



When is It Safe to Start VTE Prophylaxis After Blunt Solid Organ Injury? A Prospective Study from a Level I Trauma Center

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Abstract

Background The optimal timing of VTE prophylaxis initiation after blunt solid organ injury is controversial. Retrospective studies suggest initiation ≤ 48 h is safe. This prospective study examined the safety and efficacy of early VTE prophylaxis initiation after nonoperative blunt solid organ injury.

Methods All patients >15 years of age presenting after blunt trauma (12/01/16–11/30/17) were prospectively screened. Patients were included if solid organ injury (liver, spleen, kidney) was diagnosed on admission CT scan and nonoperative management was planned. ED deaths, transfers, patients with pre-existing bleeding disorders or home antiplatelet/anticoagulant medications, and those who did not receive VTE prophylaxis were excluded. Demographics, injury/clinical data, type/timing of VTE prophylaxis initiation, and outcomes were collected. Patients were dichotomized into study groups based on VTE prophylaxis initiation time: Early (≤ 48 h) vs Late (>48 h after admission). Prophylaxis initiation was at the discretion of the attending trauma surgeon. The primary study outcome was VTE event rate. Secondary outcomes included hospital length of stay (LOS), intensive care unit (ICU) LOS, need for and volume of post-prophylaxis blood transfusion, need for delayed (post-prophylaxis) interventional radiology (IR) or operative intervention, failure of nonoperative management, and mortality. Outcomes were compared with univariate analysis. Multivariate analysis with logistic regression determined independent predictors of late VTE prophylaxis initiation.

Results After exclusions, 118 patients were identified. Median ISS was 22 [IQR 14–26]. Median AAST grade of injury was 2 [IQR 2–3] for liver, 2 [IQR 1–3] for spleen, and 3 [IQR 2–3] for kidney. Compared to late prophylaxis patients ($n = 57$, 48%), early prophylaxis patients ($n = 61$, 52%) had significantly fewer DVTs ($n = 0$, 0% vs $n = 5$, 9%, $p = 0.024$) but similar rates of PE ($n = 2$, 3% vs $n = 3$, 5%, $p = 0.672$). TBI was the only significant risk factor for late prophylaxis (OR 0.22, $p = 0.015$). No patient in either group required delayed intervention (operative or IR) for bleeding. There was no difference in volume of post-prophylaxis blood transfusion.

Conclusions In this prospective study of patients with nonoperative blunt solid organ injuries, early (≤ 48 h) initiation of VTE prophylaxis resulted in a lower incidence of DVTs without an associated increase in bleeding or need for intervention. Early initiation of VTE prophylaxis is likely to be safe and beneficial for patients with blunt solid organ injury.

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Introduction

Patients who sustain a solid organ injury after blunt trauma present many clinical management challenges. Of these, the timing of venous thromboembolism (VTE) prophylaxis initiation remains a controversial issue in contemporary clinical practice. Blunt intra-abdominal solid organ injuries (liver, spleen, and kidney) are frequently managed non-operatively and therefore carry a risk of bleeding. This may be exacerbated by VTE prophylaxis and could contribute to failure of nonoperative management. Conflictingly, blunt trauma patients are also at high risk for VTE and may benefit from prompt initiation of chemoprophylaxis [1]. The optimal timing for VTE prophylaxis initiation among patients with blunt solid organ injury is not well defined by the current literature, although a small number of retrospective studies suggest that initiation within 48 h may be safe [2–5]. Prospective validation of these retrospective findings is required.

The primary objective of this study was to prospectively determine the optimal timing of VTE prophylaxis initiation among patients with blunt solid organ injury managed non-operatively. Our hypothesis was that initiation within 48 h would result in a lower rate of VTE without an increased risk of bleeding or failure of nonoperative management.

