Effectiveness of clinical guidelines for deep vein thrombosis prophylaxis in reducing the incidence of venous thromboembolism in critically ill children after trauma

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BACKGROUND: Historically, 6% of critically ill children developed clinically apparent venous thromboembolism (VTE) after trauma at our Level I pediatric trauma center. We hypothesized that implementation of clinical guidelines for thrombosis prophylaxis incorporating both VTE risk and bleeding risk would reduce VTE incidence without increased bleeding.

METHODS: VTE, both clinically apparent and those only detected by guideline-directed screening, were prospectively identified for all children admitted to the intensive care unit after trauma during three time periods: preimplementation of guidelines for VTE thromboprophylaxis (PRE; April 1, 2006–June 30, 2007), the intervening period (ROLL OUT; July 1, 2007–November 4, 2008), and postguideline implementation (POST; November 5, 2008–June 1, 2010). For patients classified as high risk for VTE, anticoagulation was recommended. For those patients at high risk of VTE with high risk of bleeding, anticoagulation was deferred and screening ultrasound performed.

RESULTS: Fourteen of 546 subjects developed VTE. There was a decrease in total VTE ($p = 0.041$) and clinical VTE ($p = 0.001$) after guideline implementation. The nine VTE PRE (5.2%) were clinically symptomatic, while the three VTE POST (1.8%) were detected by guideline-directed screening ultrasound. Implementation of guidelines did not increase overall thromboprophylaxis, with decreased anticoagulation in patients at low risk of VTE. No bleeding complications occurred. No patients classified by the guidelines as low risk for VTE developed VTE.

CONCLUSION: The incidence of clinical VTE and total VTE decreased after implementation of clinical guidelines for thromboprophylaxis in critically ill children after trauma. This decrease in VTE was not associated with increased prophylactic anticoagulation nor increased bleeding. The guidelines were predictive in identifying patients at low risk for VTE. (*J Trauma.* 2012;72: 1292–1297.

LEVEL OF EVIDENCE: II, therapeutic study.

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Venous thromboembolism (VTE) causes major morbidity in the adult trauma population, occurring in 20% to 50% of patients without thromboprophylaxis.[1,2] Previous studies in children hospitalized for trauma have shown a much lower incidence of VTE in the range of 0.05% to 0.33%.[3–8] However, the incidence of VTE in children admitted to an intensive care unit (ICU) after trauma is estimated to be 6% in the absence of consistent thromboprophylaxis.[9]

As thromboprophylaxis has been shown to decrease the rate of VTE in adults after trauma, thromboprophylaxis could also be beneficial in children at high risk of VTE. However, in a population with traumatic injury, the risk of VTE needs to be carefully balanced against the competing risk of bleeding. Thromboprophylaxis should be avoided in children at high risk of bleeding, even if they have high VTE risk. Likewise, given the risks of thromboprophylaxis, it should not be used in patients with low risk of VTE. To balance the competing risks of VTE and bleeding, we developed and implemented clinical guidelines for VTE prevention, based on the risk factors for VTE identified by our previous study of VTE in children admitted to the pediatric ICU (PICU) after trauma at our Level I pediatric trauma center.[9]

For children at high risk of VTE and low risk of bleeding, the guidelines recommend heparin be started within

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the first 24 hours of ICU admission. For children at high risk of VTE but with concurrent high risk of bleeding, strategies other than anticoagulation may be needed. In the guidelines that we developed, bleeding risk is evaluated, and patients at high risk of VTE and high risk of bleeding are recommended to avoid anticoagulation, to use sequential compression devices (SCDs), and to undergo screening ultrasound (US) if they are still in the PICU 7 days after admission. If the bleeding risk decreases during the PICU stay, it is recommended to start anticoagulation at that time in these patients at high risk of VTE. We hypothesized that implementation of these clinical guidelines would decrease the incidence of VTE in this critically ill population and lead to more appropriate use of thromboprophylaxis.

