Title: VTE Safety Toolkit: A Systems Approach to Patient Safety

Principal Investigator: Brenda K. Zierler, PhD[1]
Team Members:
Ann Wittkowsky, PharmD[2]
Robb Glenny, MD[3]
Seth Wolpin, PhD[1]
Jung-Ah Lee, MN[1]
Gene Peterson, MD, PhD[3]
Fred Wolf, PhD[3]
Lynne Robins, PhD[3]
Pamela Mitchell, PhD[1]
Tom Payne, MD[3]
Paul Hendrie, MD[3]
Courtney Jacobson, BA[1]
Geunhye Han, MSN[1]
Hyunjin Oh, MSN[1]
Affiliations:
School of Nursing, University of Washington[1]
School of Pharmacy, University of Washington[2]
School of Medicine, University of Washington[3]

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STRUCTURED ABSTRACT (200-words maximum). Include five headings: Purpose, Scope, Methods, Results, and Key Words

Purpose: The purpose of this program was to increase the implementation of safe practice interventions for patients at risk for or who are diagnosed with venous thromboembolism (VTE), through use of an evidenced-based and system-supported interactive ***VTE Safety Toolkit***.

Scope: VTE is one of the most common clinical disorders among both inpatients and outpatients, and PE is the most common preventable cause of death among hospitalized patients in the United States.

Methods: The study design was a pre/post intervention using retrospective medical chart reviews. We have completed the pre-intervention data collection and the implementation of the interventions, but we have not collected post-intervention data.

Results: Inappropriate utilization of imaging tests to rule out VTE was documented and has implications for both cost and outcomes. The recommended guidelines using clinical probability assessment and D-dimer testing as the initial screening tests for VTE diagnosis were underutilized. The implementation of the ***VTE Safety Toolkit*** should increase the appropriateness of the diagnostic studies ordered. Preventive measures for VTE, including both pharmacologic and mechanical prophylaxis, were underutilized in this series of hospitalized patients. The current pre-implementation data will be compared with post-implementation data to determine the effect of the interventions on clinical practice.

Key words: venous thromboembolism, patient safety, evidenced-based and system-supported interactive toolkit

PURPOSE (Objectives of the study)

The purpose of this program was to increase the implementation of safe practice interventions for patients at risk for or who are diagnosed with venous thromboembolism (VTE), through use of an evidenced-based and system-supported interactive ***VTE Safety Toolkit***. Multidisciplinary clinical and research teams in partnerships among the University of Washington Medical Center (UWMC), the University of Washington School of Nursing, and the Center for Health Sciences Interprofessional Education and Research developed and implemented a ***VTE Safety Toolkit*** for UWMC providers, patients, and external referring providers of the UWMC. This project was intended to inform AHRQ, providers, patients, payers, policymakers, and the public about how this safe practice intervention can be successfully implemented in diverse healthcare settings, leading to safer and better healthcare for all Americans.

The VTE Safety Toolkit is composed of several components: assessment tools, diagnostic screening tools, prophylaxis guidelines, and treatment guidelines for both inpatients and outpatients. The VTE Safety Toolkit is divided into provider, patient, and system components. The provider component includes educational tools for increasing knowledge on assessment of risk for developing VTE, for using prophylaxis for VTE, for understanding diagnostic strategies for VTE, for treating acute VTE patients as inpatients or outpatients, and for managing patients post-treatment (long-term management). The patient component consists of educational tools for improving knowledge on prevention and treatment of VTE. Systems components include clinical tools, infrastructure support, and expert consultants for improving communication between providers and patients and for improving the coordination of care throughout the continuum. The clinical tools include treatment and prevention guidelines, provider order sets, risk assessment templates, communication tools (ULINK), and clinical alerts. Although they are not “tools” per se, the infrastructure support consists of an integrated clinical database, computerized physician order entry, standardized reporting, quality improvement tools, and computerized logbooks. The expert consultants’ part of the systems component includes physician and nurse champions, anticoagulation experts, boundary spanners, and informatics personnel.

The UWMC VTE Safety Toolkit was developed by a group of multidisciplinary providers at UWMC using clinical evidence and established guidelines from the American Chest College of Physicians. Local UWMC experts in thrombosis, vascular diagnostics, and anticoagulation from the disciplines of medicine, surgery, anesthesiology, nursing, and pharmacy participated in development of the pathways, order sets, guidelines, and patient handouts. Each element was designed to address a specific safety issue related to VTE management and was targeted to a particular audience. The VTE Safety Toolkit is generalizable to all populations of hospitalized patients at risk for or diagnosed with VTE and to all levels of providers, from internal UWMC to external community WWAMI providers.