Materials and methods

In this prospective observational study, all adult (>15 years) blunt trauma patients who presented to LAC + USC Medical Center between December 1, 2016, and November 30, 2017, and sustained a solid organ injury (liver, spleen, and/or kidney) managed nonoperatively were screened for inclusion. Patients were excluded if they were transferred from an outside hospital, died in the emergency department (ED), had a pre-existing bleeding disorder, were on home antiplatelet or anticoagulation medication, or if they received no VTE prophylaxis during their hospital admission. Eligible patients were identified and enrolled on admission. Nonoperative management was defined by a documented plan in the ED by the trauma team for nonoperative management and the lack of laparotomy within 4 h of admission. Failure of

nonoperative management was defined by exploratory laparotomy ≥ 4 h after admission. Angioembolization was not an exclusion criterion. Institutional Review Board approval was obtained from the University of Southern California. Due to the observational nature of the study, consent was waived.

Patient demographics (age, gender), injury data [type and American Association for the Surgery of Trauma (AAST) grade of solid organ injury, abbreviated injury scale (AIS) score by body region, injury severity score (ISS)], and clinical data [vital signs and Glasgow coma scale (GCS) score on presentation] were recorded. The type of VTE prophylaxis, dosing schedule, and timing of the first dose, measured to the nearest minute, were recorded. The primary outcome was VTE event rate [deep vein thrombosis (DVT) and pulmonary embolism (PE)]. Secondary outcomes included hospital length of stay (LOS), intensive care unit (ICU) LOS, need for and volume of post-prophylaxis blood transfusion, need for delayed (post-prophylaxis) interventional radiology (IR) or operative intervention, failure of nonoperative management, and mortality. All patients without contraindication (e.g., lower extremity fracture) received sequential compression devices to bilateral lower extremities until ambulation. We do not routinely screen for VTE at LAC + USC. Symptomatic patients with DVT were diagnosed with duplex ultrasonography, and those with PE were diagnosed with computed tomographic pulmonary angiography (CTPA).

The decision to initiate VTE prophylaxis was at the discretion of the attending trauma surgeon. Patients were dichotomized into study groups based on the timing of the first dose of VTE prophylaxis from the time of admission to hospital: early prophylaxis (≤ 48 h) and late prophylaxis (>48 h). Univariate analysis was used to compare baseline characteristics and outcomes between groups. Continuous variables were compared using the Mann–Whitney *U* test and are presented as median [interquartile range (IQR)]. Categorical variables were compared using Fisher's exact test and are presented as number (%). Multivariate analysis with logistic regression was performed to determine independent risk factors for late prophylaxis initiation. The covariates for the logistic regression were selected a priori and included gender, traumatic brain injury (TBI), lower extremity fractures, pelvic fractures, ICU LOS, and ISS. Although obesity is a known risk factor for VTE, the number of obese patients in this study ($n = 2$) was too low to include obesity as a covariate. A receiver operating characteristic (ROC) curve was performed to determine the time-to-prophylaxis cutoff point. Statistical significance was defined as $p < 0.05$.

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Results

Patient demographics and clinical data

Over the study period, 2191 patients presented to LAC + USC after blunt trauma (Fig. 1). Of these, 238 (11%) sustained a solid organ injury. After excluding those who were managed operatively ($n = 49$), died in the ED ($n = 8$), transferred from an outside hospital ($n = 15$), had a pre-existing bleeding disorder ($n = 5$), those on home antiplatelet or anticoagulation medications ($n = 3$), and those who received no VTE prophylaxis during hospital admission ($n = 40$), 118 patients remained for analysis.

The median age was 36 years [IQR 27–55], and 66% of patients ($n = 78$) were male (Table 1). Few patients were hypotensive (SBP < 90 mmHg) ($n = 13$, 11%) or tachycardic (HR > 120 bpm) ($n = 17$, 14%) on admission. Median GCS was 15 [IQR 14–15]. Median ISS was 22 [IQR 14–26]. In terms of solid organ injuries, liver injuries occurred in 57 patients (48%), splenic injuries in 43 (36%), and kidney injuries in 34 (29%). Overall, 16% of patients ($n = 19$) had more than one solid organ injury. Associated injuries were common (Table 1).

Early versus late VTE prophylaxis initiation

Of the 118 study patients, 61 (52%) received early prophylaxis and 57 (48%) received late prophylaxis. Patient demographics, admission vital signs, GCS, AIS in each body region, solid organ injury type and AAST grade, pelvic fractures, and lower extremity fractures did not vary between groups ($p > 0.05$) (Tables 1, 2). There were significantly more TBIs in the late prophylaxis group ($n = 18$, 32% vs $n = 5$, 8%, $p = 0.002$). Need for angioembolization did not vary between groups ($n = 10$, 16% vs $n = 14$, 14%, $p = 0.821$).

