Poor adherence to risk stratification guidelines results in overuse of venous thromboembolism prophylaxis in hospitalized older adults

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Poor adherence to risk stratification guidelines results in overuse of venous thromboembolism prophylaxis in hospitalized older adults

Running Title: Overuse of VTE prophylaxis in older adults

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TO THE EDITOR:

Venous thromboembolism (VTE) prophylaxis is an important consideration for every older adult admitted to the hospital, but should not be prescribed to all patients. Use of anticoagulants (specifically low-molecular-weight heparin, low-dose unfractionated heparin, and fondaparinux) when not medically indicated may be harmful, especially for older adults who on average have more chronic conditions, take more potentially interacting medications, and have higher risks of bleeding. The American College of Chest Physicians (ACCP) 9th Edition guidelines for Antithrombotic Therapy and Prevention of Thrombosis explicitly recommend a risk-stratification approach using the Padua Prediction Score (PPS) to select those patients most likely to benefit from VTE prophylaxis. This study aimed to describe the use of risk stratification and pharmacologic VTE prophylaxis use in a population of medically ill, hospitalized older patients.

METHODS: We conducted a retrospective cohort study using data from patients aged 70 years or older, admitted to Duke University Hospital general medicine services, between January 1, 2014 to December 31, 2014. The PPS variables, 11 in total, are each weighed and sum to a score that stratifies patients into either high or low risk for VTE occurrence. Manual chart abstraction was performed using the electronic medical record to determine each patient’s PPS, inpatient pharmacologic VTE prophylaxis use, and contraindications to VTE prophylaxis. Descriptive statistics are presented for the important confounders/covariates, VTE risk, and VTE prophylaxis use.

RESULTS: Of the total eligible cohort (N=1,399), 400 patients were randomly selected for manual chart review; 89 of these patients were not eligible because they were on anticoagulation upon admission, leaving n=311 patients in the analytic sample. Mean age for the sample was 80.6 years (SD 7.3); 42% were male and 34% were African-American, and median length of stay was 4.0 days. The
overall mean PPS for the sample was 3.6 (SD 1.8), resulting in 59% (n = 182) defined as ‘low-risk’.

Reasons for admission, median length of stay, and aspirin use did not differ between the risk groups.

Pharmacological VTE prophylaxis was present in 74% (134/182) of low-risk patients and 71% (92/129) of high-risk patients (Figure 1). In both low- and high-risk patients who received pharmacological VTE prophylaxis, over 90% had the therapy initiated within 24 hours of admission, and it was continued for over 60% of their hospital days.

DISCUSSION: We found no association between PPS and use of anticoagulants for VTE prophylaxis, suggesting that risk stratification is not being used to guide clinical decision-making. There are several barriers to implementing guideline directed use of VTE risk stratification. First, there is a lack of consensus on which VTE risk assessment tool is best to use with medically ill, hospitalized patients. While the ACCP 9th Ed. guidelines support the use of the PPS, the American College of Physicians does not recommend a specific tool for VTE risk assessment. Although, other risk stratification tools exist, concordance between these tools has not been well studied. Second, manual calculation of the PPS can be cumbersome, error prone, and disruptive to the clinical workflow. Automated data extraction leveraging existing structured data elements in the EHR may be particularly attractive to many health systems striving to use EHRs to improve care. Designing and testing auto-populated VTE risk stratification tools may facilitate translation of evidence-based guidelines into routine clinical practice. Lastly, a key barrier is clinician education and awareness about these tools. Adding risk stratification tools to admission order sets is one way to increase clinician awareness, and has been shown to decrease inappropriate VTE prophylaxis use. High quality studies, using implementation science to promote uptake and efficacy of risk stratification tools into clinical practice, are urgently needed.

Our study has several limitations. First, this was a single site study at an academic center, which may limit generalizability of the findings. However, our design enabled us to look at other specific
patient level data that is typically not available in larger databases. Second, determination of PPS is limited to data available in the EHR, resulting in measurement error, and possibly underreporting of risk factors. Finally, due to feasibility and the low probability of VTE, we did not collect data on long-term VTE outcome and were unable to determine the impact that inappropriate VTE prophylaxis use has in low-risk hospitalized older adults.

In summary, we found poor adherence to risk stratification guidelines among medically ill, hospitalized older adults, resulting in overuse of anticoagulants for VTE prophylaxis. Automating risk stratification tools and incorporating results into order sets may ensure that adequate prophylaxis is used for patients who need it while minimizing excess prophylaxis in those who do not.
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REFERENCES:


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ABSTRACT

Background: The use of anticoagulants for venous thromboembolism (VTE) prophylaxis, when not medically indicated, may be harmful and places a significant cost burden on health systems.

