RESEARCH ARTICLE

Screening Guidelines for Venous Thromboembolism Risk in Hospitalized Children Have Low Sensitivity for Central Venous Catheter–Associated Thrombosis

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ABSTRACT

OBJECTIVES: Local pediatric screening guidelines for venous thromboembolism (VTE) are developed from incomplete pediatric data and extrapolated from adult data in which immobility is a major risk factor. We hypothesized that screening guidelines centered on immobility are inadequate for identifying children at risk of central venous catheter (CVC)–associated VTE.

METHODS: This retrospective case-control (4:1) study at an academic, quaternary-level, free-standing children's hospital applied screening guidelines for VTE risk to all cases of VTE from July 2012 to April 2014. Cases and controls were classified as "at risk" or "not at risk" of VTE by guideline criteria. These guidelines assessed VTE risk factors, including CVC, as reported in the pediatric literature.

RESULTS: VTE prevalence was 0.5 per 100 admissions. Sixty-nine of 114 patients with radiographically confirmed VTE were classified as being "at risk" by the guidelines, with a sensitivity of 61%, specificity of 90.8%, a positive predictive value of 2.4%, and negative predictive value of 99.8%. There was no difference in screening guidelines sensitivity for identifying CVC-associated VTE versus non–CVC-associated VTE. Half of the 45 patients with VTE who were not captured as being "at risk" did not have decreased mobility, the entry point to the algorithm, and 80% of these patients had a CVC.

CONCLUSIONS: Screening guidelines have low sensitivity for identifying hospitalized children at increased risk of both CVC-associated and other VTE events. Decreased mobility is not a requirement for CVC-associated VTE. Risk factors extrapolated from adult data are insufficient for identifying children at risk of VTE.

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The prevalence of venous thromboembolism (VTE) has increased from 34 to 58 per 10 000 admissions from 2001 to 2007 across all age groups of hospitalized children.[1] The increase in the prevalence of hospital-acquired VTE has been attributed, in part, to children surviving with increasingly complex medical disease and the technologic support required for this care, including central venous catheters (CVCs). VTE is associated with significant morbidity in children: pulmonary emboli occur in up to 25% of VTE, half of which are secondary to undiagnosed VTE.[2,3] In addition, children are at higher risk of post-thrombotic syndrome than adults; chronic venous insufficiency after VTE occurs in >25% of children, resulting in pain, edema, or skin ulceration months to years after the VTE event.[4,5] Increased hospital length of stay of 8 days and excess costs of $27 000 have been attributed to each pediatric VTE event.[6]

Given this critical and growing problem, several important pediatric organizations and regulatory bodies (Solutions for Patient Safety, Joint Commission, Surgeon General) have charged pediatric hospitals with developing initiatives to prevent VTE.[7] Although risk factors for VTE in children have been identified, there are large gaps in the pediatric literature regarding the usefulness of VTE screening and the efficacy of pharmacologic or mechanical prophylaxis in preventing VTE. A combination of expert consensus, strategies derived from adult data, and the limited pediatric data form the basis of any current pediatric guidelines for VTE screening.[2,3,8] Accordingly, our quaternary-care children's hospital has developed VTE screening guidelines with high-risk criteria (Fig 1) on the basis of published local data and other limited evidence in the literature, including patient age, ICU or surgical status, CVC use, and other risk factors.[2,9–19]

The presence of a CVC is the single most important risk factor for the development of VTE in children but not in adults.[20] It is not clear if screening guidelines centered on immobility, as extrapolated from the adult-based evidence, will be adequate for assessing the risk of CVC-associated VTE in children. In this retrospective case-control study, we aimed to determine the sensitivity and specificity of the VTE screening guidelines currently in use in our institution for hospitalized children. We hypothesized that the screening guidelines generally has low sensitivity and specificity, and even more so in patients with CVC-associated VTE.

