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Authors

Falksen, Jessica A
Duby, Jeremiah J
Wilson, Machelle D
et al.

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Effect of Delay and Disruption in Venous Thromboembolism Prophylaxis in Trauma Patients: A Case Control Study

Jessica A Falksen, PharmD[a],

Jeremiah J Duby, PharmD[a],

Machelle D Wilson, PhD[b],

Jeffrey R Fine, MPH[b],

Christine S Cocanour, MD, FACS[c]

[a]University of California, Davis Health – Department of Pharmacy, 2315 Stockton Blvd, Sacramento, CA 95817, USA

[b]University of California, Davis Health – Department of Public Health Sciences, 2315 Stockton Blvd, Sacramento, CA 95817, USA

[c]University of California, Davis Health – Department of Surgery, 2315 Stockton Blvd, Sacramento, CA 95817, USA

Abstract

Background—Trauma patients are at high risk for venous thromboembolism (VTE) and bleeding. The purpose of this study was to characterize percentage of VTE chemoprophylaxis given to trauma patients with and without a VTE.

Study Design—This retrospective case-control study evaluated trauma patients admitted to a Level I Trauma Center. Adult patients were included when hospitalized at least 2 days and had a head abbreviated injury score of 1 or less. Non-VTE patients were matched by decade of life and injury severity score (ISS). The primary outcome was percentage of VTE chemoprophylaxis received over the first 14 days of admission. Descriptive statistics, chi squared test, students t-test, and Cox proportional hazard were used for analysis.

Results—A total of 44 VTE patients were included with 125 matched non-VTE patients. Baseline demographics included age in years (50.7 ± 19.6 vs 49.6 ± 19.4), ISS (18.9 ± 11.3 vs 19 ± 11.6), and lower extremity fracture (54.5% vs 40%), for VTE and non-VTE groups, respectively. The primary outcome of VTE chemoprophylaxis doses given was significantly lower for VTE patients than non-VTE patients (49.3% vs 59.3%, p=0.0069). Significant predictors of VTE were percentage of VTE chemoprophylaxis doses given (p=<0.0001) and weight (p=0.0042) based on regression analysis. Notably, there was a 7% decrease in the hazard for VTE for every 1% increase in VTE chemoprophylaxis given.

Corresponding Author: Jessica Falksen, PharmD, University of California, Davis Health, Department of Pharmacy, 2315 Stockton Blvd, Sacramento, CA 95817, *Phone*: 1-651-246-4137, jafalksen@ucdavis.edu.

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Conclusions—Patients that developed VTE were more likely to have delays and disruptions in VTE chemoprophylaxis, even after controlling for age, sex, ISS, lower extremity fractures, and number of operations.

Precis:

This retrospective case-control study compared percentage of VTE chemoprophylaxis given to hospitalized trauma patients with and without VTE. The risk for developing a VTE decreased 7% for every 1% increase in the rate of VTE chemoprophylaxis, even after controlling for age, injuries, operations, lower extremity fractures, and weight.

Keywords

anticoagulation; trauma; thrombosis

Introduction

Trauma patients are at high risk for venous thromboembolism (VTE) due to immobility, injury, and inflammation. The reported rate of these events is variable, ranging from 2-70%[1]. This wide range in reported prevalence is likely due to the screening approach for these events, severity of trauma in the reviewed population, and indications for delaying VTE chemoprophylaxis. Initiation and deferral of VTE chemoprophylaxis varies by population and provider. The risk-benefit balance of bleeding and VTE events can be complicated by multiple injuries and comorbidities in the trauma population.