Objective: To determine pharmacologic VTE prophylaxis use among low-risk hospitalized older adults.

Design: Retrospective cohort study between 1/1/2014 and 12/31/2014.

Setting: Academic medical center.

Participants: General internal medicine patients, aged 70 and older, not on anticoagulation.

Main Outcomes and Measures: Manual chart abstraction was performed using the electronic medical record to determine each patient’s Padua Prediction Score, inpatient pharmacologic VTE prophylaxis use, and contraindications to VTE prophylaxis.

Results: Of the total eligible cohort (N=1,399), 400 patients were randomly selected for manual chart review; 89 of these patients were not eligible because they were on anticoagulation upon admission, leaving n=311 patients in the analytic sample. According to the Padua Prediction Score, 59% (n = 182) were at low risk for VTE occurrence. We found that pharmacological VTE prophylaxis was used in 74% (134/182) of low-risk patients and 71% (92/129) of high-risk patients. Patients with acute or chronic respiratory failure or acute infection were more likely than those without these conditions to receive pharmacological VTE prophylaxis upon admission (ORs= 1.95, 3.37, 95% CI= (1.07, 3.52), (1.92, 5.92), respectively). Conclusions: Poor adherence to risk stratification guidelines among medically ill, hospitalized older adults may result in overuse of anticoagulants for venous thromboembolism prophylaxis among low-risk older adults. Awareness of risk stratification is needed to improve the quality and safety of anticoagulant use in medically ill, hospitalized older adults.

KEYWORDS: venous thromboembolism prophylaxis, clinical practice guidelines, geriatrics
INTRODUCTION

TO THE EDITOR:

Venous thromboembolism (VTE) prophylaxis is an important consideration for every older adult admitted to the hospital but should not be prescribed to all patients. The American College of Chest Physicians (ACCP) 9th Edition guidelines for Antithrombotic Therapy and Prevention of Thrombosis explicitly recommend a risk-stratification approach to select those patients most likely to benefit from VTE prophylaxis. Many clinicians, however, have adopted near-universal use of anticoagulants to prevent VTE, but this may not be beneficial or cost-effective in all cases. Indeed, use of anticoagulants (specifically low-molecular-weight heparin, low-dose unfractionated heparin, and fondaparinux) when not medically indicated may be harmful, especially for older adults who on average have more chronic conditions, take more potentially interacting medications, and have higher risks of bleeding. The American College of Chest Physicians (ACCP) 9th Edition guidelines for Antithrombotic Therapy and Prevention of Thrombosis explicitly recommend a risk-stratification approach using the Padua Prediction Score (PPS) to select those patients most likely to benefit from VTE prophylaxis. This study aimed to describe the use of risk stratification and pharmacologic VTE prophylaxis use in a population of medically ill, hospitalized older patients.

The ACCP 9th Ed. guidelines support the use of the Padua Prediction Score (PPS) to classify risk of VTE and select the most appropriate population for prophylaxis. The PPS was prospectively validated in a large hospitalized patient population of adults in Padua, Italy. For acutely ill, hospitalized medical patients classified as low risk for thrombosis (0.4% risk of developing symptomatic VTE), the use of pharmacologic or mechanical prophylaxis is not recommended (Grade 1B recommendation). Prophylaxis is recommended for high-risk patients (6% risk of developing VTE, Grade 1B...
recommendation). Several studies have shown that pharmacologic VTE prophylaxis is underused in high-risk patients. However, few studies have examined over-use of VTE prophylaxis in low-risk populations, or the extent to which clinical decisions incorporate evidence-based risk stratification.

This study aimed to 1) describe the use of risk stratification for determination of VTE prophylaxis in a population of medically ill, hospitalized older patients, 2) determine whether pharmacologic VTE prophylaxis (i.e. anticoagulants) is being used appropriately in low-risk, medically ill, hospitalized elders, and 3) identify correlates of pharmacological VTE prophylaxis use in this population.