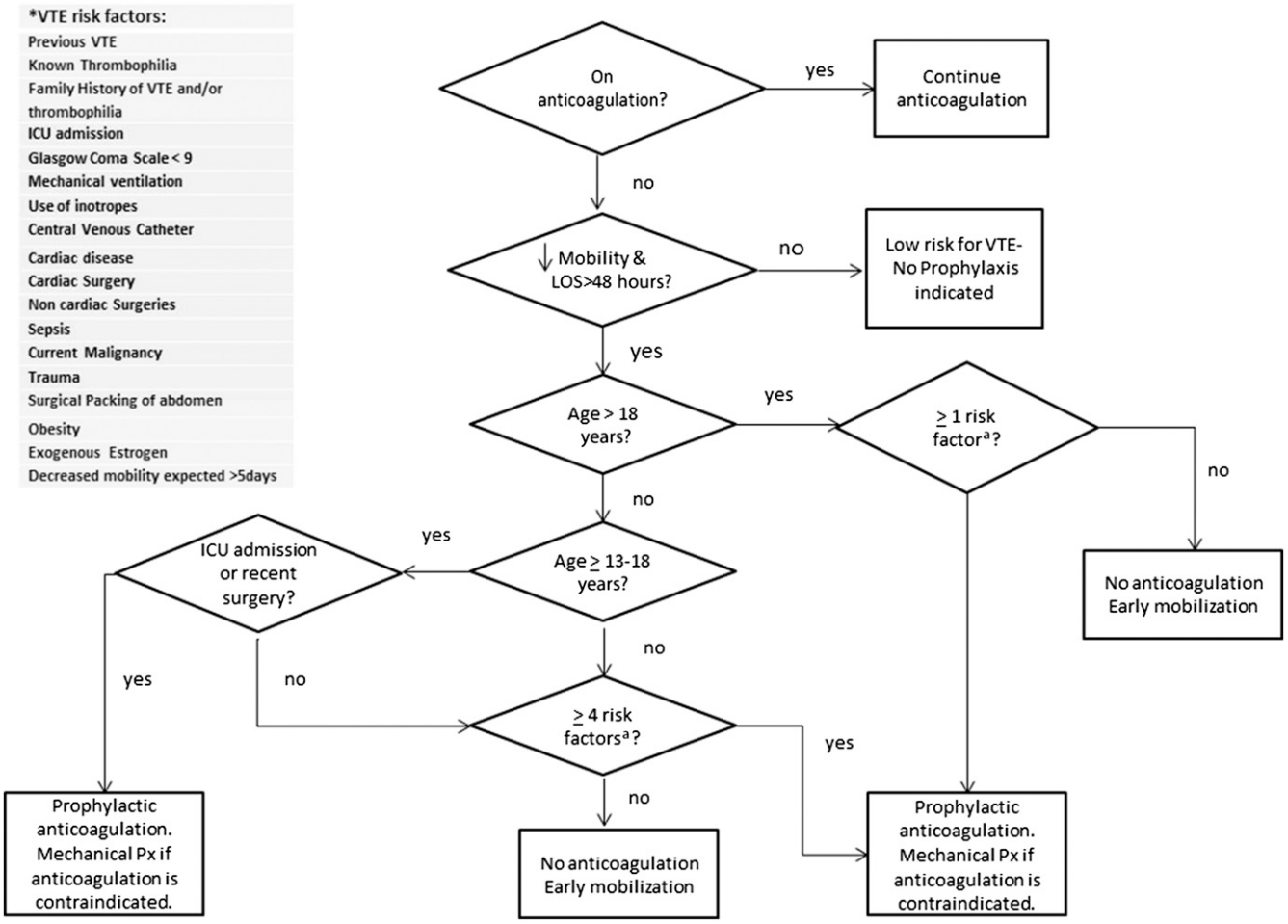

FIGURE 1 The Children's Hospital of Wisconsin's VTE Screening Guideline. A/C, anticoagulation; LOS, length of stay; Px, prophylaxis.