The aims of the study were to:

1. Measure the percentage of hospitalized patients whose risk factors for VTE were assessed and documented upon admission and on discharge.

2. Evaluate the percentage of hospitalized patients without contraindications who received prophylaxis.
3. Determine changes in the volume of inappropriately ordered venous duplex scans compared with the rate of duplex scans ordered among patients for whom it was appropriate.
4. Measure the percentage of patients with a diagnosed VTE who receive appropriate therapy in hospital and who were discharged with appropriate outpatient therapy.
5. Determine the rate of recurrent VTE and major bleeding during hospitalization and after discharge.
6. Measure VTE prophylaxis knowledge of all providers at University of Washington and Harborview Medical Centers using an online, interactive, web-based educational intervention.

SCOPE

Background and Significance

Venous thromboembolism is one of the most common clinical disorders among both inpatients and outpatients, and PE is the most common preventable cause of death among hospitalized patients in the United States. Approximately two thirds of patients with symptomatic VTE manifest DVT alone, whereas one third of patients manifest PE.[1] The recurrent rate of VTE, despite anticoagulant therapy is 7% at 6 months, and death occurs in 6% of DVT cases and 12% of PE cases within 1 month of diagnosis.[1] Errors from omission of prophylaxis or objective diagnostic testing, or from inadequate treatment, are estimated to result in significant harm to hospitalized patients. Data from randomized trials involving surgical patients suggest that adequate prophylaxis in high-risk patients can prevent VTE in one of 10 patients and save the life of one of 200 patients annually.[2] A fundamental understanding of prophylaxis, diagnosis, and treatment is necessary for providers throughout the continuum of patient care. Approximately 2.5 million cases of DVT and 600,000 cases of PE are diagnosed per year in the United States.[3] About 30% to 40% of postoperative patients will develop some form of DVT, and VTE is associated with more than 300,000 hospitalizations annually.[3-5] Given the magnitude of the problem, it is not surprising that the diagnosis and management have been better defined for VTE than for other common diseases. Appropriate prophylactic regimens for many patient groups have been determined by randomized clinical trials, as has the appropriate treatment of established DVT.[6,7] Several groups have also established consensus recommendations based upon these trials.[8]

Unfortunately, despite the substantial literature regarding the appropriate management, VTE has been identified as an area of concern by several national groups involved with patient safety or quality improvement (Surgical Care Improvement Project, National Quality Forum, The Leapfrog Group for Patient Safety, and the Joint Commission on Accreditation of Healthcare Organizations). The UWMC has recently documented an increased incidence of postoperative VTE, and addressing this clinical problem has now become a major priority of the UWMC and the UWMC Center for Clinical Excellence. The risk assessment data from various sources have demonstrated multiple problems with the diagnosis, management, and prevention of VTE at UWMC from the level of the provider, patient, and system. This is not a new clinical problem, but it is a unique clinical problem that requires coordination of care across multiple locations (in hospital, outpatient clinics, at home) by multiple providers (nursing, medicine, pharmacy, and surgery), supported by a system that assists in the process of delivering care.

The benefits to the institution from implementing the safe practice intervention outweighed the costs that would have been incurred from doing nothing. The benefits from this project are improved patient outcomes, a decrease in the number of medical errors or harm experienced by patients, an improvement in communication among internal and external providers and their shared patients, increased knowledge of VTE assessment and management, and a shift in the culture or context of care toward a culture of safety. Lack of administrative support and the lack of integration of clinical research into daily practice have been barriers to adopting these VTE safe practices in the past. These barriers were addressed, and we attempted to change practice by taking advantage of the following developments: 1) The administration at UWMC changed; with the personnel change, there appeared to be a change in the culture. The culture has been more focused on patient safety and on delivering quality healthcare across the continuum of care. 2) A new center was developed at the UWMC (The Center for Clinical Excellence, led by Dr. Gene Peterson, Co-Investigator). Reduction of VTE had been documented as a priority for patient safety at UWMC, as evidenced by its inclusion on the FY2005/06 Operating Plan. 3) The UWMC administration's implementation of a culture of safety to UWMC Division and Service Chiefs, nursing personnel, and house staff has been successful, and each are held accountable for addressing specific patient safety issues.

