By Andrea S. Prentiss, RN, MSN, CNS-BC, ARNP-BC, CCRN

**Background**

The incidence of venous thromboembolism in children has increased dramatically, with most cases occurring in children with cancer, surgery, trauma, congenital heart disease, and systemic lupus erythematosus. Early assessment of risk factors present in children would minimize morbidity and mortality from these events.

**Objectives**

To evaluate the reliability and validity of a tool for assessing risk for venous thromboembolism in children.

**Methods**

The tool was developed after a review of the literature with assessment of content validity by a multidisciplinary team of experts. Patients' charts were reviewed retrospectively to establish reliability and validity of the tool. A $P$ value less than .05 was considered statistically significant.

**Results**

Thirty-five charts were assessed for tool validity and were found to be statistically significant for all 3 risk score assessment categories. Logistic regression was used to assess 1001 patients' charts for internal consistency, which was found to be high ($\chi^2 [n = 1001] = 100.6, P<.001$). Results indicated that most patients at risk for venous thromboembolism were between the ages of 13 and 17 years, with females having more than 7 times greater risk than males.

**Conclusions**

Descriptive statistics show that the assessment tool displays strong reliability and validity. Results validated a significant relationship between the risk score and the incidence of venous thromboembolism. Findings suggest that use of the assessment tool could significantly reduce adverse outcomes associated with venous thromboembolism in children. (American Journal of Critical Care. 2012;21(3):178-184)
Thromboembolic events have historically been considered an adult phenomenon. However, the reporting of events in children and neonates has been increasing because of improved diagnosis and care of children with congenital heart disease, cancer, and prematurity. Thromboembolic events may go unreported and undiagnosed, as children often cannot report symptoms.

According to the Institute for Healthcare Improvement, venous thromboembolism (VTE) includes pulmonary embolism, asymptomatic calf vein thrombosis, and symptomatic deep vein thrombosis (DVT). For adult patients seen in the hospital, assessment and early prophylaxis for VTE has become a routine of care. Recognizing the mortality and morbidity associated with VTE, multiple national groups have identified regulations for assessing, preventing, and reporting these events.

The National Quality Forum endorsed the use of a multidisciplinary approach for risk assessment and prophylaxis guidelines during hospitalizations and for establishing evidence-based guidelines for inpatient and postdischarge prophylaxis. As of July 31, 2008, the Centers for Medicaid and Medicare Services implemented requirements in the adult population stating that hospital reimbursement will be for services not related to complications when a DVT or pulmonary embolism develops after hip or total knee replacement. They have implemented a pay for performance initiative empowering physicians and nurse practitioners to voluntarily report VTE occurrences and enabling them to receive bonus payments from Medicare. Hospitals already have mandatory requirements for reporting patients’ admission assessments for VTE and the numbers of patients receiving prophylaxis on the basis of this assessment. Those hospitals not meeting this requirement could lose 2% of Medicare reimbursement for the year.

Venous thromboembolism is an extremely serious and potentially fatal condition and is considered very preventable. The literature concerning assessment, complications, and prevention in adults is abundant, but little is known about pediatric and neonatal patients.

An extensive literature review was conducted by using electronic and manual searches of research literature. Once identified, reference lists for the studies included in the review were considered, and additional studies found and used by other authors in this area were obtained and reviewed. Literature searches were conducted in MEDLINE and CINAHL for all indexed years by using the following key words: risk assessment tool, pulmonary embolism, pediatric and neonates, and deep venous thrombosis. Search fields were narrowed to age ranges from birth to 21 years of age. A neonatal/pediatric specific risk assessment tool was not found in the literature review. Scarvelis and Wells (as cited by Ramzi and Leeper) adopted a set of rules for clinical prediction of DVT that was based on a previously established set of clinical criteria for pulmonary embolism in adults that had been modified for use in the neonatal/pediatric population. However, to date there is not a pure neonatal/pediatric risk assessment scoring system available in the literature. The literature review confirmed the lack of research published on the assessment and risk associated with VTE in neonates and children.

A pediatric study in 2004 summarized findings from approximately 5000 calls received in the 1-800-NO-CLOTS consultation services. Data compiled from 1776 children with systemic thromboembolism diagnosed between September 1996 and August 2001 indicated that 74% of the children (n = 1312) had venous thrombus and 18% (n = 230) of these were neonates. Infants less than 1 year old (47%, n = 841) denoted the largest distinct pediatric age group, and this included 26% neonates (n = 464). The neonatal period (defined as less than 1 month of age) accounted for 57% (n = 221) of the thromboembolic events while the remaining 43% (n = 170) had a clot develop after the first month of life.

Other pediatric research described annual incidence rates of 0.07 to 0.14 per 10,000 children with rates between 4.9 and 8 per 10,000 admissions to a pediatric hospital and 24 per 10,000 admissions to a neonatal intensive care unit. More recent estimates...
from a retrospective study from 2001 to 2007 indicate that the annual rates have increased by 70% to 58 cases per 10,000 hospital admissions seen in all pediatric age groups. Although pediatric rates pale in comparison to the annual 200,000 to 600,000 estimated adult rates published in the white paper from the American Public Health Association, the morbidity and mortality associated with them are as significant.