The risk of VTE is increased by initiation delays or non-modifiable contraindications to VTE chemoprophylaxis. Previous studies in trauma patients have correlated the risk of VTE with delay of chemoprophylaxis more than 24 hours from admission[2,3]. Louis and colleagues found missing more than one dose of enoxaparin chemoprophylaxis, regardless of the reason, was associated with increased rate of deep vein thrombosis[4]. The relationship between VTE chemoprophylaxis and VTE risk has not been well described. More clearly defining risks from disruptions in VTE chemoprophylaxis will inform the risk-benefit calculation in medical decision making. The purpose of this study is to characterize rates of VTE chemoprophylaxis in trauma patients with and without symptomatic VTE.

Methods

Design and Setting

This was a retrospective, single-center, case-control study at a large, tertiary, academic level I trauma center. This study was submitted for review by the institutional review board and deemed exempt.

Patient Selection

The Trauma One Registry was used to identify trauma patients in the review period (January 2015 through November 2020). Adult patients over 18 years of age with a head abbreviated injury scale (AIS) of 1 or less were included if hospitalized for at least two days. Patients were excluded if they had a known VTE, had a diagnosis of heparin-induced

thrombocytopenia (HIT) at the time of VTE diagnosis, were pregnant, or were a prisoner. VTE patients were identified through the trauma registry. Thrombotic events were confirmed by reviewing the official imaging report (i.e., CT and venous duplex ultrasound). Matching was used to match non-VTE to VTE patients in a 3:1 selection ratio. All patients eligible who met inclusion criteria were matched by decade of life and injury severity score (ISS). Non-VTE patients were considered a match if their ISS was either the same or 1 value different from a VTE patient. If a VTE patient had no available non-VTE patients with similar ISS scores, the non-VTE patient with the closest ISS was selected. If there were more than 3 non-VTE patients available for matching, patients were selected for review through random number generation using Excel. Additional risk factors were collected but deferred for comparison and regression analysis due to the number and diversity of the characteristic (e.g., frequency of surgical intervention) or availability of the risk factor in the Registry (e.g., lower extremity fracture and immobility). Active surveillance for deep vein thrombosis was not performed at this institution.

Data Collection

VTE chemoprophylaxis was assessed every day from admission (Day 1) for up to 14 days. Chemoprophylaxis data collection was stopped the day a VTE was identified or the day of discharge if no VTE occurred. The type, dose, and frequency of the initial chemoprophylaxis ordered was recorded, including the time and date of first dose given. Proportion of doses given was recorded daily based on the frequency of administration ordered at that time. If a patient changed prophylaxis types in the middle of a day, the frequency was determined by the agent ordered at the start of the day. If a patient was on an unfractionated heparin infusion, regardless of the monitoring target, it was assessed every 8 hours as either on or off to determine daily coverage. If a patient was previously or currently on warfarin and had a therapeutic INR, the day was marked as fully covered regardless of whether any medication was administered. After collecting VTE chemoprophylaxis administration, all daily doses were transformed into a standardized frequency to ensure more frequently administered regimens did not have greater weight in the assessment.

Baseline characteristics included age, sex, race, head AIS, ISS, weight, and height, which were obtained from the Registry. Patients were assessed for lower extremity fractures using the initial patient note, tertiary exam note, and imaging studies. If a fracture in the pelvis or lower extremity was noted, they were marked as having a lower extremity fracture unless there was documentation from initial notes that the injury was weight-bearing as tolerated.

At this center patients are assessed for VTE chemoprophylaxis based on risk status (e.g., high risk, low risk, no risk). The preferred VTE chemoprophylactic agent is low-molecular weight heparin (LMWH) with dose adjustment based on risk (e.g., lower extremity fracture) and weight. Enoxaparin 30 mg BID is recommended for patients with non-weight-bearing lower extremity or pelvic fractures. A higher dose (e.g., enoxaparin 40 mg BID) is suggested for trauma patients weighing over 100 kg. For patients with a head injury or renal dysfunction, subcutaneous unfractionated heparin (SQH) is used. Underdosing is identified when patients received LMWH dosed daily instead of twice daily if they had non-weight-bearing lower extremity or pelvic fractures.