Study Population

The study population included patients who were at risk for or diagnosed with VTE at UWMC, referring providers of patients discharged with a diagnosis of VTE at UWMC, and surgical and medical residents UWMC/HMC who were involved in patient care.

METHODS (Study Design, Data Sources/Collection, Interventions, Measures, Limitations)

Study Design

The study design was a pre/post intervention retrospective review for Aims 1-5 and a randomized controlled trial for Aim 6. We have completed the pre-intervention data collection and the implementation of the interventions, but we have not collected post-intervention data. The data sources that we utilized were patient medical records and provider surveys and responses to an online provider training module.

Data Sources/collection

The sample was composed of 1161 consecutive inpatients and outpatients referred for a VDS, a spiral CT, or a V/Q scan for a suspected VTE at UWMC during the period of October 2005 to March 2006. All patients aged 18 years and older who underwent VDS, CT, or V/Q scans for suspected VTE were included in this study. The medical records were retrospectively reviewed to document patient demographics, diagnostic strategies to rule out DVT and PE, indications for the imaging studies, signs and symptoms, and VTE risk factors at the time of the objective testing. Moreover we performed in-depth reviews of 660 inpatients among 1161 at risk for VTE to evaluate their VTE prophylaxis and treatment patterns and 3-month clinical outcomes on any bleeding episodes after anticoagulation therapy or mortality after DVT or PE diagnosis.
In addition to medical chart review of patients at risk for VTE, we randomly selected 100 medical inpatients who did not have any surgical procedures and 100 surgical inpatients who had a major surgery (operating time greater than 3 hours) to evaluate their VTE prophylaxis patterns.

Four research assistants had been involved in data collection. A lead research assistant experienced with DVT research trained three other research assistants in a systematic way. All data were entered into a Microsoft Access program. Interobserver reliability was considered to compare data collected from two different research assistants in a certain periodic timepoint, and different information was discussed to provide for consistency in the way data were collected.

Interventions:

The interventions included a web-based VTE Safety Toolkit and an online Provider Training Module on VTE Prevention. The ***VTE Safety Toolkit*** consists of diagnostic, preventive, and therapeutic algorithms as well as a mandatory web-based VTE educational intervention for providers and patients (patient educational materials). The toolkit was divided into provider, patient, and system s*ections*. The provider component included educational tools for increasing knowledge on the assessment of risk for developing VTE, for using VTE prophylaxis strategies, for understanding diagnostic strategies for VTE, for treating acute VTE in both inpatients and outpatients, and for managing patients post-treatment. The patient components consisted of educational tools for improving knowledge about the prevention of VTE and about outpatient treatment options. Systems components included clinical tools, infrastructure support, and expert consultants for improving communication between providers and patients and for improving the coordination of care throughout the continuum. The ***VTE Safety Toolkit*** has been disseminated locally, regionally and nationally. The online Provider Training Module is still being tested, and this part of the study is not complete.

Measures and Evaluation

The key outcomes were as follows: **primary**: the change in the percentage of patients who were assessed, screened or treated for VTE events; **secondary**: the change in the percentage of hospitalized patients without contraindications who receive anticoagulation prophylaxis; the change in the percentage of hospitalized patients whose risk factors for VTE are assessed and documented upon admission and discharge; the change in the volume of inappropriately ordered VDS while not decreasing the volume of duplex scans ordered among patients for whom it is appropriate; the percentage of patients with a diagnosed VTE who received appropriate therapy in hospital and who were discharged with appropriate outpatient therapy; the change in the rate of recurrent VTE and major bleeding during hospitalization and after discharge; and the change in knowledge of physicians on VTE prophylaxis. Specific evaluation measures for each aim are outlined below.

Aim 1. Improve the assessment of risk factors for VTE upon admission and discharge. Expected outcome: increase the percentage of hospitalized patients whose risk factors for VTE are assessed and documented upon admission and on discharge.