MATERIALS AND METHODS

Subjects

The Children's Hospital of Wisconsin (CHW) institutional review board approved this observational study. All children admitted to the PICU after trauma, from April 1, 2006, to June 1, 2010, were included as registered in the CHW Trauma Registry and the VPS, LLC clinical database. VPS is a prospective clinical database used in many children's hospitals to standardize data sharing and benchmarking and tracks all children admitted to the CHW PICU.

Patients were identified as having VTE through the Quality Improvement PICU Thrombosis Database Project maintained since April 1, 2006. In this database, all children admitted to the CHW PICU were followed prospectively for the development of clinically apparent VTE. Identification of VTE involved daily review of all medication, nursing, radiology, and consult orders, all laboratory results, all diagnostic imaging such as computed tomography, magnetic resonance imaging, angiogram, or US of head, chest, heart, abdomen, pelvis, or extremity, and all procedural or surgical notes. In addition, the critical care team was queried weekly (S.J.H.) regarding patients who develop VTE.

Guidelines

The clinical guidelines for VTE prophylaxis in children after trauma were introduced at CHW on November 5, 2008 (Fig. 1). After this time, patients were classified by the guidelines into the following categories:

1. High risk for VTE and without high risk of bleeding: Recommended prophylactic anticoagulation with low-molecular-weight heparin and application of SCDs.
2. High risk for VTE and with high risk of bleeding: Recommended application of SCDs but not anticoagulation. Instead, this group underwent screening US for VTE if still in the PICU on hospital day 7. If screening US showed VTE, therapeutic heparin was started if bleeding risk had diminished.
3. Low risk for VTE: Recommended not to receive prophylactic anticoagulation or application of SCDs. No surveillance US recommended.

Data Collection

The study was classified into three time periods:

VTE Prophylaxis Guidelines

For patients at **high risk of VTE**[1] with **low risk of bleeding**[2]:
- anticoagulate with low molecular weight heparin at 0.5mg/kg subcutaneous, twice daily until hospital discharge

For patients at **high risk of VTE**[1] with **high risk of bleeding**[3]:
- apply sequential compression devices
- on PICU day 7 obtain screening ultrasound of bilateral lower extremities, and upper extremity if CVL is present

For patients at **low risk of VTE**[4]:
- no anticoagulation or other clinical intervention indicated

Risk Factors for VTE:
- projected immobility > 5 days
- Glasgow Coma Scale less than 9
- presence of CVL
- spinal cord injury
- complex lower extremity fracture
- operative pelvic fracture
- use of inotropes
- CPR during resuscitation
- exogenous estrogen
- chronic inflammatory state
- history of previous clot
- known thrombophilia
- current malignancy

Risk Factors for Bleeding:
- intracranial bleed
- solid organ injury
- planned surgical intervention or invasive procedure in the next 24 hours
- heparin allergy
- high risk of severe bleeding
- renal failure

[1]High risk of VTE defined as age greater than 13 years OR age less than 13 years with four or more risk factors for VTE.
[2]Low risk of bleeding defined as no risk factors for bleeding.
[3]High risk of bleeding defined as one or more risk factors for bleeding.
[4]Low risk of VTE defined as age less than 13 years AND three or fewer risk factors for VTE.

VTE = venous thromboembolism; PICU = pediatric intensive care unit; CVL = central venous line; CPR = cardiopulmonary resuscitation

Figure 1. Clinical guidelines to classify risk of VTE and bleeding in children admitted to the PICU after trauma.

1. Preimplementation of guidelines for thrombosis prophylaxis (PRE; April 1, 2006–June 30, 2007) in which prophylactic anticoagulation was variable and administration based on the preference of the attending physician.
2. Intervening period (ROLL OUT; July 1, 2007–November 4, 2008) in which some awareness of the previous study resulted in intermittent assessment of patient risk factors and the need for prophylactic anticoagulation.
3. Postguideline implementation (POST; November 5, 2008–June 1, 2010) in which there was consistent assessment of risk factors for VTE and bleeding directed the use of prophylactic anticoagulation.

