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The “High-Risk” DVT Screening Protocol for Trauma Patients – Is it practical?

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Abstract

Background—Many centers advocate aggressive lower extremity deep venous thrombosis (DVT) screening using ultrasound (LUS) for patients meeting high-risk criteria. We hypothesized that a high-risk screening protocol is impractical and costly to implement.

Methods—The University of Virginia's trauma database was queried to identify 6,656 patients admitted between 2009 and 2013. Patient characteristics and outcomes were recorded. Multivariate analyses were performed on patients who underwent LUS to assess the association between patient characteristics and the development of DVT. A predictive model for DVT was applied to the entire population to determine performance and resources required for implementation.

Results—Overall, 2,350 (35.3%) of admitted patients underwent US. 146 patients (6.2%) developed DVT. Patients who underwent US were significantly older (54.5 vs. 50.4 years, $p<0.0001$), had higher injury severity scores (13.5 vs. 8.6, $p<0.0001$), and longer admissions to the intensive care unit (ICU) (5.6 vs. 0.9 days, $p<0.0001$). Backwards selection multivariable logistic regression identified ICU length of stay, transfusion of blood products, spinal cord injury, and pelvic fracture to be associated with DVT (c-statistic 0.76). The model was applied to the entire population to evaluate probability of DVT (c-statistic 0.87). Predictive performance and costs were determined using a cost per LUS of \$228. The most sensitive threshold for screening would detect 53% of DVTs, require screening of 26% of all trauma patients, and cost nearly \$600,000 to implement over the study period.

Conclusions—Although a predictive model identified high-risk criteria for the development of DVT at our institution, the model demonstrated poor sensitivity and positive predictive value. These results suggest that implementing a high-risk screening protocol in trauma patients would

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require a costly and burdensome commitment of resources and that high-risk DVT screening protocols may not be practical or cost-effective for trauma patients.

Level of evidence—Diagnostic tests or criteria, level III.

Keywords

deep venous thrombosis; venous thromboembolism; pulmonary embolism; trauma; ultrasound; screening; quality; cost-effectiveness

Background

Venous thromboembolism (VTE) is a common cause of morbidity and mortality in hospitalized patients and, in particular, trauma patients, where pulmonary embolism (PE) is among the leading causes of death of trauma patients who survive beyond the first day of hospitalization.¹ In addition, insurers and oversight organizations have identified VTE as a potentially preventable complication and a metric for use in evaluating quality of care. Although isolated lower extremity deep venous thrombosis (DVT) is rarely a clinically-significant event, thromboembolism may result in potentially devastating PE. As a result, efforts to reduce the clinical sequelae of VTE in trauma patients have included screening methods to preemptively identify DVT so that early intervention may prevent the development of PE.

In the trauma community, the use of lower extremity ultrasound screening protocols for high-risk trauma patients has generated vigorous debate. Trauma practitioners disagree widely on high-risk variables for the development of VTE, the appropriate frequency for DVT screening, the utility of DVT screening in improving outcomes, and the cost-effectiveness of DVT screening.² As a result of this controversy, widely divergent patterns of DVT screening exist among trauma institutions, reflecting a lack of consensus about what defines a trauma patient whose risk for thromboembolism warrants routine screening for asymptomatic DVT. Consequently, numerous authors have sought to develop predictive models for screening in high-risk trauma patients, often using small, single-institution datasets that identify a set of risk factors for DVT. Unfortunately, these studies often fail to consider how such models would function as a screening test, which should be sensitive, specific, reasonably priced, and which should identify a condition that causes significant morbidity and mortality if left untreated. We sought to demonstrate the limitations of high-risk DVT screening models in trauma patients developed using single-institution data and hypothesized that a high-risk DVT screening model is both resource intensive and poorly adapted to meet these parameters.

Methods

Data Source

The University of Virginia trauma database was utilized to identify patients for this study. Our institution is a level one trauma center that participates in the American College of Surgeons' National Trauma Data Bank (NTDB). The NTDB aggregates data from participating centers on an annual basis for development of annual reports, hospital

benchmark reports, and datasets for researchers. At our institution, the trauma database is maintained by trained nurse abstractors who review clinical charts and records of all patients admitted to the trauma service.