Patients in the early prophylaxis group were started on prophylaxis at a median of 2105 min [IQR 1830–2512], or approximately 35 h after admission. Patients in the late prophylaxis group were initiated on prophylaxis at a median of 4320 min [IQR 3420–5760], or approximately 72 h, after admission. Prophylaxis was delivered as enoxaparin or heparin. The majority of patients received enoxaparin, with similar rates of heparin use in both groups ($n = 5$, 8% vs $n = 6$, 11%, $p = 0.667$).

The solid organ injuries sustained by both groups are delineated in Table 2. The median AAST grade of solid organ injury did not vary between groups ($p > 0.05$). The type of solid organ injured (liver, spleen, or kidney) did not vary between groups ($p > 0.05$). There was no difference between groups in the number of patients with >1 solid organ injured ($p = 0.323$) (Table 1).

Outcomes

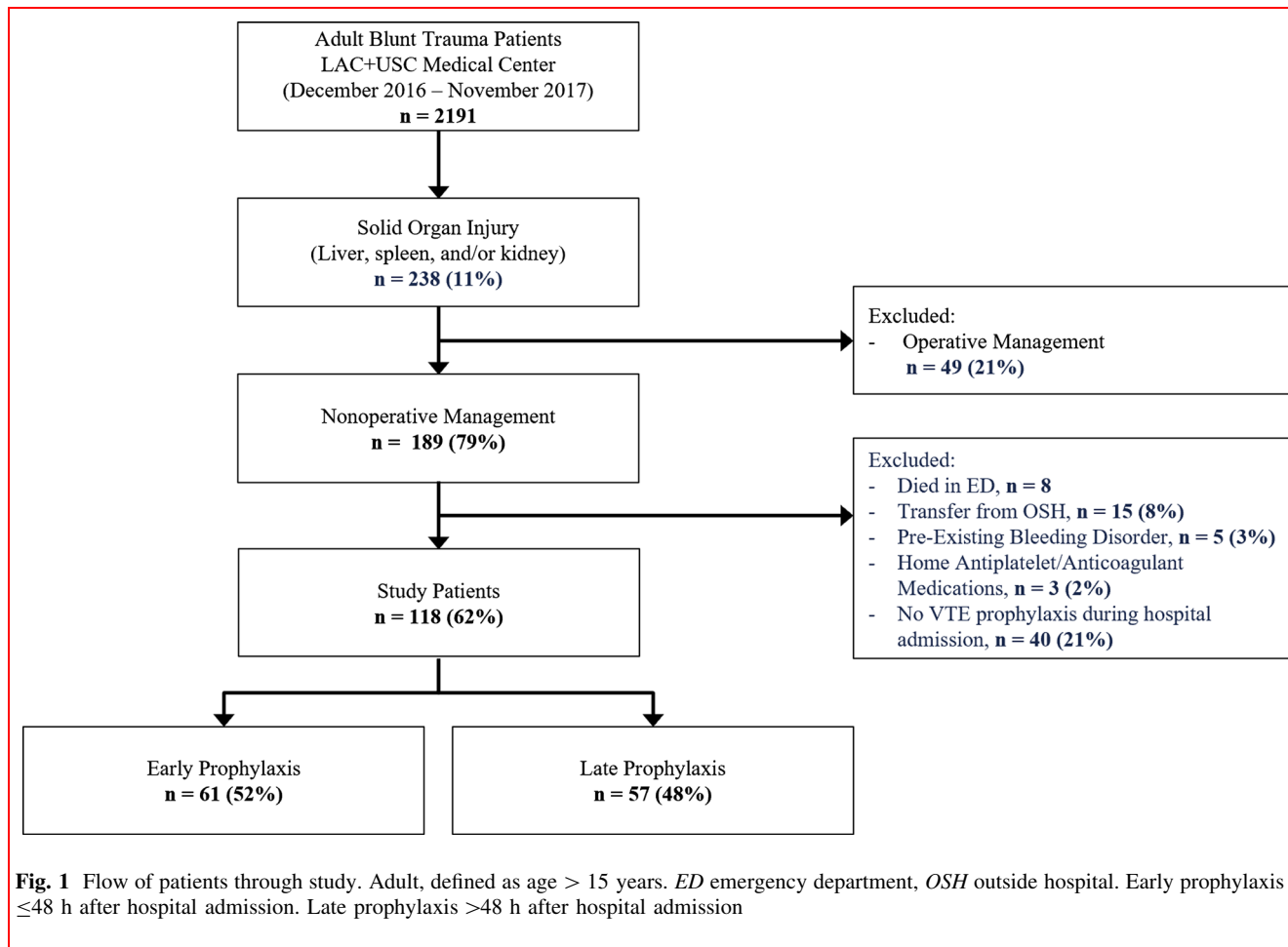
Overall, 10 VTEs occurred in 8 patients. There were 3 patients (3%) with isolated DVTs, 3 (3%) with isolated PEs, and 2 (2%) with concomitant DVTs and PEs, both of which occurred in the late prophylaxis group. Univariate analysis of outcomes revealed a lower rate of DVT among early prophylaxis patients ($n = 0$, 0% vs $n = 5$, 9%, $p = 0.024$). There was no difference between early and late prophylaxis groups in VTE rate ($n = 2$, 3% vs $n = 6$, 11%, $p = 0.153$) or PE rate ($n = 2$, 3% vs $n = 3$, 5%, $p = 0.672$) (Table 3). No patient in either study group failed nonoperative management. No patient in either group required angioembolization or operative intervention after initiation of VTE prophylaxis. There was no difference in the volume of post-prophylaxis blood transfusion between groups (median 0 [IQR 0–0] vs 0 [IQR 0–0], $p = 0.180$). There was no difference in mortality ($n = 2$, 3% vs $n = 1$, 2%, $p = 1.000$). Hospital and ICU LOS were significantly longer in the late prophylaxis group (14 days [7–35] vs 6 days [4–11], $p < 0.001$; 7 days [4–12] vs 3 days [2–6], $p < 0.001$) (Table 3). There was no difference between groups in need for ICU admission ($n = 52$, 85% vs $n = 52$, 91%, $p = 0.398$).