The incidence and risk factors for VTE and risk for bleeding were compared for the three epochs using the CHW Trauma registry, VPS, LLC clinical database, and chart review. Demographics, injury and trauma severity scores, prophylactic and therapeutic anticoagulation use, diagnostic imaging for thrombosis, presence of VTE, and bleeding complications were collected from admission to hospital discharge.

VTE Definitions

Clinical VTE were defined as any VTE detected by clinical symptoms prompting imaging for thrombosis.

Screening VTE were defined as VTE detected by the screening US in those patients identified by guidelines as high risk of VTE and high risk of bleeding.

Total VTE were defined as the sum of both clinical VTE and screening VTE.

VTE Risk Factors

Risk factors for VTE were collected from admission to PICU, transfer, or discharge and included projected immobilization greater than 5 days, Glasgow Coma Scale score <9, presence of central venous line, spinal cord injury, complex lower extremity fracture, operative pelvic fracture, inotrope use, cardiopulmonary resuscitation, exogenous estrogen use, chronic inflammatory state such as rheumatoid arthritis, history of previous clot or stroke, known thrombophilia, and current malignancy.

Bleeding Risk Factors

From admission to the PICU through transfer or discharge, the following risk factors for bleeding were collected: intracranial bleeding, solid organ injury, planned surgical intervention/invasive procedure in the next 24 hours, and renal failure. For the categorization of "high risk of severe bleeding," retrospective chart review by physicians in critical care, surgery, and hematology (authors S.J.H., M.J.A., R.C.P.) was used to independently confirm the clinical team's assessment. Examples of patients in this category include those with large body surface burns requiring skin grafting, open fasciotomies, retroperitoneal hematomas, and significant hemothorax.

Statistical Analysis

Continuous data were compared between groups using a nonparametric Kruskal-Wallis or a Mann-Whitney test, where the data were skew. Categorical variables were compared using a χ^2 or Fisher's exact test. The main outcome of interest was incidence of clinical VTE by time period (PRE and POST guidelines ROLL OUT). Secondary objectives were comparison by time period in rates of appropriate prophylaxis use and in all VTE (clinical and screened).

RESULTS

As listed in Table 1, there were significant age differences in the study periods (median age: 12 years PRE, 10 years ROLL OUT, and 7 years POST, with similar ranges, $p = 0.043$). There were no difference in patient sex or injury and illness severity scores including initial Glasgow Coma Scale, raw Revised Trauma Score, Pediatric Trauma Score, Injury Severity Score, Pediatric Index of Mortality 2, and Pediatric Risk of Mortality Score 3 between the three epochs.

When retrospectively applying the guideline criteria to the PRE and ROLL OUT groups and comparing with the POST group, there was no difference in the patients categorized as high risk or low risk for VTE. There was no difference in the rate of prophylactic anticoagulation between the epochs, with 10% of all patients receiving thromboprophylaxis in PRE (18 of 174) and POST (17 of 169). Similarly, there was no difference in the rate of thromboprophylaxis for patients classified as high risk for VTE (15 of 96 [16%] PRE vs. 13 of 76 [17%] POST, $p > 0.05$; Table 2). There was a decrease in prophylaxis between epochs in patients classified as low risk for VTE (2 of 11 [18%] PRE vs. 1 of 25 [4%] POST, $p = 0.03$). The risk factors identified in patients classified by the guidelines as high risk for VTE are summarized in Table 3.