Data Analysis

The primary outcome of this study was proportion of VTE chemoprophylaxis doses given over the first 14 days of hospitalization. Secondary outcomes included ICU length of stay, hospital length of stay, survival to discharge, and time to first dose of VTE chemoprophylaxis. The Chi squared test was used for proportional data and the student's t test was used for normally distributed numerical data using Excel software version 2102. A Cox proportional hazard multivariate regression was performed, accounting for clustering of matched pairs, to examine time to VTE. The proportionality assumption was tested using graphical analysis for categorical variables and the proportionality test for continuous variables. The Cox proportional hazard model was fit for VTE risk factors of age, weight, ISS, lower extremity fracture, number of operations, and the proportion of VTE chemoprophylaxis doses given using SAS software version 9.4 for Windows (SAS Institute Inc., Cary, NC).

Results

During the study period 18,898 patients were screened and 7,435 patients met inclusion criteria (Fig. 1). There were 63 patients with VTE identified; 19 patients were excluded leaving 44 patients in the VTE cohort for analysis. The primary reason for exclusion from the VTE cohort was VTE identified on arrival (n = 17). One hundred thirty-two non-VTE patients were matched for age and ISS; of these, 7 patients were excluded without replacement.

The average age was 50.7 ± 19.6 versus 49.6 ± 19.4 years and the ISS was 18.9 ± 11.3 versus 19 ± 11.6 in the VTE and non-VTE groups, respectively (Table 1). The VTE cohort had a significantly higher weight (97.4 ± 27.6 vs 86.6 ± 25.8 kg, p = 0.021) and BMI (32.2 ± 8.8 vs 29.1 ± 7.9 kg/m^2, p = 0.034). The VTE cohort had a higher average number of operations (2.5 ± 3.1) compared to non-VTE patients (1.3 ± 1.7), p=0.001. There was a trend towards more lower extremity fractures in VTE patients at 54.5% versus 40% in non-VTE patients (p=0.096).

In the VTE cohort, 29.5% of patients never received VTE chemoprophylaxis prior to developing a thrombus (Table 2). In the non-VTE cohort, 16.8% never received VTE chemoprophylaxis prior to discharging from the hospital. Of the patients that received VTE chemoprophylaxis, the average time to first dose was 56 ± 54 and 50.5 ± 34.6 hours, for VTE and non-VTE patients, respectively (Table 1). The mean and median times to first VTE chemoprophylaxis dose differed substantially from each other. For the patients that received VTE chemoprophylaxis, the dose was ruled subtherapeutic for 22.7% versus 17.6% for VTE versus non-VTE patients, respectively (Table 2). VTE chemoprophylaxis dose was reduced due to epidural placement for one VTE patient and one non-VTE patient. Of all the doses initially received, two (6.8%) VTE patients received enoxaparin 40mg BID or higher compared to five (4%) non-VTE patients. There were a wide range of reasons that chemoprophylaxis was deferred (Table 3). Decreasing hemoglobin and operations were the most common reasons cited.

The primary outcome, VTE chemoprophylaxis doses given, was significantly lower for VTE patients than non-VTE patients at 49.3% versus 59.3% (Fig. 2, p=0.0069). For secondary outcomes, the VTE cohort experienced a longer duration of hospitalization (21 ± 14.6 vs 10.7 ± 10.6 days, p=0.0000017) and a lower hospital survival rate (86.4% vs 96.8%, p=0.0114) than non-VTE patients, respectively. There was a trend for the VTE cohort to have a greater length of stay in the ICU than non-VTE patients (7.3 ± 7.8 vs 4.1 ± 9.7 days, p=0.052).

The percentage of VTE chemoprophylaxis given and patient weight were statistically significant factors in time to VTE after adjusting for age, ISS, lower extremity fractures, and number of operations. There was a 7% decrease in VTE hazard for every 1% increase in VTE chemoprophylaxis given. There was a 1.7% increase in VTE hazard for every 1 kg increase in weight.

