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Venous thromboembolism testing practices after orthopaedic trauma: prophylaxis regimen does not influence testing patterns

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Abstract

Objectives: To determine venous thromboembolism (VTE) testing patterns in an orthopaedic trauma population and to evaluate for differences in VTE surveillance by prophylaxis regimen through a secondary analysis of the ADAPT trial.

Design: Prospective randomized trial.

Setting: Level I trauma center.

Patients: Three hundred twenty-nine adult (18 years and older) trauma patients presenting with an operative extremity fracture proximal to the metatarsals/carpals or any pelvic or acetabular fracture requiring VTE prophylaxis.

Intervention: VTE imaging studies recorded within 90 days post injury.

Main Outcome Measurements: Percentage of patients tested for VTE were compared between treatment groups using Fisher's exact test. Subsequently, multivariable regression was used to determine patient factors significantly associated with risk of receiving a VTE imaging study.

Results: Sixty-seven patients (20.4%) had VTE tests ordered during the study period. Twenty (29.9%) of these 67 patients with ordered VTE imaging tests had a positive finding. No difference in proportion of patients tested for VTE by prophylaxis regimen (18.8% on aspirin vs. 22.0% on LMWH, $P = 0.50$) was observed. Factors associated with increased likelihood of VTE testing included White race (adjusted odds ratio [aOR]: 2.61, 95% CI: 1.26–5.42), increased Injury Severity Score (aOR for every 1-point increase: 1.10, 95% CI: 1.05–1.15), and lower socioeconomic status based on the Area Deprivation Index (aOR for every 10-point increase: 1.14, 95% CI: 1.00–1.30).

Conclusions: VTE surveillance did not significantly differ by prophylaxis regimen. Patient demographic factors including race, injury severity, and socioeconomic status were associated with differences in VTE surveillance.

Level of Evidence: Level I, Therapeutic.

Key Words: venous thromboembolism, VTE surveillance, VTE imaging tests, prophylaxis regimen

1. Introduction

Trauma patients, especially those with orthopaedic trauma, are at extremely high risk of venous thromboembolism (VTE), and pulmonary embolism (PE) is one of the most common causes of death in patients who survive beyond the first 24 hours post injury.[1–9] Early chemoprophylaxis is known to reduce risk of deep vein thrombosis (DVT) and PE.[9,10] Although it is thought that treatment with chemoprophylaxis is protective for fatal PE, current studies have not had statistical power to detect this difference in fatal PE.[10] As a result, the VTE outcome measure as a preventable cause of morbidity and mortality has become a key component of quality improvement and public reporting initiatives and can even affect medical reimbursement.[9,11–14] For example, the Agency for Healthcare Research and Quality

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ADAPT Investigators are listed in Appendix 1.

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includes VTE as one of the quality indicators classified as a patient safety indicator for tracking clinical performance and outcomes.[10] The Centers for Medicare and Medicaid Services adjusts payments based on quality of care and can impose financial penalties when some hospitalized patients develop VTE.[12,13]

At the same time, many have argued that VTE is a flawed outcome measure because of a propensity for surveillance bias or "the more you look the more you find" phenomenon.[13–18] With surveillance bias, an outcome is diagnosed more frequently when it is tested for more frequently.[15] This is particularly problematic in the trauma population since no current consensus exists on whether routine screening of high-risk asymptomatic patients for VTE should be performed.[13] The Eastern Association for the Surgery of Trauma (EAST) guidelines suggest some patients at high risk might benefit from routine screening while the American College of Chest Physicians (ACCP) does not recommend surveillance for major trauma or orthopaedic surgery patients.[19–23] With ongoing debate on who should be tested, testing practices among surgeons vary resulting in more VTEs at centers where testing is more frequent. Billmoria et al looked at data from over 2800 hospitals and found that risk-adjusted VTE rates increased significantly with VTE imaging use rates, and hospitals with greater VTE prophylaxis adherence rates and increasing structural quality scores had higher risk-adjusted VTE event rates.[14] Other studies similarly found that trauma center ultrasound practices were a significant predictor of DVT, even controlling for other patient risk factors.[15–17,24,25] Another study showed that implementation of a DVT screening guideline at one trauma center resulted in a 4-fold increase in duplex ultrasound rates and a 10-fold increase in DVT rates.[26] Authors of some of these studies have argued that higher VTE rates could even be an indicator of better quality.[16,18]