The patient flow after implementation of the guidelines (POST) is illustrated in Figure 2. In adherence with the guidelines, prophylactic anticoagulation was not given to 60 patients at high risk for VTE as they were also at high risk for bleeding. Prophylaxis was not implemented in 13 patients categorized as high risk for VTE and low risk for bleeding who had a PICU stay ≤1 day. Guideline recommendations for prophylaxis were not implemented in one patient at high risk for VTE and low risk of bleeding with a PICU stay >1 day. Of the 60 patients at high risk for VTE with a high risk of bleeding, 23 were in the PICU on hospital day 7 and 6 patients (26%) received a screening Doppler US per guideline recommendations. US results yielded three cases of VTE (50%). No patients in the POST epoch had clinical symptoms of VTE.

There was a decreased incidence of total VTE ($p = 0.041$) and clinical VTE ($p = 0.001$) after implementation of the clinical guidelines (Table 4). All nine VTE PRE (5.2% incidence) and two VTE during ROLL OUT (1.0% incidence) were clinically symptomatic. The three VTE POST (1.8% incidence) were detected by guideline-driven screening US on PICU day 7, occurring in high VTE risk/high bleeding risk patients who by protocol did not receive prophylactic heparin. There were no VTE in patients categorized by the guidelines as low risk for VTE.

TABLE 1. Patient Characteristics by Epoch

	Preguidelines, Median (Range) or N (%)	ROLL OUT, Median (Range) or N (%)	Postguidelines, Median (Range) or N (%)	*p*
Age (yr)	12 (0–18)	10 (0–19)	7 (0–18)	**0.043**
Sex, male	118 (68)	138 (68)	122 (73)	0.485
Glasgow Coma Scale	11 (3 to 15)	11 (3 to 15)	13 (3 to 15)	0.084
Pediatric Trauma Score	6 (−1 to 12)	6 (−1 to 12)	6 (−3 to 12)	0.851
Revised Trauma Score	6.75 (1.47 to 7.84)	6.61 (1.47 to 7.84)	7.55 (1.47 to 7.84)	0.103
Injury Severity Score	17 (1 to 50)	17 (1 to 75)	16.5 (1 to 59)	0.051
PIM2	0.01 (0 to 0.97)	0.01 (0 to 0.98)	0.01 (0 to 1.00)	0.675
PRISM3	2 (0 to 44)	2 (0 to 43)	1 (0 to 49)	0.982

PIM2, Pediatric Index of Mortality 2; PRISM3, Pediatric Risk of Mortality Score 3.

TABLE 2. High- and Low-Risk Status by Epoch

	Preguidelines	ROLL OUT	Postguidelines	*p*
High risk of VTE	96/174 (55%)	112/203 (55%)	76/169 (45%)	0.09
High risk of bleeding	70	84	60	
Prophylaxis	6/70 (9%)	15/84 (18%)	11/60 (18%)	0.19
No prophylaxis	64/70 (91%)	69/84 (82%)	49/60 (82%)	
Low risk of bleeding	26	28	16*	
Prophylaxis	9/26 (35%)	7/28 (25%)	2/16 (13%)	0.28
No prophylaxis	17/26 (65%)	21/28 (75%)	14/16 (87%)*	
Low risk of VTE	78/174 (45%)	91/203 (45%)	93/169 (55%)†	
High risk of bleeding	67	61	68	
Prophylaxis	1/67 (1%)	0/61 (0%)	3/68 (4%)†	0.33
No prophylaxis	66/67 (99%)	61/61 (100%)	65/68 (96%)	
Low risk of bleeding‡	11	30	25	
Prophylaxis	2/11 (18%)	0/30 (0%)	1/25 (4%)†	**0.03**
No prophylaxis	9/11 (82%)	30/30 (100%)	24/25 (96%)	

* Guidelines not implemented in 13 patients at high risk of VTE because of single risk factor of age older than 13 years and low risk of bleeding with PICU length of stay 1 day or less; guidelines not followed in one patient.
† Four patients classified as low risk for VTE in POST had anticoagulation for other reasons than VTE prophylaxis such as arterial graft patency and carotid artery dissection.
‡ There was a significant decrease in prophylaxis between epochs in patients at low risk of VTE and low risk of bleeding ($p = 0.03$).