Discussion

Trauma patients have increased risk of both bleeding and VTE events. Balancing these concerns can be challenging, especially as risks change daily. Louis and colleagues found that missing two or more doses of prescribed enoxaparin increased the risk of DVT occurrence in trauma and general surgery patients[4]. Building on their findings, this study included the heterogenous trauma population and did not restrict patients to only those reaching the point of having enoxaparin ordered and given. This study is the first to characterize the overall percentage of VTE chemoprophylaxis given to trauma patients as it relates to VTE occurrence. There was a surprisingly small difference in percentage (10%) of VTE chemoprophylaxis doses given between those patients who developed a VTE from those that did not. The risk for developing a VTE decreased by 7% for every 1% increase in the rate of VTE chemoprophylaxis. The effect of VTE chemoprophylaxis on risk of VTE was significant even after controlling for age, injuries, operations, lower extremity fractures, and weight. Understanding the risk of holding VTE chemoprophylaxis can guide the decision-making process for patients with relative contraindications. It also emphasizes the need to resume VTE chemoprophylaxis as soon as a contraindication is removed. Optimal VTE chemoprophylaxis is difficult if not impossible to achieve in every patient but small changes can make a difference.

The decreased rate of VTE chemoprophylaxis can be accounted for by the time to first dose, and the number of doses held or missed. The time to initiate VTE chemoprophylaxis is important, as receiving the first dose within 24 hours is associated with decreased risk of VTE[2,3]. More patients who developed a VTE in this study never started VTE chemoprophylaxis when compared to the non-VTE patients. The proportion of patients who never received VTE chemoprophylaxis was lower than reported in other studies of critically ill trauma patients[1,5,6]. For patients who did start VTE chemoprophylaxis, the average time to first dose in this study was greater than 48 hours, which is consistent with reported literature[4,6]. The delay in starting VTE chemoprophylaxis in this study was similar between groups and did not account for the difference in VTE. This delay is challenging to change given the presence of early hemodynamic instability, decreasing hemoglobin, and need for operation which must be assessed in each individual patient.

In patients where surgical intervention is required, VTE chemoprophylaxis is often held in anticipation of surgery. In this study VTE patients had a higher rate of operations, which increases the number of doses held for surgery. When surgeries are delayed and/or rescheduled, held doses have the potential to multiply. Patients with VTE were also more likely to have lower extremity fractures which is a known risk factor. Unfortunately, patients with lower extremity fractures often need surgery which increases the potential for missing more doses of VTE chemoprophylaxis. Current guidelines do not address whether VTE chemoprophylaxis should be held prior to surgery; therefore, it may be beneficial to consult with the operating surgeon to determine whether VTE chemoprophylaxis needs to be held[7,8,9].

In addition to deciding when to start VTE chemoprophylaxis, providers must also determine the appropriate type and dose. The dose was assessed for appropriateness based on the patient's weight, renal function, and presence of lower extremity fractures. Patients with VTE were more likely to receive an initial dose that was subtherapeutic (Table 2). There is limited application of these findings as this study does not assess subsequent changes in VTE chemoprophylaxis ordered. However, these findings highlight a second layer of consideration as clinicians work to reduce risk of VTE. Many institutions utilize a fixed-dose strategy for VTE chemoprophylaxis. Within this study the average weight of VTE patients was significantly higher than non-VTE patients by over 10 kg. The hazard for VTE increases by 1.7% for every 1 kg increase in weight, even after controlling for lower extremity fractures, ISS, number of operations, and the age and sex of the patient. The increased occurrence of VTE observed may be due to subtherapeutic dosing in obese patients which supports literature utilizing a weight-based dosing strategy[10,11,12].