For the period of this study, our institutional trauma service protocol was to perform LUS screening on all admitted patients beginning on the fifth day of admission and every five days thereafter. In addition, LUS was performed as clinically-indicated at the discretion of practitioners. Upper extremity studies were not included. DVT was recorded for evidence of either proximal or distal thrombus. Records of LUS ultrasound studies were matched to trauma patients using a local radiology database. The institutional clinical data repository (CDR) was accessed to identify costs and charges of LUS studies. The University of Virginia Institutional Review Board approved this study.

Patients and Outcomes

The institutional trauma database was queried to identify 6,656 patients admitted to the trauma service between January 2009 and August 2013. Patient demographics, injury characteristics, LUS studies, and associated costs were identified and included for analysis. The primary outcome of interest was a risk-adjusted predictive model for the development of DVT to identify high-risk patients for screening with LUS. A secondary outcome were the model's performance when applied to the entire patient cohort and costs associated with implementation of this model.

Patient Characteristics and Risk Factors

Independent, *a priori* variables that have been previously identified to predispose trauma patients to VTE, as described in earlier literature and which were available from the trauma database, were included for analysis.^{1,3-9} These variables included age, penetrating mechanism of injury, spine fracture, lower extremity fracture, injury severity score (ISS) greater than 15, intensive care unit (ICU) length of stay, transfusion of blood products, spinal cord injury, and pelvic fracture.

Statistical Analysis

Descriptive, univariate analysis was performed to characterize demographics and injury characteristics between patients that underwent any LUS versus patients that were not evaluated with a LUS. Descriptive analysis was then performed among the cohort of patients that underwent any LUS (LUS cohort), stratified by DVT status. Finally, descriptive comparisons were performed among the entire study population stratified by DVT status. Categorical values are reported as a percentage of the total population of each group, and were compared using the Chi-square test or Fisher's exact test as appropriate. Continuous data are reported as mean values and were compared using the Wilcoxon rank-sum test.

Multivariate logistic regression using backwards selection was first performed on the LUS cohort to identify variables predictive of the development of DVT. Modeled factor likelihood ratios (Wald 2 statistic) were utilized to estimate the predictive strength and relative contribution of each covariate with the odds of DVT. Results are reported as adjusted odds ratios (AOR) with 95% confidence intervals (CI). Model performance was

assessed using the calculated Area Under the Receiver Operating Characteristic Curve and the Hosmer-Lemeshow test.

Statistical significance was determined using the standard alpha value of <0.05 . All data analyses were performed using SAS software, version 9.4 (SAS Institute, Cary, NC). All calculated test statistics were used to derive reported two-tailed p-values.

Next, the predictive model was applied to the entire study sample to evaluate the model's predictive performance for DVT. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated at various thresholds to trigger screening, with the threshold serving as the number of high-risk variables present. For example, if the threshold was set to one variable, any trauma patient with one high-risk variable would trigger screening for DVT with LUS. This method was chosen to simulate a simple application of a high-risk screening model that would resemble practical use in the clinical setting. The number of patients to be screened at each threshold was calculated and the cost of implementing a high-risk screening protocol was derived for each threshold using median charges and median total cost – including direct and indirect, fixed and variable expenses – of a LUS over the study period. Finally, the cost per DVT detected was calculated by dividing the total cost of the protocol by the number of DVTs identified.

Results

Patient and injury characteristics for the entire study population are listed in **Table 1**, and stratified by ultrasound status. Over 35% of all patients received at least one LUS during admission. Patients who underwent at least one LUS were older, more severely injured, more commonly underwent surgery, and had longer lengths of stay than patients who did not undergo LUS.

Table 2 displays patient and injury characteristics for the LUS cohort of patients, stratified by DVT status. Patients diagnosed with DVT were more commonly male, more severely injured, more commonly received transfusions of blood products, more commonly underwent surgery, and had longer hospitalizations than patients that were not diagnosed with DVT. **Table 3** displays patient and injury characteristics for the entire study population, stratified by DVT status, where differences in variables similar to those chosen for LUS (Table 2) are observed between patients diagnosed with DVT and those that were not.

Table 4 presents results of the predictive model for DVT, developed using multivariate logistic regression to examine the independent, adjusted associations between risk factors and the diagnosis of DVT among the LUS cohort. Pelvic fracture, transfusion of blood products, spinal cord injury and ICU length of stay were associated with increased risk of DVT. **Table 5** presents results of the predictive model when applied to the entire cohort. Of note, ISS >15 was added to control for severity of injury. All model variables were associated with increased risk for DVT.