Evaluation: Conduct retrospective chart reviews on a random sample of patients' charts from two time intervals: October 2004-March 2005 (pre-intervention) and September 2007-March 2008 (post-intervention). A previous audit at UWMC had shown that only 20% of medically ill patients and less than 5% of surgical patients are assessed for VTE risk factors. Because the incidence rate of VTE for postoperative patients is a current safety problem at the UWMC, the goal is to increase the percentage of surgical patients who are assessed for VTE risk factors

before and after surgery to at least 75%. A sample of 100 charts pre-intervention plus another 100 charts post-intervention will give 88% power for detecting an improvement from 20% to 40% in percent of patients assessed for VTE risk factors, or 90% power for detecting an improvement from 5% to 20% (α=.05, two tailed). Thus, there will be good power for detecting an improvement, even if the amount of improvement is much less than the goal. Statistical analysis will use chi-squared tests to compare the percent of patients assessed for VTE risk factors before versus after the intervention.

Aim 2. Improve the use of prophylaxis. Expected outcome: increase the percentage of hospitalized patients without contraindications who receive prophylaxis.

Evaluation: Conduct retrospective chart reviews on a random sample of surgical patients' charts from the pre- and post-intervention time periods October 2004-March 2005 (pre-intervention) and September 2007-March 2008 (post-intervention) to determine if patients were assessed and given prophylaxis. In each time period, surgical patients will be randomly selected until 100 patients are identified for whom anticoagulation prophylaxis would be appropriate. The post-intervention goal is that 75% of these patients will be anticoagulated. The precise current rate is unknown but is certainly low, below 10%. With this sample size, there will be 95% power for detecting an improvement from 10% to 30% (α=.05, two tailed). Statistical analysis will use chi-squared tests.

Aim 3. Improve the use of diagnostic procedures when VTE is suspected. Expected outcomes: decrease the volume of inappropriately ordered venous duplex scans while increasing the rate of duplex scans ordered among patients for whom it is appropriate.

Evaluation: Approximately 2000 patients are scanned per year, and the current incidence of DVT is 10%. The electronic logbook will be reviewed for all scans performed during the two 6-month periods specified under Aim 1: October 2004-March 2005 (pre-intervention) and September 2007-March 2008 (post-intervention), approximately 1000 scans in each period. Of these, approximately 30%, or 300 scans, are inappropriate, with no appropriate indications for VTE. The goal is to decrease the number of inappropriate scans to 15%. With this sample size, there will be 94% power for detecting a decrease from 30% to 23% (α=.05, two tailed) and 100% power if the goal is actually achieved. Statistical analysis will use chi-squared tests.

Aim 4. Improve the treatment of VTE once it occurs, both in hospital and after discharge. Expected outcomes: increase percentage of patients with a diagnosed VTE who receive appropriate therapy in hospital and are discharged with appropriate outpatient therapy; decrease the rate of recurrent VTE and major bleeding during hospitalization and after discharge.

Evaluation: Conduct chart reviews on all patients diagnosed with VTE (based on vascular laboratory logbook) during the periods October 2004-March 2005 (pre-intervention) and September 2007-March 2008 (post-intervention), approximately 100 patients per period. Determine the percent of patients who received appropriate therapy while hospitalized, the percent who were discharged on appropriate therapy, and the percent with recurrent VTE and percent with bleeding. The current rate of appropriate therapy is about 70%, and the goal is to

increase this to 90%. There will be 95% power (α=.05, two tailed) for detecting an improvement if this goal is achieved.

Aim 5. Compare online standard didactic training versus online interactive case studies for the training of 700 physicians in venous thromboembolism (VTE) prevention. Expected outcomes: increase provider knowledge and understanding of VTE risk assessment, indications for VTE prophylaxis, contraindications for VTE prophylaxis, and dose and duration of VTE anticoagulation prophylaxis; improve provider satisfaction with mandatory educational interventions through the use of interactive case studies.

Evaluation: We are conducting a randomized, controlled trial to determine how to best deliver this type of training. Each provider will be randomized to one of two approaches for delivering the VTE prophylaxis content: standard didactic or standard didactic plus interactive case studies. Only de-identified data will be used for this research. The goal of this research is to increase the percentage of hospitalized patients without contraindications who receive anticoagulation prophylaxis by increasing provider knowledge on VTE prophylaxis. We will also be testing the method of delivering the VTE prophylaxis content to the providers. Approximately 700 physicians from UWMC and HMC will take the mandatory online VTE prophylaxis training. The analysis will compare the pre- and post-assessment testing of the VTE prophylaxis content using the two methods of delivering educational material (standard didactic versus online interactive case studies). A survey will be conducted at the end of training to ascertain the provider's satisfaction with the online educational format. Approximately 108 providers have completed the training as of 9/9/08.