TABLE 3. Risk Factors in Patients at High Risk of VTE by Epoch

	All Epochs, n (%)	Preguidelines, n (%)	ROLL OUT, n (%)	Postguidelines, n (%)	*p*
Age older than 13 yr	214 (75)	79 (82)	84 (75)	51 (67)	0.07
Projected immobility greater than 5 d	166 (58)	53 (55)	68 (61)	45 (59)	0.72
GCS < 9	138 (49)	43 (45)	57 (51)	38 (50)	0.65
Presence of CVL	131 (46)	37 (38)	56 (50)	38 (50)	0.19
Spinal cord injury	23 (8)	3 (3)	14 (13)	6 (8)	0.05
Complex lower extremity fracture	35 (12)	14 (15)	14 (13)	7 (9)	0.57
Operative pelvic fracture	6 (2)	1 (1)	1 (1)	4 (5)	0.13
Use of inotropes	99 (35)	25 (26)	44 (39)	30 (39)	0.08
CPR during resuscitation	39 (14)	10 (10)	15 (13)	14 (18)	0.31
Exogenous estrogen	2 (0.7)	2 (2)	0	0	0.18
Known thrombophilia	2 (0.7)	1 (1)	0	1 (1)	0.52

GCS, Glasgow Coma Scale; CVL, central venous line; CPR, cardiopulmonary resuscitation.
No study patients in any epoch had a chronic inflammatory state, history of previous clot, or current malignancy.

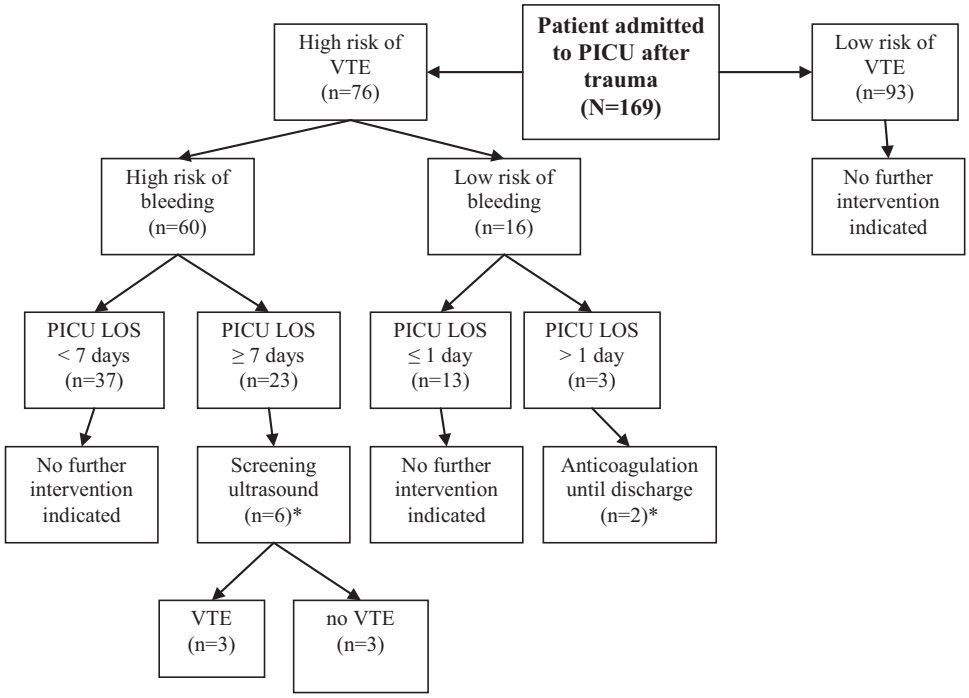
Time to VTE detection was a median of 7 days (range, 7–9 days) by guideline-directed screening in the POST guideline epoch versus 10 days (range, 2–125; $p = 0.4$) for clinical VTE in the PRE and ROLL OUT epochs. All VTE were treated with anticoagulation after detection. There were no bleeding complications in any epoch in patients receiving anticoagulation.