In orthopaedic trauma, the debate on best practices for VTE prevention is further complicated by lack of evidence and ambiguous guidelines on which prophylaxis regimen is best in this population. The EAST and ACCP guidelines recommend low–molecular weight heparin (LMWH) for VTE prophylaxis in trauma patients, but many orthopaedic surgeons prefer aspirin based on recent studies that suggest aspirin can be an equally effective alternative with reduced risk of wound and bleeding complications.[21,22,27–33] In the A Different Approach to Preventing Thrombosis (ADAPT) trial, there was no significant difference in the probability of VTE prophylaxis superiority for either regimen with respect to a composite outcome of bleeding complications, VTE rates, deep surgical site infections, and death occurring within 90 days of injury.[34] The most recent ACCP guidelines now include aspirin as an option for chemoprophylaxis in high-risk orthopaedic surgery patients.[21] In 2015, the Orthopaedic Trauma Association Evidence-Based Quality, Value and Safety Committee published the results of a survey of the OTA/AO membership that showed wide variability in prescribed VTE prophylaxis regimens among OTA/AO members.[35] This same group reviewed the current literature and recommended LMWH as the optimal form of VTE prophylaxis in patients with musculoskeletal injury who are unable to mobilize or have other risk factors, as long as no contraindications to LMWH exist. Aspirin was recommended over no prophylaxis in situations where LMWH is contraindicated.[35]

High-quality randomized trials comparing VTE event rates with these regimens are important to inform guidelines in this population. Since VTE event rates can be influenced by surveillance bias, it is important to understand if clinician biases affect VTE testing rates in this population particularly if they result in differential testing rates by prophylaxis regimen before comparing effectiveness. Although Chung et al suggested that nonclinical factors predominantly drive hospital VTE imaging practices,[36] other studies have found significant associations of diagnostic imaging rates with patient factors like sex, age, race, visit setting, socioeconomic status, and number of medications.[37–41] The objective of this secondary analysis of the ADAPT randomized trial was to describe VTE testing patterns and indications for VTE imaging studies in an orthopaedic trauma population and to evaluate differences in VTE surveillance by prophylaxis regimen. In addition, we investigated the patient factors associated with an increased likelihood of VTE surveillance.

2. Methods

2.1. Study Setting, Design, and Population

This study was conducted as a secondary analysis of patients enrolled in the ADAPT randomized controlled trial as registered on clinicaltrials.gov (Identifier: NCT02774265).[34,42] All adult (18 years and older) trauma patients presenting to the R Adams Cowley Shock Trauma Center with an operative extremity fracture proximal to the metatarsals/carpals or any pelvic or acetabular fracture requiring VTE prophylaxis were included in the trial. Prisoners, pregnant patients, non-English speaking patients, and patients on preexisting anticoagulation (not including antiplatelet agents), with an indication for therapeutic anticoagulation or aspirin dose >81 mg daily or with a contraindication to either prophylaxis regimen, were excluded. Patients on or requiring low-dose daily aspirin or other antiplatelets were included in the study since these patients would typically receive VTE chemoprophylaxis in addition to their antiplatelet agents at our institution. Eligible patients were approached before the third dose of prophylaxis, and informed consent was obtained for all enrolled patients. Since these trauma patients present at all hours of the day and night, it was not possible to enroll all patients before administration of prophylaxis, so some patients received no more than 2 doses of the nonrandomized treatment before enrollment. The total number of doses and timing of initiation and cessation of the treatment course were determined by the clinical team based on what was clinically indicated and varied between patients. This study was approved by our Institutional Review Board (IRB).