METHODS

This retrospective case-control study was approved by the institutional review board at our free-standing children's hospital. Cases were identified as all children in the Children's Hospital of Wisconsin's VTE thrombosis database, which includes all radiographically confirmed VTE in hospitalized children from July 2012 to April 2014 collected by prospective surveillance of radiology imaging reports, hematology consults, and pharmacy records for new anticoagulation orders. Included VTEs were all deep vein thrombosis (including mesenteric and cerebral sinuses) or pulmonary embolus. Superficial thrombophlebitis, CVC fibrin sheath, and arterial thrombosis were excluded. We restricted our sample to patients who were ≤18 years of age and the first VTE event for the study period. Patients already receiving anticoagulation at the time of hospitalization and those with non–hospital-acquired VTE (ie, present upon admission) were excluded. Controls were selected as the next 4 consecutive hospital admissions after an admission of a VTE case in the database.

The Children's Hospital of Wisconsin's VTE screening guidelines (Fig 1) was applied retrospectively to each case and control, and each was then classified as "at high risk" or as "not at high risk" of VTE. Hospital records were reviewed for demographic variables and the various risk factors for VTE incorporated in the screening guidelines. We defined CVC-associated VTE as a thrombosis within the same vessel as the CVC. Decreased mobility was defined as a state of altered mobility from baseline. For example, a child who is normally wheelchair dependent and able to go to school but is now on bedrest would be considered to have decreased mobility. Similarly, an infant who cannot be held would be considered to have decreased mobility. Obesity was defined as a BMI ≥95% for age.

The prevalence of VTE was defined as cases of hospital-acquired VTE per 100 patient admissions during the study period. χ^2 Test was used to compare the groups, and Fisher's exact test was used instead when sample sizes were small. Sensitivity, specificity, positive predictive value, negative predictive value (NPV), and their 95% confidence intervals (CIs) were calculated for the VTE screening guidelines. Ten random subsamples of the control group who had the same age distribution as the VTE group were collected, and the mean specificity was calculated from these values. A classification tree analysis that used the Gini method was performed with the binary outcome of VTE versus control and included all the screening guidelines risk factors as predictors. The terminal nodes of the tree were set to be ≥5 and the split nodes were ≥10. A 10-fold cross-validation was used for testing. For all comparisons, $P < .05$ was considered statistically significant.

RESULTS

There were 114 cases of VTE of 21 919 hospital admissions during the study period, for a VTE prevalence of 0.5 per 100 admissions. Three hundred seventy-one controls were selected by admission date. The distribution of risk factors in the cases of VTE and the control groups is shown in Table 1. Although with a similar median age, the 2 groups were significantly different in numbers of patients per age group (<13 years versus 13–18 years); the control group had more subjects in the younger age group (83% vs 63%; $P < .001$). The sensitivity of the VTE screening guidelines was 61% (69 of 114; 95% CI: 51–70%) and the specificity was 91% (95% CI: 87–94%) (Table 2). The positive predictive value of the screening guidelines was 2.4% (95% CI: 1.9–3.1%), and the NPV was 99.8% (95% CI: 99.8–99.9%).

To adjust for the difference in age distribution between the control group and the VTE group, we randomly sampled 108 subjects <13 years old and 63 subjects aged between 13 and 18 years from the control group. The total number of subjects in the control group was therefore 171. We performed this random sampling 10 times and found that the specificity ranged from 84.8% to 91.2%, with a mean of 88.9%. There was no significant difference between the sensitivity of the guidelines for identifying those at risk of CVC-associated VTE (35 of 64 patients with CVC-associated VTE were identified at high risk, with a sensitivity of 55%; 95% CI: 42–67%) versus non–CVC-associated VTE (34 of 50 identified at risk of VTE, with a sensitivity of 68%; 95% CI: 53–81%).

Among the VTE cases who were not captured as being at risk of VTE by the guidelines, 71% (32 of 45) had CVCs. Approximately half of the patients (51%; 23 of 45) who were incorrectly classified as "not at risk for VTE" by the screening guidelines did not have decreased mobility from baseline. Sixty percent of patients in our study (27 of 45) who were not captured by the screening guidelines as being at "high risk for VTE" had an ICU admission.