METHODS:

Participants: We conducted a retrospective cohort study using data from patients aged 70 years or older admitted to Duke University Hospital over a 1-year period (general medicine services, between January 1, 2014 to December 31, 2014). Data from only the first hospital admission in that year was included. To allow time for guideline dissemination and implementation, the beginning of the observation period was approximately two years following the release of the ACCP 9th Ed. guidelines. The lower bound of age 70 years was selected due to the high frequency of comorbidities and risk of bleeding related to anticoagulant therapy. The study includes only patients hospitalized for medical illness because the PPS has not been validated in surgical patients. Patients who had surgery during their hospitalization (n=83) and patients admitted to the hospital < 24 hours (n=36) were excluded. After applying these inclusion and exclusion eligibility criteria, 1,399 patients were eligible for the study.

Analysis: The PPS variables were abstracted from the electronic health records of Duke University Health System (DUHS) electronically via the Duke Enterprise for Data Unified Content Explorer (DEDUCE) data portal and supplemented with manual review of records. DEDUCE is a
research tool that provides investigators access to patient level administrative clinical information, including medications. The Duke University institutional review board approved the study.

**Padua Prediction Score:** A PPS was calculated for all patients based on clinical and demographic factors at the time of admission. Individual risk scores were assigned based on a 20-point scoring system of risk factors including active cancer, previous VTE, myocardial infarction, congestive heart failure or respiratory failure, trauma, surgery, age ≥ 70 years, reduced mobility, acute infectious or rheumatologic disease, thrombophilic condition, obesity (BMI ≥ 30 kg/m²), or hormone use (see Table 2). A patient with 11 in total, are each weighed and sum to a score of 4 or less is considered low risk.

Data was extracted manually from the electronic health record including PPS co-morbidities, orders for reduced mobility (i.e., bedrest), and medication lists that stratifies patients into either high or low risk for VTE occurrence. Manual chart abstraction was performed using the electronic medical record to determine each patient’s PPS, inpatient pharmacologic VTE prophylaxis use, and contraindications to VTE prophylaxis. Descriptive statistics are presented for the important confounders/covariates, VTE risk, and VTE prophylaxis use.

**VTE prophylaxis use:** Inpatient medication data for each day of hospitalization was abstracted from the electronic health record including class, name, route of administration, dose strength, and administration times. Low molecular weight heparin (LMWH), low-dose unfractionated heparin (LDUH), and fondaparinux were considered pharmacologic VTE prophylaxes. Whereas there is evidence for the use of high dose aspirin for VTE prophylaxis in orthopedic patients, practice guidelines do not support its use in medically ill patients; therefore, it was not included in our study. We recorded whether patients were on full-dose anticoagulants, including warfarin and novel oral anticoagulants, prior to or on admission. Patients on anticoagulants prior to admission were excluded from the analysis (n=89). Information on whether patients were on varying doses of aspirin (81 mg, 161 mg, or 325 mg)
on or prior to admission was also recorded. Orders for non-pharmacologic VTE prophylaxis (sequential compression devices (SCDs) were also documented. Documentation (if any) of clinical reasoning regarding VTE prophylaxis were recorded from medical notes on Hospital Day 1 or upon discontinuation of VTE prophylaxis. Documentation of any bleeding complications during hospitalization was identified from the discharge note.

Analysis

There were 1399 patients in the study following implementation of eligibility criteria. For feasibility of manual chart review, RESULTS: Of the total eligible cohort (N=1,399), 400 patients were randomly selected from these eligible patients for manual chart review. Specifically, a random systematic sampling approach (stratified by month over the year of study) was applied to these eligible patients to ensure adequate representation of physician trainee experience, which can lead to variability in risk stratification and prescribing patterns.

Descriptive characteristics were calculated for all variables, including the distribution of PPSs and the proportion of patients who were at low and high risk for VTE by PPS score. Differences in demographics, clinical characteristics, and each PPS risk factor between low- and high-risk patients were evaluated with t-tests or chi-square tests as appropriate. We calculated the proportions of low- and high-risk patients who received 1) pharmacologic VTE prophylaxis, 2) non-pharmacologic VTE prophylaxis, 3) both pharmacologic and non-pharmacologic VTE prophylaxis, or 4) no VTE prophylaxis. For patients who were prescribed VTE prophylaxis, time to prophylaxis initiation from baseline risk assessment, duration of prophylaxis use, and reasons for discontinuation were examined. Bivariate analyses were performed to examine the association between individual PPS variables and the outcome of VTE prophylaxis use. As a next step, adjusted logistic regression analyses were performed to determine which individual PPS variables predicted VTE prophylaxis use after controlling for
demographic characteristics of age, gender, and race. Only those variables in which bivariate analyses detected a significant association between individual PPS variables and the outcome were further tested.

All analyses were performed using SAS Version 9.3 (SAS Institute, Cary, NC).