2.2. Intervention

Enrolled patients were randomized at the beginning of their index admission to receive either LMWH 30 mg BID (with allowance for dose adjustment according to body mass index [BMI] by the clinical team if indicated based on Xa levels, n = 164) or aspirin 81 mg BID (n = 165) for the remainder of their VTE prophylaxis course. Of note, the off-label use of 81 mg of aspirin for the indication of VTE prophylaxis was approved by the IRB of record. Randomization was performed in the study's REDCap database at the time of consent with a 1:1 allocation ratio and block sizes of 6. After randomization, the study team notified the clinical team of the patient's enrollment status and treatment arm. The clinical team was responsible for ordering the chemoprophylaxis for study patients. The study team, clinical team, and patients were not blinded to the treatment arm.

2.3. Data Collection and Statistical Analysis

Enrolled patients were followed for 90 days post injury, and all imaging studies performed to evaluate for VTE were recorded

including indications, study type, results, and setting (inpatient vs. outpatient) in the study's REDCap database. Standard practice at our center does not include any routine VTE surveillance for trauma patients. Rather, patients are only tested when or if a clinician feels that testing is indicated based on the clinical picture. No study intervention was performed to guide clinicians on this decision making since this was a pragmatic trial. As a result, we felt it was necessary to evaluate potential for surveillance bias in testing practices as a secondary analysis. All inpatients were followed daily via chart reviews and discussions with the clinical team, and these patients were evaluated at 3 months post injury through in-person or phone interview and/or chart review to determine if any outpatient imaging studies had been ordered post discharge. Outside imaging centers were contacted to confirm patient-reported findings for study results that were not available in our medical records. Full 90-day follow-up was achieved for 93% of the study population.

2.4. Statistical Analysis

As this was a secondary analysis of the ADAPT trial, an independent a *priori* sample size calculation was not performed. Sample size calculation for the ADAPT trial was performed for medication safety and based on a retrospective review of wound and bleeding complications in orthopaedic trauma patients who received LMWH prophylaxis at our institution.

Patterns of VTE testing and the indications for VTE testing were described using counts and proportions. Fisher's exact test was used to compare the proportion of patients tested for VTE between the 2 prophylaxis regimens. To determine the patient factors associated with an increased likelihood of VTE testing, a backward stepwise elimination technique was used to select covariates based on a minimum Akaike information criterion (AIC) to be included in a multivariable regression model. Candidate covariates included study medication, age, sex, race (White vs. non-White), BMI, history of tobacco use or VTE, preinjury antiplatelet medication, diabetes, Injury Severity Score (ISS), pelvic or lower extremity injury, presence of concomitant head injury, insurance status (insured vs. uninsured), and socioeconomic status as determined by the Area Deprivation Index.[43] Area Deprivation Index is a measure of socioeconomic deprivation based on the ZIP + 4 address of the study participant and is calculated using census data on education, employment, income, and household condition for the geographic area. The factors included in the model are reported using adjusted odds ratios (aOR) with 95% confidence intervals (CIs).

3. Results

Between January 19, 2016, and November 1, 2016, 482 patients met study exclusion/inclusion criteria, of which 329 patients (68.3%) consented to enrollment and were randomized to receive VTE prophylaxis by LMWH (n = 164) or aspirin (n = 165). Patient enrollment CONSORT diagram and patient demographics are described in the main ADAPT results article.[34]

Sixty-seven patients (20.4%) had VTE tests ordered during the study period. Twenty (29.9%) of the 67 patients with ordered VTE imaging tests had a positive finding. No difference in proportion of patients tested for VTE by prophylaxis regimen (18.8% on aspirin vs. 22.0% on LMWH, $P = 0.50$) was observed. Table 1 presents the number of imaging studies obtained, study results (positive vs. negative), and study setting (inpatient vs. outpatient). Consistent with these findings, the most common indications for VTE inpatient imaging were tachycardia and increase in oxygen requirement (Table 2). The most common indications for outpatient imaging were pain/pressure and swelling.