A classification tree analysis was performed (Fig 2) with the binary outcome of VTE versus control and included all of the screening guidelines risk factors as predictors. We found that the most import predictor was "current CVC." A total of 85 of 131 subjects (65%) with current CVC were in the VTE group, whereas only 8% without CVC had VTE. For those without CVC, the tree analysis further delineated the patients by age 13: 28% of those aged ≥13 years were in the VTE group, whereas only 3% of those aged <13 years had VTE. The next split was for those aged ≥13 years according to "exogenous estrogen exposure."

DISCUSSION

Current efforts to assess VTE risk and apply screening guidelines for VTE prophylaxis are based on limited evidence in hospitalized children. An objective evaluation of these screening guidelines for CVC-associated and other hospital-acquired VTE is needed to assess their effectiveness given the risks associated with misclassification of VTE risk, such as bleeding from unnecessary prophylaxis or VTE from missed prophylaxis. Our study evaluated the validity of a screening algorithm for real-time identification and stratification of hospitalized children for VTE risk. This study provides new information on the sensitivity and specificity of clinical guidelines to determine VTE risk in hospitalized children, including the risk of CVC-associated VTE. Although this study

TABLE 1 Distribution of Risk Factors for VTE Between Cases and Controls

VTE Risk Factors	VTE Cases (n = 114)	Controls (n = 371)	P
Age, median (IQR), y	2.6 (0.2–14.5)	4.0 (1.0–10)	.52
Age >13 years	42 (37)	65 (18)	<.001
Male sex	60 (53)	184 (50)	.57
Previous VTE	9 (8)	3 (0.8)	<.001
Known thrombophilia history	8 (7)	0 (0)	<.001
Family history of VTE and/or thrombophilia	14 (12)	5 (1)	<.001
Decreased mobility from baseline	79 (69)	163 (44)	<.001
ICU admission	87 (76)	79 (21)	<.001
Glasgow Coma Scale <9	32 (28)	13 (4)	<.001
Mechanical ventilation	45 (39)	17 (5)	<.001
Use of inotropes	33 (29)	14 (4)	<.001
CVC	85 (75)	46 (12)	<.001
Cardiac disease	37 (32)	44 (12)	<.001
Cardiac surgery	28 (25)	26 (7)	<.001
Noncardiac surgery	31 (27)	155 (42)	.0051
Sepsis	42 (37)	47 (13)	<.001
Current malignancy	8 (7)	15 (4)	.19
Trauma	14 (12)	19 (5)	.0079
Surgical packing of abdomen	11 (10)	3 (1)	<.001
Obesity	34 (30)	100 (27)	.55
Exogenous estrogen	6 (5)	0 (0)	<.001
Pulmonary hypertension	5 (4)	7 (2)	.16
CPR	7(6)	1 (0.3)	<.001
Chronic/active inflammatory disease	8 (7)	18 (5)	.37
DKA	1 (0.9)	2 (0.5)	.55
Burn	0 (0)	7 (2)	.21
Lower extremity fracture	4 (4)	7 (2)	.30
Operative pelvic fracture	1 (0.9)	3 (0.8)	>.99
Spinal cord injury	0 (0)	3 (0.8)	>.99

Data are presented as n (%) unless otherwise indicated. CPR, cardiopulmonary resuscitation; DKA, diabetic ketoacidosis; IQR, interquartile range.

may be perceived as a "negative" study, it does evaluate a VTE screening algorithm that is commonly used in pediatric hospitals. It is important to recognize the limitations in the sensitivity of local guidelines and the need for validation of these tools.

Our screening guidelines has low sensitivity for identifying children at increased risk of both CVC-associated and other VTE events. The sensitivity of the VTE screening guidelines was not different for CVC-associated VTE versus VTE events not associated with a CVC. A sensitivity of 61% for a screening guideline is poor by all measures and misses almost 40% of patients who may benefit from VTE prophylaxis. The algorithm did have a high specificity and NPV, supporting the practice model that only high-risk patients are recommended for prophylactic anticoagulation. This high NPV is influenced by a low VTE prevalence in this population.