Multivariate analysis with logistic regression was performed to examine independent predictors of late VTE prophylaxis initiation (Table 4). TBI was significantly associated with late prophylaxis initiation (adjusted OR 0.22, 95% CI 0.07–0.74, $p = 0.015$).

ROC curve analysis demonstrated that a time-to-prophylaxis cutoff of 56 h had a sensitivity of 1.00 and specificity of 0.65 for the development of VTE (AUROC 0.825) (Fig. 2).

Discussion

Care of the injured patient involves careful consideration of the risks and benefits of intervention. One major consideration surrounds the optimal timing of VTE prophylaxis initiation. Trauma patients are known to be at high risk for VTEs, with rates that approach 15% [6]. This is significant since VTEs are an important cause of morbidity and mortality among patients who survive beyond the first 72 h [7, 8]. Pharmacologic VTE prophylaxis exists and is effective at decreasing the rates of VTE. One study demonstrated that a delay in VTE prophylaxis initiation beyond 4 days resulted in a threefold increase in the risk of VTE [1]. However, patients with nonoperatively managed blunt solid organ injury present a competing concern for



the possible precipitation of bleeding after VTE prophylaxis administration. With the rise in rates of nonoperative management over the past decade, determination of the appropriate time to initiate VTE prophylaxis in these high risk patients is of paramount importance. Major trauma society guidelines indicate that pharmacologic prophylaxis can be initiated among patients with blunt solid organ injury without increasing the rate of failure of nonoperative management [9, 10]. However, because only a small number of retrospective studies have examined this issue thus far [2–5], these guidelines are unable to make an evidence-based recommendation about the optimal timing for initiation of therapy. One excellent thromboelastography (TEG)-based study demonstrated that patients with blunt solid organ injury transition into a hypercoagulable state at approximately 48 h post injury, suggesting that VTE prophylaxis initiation before that time may be wise [11].