Table 6 displays model performance of the predictive model, as well as the total cost, charges, cost per DVT, and charge per DVT of implementing a high-risk screening protocol using this model. ICU LOS was omitted from these calculations because this variable would

not be available for use in a predictive model. Total costs and charges are estimated by multiplying the cost and charge, respectively, per LUS by the number of ultrasounds to be performed over the mean length of stay of the population eligible for screening using a screening frequency of five days. All screening thresholds are characterized by low sensitivity and low PPV, which is a measure of the probability of detecting a DVT among patients indicated for screening.

Discussion

High risk DVT screening remains a subject of controversy within the trauma community. Previous research demonstrates that practitioners disagree on nearly all aspects of DVT screening. One survey conducted by Haut et al. demonstrated that trauma providers disagree about patient characteristics that constitute high-risk variables for the development of VTE, the appropriate frequency for DVT screening, the utility of DVT screening in improving outcomes, and the cost-effectiveness of DVT screening. For example, roughly one-third of respondents reported that published data supports screening of high-risk asymptomatic patients, one-third disagreed that published data exists, and one-third was unsure.² Similar variation was observed among respondents when asked whether high-risk screening is cost-effective.² As a result of uncertainty about the role of high-risk screening, practice patterns vary widely among trauma institutions. In the same survey, 40% of respondents worked at institutions with a written guideline or protocol for DVT screening in high-risk patients, while the remaining 60% worked at institutions without algorithms.²

Consensus guidelines on DVT screening in trauma patients from the Eastern Association for the Surgery of Trauma (EAST) and the American College of Chest Physicians (CHEST), which recommend screening for select populations of high-risk patients, reflect the weakness of underlying data. CHEST guidelines, for example, support screening in asymptomatic “high-risk” trauma patients – those with spinal cord injury, lower-extremity or pelvic fracture, or major head injury – who have received suboptimal thromboprophylaxis.¹ The grading of this recommendation is 1C, indicating that the supporting data contains serious flaws.

This lack of consensus and variability in practice patterns demands attention for important reasons. First, the costs and resource requirements of DVT screening are significant. At our institution, DVT screening is performed routinely in trauma patients with LOS greater than five days. The institutional costs and charges for a routine LUS for DVT screening are \$228 and \$951, respectively. Using these figures, the costs and charges to implement a screening model for patients with any of the identified high-risk variables over the three and a half year study period would have approximated \$598,848 and \$2,497,825, respectively, representing a cost and charge per DVT of \$7,777 and \$32,439, respectively. Second, the clinical benefits of DVT screening remain unclear. While aggressive LUS screening has been shown to detect more DVT – a phenomenon attributable to screening bias⁹ – the impact on relevant clinical outcomes, notably pulmonary embolism, remains unclear. While some studies support the role of DVT screening in reducing PE, other evidence suggests that screening does not reduce PE or mortality.^{6,10}

That the merits of DVT screening remain unclear despite many efforts to define its role should raise concern that many institutions utilize screening in a wasteful manner. Consensus guidelines, which advocate screening only in select patients who have received suboptimal prophylaxis, would suggest that optimal screening rates should be quite low. It is clear, however, that many trauma centers utilize screening at much higher rates, even after controlling for case mix.⁹

The concept of a predictive model to predict risk of DVT in trauma patients has obvious appeal. Because of the morbidity of thromboembolism in trauma, early detection of DVT may enable intervention to reduce PE, notably therapeutic anti-coagulation or placement of an inferior vena cava filter. Furthermore, a protocol-driven approach to LUS utilization may reduce variation in care by simplifying clinical decision-making. Indeed, a number of authors have described criteria for high-risk screening models. For example, one single-institution study identified age, length of stay, ICU days, and GCS as variables associated with the development of DVT.⁵ Although this model correctly classified 97% of patients as not having DVT, only 15% of DVTs were correctly predicted.⁵ Other single-institution studies are plagued by similar limitations, and perhaps most importantly, an inability to demonstrate a reduction in PE as a result of screening.^{8,11,4,12,3}

Meanwhile, authors frequently fail to consider the costs and resource requirements associated with implementation of a screening regimen based on identified high-risk criteria, as well as the risks of intervention once an asymptomatic DVT has been identified. For example, a recent meta-analysis suggests that the inferior vena cava filter (IVCF), a commonly utilized therapeutic option following the discovery of LUS DVT in trauma patients, offers little, if any, protection from PE and that the risks of the procedure likely outweigh any benefits.¹³ In fact, the authors estimated that the number of patients needed to treat with IVCFs to prevent one fatal PE exceeds 1,000.¹³

Our findings demonstrate what many authors have already illustrated in previous work – that single-institution, retrospective analysis can be used to identify risk factors associated with DVT. In addition, we developed a clinical predictive model that demonstrated excellent accuracy and goodness-of-fit, as measured by the area under the receiver operating characteristic (0.865) and Hosmer-Lemeshow test (0.051). However, from a practical perspective, the most sensitive variation of the model detects only slightly more than half of all DVTs and would require screening of approximately one-third of all trauma patients admitted to our institution.

