiac (*n* = 20)	Vascular (*n* = 20)	Prostatectomy (*n* = 18)	Major Urologic (*n* = 22)
Patient received prophylaxis	82	15 (75)	20 (100)	18 (90)	8 (44)	21 (95)
Patient received adequate prophylaxis	29	3 (15)	15 (75)	9 (45)	2 (11)	0 (0)
Patient experienced venous thromboembolism	2	0 (0)	0 (0)	0 (0)	1 (6)	1 (5)
Patient experienced hemorrhage*	7	0 (0)	0 (0)	0 (0)	5 (28)	2 (9)

*Hemorrhage was minor in all cases.

Table 4. Reasons for Inadequate Thromboprophylaxis

Reason	Type of Surgery; No. (%) of Patients					
	Overall (*n* = 71)	General (*n* = 17)	Cardiac (*n* = 5)	Vascular (*n* = 11)	Prostatectomy (*n* = 16)	Major Urologic (*n* = 22)
Failure to initiate prophylaxis	18 (25)	5 (29)	0 (0)	2 (18)	10 (62)	1 (5)
Failure to initiate prophylaxis within 24 h after surgery	10 (14)	0 (0)	3 (60)	0 (0)	6 (38)	1 (5)
Failure to administer recommended dose	2 (3)	0 (0)	2 (40)	0 (0)	0 (0)	0
Failure to properly stratify patient's risk	41 (58)	12 (71)	0 (0)	9 (82)	0 (0)	20 (91)

these minor hemorrhages, the patients continued to receive thromboprophylaxis. For all patients, there was sufficient information in the chart (type of surgery, age, height, and weight) to stratify risk according to the 4 defined levels.

DISCUSSION

This clinical audit provided insight into prophylaxis for venous thromboembolism after elective surgery at VIHA-SI. Most of the surgical patients included in the audit had received thromboprophylaxis. However, comparison of each patient's thromboprophylactic regimen with the regimen recommended for the assessed level of risk revealed that a large proportion of the patients (71%) were receiving suboptimal therapy. In fiscal year 2005/2006, the VIHA-SI had a total of 30 181 surgical cases (both emergent and elective). As such, more than 20 000 patients may have received suboptimal thromboprophylaxis, which might have led to cases of preventable venous thromboembolism. The low rate of adherence is consistent with the results of other studies that have examined compliance with thromboprophylaxis guidelines.[5-10] For example, Yu and others[5] reported compliance rates for hospitals throughout the United States. They found that for 123 304 medical and surgical patients, adherence to the ACCP guidelines was low (13.3%). More specifically, only 12.7% of patients who underwent general surgery and 9.9% of those who underwent urologic surgery received adequate therapy in terms of the ACCP guidelines.

Reasons for inadequacy of thromboprophylaxis identified in the current audit are consistent with those reported in other studies. The major reason for inadequacy of therapy was inappropriate risk stratification. Any patient whose risk of venous thromboembolism was assessed in the "highest risk" category should have received a thromboprophylactic regimen appropriate to that category, such as LMWH. However, many such patients received a "moderate risk" thromboprophylactic regimen instead, such as heparin 5000 units every 12 h. This situation represents understratification of risk. Practitioners might have understratified patients' risk secondary to appropriate concerns about potentially excessive bleeding with utilization of thromboprophylaxis after a surgical procedure, a belief that the risk of venous thromboembolism was low, or a lack of awareness of the recommended guidelines.[8,9] Unfortunately, current risk assessment tools do not take into account the patient's risk of hemorrhage. If the patient's history as recorded in the chart was missing risk factor data, the patient's risk might have been understratified according to the thromboprophylaxis protocol, which might further reduce the adequacy rate found in this audit.

Failure to start thromboprophylaxis within 24 h after surgery accounted for 14% (10/71) of cases of inadequate therapy. One weakness of the current thromboprophylaxis protocol is the absence of a recommended time of initiation of anticoagulation therapy. The recommended duration of therapy is also absent from the protocol, although no cases of inappropriate duration of thromboprophylaxis were revealed by this audit. The issues of time of initiation and duration of thromboprophylaxis will be addressed in a future revision of the protocol.

The major risk associated with thromboprophylaxis is hemorrhage. In this audit, several minor hemorrhages were documented. However, the causality of hemorrhage was difficult to assess, as this complication may be associated with thromboprophylaxis or with the surgical procedure. Because anticoagulation was continued in every such case, the hemorrhages were considered to be routine following the surgical procedure and not related to the thromboprophylaxis.

The results of this audit will help in revising the thromboprophylaxis protocol on surgical order forms in the VIHA-SI. McEleny and others[13] conducted an audit and feedback study assessing the proportion of at-risk patients who received thromboprophylaxis and its adequacy in relation to the recommendations of the 1995 Scottish Intercollegiate Guidelines Network (SIGN).[14] They determined that 73% of patients had received thromboprophylaxis, but the adequacy rate was only 55%.[13] After an iterative process, whereby initial audit results were presented to clinical specialists and local guidelines consistent with the SIGN guidelines were implemented, another audit showed improvement in both outcomes, with 97% of at-risk patients receiving thromboprophylaxis and an adequacy rate of 96% ($p < 0.001$).[13]

Introduction of a formal risk assessment tool for venous thromboembolism, including a checklist for risk factors, may increase rates of adequate thromboprophylaxis.[15,16] Byrne and others[15] described a risk assessment table for deep vein thrombosis, which was included on order forms. Nurses were educated to contact prescribers if the risk assessment was not completed, which increased appropriate thromboprophylaxis from 51% to 90% of patients.[15] Thus, modifying the thromboprophylaxis protocol to include a checklist of risk factors for venous thromboembolism and bleeding may improve adherence rates.

Education of practitioners about risk stratification and the benefits of thromboprophylaxis may also help to improve compliance. Studies evaluating the effect of practitioner education on thromboprophylaxis have shown improvement in adherence to the hospital's protocol in subsequent audits.[8,17,18] The following educational interventions have been used: meetings with the hospital's surgical and anesthesia executive committees; grand rounds or articles in the hospital's drugs and therapeutics bulletin highlighting baseline audit results and providing information about the hospital's thromboprophylaxis guidelines; and production of posters, laminated cards, or handouts incorporating the hospital's thromboprophylaxis guidelines and the risk assessment process.[17,18] Peterson and others[17] found that educational interventions improved the rate of adequate prophylaxis against venous thromboembolism among surgical patients from 59% to 70% at 2 weeks after implementation. Hence, education about a thromboprophylaxis protocol may improve compliance, which can be documented through sequential quality assurance audits.

The main limitations of this clinical audit were the small sample size, reliance on the documented patient history, and the retrospective nature of the study. In addition, the study design did not permit any statistical analyses. However, in light of the findings, future clinical audits of adherence to thromboprophylaxis guidelines should be designed to include statistical analyses and should use a sample size sufficient to assess the statistical significance of the findings.

In conclusion, among surgical patients treated at the VIHA-SI, the use of adequate thromboprophylaxis, as defined by the thromboprophylaxis protocol, was low. Revision of the protocol to include the recommended time of initiation, the recommended duration of therapy, and a thrombosis risk assessment checklist, as well as education of practitioners about risk stratification and the benefits of thromboprophylaxis, may improve adherence rates.

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