Limitations

We have not completed data from the post-implementation period due to a lack of funding and because the implementation of the provider training module was delayed by more than 1 year. Potential confounders will include patient demographics, types and level of providers, institutional factors, systems characteristics, and potentially other factors. Multivariate analysis will be used to control for those variables.

RESULTS (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications)

The following findings reflect data collected during the pre-implementation period.

VTE prophylaxis for inpatients with suspected VTE

Acute VTE was diagnosed in 138 (21%) of the 660 inpatients who were referred to vascular or radiology laboratories to rule out DVT/PE for a 6-month pre-implementation period from October 2005 to March 2006; the incidence of DVT and PE was 18% and 25%, respectively. The mean age was 56 ±17; 52% were women, and the majority of patients were Caucasian. Only 61% of eligible patients received pharmacologic prophylaxis. Mechanical prophylaxis was used in 43% of patients. The incidence of VTE was higher in patients who did not receive pharmacologic prophylaxis (30%) compared with patients who did (16%, $p<0.001$).

Table 1. The type of prophylaxis in patients with suspected VTE

Type of VTE prophylaxis	Frequency (%)	VTE (%[*])[¶]
Both anticoagulation[†] and mechanical compressions[‡]	205 (31.1)	25(12.2)
Anticoagulation only	171 (25.9)	36 (21.1)
Mechanical compressions only	79 (12.0)	11 (13.9)
None[§]	205 (31.0)	66 (32.2)

[*] Percentage of patients with VTE within each type of VTE prophylaxis.

[†] Anticoagulation for VTE prophylaxis included low-dose unfractionated heparin, low-molecular-weight heparin, and warfarin. Aspirin was not included for VTE prophylaxis.

[‡] Mechanical compressions included graduated compression stockings and intermittent pneumatic compression devices.

[§] No prophylaxis included the patient cases with insufficient medication information due to retrospective chart reviews.

p<.001: type of VTE prophylaxis vs. VTE incidence

The types of VTE prophylaxis used in hospitalized patients with suspected VTE are presented in Table 1. Pharmacologic prophylaxis was used in 57% of the patients; mechanical compressions, including graduated compression stockings or/and sequential pneumatic compression devices, were applied in 43% of the patients prior to the diagnosis of VTE. Approximately 31% (205 of 660) of the patients in this study did not receive any form of prophylaxis (mechanical or pharmacologic). Approximately 7% (48 of 660) of hospitalized patients were not eligible to receive pharmacologic prophylaxis due to contraindications (bleeding tendencies or a history of heparin-induced thrombocytopenia). Among those who were ineligible for pharmacologic prophylaxis, 44% (21 of 48) received mechanical compression as a prophylaxis measure, and more than half of the patients (56%, 27 of 48) had no mechanical prophylaxis measures used. Except for those with contraindications, approximately 61% (374 among 612) of the patients received pharmacologic prophylaxis measures to prevent VTE. The incidence of VTE was higher (30%, 71 of 238) in patients who did not receive pharmacologic prophylaxis than in those who had pharmacologic prophylaxis (16%, 61 of 374) (p<.001).

Table 2. VTE incidence in inpatients eligible to receive pharmacologic prophylaxis adjusted by the number of risk factors

VTE risk factor category	Pharmacologic prophylaxis[†]	VTE in pharmacologic prophylaxis[*]	VTE in non pharmacologic Prophylaxis[*]	P value
None (n=82)	38/82 (46.3%)	5 (13.2%)	12 (27.3%)	.116
1-2 risk factors (n=448)	270/448 (60.3%)	40 (14.8%)	50 (28.1%)	<.001
≥ 3 risk factors (n=82)	66/82 (80.5%)	16 (24.2%)	9 (56.3%)	.013

[*] Percentage (%) of patients who were diagnosed with VTE within received pharmacologic prophylaxis or not.

[†]p<.001.

Table 2 describes VTE incidence and pharmacologic prophylaxis utilization by each VTE risk category for patients eligible to receive prophylactic anticoagulants. The proportion of patients receiving pharmacologic prophylaxis significantly increased with the number of risk factors for VTE (no risks – 46.3%, 1-2 risk factors – 60.3%, ≥3 risk factors – 80.5%, p<.001). Patients without pharmacologic prophylaxis had a significant higher incidence rate of VTE than did patients with pharmacologic prophylaxis for all groups (p<.001 in patients with 1-2 risk factors, p=.013 patients with ≥3 risk factors).