This study has several important limitations, including the use of retrospectively-collected data from our institutional trauma database. Errors or missing data, particularly regarding the incidence of DVT, could alter our findings and the relationships between risk factors and odds of DVT. The effect of this limitation is presumably limited because all chart review has been performed by experienced nurse abstractors. Another limitation was our inability to identify the indication – screening or clinically-indicated – for the performance of LUS in the study population. The inclusion of clinically-indicated studies, however, should improve the apparent performance of our models, if one accepts that a DVT is more likely to be discovered in a study ordered for clinical indications than as part of a screening regimen. We

would therefore expect the exclusion of clinically-indicated studies to further strengthen our conclusions. Finally, our study is subject to the same risks for surveillance bias that we have noted for other studies regarding this topic. Because the underlying true incidence of DVT among trauma patients is unclear, and because of the differences in patient characteristics between patients that underwent LUS and those that did not, the resulting relationships that we identified between patient characteristics and odds of DVT may be inaccurate. For example, the overall rate of DVT in entire study population is likely higher than the 2.2% rate derived by dividing the total number of diagnosed DVTs by the entire admitted population. In fact, a subset of the 4,306 patients that did not undergo LUS undoubtedly developed clinically-silent DVT that may have been detected by a more rigorous screening protocol; this assertion is supported by well-documented evidence of surveillance bias in DVT screening. However, the clinical relevance of undetected, clinically-asymptomatic DVTs must be questioned, particularly in the absence of strong evidence that aggressive screening reduces PE.

Although it is beyond the scope of this study, the detection of an asymptomatic DVT as part of a screening program results in additional costs beyond those associated with the performance and interpretation of LUS. The incremental costs of lab tests, medications, procedures, complications, and associated care would need to be considered in a formal cost-effectiveness analysis. However, such an analysis cannot be credibly conducted without a better understanding of the relationship between LUS screening and meaningful clinical outcomes (i.e. reduction in the incidence of PE).

Porter and colleagues have advocated for the use of “value” as a metric to evaluate clinical outcomes as a function of cost, which would function as a tool to eliminate wasteful practices in American healthcare.^{14–17} As healthcare institutions and providers are increasingly challenged to contain costs, such an approach will allow consumers to compare systems on the basis of both quality and cost. Providers that provide high-quality care at low-cost would therefore deliver greater value than providers with similar outcomes but higher cost. Bangle et al. attempted to define value for LUS screening in trauma and reported a metric that justified screening in high-risk patients; however the analysis was plagued by the use of DVT as the outcome of interest, not pulmonary embolism or a broader measure encompassing complications of treatment.¹⁸ Again, the absence of high-quality evidence linking LUS screening to reductions in PE makes the derivation of value impossible at the present time. As a result, future efforts should be focused on defining this relationship in a prospective, multi-center trial.

In summary, we have shown that the development of a practical, clinically-relevant predictive model for DVT in trauma patients is challenged by poor sensitivity, positive predictive value, and high resource requirements. While algorithms for DVT screening in trauma have wide appeal, these protocols may be resource-intensive, costly, and ultimately only marginally effective in reducing PE, if at all. The appropriate role for DVT screening in trauma patients is most likely quite limited, utilized for positive clinical findings, and at the discretion of the judicious practitioner for only very select high-risk patients. High-risk screening protocols must be judged in terms of practicality and cost-effectiveness, and data,

particularly from single-institution studies, should be judged with these considerations in mind.