Strengths and Limitations

Strengths of this study included the pragmatic design which allowed for the heterogeneity of the trauma population. Matching for cohorts of patients enabled reasonable control of similar risk factors. The rate of VTE occurrence cannot be inferred in this population as not all eligible patient charts were reviewed, and patients were not routinely screened for DVTs. Limitations of this study included its retrospective and observational design which limits the conclusions that can be drawn from its findings. Measuring and assessing all factors associated with VTE occurrence was beyond the scope of the study. Decisions on timing and type of chemoprophylaxis given were not always clear when assessing retrospectively. The initial agent and indication were used to categorize the therapy the patient received. Subjects frequently changed therapies and indications throughout the dynamic course of their hospitalization. Patients with a known thrombus on admission were excluded from this study; however, a small subset of patients intermittently received therapeutic anticoagulation for other indications (e.g., atrial fibrillation, concern for myocardial infarction). Our VTE chemoprophylaxis dosing recommendations may differ from other institutions and may limit extrapolation to other populations. VTE chemoprophylaxis was treated as a binary explanatory variable, such that agents and dosing were considered equivalent. Enoxaparin was the preferred agent based on the existing evidence and institutional guidelines. However, clinicians were often compelled to use alternative agents and dosing strategies based on co-morbidities and concurrent therapy. Additionally, there was insufficient

power, equipoise, and consistency throughout a hospitalization to compare different agents administered. Bleeding was not assessed in these patients as this process is fraught with errors in a retrospective review where patients may have other reasons for bleeding and chemoprophylaxis may be administered intermittently. Matching also has inherent risk of bias based on matching characteristics selected. Within this study, age and ISS were used in matching as streamlined and consistently documented values. Other risk factors for VTE were not directly controlled through matching and thus there may have introduced selection bias in the pairs identified. However, the use of inconsistently queried or documented characteristics to create matched pairs likely would have resulted in information bias associated with missing data.

Conclusion

Patients that developed VTE were more likely to have had delays and disruptions in VTE chemoprophylaxis. The difference in VTE chemoprophylaxis received remained significant even after controlling for age, sex, ISS, lower extremity fractures, and number of operations. Additionally, obesity and subtherapeutic VTE chemoprophylaxis dosing appear to be associated with a higher rate of VTE.

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WSA Discussion of 2022-395

Effect of Delay and Disruption in Venous Thromboembolism Prophylaxis in Trauma Patients: Case Control Study

DR KAREN BRASEL (Portland, OR): There were 2 things that struck me with your data. One was the significant difference in secondary outcomes between the 2 groups, and I know your data were matched on Injury Severity Score (ISS). Is the venous thromboembolism (VTE) really causing the difference in length of stay? And does that really account for the mortality difference? Even in the patients who did not have a VTE, there was only 59% compliance, and I just wondered what your thoughts are about being able to increase the compliance with the ordered dose.

DR CHRISTINE COCANOUR (Sacramento, CA): We have difficulty getting into our operating room (OR) and is not unusual to hold deep vein thrombosis prophylaxis when people are thought to be going to the OR. If you have someone waiting to go to the OR and then they do not go, they are off for that day, or they may only get one dose. They are on call for several days in a row, and that is one of our biggest problems. Some of our orthopaedic surgeons will let us continue Lovenox, so I think we have get that word out to our residents

and trainees and attendings to not stop the Lovenox when we are waiting for patients to go to the OR. I think that is going to make the biggest difference. Things like continued drop in hemoglobin, that is not something we can really deal with. That is not going to change things.

Regarding difference in secondary outcomes being totally accounted for by the VTE, I am not sure what the cause is, and that was one of the reasons we did try to adjust using ISS. I cannot imagine that it is completely attributable to just the VTE diagnosis. That is something that will take some more work; to see why there was a difference. Length of stay is always a bad outcome parameter anyway, especially if you have a non-resource population, because with lower extremity fracture, they may stay in the hospital forever because they have no place else to go.