In our multivariable regression model, patient factors significantly associated with increased likelihood of VTE testing included White race, more severe injury, and lower socioeconomic status based on the Area Deprivation Index (Table 3). Specifically, White patients were more than twice as likely to be tested for VTE compared with non-White patients (aOR: 2.61, 95% CI: 1.26–5.42). Active smokers were half as likely to be tested for VTE compared with nonsmokers (aOR: 0.45, 95% CI: 0.23–0.90). Each additional ISS point was associated with a 10% increase in the likelihood of testing (aOR: 1.10, 95% CI: 1.05–1.15). Every 10-point increase in the Area Deprivation Index (lower socioeconomic status) increased the likelihood of VTE testing by 14% (aOR: 1.14, 95% CI: 1.00–1.30). The area under the receiver-operating characteristic curve for the model is 0.70 (95% CI: 0.61–0.77).

4. Discussion

In the orthopaedic trauma setting, multiple factors create a potential for surveillance bias when studying VTE as an outcome. First, there is ongoing debate on which patients to test where some clinicians advocate for universal screening in this high-risk population and others argue against it.[13,19–23] Second, a lack of evidence exists for what is the most effective prophylaxis regimen in this population resulting in a wide variability in prescribed regimens.[21,22,27–33,35] This variability could imply that physician biases for certain regimens exist. In addition, previous studies have well documented the existence of surveillance bias in VTE testing where centers that test more frequently have higher VTE rates, even in centers with higher quality ratings.[13–18,24–26] However, few studies have looked at factors that could result in VTE surveillance bias, and to our knowledge, no other studies have examined the potential for surveillance bias with respect to prophylaxis regimen. In this secondary analysis of the ADAPT randomized clinical trial, we did not find any significant difference in VTE testing by prophylaxis regimen. Patient factors that were associated with the likelihood of VTE testing included race, injury severity, tobacco use, and socioeconomic status.

One-fifth of enrolled patients had at least one imaging study ordered during the study period with an overall positive test rate of 21.1% for CTA and 29.8% for duplex ultrasonography. CTAs were ordered for more inpatients than outpatients, whereas duplex ultrasounds were ordered for more outpatients. However, the positive test rate was higher for duplex ultrasounds performed in the inpatient setting. These testing patterns could be expected since signs and symptoms (tachycardia, tachypnea, change in oxygen requirement) that prompt CTA testing are more common in the acute inpatient setting immediately post injury and postoperatively and can result from VTE or other factors including postoperative pain or atelectasis. By contrast, signs and symptoms (pain/pressure and swelling) that prompt duplex ultrasonography are more likely to persist into the outpatient setting. The most common clinical indications for imaging in our study support this theory, with tachycardia being the most common clinical indication for VTE imaging studies in inpatients and pain/pressure and swelling being the most common indications in outpatients.

We found no difference in VTE testing rates by prophylaxis regimen. This should reassure clinicians that physician bias for a

TABLE 1

Patterns of VTE Testing: Study Type, Results, and Setting

Setting	Total Test	Positive Test	Negative Test	Positive Test Rate
Inpatient tests, % (patients)				
CTA	7.9% (26)	1.5% (5)	6.4% (21)	19.2%
Duplex	5.2% (17)	2.1% (7)	3.0% (10)	41.2%
Outpatient tests, % (patients)				
CTA	4.0% (13)	0.9% (3)	3.0% (10)	23.1%
Duplex	9.1% (30)	2.1% (7)	7.0% (23)	23.3%
Combined totals in inpatient and outpatient testing, % (patients)				
CTA	11.6% (38)	2.4% (8)	9.1% (30)	21.1%
Duplex	14.3% (47)	4.3% (14)	10.0% (33)	29.8%

CTA, computed tomography angiography; VTE, venous thromboembolism.