Table 3. Multivariate logistic regression analysis of the incidence of VTE in hospitalized patients

Variables	Odds Ratio	95% CI*		P value
		Lower	Upper	
Age	1.000	.986	1.015	.983
Gender (male)	.625	.386	1.012	.056
Race (Caucasian)	2.009	1.016	3.974	.045
Pharmacologic prophylaxis	.397	.240	.656	<.001
Prior VTE	3.179	1.797	5.621	<.001
Active cancer	2.099	1.229	3.584	.007
Cardiac diseases	.738	.422	1.292	.288
Major surgery	1.158	.701	1.914	.566
Lower limb trauma	1.152	.346	3.840	.817
Hormonal therapy	1.449	.433	4.843	.547
Hypercoagulable state	1.096	.350	3.430	.875
Morbid obesity (BMI ≥ 40)	.920	.314	2.693	.879

* 95 % CI= 95 % Confidence Interval.

Table 3 describes the significant factors that were associated with VTE in hospitalized patients using a multivariate logistic regression analysis. The cut off point for the p value for significance was .05. Caucasians were more likely to have VTE than other ethnic groups. Patients who had prior history of VTE or active cancer were more likely to have VTE (all odds ratios [OR] >1, p<.05). Patients who received pharmacological prophylaxis were less likely to have VTE (OR=0.397, p<.001). Female gender was a marginally significant factor for VTE (p=.056) while controlling for other covariates (e.g., age, and other VTE risk factors) in this study.

VTE prophylaxis in randomly selected medical and surgical inpatients

Of the 100 randomized medical inpatients, 46 were placed on anticoagulation prophylaxis only or anticoagulation and mechanical prophylaxis. Of these 46, 13 were on chronic warfarin therapy, which means that they were already anticoagulated and therefore did not need additional prophylaxis to prevent VTE. Seven patients were ineligible for anticoagulation due to contraindications; thus, 46 of 93 (49.5%) eligible patients received appropriate therapy. Approximately 50% (48 of 95) surgical inpatients received pharmacological prophylaxis either anticoagulation alone or anticoagulation with mechanical prophylaxis. Eight of 28 patients (29%) who were considered to be at moderate risk for VTE, 18 of 38 patients (47%) who were categorized to be at high risk, and 23 of 30 patients (77%) who were at the highest risk received pharmacological prophylaxis. Five were ineligible for prophylactic anticoagulants due to documented contraindications, such as bleeding and coagulopathies.

Of the 52 surgical inpatients who did not receive pharmacological prophylaxis, 42 patients (82%) received mechanical prophylaxis only. Nine patients who had major surgery did not receive any form of VTE prophylaxis.

Table 4. VTE prophylaxis in medical and surgical patients by risk for VTE

	Medical 100 Inpatients		Surgical 100 Inpatients	
		% prophylaxis		% prophylaxis
Highest risk	34	52 %	36	47%
High risk	49	43 %	38	62%
Moderate risk	17	67 %	26	38%

VTE diagnostic procedures

Medical records of adult patients who underwent lower extremity venous duplex scans (VDS), chest computerized tomographic (CT) angiography, or ventilation and perfusion (V/Q) scans during a 6-month pre-intervention period were retrospectively reviewed in UWMC. A total of 1161 consecutive patients underwent diagnostic testing to rule out VTE. Among those, 817 (70%) patients were suspected for DVT and 504 (43%) patients were suspected for PE. The majority of patients were women and were Caucasian. The mean age was 56 years in patients with VDS and 53 years in patients who underwent lung scanning. The median length of hospital stay was 10 days in inpatients with suspected DVT and 6 days in inpatients with suspected PE. The majority of patients diagnosed with VTE were inpatients. Approximately 10% of patients (34 of 357) who were referred from outpatient clinics or emergency room had DVT diagnosed, whereas 18% (81 of 460) of inpatients were diagnosed with DVT.