Abbreviations:

VTE	venous thromboembolism
AIS	abbreviated injury scale
HIT	heparin induced thrombocytopenia
ISS	injury severity score
LMWH	low-molecular weight heparin
SQH	subcutaneous heparin
SBP	systolic blood pressure
GCS	Glasgow coma score

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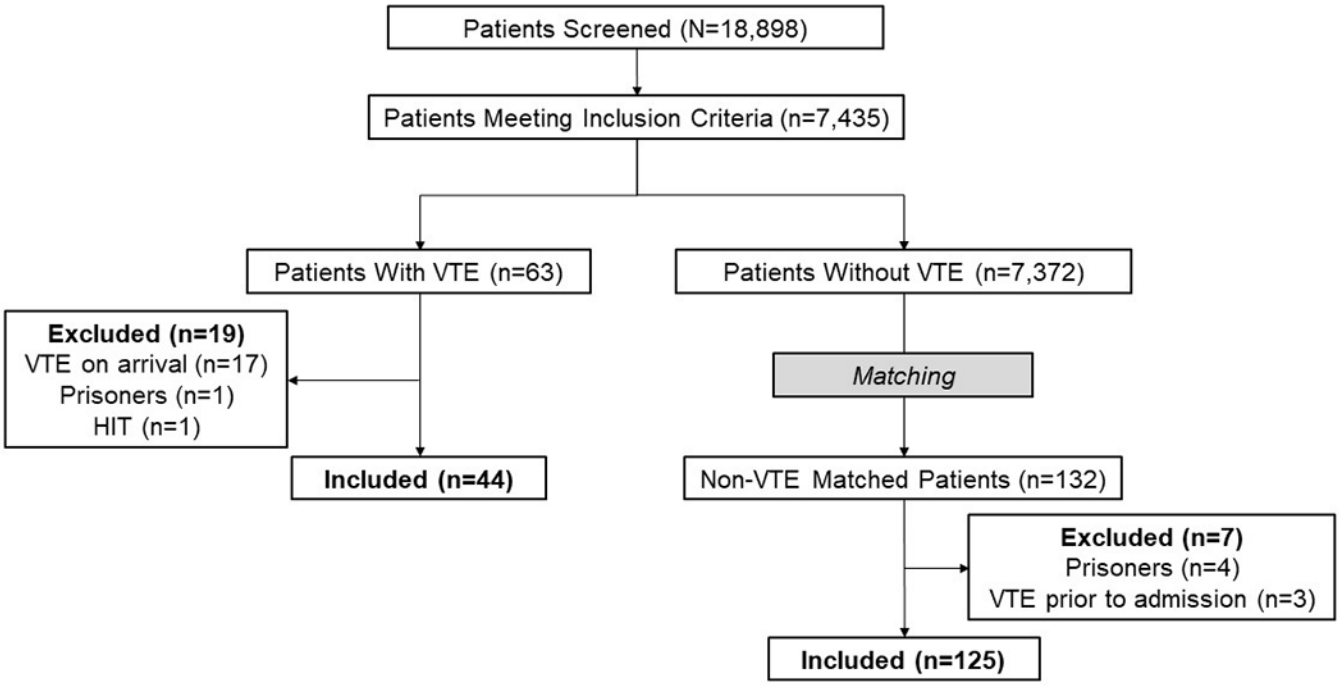