In this study, we prospectively examined patients who presented to our Level I trauma center over a 1-year period with a blunt solid organ injury managed nonoperatively. We found that initiation of VTE prophylaxis within 48 h of

admission resulted in a significantly lower rate of DVT among blunt trauma patients with solid organ injury. Based on ROC curve analysis, the risk of VTE appeared to increase most notably when prophylaxis was not initiated in the first 56 h. Importantly, no patient required operative intervention or angioembolization for bleeding after initiation of prophylaxis. There was no difference in the volume of post-prophylaxis transfusion between patients in the early and late prophylaxis groups. Our findings prospectively validate previous retrospective studies on VTE prophylaxis among patients with solid organ injury which suggested that prophylaxis can safely be initiated within 48 h without increasing the need for post-prophylaxis transfusion or failure rates of nonoperative management [2–5].

Therefore, in the absence of contraindications related to associated injuries (for example, expanding intracranial hemorrhage), the best available evidence supports that VTE prophylaxis can safely be initiated within 48 h of admission for blunt solid organ injury, regardless of injury grade, without concern for exacerbation of bleeding or failure of nonoperative management.

Table 1 Patient demographics, clinical data, and injury data

	All patients (<i>n</i> = 118)	Early prophylaxis (<i>n</i> = 61, 52%)	Late prophylaxis (<i>n</i> = 57, 48%)	<i>p</i>
Demographics				
Age, years	36 [27–55]	36 [27–54]	36 [27–56]	0.631
Male	78 (66%)	39 (64%)	39 (68%)	0.698
Clinical data on admission				
SBP, mmHg	127 [112–146]	126 [105–144]	129 [115–149]	0.250
SBP < 90 mmHg	13 (11%)	8 (13%)	5 (9%)	0.561
HR, bpm	96 [79–108]	95 [79–107]	97 [79–113]	0.465
HR > 120 bpm	17 (14%)	5 (8%)	12 (21%)	0.066
GCS	15 [14–15]	15 [14–15]	14 [13–15]	0.009
Injury severity				
ISS	22 [14–26]	17 [14–22]	22 [17–27]	0.002
AIS head/neck	0 [0–2]	0 [0–0]	0 [0–3]	0.368
AIS face	0 [0–0]	0 [0–0]	0 [0–0]	0.395
AIS chest	2 [0–3]	3 [1–3]	2 [2–3]	0.522
AIS abdomen/pelvis	3 [2–3]	3 [2–3]	2 [2–3]	0.920
AIS extremities	2 [0–2]	2 [0–2]	2 [0–2]	0.101
AIS external	1 [0–1]	1 [0–1]	1 [0–1]	0.689
Solid organ injury				
Liver	57 (48%)	31 (51%)	26 (46%)	0.586
Spleen	43 (36%)	22 (36%)	21 (37%)	1.000
Kidney	34 (29%)	17 (28%)	17 (30%)	0.841
>1 Solid organ injury	19 (16%)	12 (20%)	7 (12%)	0.323
Associated injuries				
TBI	23 (19%)	5 (8%)	18 (32%)	0.002
Pelvic fracture	42 (36%)	22 (36%)	20 (35%)	1.000
LE fracture	26 (22%)	9 (15%)	17 (30%)	0.074
Need for angioembolization	22 (19%)	10 (16%)	12 (21%)	0.637

Continuous variables presented as median [interquartile range] and compared using the Mann–Whitney *U* test. Categorical variables presented as *n* (%) and compared using the Fisher's exact test

SBP systolic blood pressure, *HR* heart rate, *Bpm* beats per minute, *GCS* Glasgow coma scale score, *ISS* injury severity score, *AIS* abbreviated injury scale, *TBI* traumatic brain injury, *LE* lower extremity

Approximately half of our patients were initiated on VTE prophylaxis >48 h after hospital admission. The higher incidence of TBI among the late prophylaxis group provides a plausible explanation for the delay in VTE prophylaxis initiation in these patients. In fact, after controlling for potential confounders, the presence of TBI was independently associated with late initiation of VTE prophylaxis. Although there was no institutional policy at the time of this study for VTE prophylaxis among TBI patients, many clinicians withhold prophylaxis for a period of time after an interval CT scan of the head demonstrates stability of the intracranial bleeding. The greater incidence of concomitant TBI in the late prophylaxis group is a potential confounding factor which must be considered in the interpretation of these results.