Diagnostic procedures for DVT

The incidence of DVT in patients who underwent VDS was 14% (115 of 817), and the incidence of PE was 18.5% (93 of 504) in patients who underwent either spiral CT or V/Q scanning. Thirty patients were diagnosed with both DVT and PE during the 6-month study period. The most common risk factor for VTE was surgery in patients suspected with DVT ($p<.05$) and cardiac disease in patients suspected with PE ($p<.05$).Table 2 describes the incidence of DVT by indication in patients who were referred to the vascular laboratory to rule out DVT by VDS. Approximately 70% (567 of 817) of patients who underwent VDS were symptomatic; among those, 14% (78 of 567) had a positive study for DVT. About a quarter of patients (188 of 817) underwent VDS to look for a source of PE; among those, 21% (39 of 188) were diagnosed with DVT, and half of the 188 patients (n=91) presented with both leg and lung symptoms. Approximately 12% (100 of 817) of patients had VDS for surveillance purposes; among those, 13% (13 of 100) had DVT, which was similar to the incidence of DVT in the symptomatic patients (14%). About 80% of patients who underwent VDS for surveillance had one or more VTE risk factors.

Diagnostic procedures for PE

The majority of patients who were suspected of having PE underwent spiral CT (437 of 504, 87%) rather than VQ scanning. The incidence of PE was 20% in those with CT scan and 8% in those with V/Q scan. In addition to undergoing lung scanning for possible PE, 25% of these patients (124 of 504) underwent VDS; among those, 29% (36 of 124) were diagnosed with DVT and 45% (52 of 124) were diagnosed with PE by lung scanning. Table 4 describes various PE diagnostic strategies utilized in this institution. The CT-alone strategy was used most frequently to rule out PE in 65% patients with suspected PE. Approximately 25% of patients underwent both a lung scan and lower limb VDS. Sixty-three patients had VDS only to look for the source of symptomatic PE; six were diagnosed with DVT, and 57 had a negative examination with no additional lung imaging tests performed.

Incomplete or indeterminate studies

Fourteen patients had incomplete CT scanning due to reasons such as inadequate contrast opacification, respiratory motion artifact (especially in elderly patients), or obesity (obese patients too heavy for CT table). Twelve patients with incomplete CT scans did not have additional objective testing, and two patients with indeterminate CT results underwent subsequent V/Q scan or VDS to rule out PE. Nine of 12 patients who had incomplete CT scans had one or more VTE risk factors. Among three patients with intermediate V/Q scan results (or indeterminate), subsequent studies demonstrated one positive result using CT scan and two negative VDS scans. Approximately 82% (63 of 77) of V/Q studies resulted in a low clinical probability for PE, and half (31 of the 63 patients) had no additional objective imaging tests. Four patients had subsequent CT scans, and the remaining 28 patients had VDS within 7 days of symptoms. Five patients with low clinical probability on V/Q scan had abnormal D-dimer testing, but they had no more imaging tests.

D-dimer measurement as a screening test in outpatients

D-dimer testing was performed prior to objective imaging tests in patients who presented to outpatient clinics or to the emergency room. Approximately 14% of patients who underwent VDS were initially screened using D-dimer testing; a greater number (42%) of patients who underwent CT had D-dimer tests, and 23% of patients who underwent V/Q scans had D-dimer tests.

DISCUSSION

The incidence of VTE was higher in hospitalized patients who did not receive prophylaxis in this study, yet the overall incidence was similar to the literature, ranging from 11% to 28%.[9,10] Overall incidence of VTE was 21%; of DVT, 18%, and of PE, 25%, which might be due to the fact that more than a quarter of patients in this study had a diagnosis of cancer. There were no standard guidelines used in this institution to assess the baseline VTE risk in hospitalized patients on admission or discharge. Approximately 40% of hospitalized patients at risk for VTE did not receive prophylaxis to prevent VTE in the pre-implementation period. According to the 2004 ACCP Guidelines,[11] pharmacological prophylaxis should be used in all hospitalized patients unless they are ineligible due to contraindications to anticoagulation, such as bleeding tendencies or other coagulopathies; in those patients that are ineligible for pharmacologic prophylaxis, mechanical prophylaxis should be utilized.

We identified underutilization of evidence-based screening tests and overutilization of objective imaging tests. There appeared to be no standard approach for the diagnosis of DVT or PE. Some patients received multiple objective imaging tests, even after an initial diagnosis of VTE was found. Other patients received only one imaging test when a second confirmatory test was indicated.