Figure 1.
Consort diagram

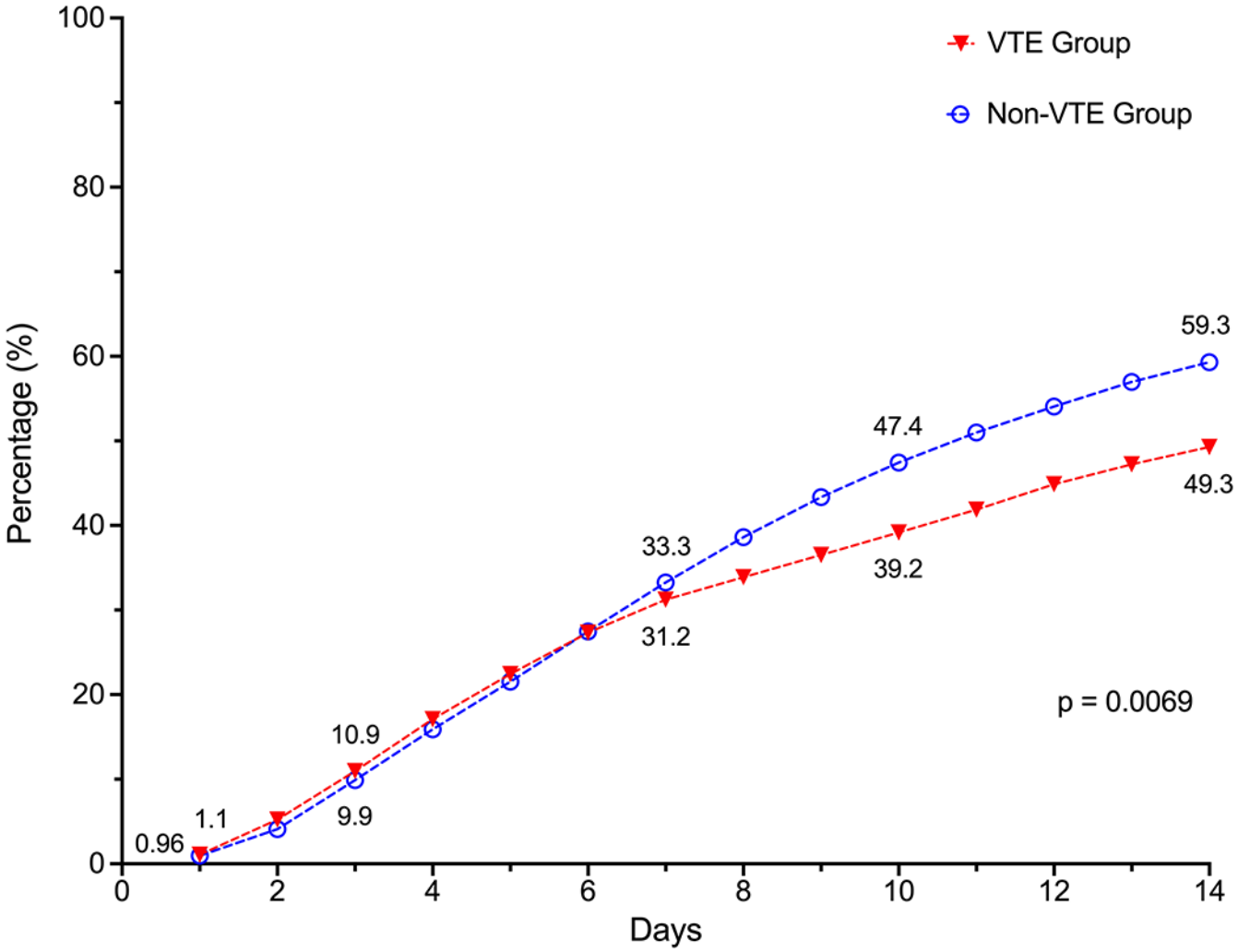

Figure 2.
Primary outcome: percentage of VTE chemoprophylaxis doses received

Table 1.