RESULTS:

Sample characteristics: Of the 1,399 patients initially meeting eligibility by automated chart screening, 400 patients were selected by random stratified sampling for manual chart review and analysis. From this sample, 89 were excluded due to: 89 of these patients were not eligible because they were on anticoagulation use prior to or upon admission, leaving \( n = 311 \) patients in the final analytic sample.

Mean age for the sample was 80.6 years (SD 7.3); 42% were male and 34% were African-American. A majority (85%) of the cohort was admitted by residents, while 15% were admitted by a hospitalist.

Median length of stay, and median length of stay was 4.0 days. (Table 1) According to The overall mean PPS Predication Score, for the sample was 3.6 (SD 1.8), resulting in 59% (\( n = 182 \)) were defined as ‘low risk’. When low- and high-risk groups were compared (Table 1), the reasons risk’ Reasons for admission, median length of stay, and aspirin use were similar. No inpatient bleeding complications were documented at discharge for either risk group-did not differ between the risk groups.

The overall mean PPS for the sample was 3.6 (SD 1.8; Figure 1), and the average number of PPS risk factors per patient was 3. (Table 2) The most common PPS conditions present were acute infection, rheumatological condition, obesity, respiratory failure, and heart failure.

Exposure to pharmacological VTE prophylaxis. Of the patients with low risk for VTE occurrence (according to PPS), 74% (\( n = 134 \)) received pharmacological VTE prophylaxis either alone (52%) or in combination with SCDs (22%; Figure 2). Similarly, 71% (\( n = 92 \)) of high-risk patients who received pharmacological VTE prophylaxis, either alone (54%) or in combination with SCDs (17%). Of the 29% (\( n = 37 \)) of high-risk patients who did not receive pharmacological VTE prophylaxis, 21% received
Among low-risk patients (n=48), 19% received SCDs, while 7% received no form of VTE prophylaxis. (Figure 2) For patients with documented reasons for not prescribing pharmacological VTE prophylaxis (n=46), the primary explanation was ongoing or high risk of bleeding and pending procedure; for only 7% (2/27) of low-risk patients was ambulatory status a reason for not being prescribed VTE prophylaxis on admission.

Pharmacological VTE prophylaxis was present in 74% (134/182) of low-risk patients and 71% (92/129) of high-risk patients (Figure 1). In both low- and high-risk patients who received pharmacological VTE prophylaxis, over 90% had the therapy initiated within 24 hours of admission, and it was continued for over 60% of their hospital days. A higher percentage of high-risk (versus low-risk) patients discontinued pharmacological VTE prophylaxis prior to discharge (25% vs. 32%, respectively). The primary reasons for discontinuation included patient/family refusal and a change in medication. The rates of factors for discontinuation were similar between the two groups.

Relationship between PPS variables and pharmacological VTE prophylaxis use. In adjusted models for age, gender, and race, having a history of acute or chronic respiratory failure (OR 1.95, 95% CI 1.07, 3.52) and acute infection (OR 3.37, 95% CI 1.92, 5.92) were the only variables significantly associated with increased odds of receiving pharmacological VTE prophylaxis on admission. There was no association between a continuous PPS and the rate of pharmacological VTE prophylaxis (OR 1.0, 95% CI 0.9, 1.1).

DISCUSSION

In this study of medically ill, hospitalized older adults, we found no association between PPS and use of anticoagulants for VTE prophylaxis, suggesting that risk stratification is not being used to guide clinical decision-making. Nearly two thirds of adults aged ≥70 years hospitalized on a general
medicine service were identified as low risk for VTE occurrence according to the PPS; nevertheless, over 70% of these patients were prescribed pharmacological VTE prophylaxis (anticoagulants).

Prior studies have examined underuse of VTE prophylaxis in hospitalized patients and have found that 1) medical patients are less likely to receive DVT prophylaxis when compared to surgical patients and 2) nearly two thirds of medical patients receive inappropriate DVT prophylaxis. Our results suggest that the rates of overuse of VTE prophylaxis are higher than rates of underuse. Concern about overuse has been heightened by a recent literature review demonstrating that both low-molecular-weight and unfractionated heparin failed to reduce VTE mortality yet led to more bleeding and major bleeding events. Risk stratification is needed to ensure adequate prophylaxis for patients who need it, while minimizing prophylaxis in those who do not. We report that risk stratification is not being used in populations of hospitalized older adults.