TABLE 2 Sensitivity and Specificity of Screening Guidelines for Risk of VTE

	VTE Cases, n	Controls (No VTE), n	Total, n
Classified as "high risk for VTE" by guidelines	69	34	103
Classified as "not at high risk for VTE" by guidelines	45	337	382
Total	114	371	485

Sensitivity = 69 of 114 (61%; 95% CI: 51–70%); specificity = 337 of 371 (91%; 95% CI: 87–94%).

Other pediatric VTE screening validation studies that used billing data for identification of cases of VTE, such as Sharathkumar et al[15] (57–70% sensitivity and 80–88% specificity) and Branchford et al[18] (sensitivity of 45% and specificity of 95%), found similar rates in identifying patients at risk of VTE. In comparison with these studies, all risk factors included in our screening guidelines can be ascertained in real time, with the goal of identifying and perhaps providing prophylaxis to high-risk patients. A limitation of screening based on duration of exposure to ventilation or hospital admission is that the high-risk status is not reached until after the patient has already been exposed to the risk.

Previous studies in adults identified decreased mobility as the main factor leading to VTE.[21] The strong association between immobility and VTE has been clearly shown in the adult population and is supported by pediatric retrospective case-control studies.[11,14–17] A number of factors associated with VTE identified in pediatric retrospective studies are thought to confer risk due to their contribution to decreased mobility; these include obesity, prolonged hospitalization, and increasing severity of injury, mechanical ventilation, and ICU admission. Our institution's VTE screening guideline was designed with decreased mobility as the main factor for VTE risk stratification and entry point in the algorithm. However, approximately half of the cases who did not classify as being at risk of VTE (23 of 45) did not have decreased mobility from baseline, suggesting that pediatric inpatients can still remain at risk of, and develop, VTE in the absence of decreased mobility from the baseline. This finding is particularly relevant in patients with CVC, which accounted for 80% of the patients who developed VTE while at baseline mobility.