DISCUSSION

This is the first study to prospectively evaluate the implementation of clinical guidelines for VTE prophylaxis for children admitted to the PICU after trauma. The incidence of total VTE detected decreased by 65% (5.2% PRE to 1.8% POST, $p = 0.04$) after implementation of these guidelines for thrombosis prophylaxis. Even after guideline implementation, the rate of VTE in critically ill children after trauma is higher than that reported for hospitalized children[8] or critically ill children overall.[10]

The population in the POST guideline epoch was younger and trended toward a less severe Injury Severity Score ($p = 0.051$), which may have contributed to the decreased incidence of VTE. However, other markers of illness and injury severity were not different between the epochs (Table 2). The guidelines classify all patients with age older than 13 years as high risk for VTE. There was no significant difference in the percent of trauma patients admitted to the PICU classified as high risk for VTE before and after the institution of guidelines, and so the difference in median age between epochs should not have influenced the VTE rate.

All VTE in the PRE epoch were symptomatic VTE and frequently detected later in the hospital stay (median day 10, range, 2–125), often after transfer out of the PICU to the general floor. In comparison, no symptomatic VTE developed in the POST epoch, even though in both time periods, participants were followed up until hospital discharge. In the POST epoch, three VTE were detected by guideline-recommended



*Clinical compliance with guidelines was 93%; 17 patients did not receive screening ultrasounds, and 1 patient did not receive anticoagulation.

VTE = venous thromboembolism; PICU = pediatric intensive care unit; LOS = length of stay

Figure 2. Description of patient flow by VTE and bleeding risk after implementation of clinical guidelines for VTE prophylaxis in children admitted to the PICU after trauma.

TABLE 4. Incidence of VTE by Epoch

	Preguidelines	ROLL OUT	Postguidelines	*p*
All VTE	9/174 (5%)	2/201 (1%)	3/169 (2%)	**0.04**
Clinical VTE*	9	2	0	**0.001**
Screened VTE†	NA	NA	3	NA

NA, not applicable.
* Clinical VTE occurred in patients whose symptoms prompted VTE imaging.
† All screened VTE occurred in the high risk for VTE/high risk for bleeding patients who, per guidelines, did not receive anticoagulation but obtained a screening ultrasound on PICU day 7.

screening US (median day 7) before the development of clinical symptoms. It is possible that some asymptomatic VTE were missed in the patients who did not undergo US screening in both the PRE and POST epoch; however, no patient in the POST epoch went on to develop symptomatic VTE.

There is not a clearly identified optimal approach for VTE prophylaxis in the patient with high risk for VTE and high risk of bleeding complications from heparin. For our guidelines, we recommended to delay heparin use until the risk of bleeding had diminished and performed a screening US on all participants still in the PICU on day 7 after admission. The success of this approach is measured by the detection and early treatment of subclinical VTE. Delay in VTE treatment and resolution has been associated with the complication of postthrombotic syndrome, resulting in venous hypertension, pain, and swelling.[11,12] Given the longer life expectancy of children, thrombosis outcome has a substantial effect on quality of life, morbidity, and costs.[13,14] Earlier VTE detection and treatment should lead to improved long-term outcomes. The guidelines were effective in identifying patients at low risk for VTE as there were no VTE detected in those classified as low risk for VTE. All VTE in the POST epoch occurred in high VTE risk/high bleeding risk patients who did not receive anticoagulation but had US screening on PICU day 7 per guidelines.