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Table 1

Patient and Injury Characteristics Stratified by U/S

Variable	U/S	No U/S	<i>p</i>
n	2,350	4,306	
Age (mean)	54.5	50.4	<0.0001
Female	38.7%	38.6%	0.92
ISS (mean)	13.5	8.6	<0.0001
LOS (mean)	13.3	4.4	<0.0001
ICU Days (mean)	5.6	0.9	<0.0001
Penetrating	4.5%	6.7%	0.0003
Pelvic Fracture	16.7%	6.4%	<0.0001
Lower Ext Fracture	33.3%	24.7%	<0.0001
Head Injury (AIS>3)	30.6%	23.3%	<0.0001
Spine Fracture w/o SCI	38.8%	21.9%	<0.0001
C/S fx with SCI	1.3%	0.3%	<0.0001
T/S fx with SCI	1.5%	0.1%	<0.0001
S/S fx with SCI	0.1%	0.0%	0.02
Operation	60.2%	39.7%	<0.0001
Transfusion	43.2%	14.4%	<0.0001
Transfused 4 or more units	4.5%	1.0%	<0.0001

Table 2

Characteristics of U/S Patients Stratified by DVT Status

Variable	DVT	No DVT	<i>p</i>
n	145	2,205	
Age (mean)	56.0	54.4	0.41
Female	30.3%	39.2%	0.03
ISS (mean)	18.5	13.2	<0.0001
LOS (mean)	27.6	12.3	<0.0001
ICU Days (mean)	14.6	5.03	<0.0001
Penetrating	4.1%	4.5%	0.84
Pelvic Fracture	28.3%	16.0%	0.0001
Lower Ext Fracture	33.8%	33.2%	0.89
Head Injury (AIS>3)	47.6%	29.4%	<0.0001
Spine Fracture w/o SCI	46.2%	38.3%	0.06
C/S fx with SCI	3.5%	1.2%	0.02
T/S fx with SCI	3.5%	1.4%	0.05
S/S fx with SCI	0.7%	0.1%	0.05
Operation	72.4%	59.4%	0.002
Transfusion	72.4%	41.3%	<0.0001
Transfused 4 or more units	10.3%	4.1%	0.001

Table 3

Characteristics of U/S Patients Stratified by DVT Status

Variable	DVT	No DVT	<i>p</i>
n	145	6,510	
Age (mean)	55.9	51.8	0.02
Female	38.8%	30.8%	0.05
ISS (mean)	18.5	10.1	<0.0001
LOS (mean)	27.8	7.0	<0.0001
ICU Days (mean)	14.5	2.3	<0.0001
Penetrating	5.9%	4.1%	0.36
Pelvic Fracture	28.8%	9.6%	<0.0001
Lower Ext Fracture	34.3%	27.6%	<0.0001
Head Injury (AIS>3)	47.3%	25.4%	<0.0001
Spine Fracture w/o SCI	46.6%	27.5%	<0.0001
C/S fx with SCI	3.4%	0.6%	<0.0001
T/S fx with SCI	3.4%	0.6%	0.00
S/S fx with SCI	0.7%	0.0%	0.06
Operation	72.6%	46.4%	<0.0001
Transfusion	72.6%	23.5%	<0.0001
Transfused 4 or more units	10.3%	2.1%	<0.0001

Table 4Results of Multivariate Regression in U/S Cohort^{*I*}

Variable	OR	95% CI	Wald χ^2	<i>p</i>
ICU Length of Stay	1.05	(1.04 - 1.07)	54.59	<.0001
Transfusion	2.36	(1.58 - 3.52)	17.79	<.0001
Spinal Cord Injury	2.04	(1.01 - 4.09)	3.99	0.05
Pelvic Fracture	1.93	(1.30 - 2.88)	10.48	0.001

^{*I*}
c-statistic = 0.76

Table 5Results of Multivariate Regression in Entire Cohort¹

Variable	OR	95% CI	Wald χ^2	<i>p</i>
ISS > 15	1.03	(1.01 - 1.04)	10.01	0.002
Transfusion	3.72	(2.45 - 5.64)	37.96	<.0001
Spinal Cord Injury	2.20	(1.05 - 4.59)	4.40	0.04
Pelvic Fracture	2.34	(1.55 - 3.53)	16.50	<.0001

¹
c-statistic = 0.865

Table 6

Predictive Model Performance and Associated Costs

Risk Factors	Sensitivity	Specificity	PPV	NPV	Patients Screened	DVTs Detected	Total Cost	Total Charge	Cost per DVT detected	Charge per DVT detected
1	52.7%	74.3%	4.4%	98.6%	1,750	77	\$598,848	\$2,497,825	\$7,777	\$32,439
2	28.1%	95.6%	12.9%	98.3%	318	41	\$108,819	\$453,891	\$2,654	\$11,071
3	0%	99.9%	0%	97.8%	5	0	\$1,711	\$7,137	\$0	\$0