The limitations to this study must be acknowledged. First, it is a single-center study. This limits study size and event detection rates. The possibility that the study may have been underpowered, and thus that a type II error may exist, must therefore be considered. Second, we do not routinely screen for DVTs at our institution. Previous studies have shown that DVT surveillance increases the number of diagnosed DVTs [12]. It is possible that early prophylaxis has a different effect on symptomatic and asymptomatic DVTs, and this has not been addressed by the present study. Third, this study captured few patients with grade IV–V injuries, likely reflecting an increased need for operative management among these patients. The paucity of high-grade injuries in this cohort likely contributed to the finding that no patient failed nonoperative management of a blunt solid organ injury. The small

Table 2 AAST grade of solid organ injuries

	All patients	Early prophylaxis	Late prophylaxis	<i>p</i>
Liver	57 (48%)	31 (51%)	26 (46%)	0.586
Median	2 [2–3]	2 [2–3]	2 [2–3]	0.955
I	11 (19%)	7 (23%)	4 (15%)	
II	23 (40%)	13 (42%)	10 (38%)	
III	14 (25%)	6 (19%)	8 (31%)	
IV	5 (9%)	5 (16%)	0 (0%)	
V	4 (7%)	0 (0%)	4 (15%)	
Spleen	43 (36%)	22 (36%)	21 (37%)	1.000
Median	2 [1–3]	2 [2–3]	2 [1–2]	0.089
I	7 (16%)	2 (9%)	5 (24%)	
II	22 (51%)	12 (55%)	10 (48%)	
III	11 (26%)	7 (32%)	4 (19%)	
IV	2 (5%)	0 (0%)	2 (9%)	
V	1 (2%)	1 (5%)	0 (0%)	
Kidney	34 (29%)	17 (28%)	17 (30%)	0.841
Median	3 [2–3]	2 [1–3]	3 [3–3]	0.150
I	7 (21%)	4 (24%)	3 (18%)	
II	6 (18%)	5 (29%)	1 (6%)	
III	13 (38%)	4 (24%)	9 (53%)	
IV	7 (21%)	4 (24%)	3 (18%)	
V	1 (3%)	0 (0%)	1 (6%)	

Continuous variables presented as median [interquartile range] and compared using the Mann–Whitney *U* test. Categorical variables presented as *n* (%) and compared using the Fisher's exact test

number of high-grade injuries limits the generalizability of our findings, and caution must therefore be used when applying the results of this study to grade IV and V injuries. Fourth, although we defined early prophylaxis as ≤ 48 h on the basis of existing retrospective [2–5] and TEG-based [11] literature, the optimal time to initiate prophylaxis may

be early within this window. We also did not capture missed doses of VTE prophylaxis, which may confound the data. Further study will be required to determine the ideal initiation time more precisely and to define the impact of missed doses of VTE prophylaxis. Fifth, this study captured only VTEs that were diagnosed in hospital. Because the risk of VTE after trauma is at its highest for 3 months post-injury [13], it is possible that the incidence of VTE is underestimated by this study. Next, the generalizability of our data to other centers with different patient demographics is unclear. Our extremely low obesity rate, for example, is unlikely to be consistent across centers. Finally, because the time of VTE prophylaxis initiation was at the discretion of the attending trauma surgeon, there may be selection bias between the early and late prophylaxis groups wherein patients with injuries at lower risk for bleeding were initiated on prophylaxis earlier. Although an attempt was made to control for potential confounders, it is impossible to account for all such confounders. We must acknowledge that there may be differences in the study groups that we are unaware of. These limitations can be addressed in the future with a multicenter study including institutions with a variety of practice patterns.