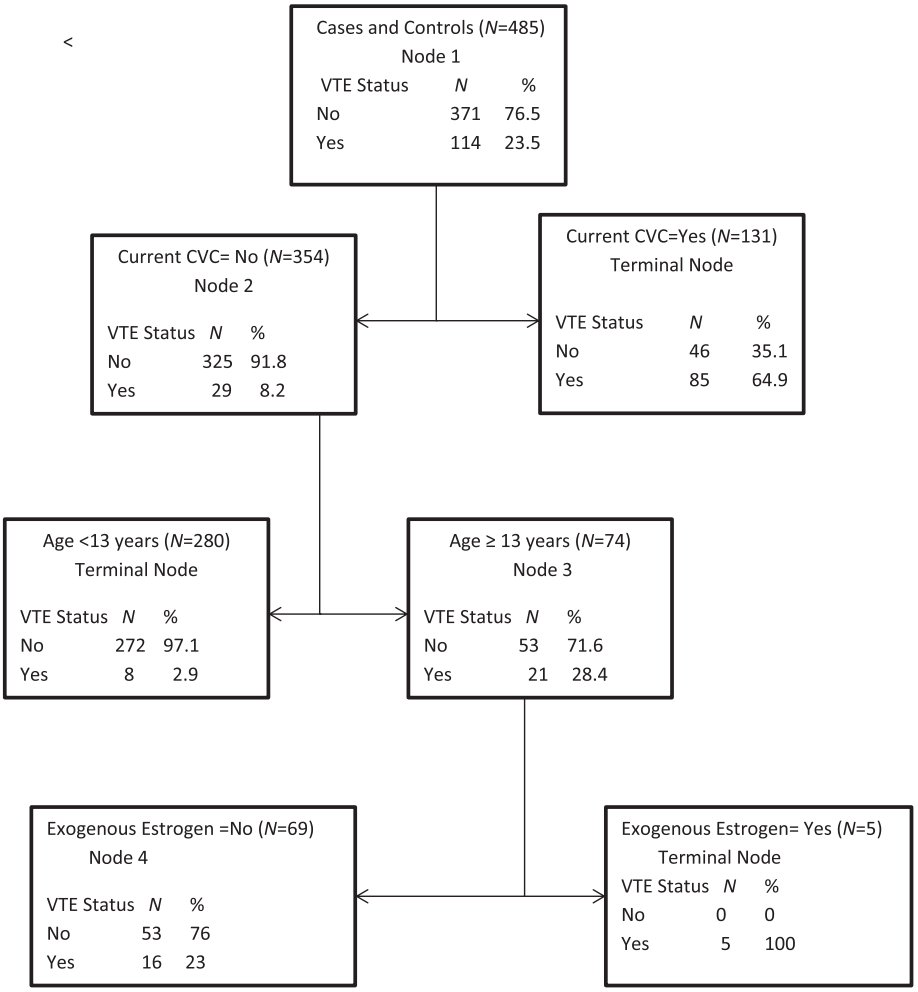

FIGURE 2 Tree analysis for risk factors for VTE.

Of the VTE cases who were not captured by the screening algorithm as being at risk of VTE, 71% (32 of 45) had a CVC, which is a major risk factor in the development VTE in hospitalized children.[9,11,15,16,22] CVC is the greatest risk by tree analysis and carries greater weight than the other risk factors identified.

Several studies that used screening for VTE in critically ill patients showed that admission to an ICU is a risk factor for VTE in hospitalized children.[11,17,18] The incidence of VTE in adult ICUs is very high, particularly in patients receiving no prophylaxis (25–31%) compared with those who receive some form of prophylaxis (11–16%).[21] Sixty percent of the cases in our study who were not captured as being high risk of VTE by the screening guidelines (27 of 45) had an ICU admission. A large number of these patients were <13 years of age, and patients in this age group require a total of 4 risk factors by the screening guidelines to be considered at risk of VTE. Critical illness associated with admission to the ICU may convey sufficiently increased VTE risk such that 4 additional risk factors may not be necessary.

When analyzed by age group, more patients in the control group were in the <13-year age group compared with VTE cases. This finding is representative of the typical age of inpatients at a tertiary care children's hospital and consistent with previous studies showing the rates of VTE being highest in infants and in teenagers.[1,21] To eliminate the effect of age on VTE rate, repetitive sampling of the control group was performed to mimic the age distribution in the cases, with very similar results in specificity. This finding may be due to the high number of CVC-associated VTE (65 of 114) in this study, which has less of an adolescent predilection.

This study has multiple limitations, including its single-center, limited sample size and retrospective application of the guidelines to patients known to have developed VTE, particularly for collecting more subjective variables such as "decreased mobility from baseline." Furthermore, we were limited in our understanding of factors with low prevalence but which confer high VTE risk, such as thrombophilia or previous VTE

history. This study did not evaluate if prophylaxis would be effective in preventing VTE if applied to the patients identified as at risk of VTE, and we did not collect data on mechanical or pharmacologic prophylaxis use during the study period. Despite the low sensitivity of the existing version of these guidelines, these data can be valuable for hospitals to develop optimal screening for VTE risk. Clinically useful screening guidelines not only need to accurately classify children as being at high or low risk of VTE development, they also need to be simple and easy to incorporate in real-time care, with objective, accessible risk factors upon hospital admission and transfer to higher level of care.

We plan to restructure our local screening algorithm for better risk stratification and guidance of prophylaxis by separate risk assessment for patients with CVC, eliminating decreased mobility as a mandatory entry point in these children and requiring fewer additional risk factors. This new suggested screening algorithm will undergo periodic evaluation with the goal of optimizing the VTE risk classification in hospitalized children, and with the overarching aim to mitigate the risk of VTE and the side effect of anticoagulation in a balanced and the safest possible way.

CONCLUSIONS

A screening guideline for VTE risk in hospitalized children has low sensitivity and higher specificity for identifying patients at increased risk of both CVC-associated and other VTE events. Decreased mobility is not a requirement for CVC-associated VTE, with more than half of the instances of screening algorithm failure to classify patients at risk of VTE occurring in patients without decreased mobility from baseline. Risk factors extrapolated from adult data are insufficient for identifying pediatric patients at risk of VTE.

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