given prophylaxis regimen might not be a potential cause of surveillance bias when designing larger trials comparing effectiveness of these medications. However, we did find that several patient demographic factors had a significant association with likelihood of VTE testing. Most notably, non-White patients were less likely to be tested than White patients. This is consistent with many studies that have found non-White patients to have lower use of health services, including advanced imaging and intervention for a variety of diseases, and complaints, such as cardiac, pulmonary, and abdominal complaints.[40,41,44,45] Possible hypothesized reasons for this disparity include conscious or unconscious racial bias, communication barriers, and lack of access. Interestingly, in our study, patients with lower socioeconomic status were more likely to have VTE testing. This is contrary to what is reported in the literature where patients with lower socioeconomic status tend to get less diagnostic imaging.[39] This is also surprising since race and socioeconomic status are often affected in the same way. However, similar associations were observed in the bivariate and multivariable regression, which controls for covariance between predictor variables, suggesting this was not the case in our study population. Ultimately, patient symptoms were likely a main driving factor for why imaging was ordered. Patients of lower socioeconomic status may also have been less likely to take the medications after discharge due to cost since the medications were not provided as part of the study, which could make providers more likely to order imaging for minor symptoms. Finally, patients with a higher ISS also had a higher likelihood of VTE imaging likely as a result of known increased risk of VTE in this population, creating a higher clinical suspicion.

Our study is limited in that it is a secondary analysis of the ADAPT randomized controlled trial and as a result was not statistically powered to compare differences in the number of tests ordered between the 2 regimens. In addition, the most common indications for testing in inpatients were tachycardia and increased oxygen requirement, which might be more related to patient presentation than to bias. However, as inpatients are continually being evaluated and might be more likely to be ordered for VTE workup, we thought it was important to analyze inpatient testing patterns in addition to outpatient. Furthermore, we do not have data on how often patients who did not receive VTE workup experienced these indications for testing. Prevalence of these indications in trauma patients is likely high and can result from other underlying causes such as those related to concomitant injuries, resuscitation status, and pain. It would, therefore, be difficult to document every instance where a testing indication was present but testing was not ordered.

However, ADAPT is a large unblinded randomized trial, so the results should reassure clinicians designing larger effectiveness trials that physician bias for a certain regimen is unlikely to result in surveillance bias in VTE outcome reporting. In addition, although the study was prospective, we relied on patient reporting of any outpatient tests that would not be available in our medical records. Recall bias might have occurred where patients forgot to report a test, but we have no reason to think patients in one treatment arm would be more likely to underreport testing. Perhaps the most important limitation is that this study was performed at a single site, so the generalizability of these findings to other sites is unknown.

TABLE 2

Clinical Indication for VTE Imaging Studies by Study Setting

Indication	Inpatient (n = 34)*	Outpatient (n = 52)*
Tachycardia	58.8% (20)	5.8% (3)
Swelling	20.6% (7)	30.8% (16)
Pain/Pressure	20.6% (7)	28.8% (15)
Dyspnea/tachypnea	20.6% (7)	13.5% (7)
Change in oxygen requirement	32.4% (11)	3.8% (2)
Fever/leukocytosis	8.8% (3)	7.7% (4)
History of VTE	11.8% (4)	1.9% (1)
Other reason	8.8% (3)	7.7% (4)

* Patients might have multiple indications for an imaging study.
VTE, venous thromboembolism.

5. Conclusion

In this secondary analysis of the ADAPT randomized trial, we found no difference in VTE testing rates between prophylaxis regimens, suggesting physician bias for a medication regimen should not be a significant contributor to surveillance bias in VTE outcome reporting. Alternatively, we did find an association between VTE surveillance and race and a significant association with other patient demographic factors including smoking status, socioeconomic status, and injury severity. These findings are hypothesis-generating and should be examined further in any future trials.

APPENDIX 1. ADAPT Investigators

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TABLE 3

Multivariable Regression Model of Patient Characteristics Associated With Risk of VTE Testing

Factor	Unadjusted Odds Ratio	95% CI	*P*	Adjusted Odds Ratio	95% CI	*P*
Race						
White	2.03	1.10–3.76	0.02	2.61	1.26–5.42	0.01
Non-White	Reference (1.00)			Reference (1.00)		
Smoker						
Yes	0.61	0.34–1.09	0.09	0.45	0.23–0.90	0.02
No	Reference (1.00)			Reference (1.00)		
Injury Severity Score per point	1.07	1.02–1.11	<0.01	1.10	1.05–1.15	<0.001
Area Deprivation Index per 10-points	1.03	0.93–1.15	0.55	1.10	1.00–1.30	0.05
R^2					0.08	
AUC					0.70 (95% CI: 0.61–0.77)	

AUC, area under the curve; CI, confidence interval.

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