In conclusion, this study provides a prospective analysis of the timing of VTE prophylaxis initiation among blunt trauma patients with solid organ injury managed nonoperatively. After adjusting for potential confounders, we found that commencement of VTE prophylaxis within 48 h of admission was associated with significantly fewer VTEs. Importantly, early prophylaxis appeared to be safe across AAST injury grade and type of solid organ injury (liver, spleen, and/or kidney), without an increased risk of bleeding that necessitated intervention or blood transfusion. In clinical practice, this has encouraged earlier

Table 3 Univariate analysis of outcomes

	All patients (<i>n</i> = 118)	Early prophylaxis (<i>n</i> = 61, 52%)	Late prophylaxis (<i>n</i> = 57, 48%)	<i>p</i>
VTE*	8 (7%)	2 (3%)	6 (11%)	0.153
DVT*	5 (4%)	0 (0%)	5 (9%)	0.024
PE*	5 (4%)	2 (3%)	3 (5%)	0.672
Hospital LOS	9 [5–21]	6 [4–11]	14 [7–35]	<0.001
Need for ICU admission	104 (88%)	52 (85%)	52 (91%)	0.398
ICU LOS	4 [3–9]	3 [2–6]	7 [4–12]	<0.001
Mortality	3 (3%)	2 (3%)	1 (2%)	1.000
Need for post-prophylaxis transfusion	31 (26%)	13 (21%)	18 (31%)	0.058
Volume of post-prophylaxis transfusion	0 [0–0]	0 [0–0]	0 [0–0]	0.180

Continuous variables presented as median [interquartile range] and compared using the Mann–Whitney *U* test. Categorical variables presented as *n* (%) and compared using the Fisher's exact test

VTE venous thromboembolic event (DVT and PE), DVT deep vein thrombosis, PE pulmonary embolism, LOS length of stay (days), ICU intensive care unit

*There were 10 VTEs in 8 patients

Table 4 Multivariate analysis of risk factors for late (>48 h) initiation of VTE prophylaxis

	Univariate OR	Adjusted OR	95% CI	<i>p</i>
Pelvic fracture	1.04	1.45	0.55–3.82	0.456
TBI	0.19	0.22	0.07–0.74	0.015
Gender (male)	1.22	1.35	0.50–3.63	0.554
Lower extremity fracture	0.41	0.36	0.12–1.05	0.063
ICU LOS	0.93	0.95	0.89–1.00	0.071
ISS	0.93	0.96	0.90–1.03	0.260

Logistic regression. *VTE* venous thromboembolism, *TBI* traumatic brain injury, *ICU* intensive care unit, *LOS* length of stay, *ISS* injury severity score, *OR* odds ratio, *CI* confidence interval

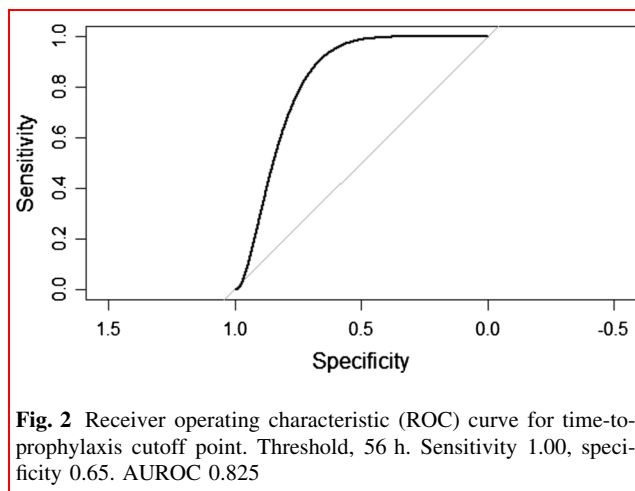


Fig. 2 Receiver operating characteristic (ROC) curve for time-to-prophylaxis cutoff point. Threshold, 56 h. Sensitivity 1.00, specificity 0.65. AUROC 0.825

initiation of VTE prophylaxis among these patients at our institution. We recommend initiation of VTE prophylaxis within 48 h of hospital admission among patients with blunt solid organ injury without contraindication to prophylaxis.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflicts of interest to disclose.

Statement of informed consent and human rights Institutional Review Board (IRB) approval was obtained from the University of

Southern California (USC). Given the observational nature of this study, waived consent was approved.

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