Baseline characteristics and course

	VTE Patients (n = 44)	Non-VTE Patients (n = 125)	P-value
Age (years), mean ± SD	50.7 ± 19.6	49.6 ± 19.4	
Gender, n (%)			
Female	14 (32%)	43 (34%)	
Male	30 (68%)	82 (66%)	
Race, n (%)			
Caucasian	29 (66%)	64 (51%)	
Black	5 (11%)	11 (9%)	
American Indian	0 (0%)	3 (2%)	
Asian	0 (0%)	3 (2%)	
Other	7 (17%)	33 (26%)	
Unknown	3 (7%)	11 (9%)	
Injury Severity Score, mean ± SD	18.9 ± 11.3	19 ± 11.6	
Weight (kg), mean ± SD; median (IQR)	97.4 ± 27.6; 93 (81.5,113)	86.6 ± 25.8; 81 (71, 94)	0.021
BMI (kg/m^2), mean ± SD; median (IQR)	32.2 ± 8.8; 31.5 (26, 37)	29.1 ± 7.9; 27 (24.5, 32)	0.034
Blunt Injury, n (%)	32 (72.7%)	103 (82.4%)	
Penetrating Injury, n (%)	12 (27.3%)	22 (17.6%)	
Hypotension on Arrival (SBP <90 mmHg), n (%)	6 (13.6%)	12 (9.6%)	
ICU Admission, n (%)	35 (79.5%)	90 (72%)	
Intubation Rate in ED, n (%)	9 (20.5%)	18 (14.4%)	
Intubation Rate During Hospitalization, n (%)	25 (56.8%)	40 (32%)	
GCS in ED, median (IQR)	15 (14, 15)	15 (14, 15)	
AIS, median (IQR)			
AIS Face	0 (0, 0)	0 (0, 0)	
AIS Head/Neck	0 (0, 0)	0 (0, 0)	
AIS Abdomen	1 (0, 3.75)	0 (0, 3)	
AIS Extremity	2 (0, 3)	2 (0, 3)	
AIS Chest	3 (0, 3)	3 (0, 3.5)	
AIS External	0 (0, 1)	0 (0, 1)	
Lower Extremity Fracture, n (%)	24 (54.5%)	50 (40%)	0.096
Number of Operations, mean ± SD	2.5 ± 3.1	1.3 ± 1.7	0.001
Time to First Dose (h), mean ± SD; median (IQR)	56 ± 54; 37 (20, 70.5)	50.5 ± 34.6; 46 (24.5, 66.8)	0.123

Abbreviations: SD = standard deviation, IQR = interquartile range (25^{th}, 75^{th}), BMI = Body mass index, SBP = systolic blood pressure, GCS = Glasgow Coma Score, AIS = Abbreviated Injury Scale

Table 2.

Assessment of initial dose ordered

Assessment, n (%)	VTE Patients (n = 44)	Non-VTE Patients (n = 125)
Appropriate		
LMWH	8 (18.2)	39 (31.2)
SQH	2 (4.5)	6 (4.8)
Other	--	3 (2.4)
Appropriate, potential to optimize		
LMHW	2 (4.5)	14 (11.2)
SQH	--	--
Other	--	--
Dose too high		
LMHW	3 (6.8)	--
SQH	--	--
Other	--	--
Dose too low		
LMWH	10 (22.7)	22 (17.6)
SQH	--	--
Other	--	--
Unknown or unclear		
LMWH	--	1 (0.8)
SQH	1 (2.3)	4 (3.2)
Other	5 (11.4)	14 (11.2)
Never started	13 (29.5)	21 (16.8)

Note: LMWH refers to enoxaparin. SQH refers to 15,000 units/day of subcutaneous unfractionated heparin. Other includes dalteparin 5000 units daily and unfractionated heparin infusions.

Table 3.

Reasons for delays and disruptions in VTE chemoprophylaxis

Assessment, n	VTE Patients (n = 92)	Non-VTE Patients (n = 257)	Total (n = 349)
Hemoglobin decrease	31	77	108
Operations	31	66	97
Unclear	17	46	63
Solid organ protocol	3	25	28
Late arrival to hospital	3	12	15
Patient refusal	1	9	10
Spine (injury or surgery)	1	8	9
On call to Operating Room	2	4	6
Other (procedure, pain block, etc.)	2	3	5
Thrombocytopenia	1	3	4
Assumed ambulatory	0	2	2
Consult recommendation	0	2	2

Note: Each reason may apply to multiple doses of medication not given. All possible reasons were selected for holding a dose for each patient.