There may be several reasons for the inadequate barriers to implementing guideline directed use of VTE risk stratification. A recent narrative article that reviewed both ACCP and ACP guidelines found that First, there is a lack of consensus on which VTE risk assessment tool was best to use with medically ill, hospitalized patients contributes to an implementation gap in guideline-directed use of anticoagulant VTE prophylaxis. Whereas the ACP does not recommend a specific tool for risk assessment, the ACCP 9th Ed. guidelines support the use of the PPS. Another study found that standard admission order sets that lack a risk stratification tool actually increase inappropriate prophylaxis use. Therefore, facilitating early risk stratification during the admissions workflow, either by automated or manual data extraction and calculation of PPS, would ensure more appropriate VTE prophylaxis use among those in whom the risks of harm may outweigh the benefit.

There are important public health concerns and system-level factors related to inappropriate use of VTE prophylaxis among medically ill, hospitalized elderly patients with low risk of VTE occurrence. First,
Age contributes to VTE risk [1,17] and bleeding risk, [18,20] making effective and safe prescribing of pharmacologic VTE prophylaxis challenging in this population. Our results demonstrate that clinical decision support, such as the American College of Physicians does not recommend a specific tool for VTE risk assessment [5,6]. Although, other risk stratification tools exist, concordance between these tools has not been well studied. Second, manual calculation of the PPS can be cumbersome, error prone, and disruptive to the clinical workflow. Automated data extraction leveraging existing structured data elements in the EHR may be particularly attractive to many health systems striving to use EHRs to improve care. Designing and testing auto-populated VTE risk stratification tools may facilitate translation of evidence-based guidelines into routine clinical practice. Lastly, a key barrier is clinician education and awareness about these tools. Adding risk stratification tools to admission order sets is one way to increase clinician awareness, and has been shown to decrease inappropriate VTE prophylaxis use [7]. High quality studies, using implementation science to promote uptake and efficacy of risk stratification tools into clinical practice, are urgently needed. Second, rates of admission for medically ill, hospitalized older adults ≥ 70 years are high, and a costly component of their care is pharmacologic VTE prophylaxis; approximately $1249–$3088 is saved per VTE case avoided [21,22]. Third, there is a hospital Joint Commission on Accreditation of Health Care Organizations (JCAHO) core measure that accounts for the number of patients who received VTE prophylaxis or have documentation on why no VTE prophylaxis was given [24]. However, this JCAHO measure should be reconsidered in light of concerns about overuse of VTE prophylaxis in low-risk older adults.

Limitations: Our study has several limitations. First, this was a single site study at an academic center, which may limit generalizability of the findings. We did not have baseline clinical information on disease severity, which may affect decisions about VTE prophylaxis. However, our design enabled us to look at other specific patient level data that is typically not available in larger databases. Second, we...
used the PPS for risk stratification as supported by the ACCP 9th Ed. guidelines. Other risk stratification tools exist but concordance between these tools has not been well studied. Although the PPS was validated in a large hospitalized patient population in Italy, it has yet to be validated in the United States. Third, determination of PPS is limited to data available in the electronic health data (EHR). Lastly, resulting in measurement error, and possibly underreporting of risk factors. Finally, due to feasibility and the low probability of VTE, we did not collect data on 30-day long-term VTE outcome. Therefore, we and were not able to determine the impact that inappropriate VTE prophylaxis use has in low-risk hospitalized older adults has on this outcome. We found, however, that there were no inpatient bleeding complications in this sample.

**Conclusions:** We found poor adherence to risk stratification guidelines among medically ill, hospitalized older adults, resulting in overuse of anticoagulant use for VTE prophylaxis among low-risk older adults. These stratification tools and incorporating results are highly relevant to more than 13.6 million adults 65 years and older who are discharged annually from nonfederal U.S. hospitals and to health systems trying to improve the quality and safety of VTE prophylaxis use as well as control costs. A consensus on validated tools for performing risk assessment and facilitating ways for providers to perform these assessments early in the admissions process will ensure that adequate prophylaxis is used for patients who need it while minimizing excess prophylaxis in those who do not.
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Figure 1. Exposure to VTE prophylaxis according to Padua Prediction Score risk stratification

Figure 1. Indicates the percentage of low-risk and high-risk patients receiving pharmacological venous thromboembolism prophylaxis (either medication alone or in combination with sequential compression devices) or no pharmacological venous thromboembolism prophylaxis (either sequential compression devices only or no prophylaxis). Med = medication, SCD = sequential compression devices, Pharm = pharmacologic, VTE = venous thromboembolism, PPX = prophylaxis.