Integrated approaches to the diagnosis of VTE have been recommended.[12-17] Patients with a low clinical probability and a normal D-dimer could safely rule out PE without additional imaging tests (such as VDS, CT scan, or V/Q scan).[12] Those integrated strategies would be safer, more convenient, and cost effective in the care of patients with suspected VTE.[12] However, in this study, diagnostic tests deemed unnecessary or inappropriate were documented. Four examples of inappropriate utilization can be described: 1) Symptomatic PE patients who were first diagnosed by CT or V/Q scan still underwent a VDS to look for the source of the PE. If a DVT is diagnosed by VDS or a PE is diagnosed by lung scanning, anticoagulation therapy should be initiated, and additional investigation to exclude PE may not be necessary.[17] 2) Nine patients at high risk for PE had incomplete CT scans, yet no other tests were performed to rule out PE or DVT. 3) D-dimer tests were underutilized as a screening tests in low-risk outpatients prior to ordering more expensive diagnostic imaging studies; objective imaging tests were directly performed in low-risk patients who were less likely to have VTE, which is not considered cost effective.[18] 4) Five pregnant patients had CT scans for suspected PE as the initial diagnostic test instead of being screened with VDS or V/Q scanning. For special cases, such as pregnant women or patients with allergies to contrast dye, the investigators of the Prospective Investigation of Pulmonary Embolism Diagnosis II[19] study recommended that a CT scan be preceded by a combination of clinical assessment and D-dimer first, followed by VDS and or pulmonary scintigraphy prior to resorting to a CT scan. There was no institutional or department-specific standard approach to VTE diagnosis used in this institution.

This study has limitations due to the study design, a descriptive study at a single institution, which provides the lowest methodological quality (descriptive reports-observational study).[20] However, this study was conducted to provide baseline data on the current practice in the diagnosis of VTE prior to the implementation of evidenced-based VTE safety toolkit, including diagnostic algorithms for DVT and PE, treatment for VTE, and patient education for VTE prevention and treatment.

Conclusion

Inappropriate utilization of imaging tests to rule out VTE was documented and has implications for both cost and outcomes. The recommended guidelines using clinical probability assessment and D-dimer testing as the initial screening tests for VTE diagnosis were underutilized. The implementation of the ***VTE Safety Toolkit*** should increase the appropriateness of the diagnostic studies ordered. The current utilization data will be compared with post-implementation data to determine the effect of the interventions on clinical practice.

Preventive measures for VTE, including both pharmacologic and mechanical prophylaxis, were underutilized in this series of hospitalized patients. If reporting of VTE prophylactic measures

were to begin today, there would be a financial loss of 2% of Medicare reimbursement at this institution due to the poor rate of pharmacologic prophylaxis.

SIGNIFICANCE, IMPLICATIONS

We have not been able to document the significance of the study, because we only had funding and time to complete the pre-intervention data collection. We experienced several barriers to implementing the VTE Safety Toolkit in a timely fashion at UWMC, although the toolkit was developed in the first year of the grant. We are still undergoing the provider training research; to date, we have had approximately 124 residents complete the training. We have been able to document an increase in VTE prophylaxis, using data from audits from the Center for Clinical Excellence (Quality Improvement Office), from 30% to approximately 70% (but this is from audit data that is collected for benchmarking with other University Hospitals). We will continue to work with the AHRQ to disseminate the toolkit components to other hospital systems, and we will continue to submit grant proposals for the post-intervention data collection.

List of Publications and Products (Bibliography of Outputs) from the study. Follow the AHRQ Citation Style Format at http://dev.ahrq.gov/fund/refstyle.htm.

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Journal article

Zierler BK, Wittkowsky A, Peterson G, et al. Venous thromboembolism safety toolkit: A systems approach to safe practice interventions. *Advances in Patient Safety 2008*. (In Press)

Conference Proceedings

Conference paper:

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Lee J, Zierler BK. The evaluation of diagnostic procedures of venous thromboembolism (VTE) in patients with suspected VTE. 2008 the 20th Annual Meeting of American Venous Forum conference, Charleston, South Carolina.

Han GH, Zierler BK, Lee J, et al. Clinical outcomes of calf deep vein thrombosis. 2007 the 22nd annual meeting of the Western Vascular Society, Kona, Hawaii.

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Zierler BK, Lee J, Oh HJ, et al. Utilization of pharmacologic prophylaxis for venous thromboembolism (VTE) prior to the implementation of a VTE Safety Toolkit. 2007 the 22nd annual meeting of the Western Vascular Society, Kona, Hawaii.

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