It is an assumption of our VTE prophylaxis guidelines that low molecular weight heparin (LMWH) prophylaxis will significantly reduce the risk of VTE, and so we chose to screen only those patients who did not receive prophylaxis and remained at the highest risk for VTE with Doppler US. This is consistent with the American College of Chest Physician guidelines for thromboprophylaxis in adult trauma patients, which states that although "routine screening for deep venous thrombosis cannot be justified in most trauma patients, selective screening might be beneficial in a limited

proportion of high-risk patients in whom early thromboprophylaxis has not been possible."[1]

There were no cases of VTE detected in the patients receiving LMWH prophylaxis. In adult trauma literature, VTE prophylaxis reduces incidence of VTE by 43% to 65%.[1] There is no similar evidence in pediatrics. If we assume the same effectiveness of LMWH prophylaxis in children, the number of screening US needed to detect one VTE will certainly be higher, given the reduced incidence of VTE in pediatrics compared with adults. More research is needed in this area to analyze the cost-effectiveness of US screening in children receiving VTE prophylaxis after trauma.

Implementation of guidelines for VTE prophylaxis did not result in increased prophylactic anticoagulation (Table 2). Rather, it standardized the care of these critically ill trauma patients, minimizing variation in application of prophylaxis. In the POST epoch, four patients classified as low risk for VTE had anticoagulation for reasons other than VTE prophylaxis, such as maintenance of arterial graft patency, or carotid artery dissection. In addition, 11 patients classified as high risk for VTE and high risk for bleeding received prophylaxis. For study analysis, risk of bleeding was captured from the time of admission. In actual patient management, the risk of bleeding commonly decreases with time, resulting in alteration of the risk/benefit ratio of anticoagulation for a given patient. If the bleeding risk decreases during the PICU stay, it is recommended to start anticoagulation at that time in these patients at high risk of VTE.

Prophylaxis was not instituted in 14 patients at high risk of VTE and low risk of bleeding. Discussion of guidelines and implementation of prophylaxis typically occurred during rounds the morning after admission. Anticipating likely patient transfer or discharge, prophylaxis was not implemented in 13 patients categorized as high risk for VTE and low risk for bleeding who had a brief PICU stay $\leq$1 day. The only risk factor for VTE in these patients was age older than 13 years who were admitted for observation overnight. We plan to modify the guidelines to classify an expected PICU stay $\leq$1 day as low risk for VTE. It is not clear why guideline recommendations for prophylaxis were not implemented in one patient at high risk for VTE and low risk of bleeding with a PICU stay $>$1 day. There were no bleeding complications in patients receiving prophylactic anticoagulation in any epoch.

Clinical acceptance of guidelines was high, with an overall compliance of 93% since introduction. Compliance with prophylactic anticoagulation of patients at high risk for VTE and low risk of bleeding was 67% (2/3) in those with $>$1 day PICU stay. Compliance with screening US on PICU day 7 for those at high risk of VTE and high risk of bleeding was less robust at 26% (6/23). This has improved more recently with the addition of Doppler US orders for VTE surveillance to the electronic admission order set to be activated on PICU day 7 and with increased familiarity with the guidelines. The compliance with US screening has improved to 60% from July 1, 2010, to June 30, 2011. The 50% positivity rate for VTE from the screening US should further reinforce this practice.

Institution of these guidelines for VTE prophylaxis in critically ill children after trauma is limited to a single tertiary care pediatric trauma center and evaluated over an 18-month study period. A multicenter study is needed to confirm the reduction in VTE rate found in this study.

CONCLUSIONS

The incidence of clinical VTE and total VTE decreased after implementation of clinical guidelines for thrombosis prophylaxis in critically ill children after trauma, without an increase in prophylactic anticoagulation use or bleeding complications. The guidelines were effective in identifying patients at low risk for VTE.

AUTHORSHIP

All authors made significant contributions to study design and manuscript revision. In addition, S.J.H., S.K.H., M.C., M.A., and K.B. were involved in data collection. P.S. and K.Y. provided statistical support. S.J.H. takes responsibility for the integrity of the data.

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DISCLOSURE

The authors declare no conflicts of interest.

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