**Risk Factors for Pediatric Deep Vein Thrombosis**

Research indicates central venous catheters as the most frequent cause of pediatric DVT, with rates being as high as 90% in the neonatal population and greater than 50% in all other age groups. Short-term use of a central venous catheter in children is described as having higher risks than long-term use of central catheters. Other risk factors identified for pediatric DVTs include previous DVT history, sepsis or acute infection, oncologic malignant growths, preexisting coagulation disorders, surgery/trauma, congenital heart disease, systemic lupus, obesity, and immobility. Children with musculoskeletal sepsis, osteomyelitis, or staphylococcal infections may be at increased risk of VTE developing, with staphylococcal virulence playing a potentially large role in DVT formation. The literature also demonstrates that most children (90%) had at least 1 associated condition and approximately 51% had 2 or more associated conditions. Perinatal asphyxia, infection, congenital heart disease, and hypovolemia have been identified as risk factors in the neonatal population.

**Mortality and Morbidity**

Earlier research indicates that the mortality risk related to pediatric VTE is 1% to 2%, compared with all-cause related mortality at 14% to 23% and cumulative incidence of a first VTE recurrence of approximately 9% after 3 years of follow-up, with rates reaching as high as 21% in other studies. More recent studies describe the mortality rate for patients with a VTE diagnosis as 8%, compared with 1% for other hospital diagnoses during the same period. The mean length of stay for patients with a diagnosis of VTE was 28 days compared with 6 days for patients admitted to the hospital for other reasons.

VTE is an increasing problem in infancy, childhood, and adolescence. Health and related costs associated with VTE are disproportionately higher in children as a result of its long-term complications. With accurate assessment and rapid treatment, children have an excellent chance for recovery from severe VTE events. Although postthrombotic syndrome could significantly limit aerobic activities necessary for normal childhood development, children could potentially live 60 to 80 years after a VTE event.

**Methods**

**Design, Sample, and Procedure**

Following an extensive literature review, a tool for assessing risk for VTE in children was developed. To establish content validity, the tool was reviewed by a multidisciplinary team of experts that included pediatric nurses, pediatricians, and pediatric intensivists, surgeons, radiologists, and pulmonologists.

After data were extrapolated from adult thromboembolism assessments and review of existing pediatric literature, the pediatric risks were categorized with points assigned for severity. Risk factors assigned 1 point each were in category 1, factors assigned 2 points each were in category 2, and factors assigned 3 points each were in category 3. Scores within each risk factor category are added, and the 3 category scores are compiled to provide a total risk score. Risk assignment is then based on the total risk score, with 1 point being potential risk, 2 points medium risk, and 3 or more points indicating high risk for VTE development. Patients were to be assessed for the presence of VTE at the point of admission through history and physical examination performed by physicians or nurses practitioners.

The assessment tool was then approved by the Department of Pediatrics for implementation. The hospital’s institutional review board approved the study to determine the reliability and validity of the risk assessment tool. Pilot testing was conducted with 20 nurses within different pediatric inpatient areas with different nursing shifts to pretest the tool. Interdisciplinary education was performed to ensure proper use of the form, and the form was implemented in November 2008, with each admitted patient having an assessment of documentation of risk.

Using the Central Limit Theorem, random sampling of 35 forms was used to determine the validity of the VTE risk assessment tool, correlating the identified risk assessment score with the medical record. Random, retrospective chart review was done by compiling a list of pediatric inpatient admissions.
The chart of every fifth patient was reviewed for those patients with preprinted admission order sets with the VTE risk assessment in place or containing specific orders written to clarify the risk score. In the event that the fifth identified record did not meet eligibility requirements, the review went to the next identified patient.

Reliability was assessed on the basis of random, retrospective chart reviews on 1001 children admitted to the pediatric inpatient area with the preprinted admission order sets with the VTE risk assessment in place or containing specific orders written clarifying the risk score between November 2008 and November 2009. Data were collected retrospectively to compare the patient’s medical record and the assessment tool to determine the risk for development of VTE. Demographic information included age, sex, and risk factor information on the risk assessment tool. Patients were also assessed for the presence of VTE.

**Statistical Analysis**

Data were analyzed by using the Statistical Package of the Social Sciences Program (SPSS) for Windows 13 (IBM SPSS, Armonk, New York). The research questions were answered by the Cramér V association test and a logistic regression model. A P value less than .05 was considered statistically significant.

In order to validate the risk assessment tool, the documented risk score was compared with the medical record notes, with risk scores categorized as follows: risk score 1, 0-6; risk score 2, 0-4; and risk score 3, 0-2 based on the assessment tool. The statistical test used to test the hypothesis was Cramér’s V association test to determine the relationship between the 2 variables with ranges from -1 to 1. Results showed statistical significance in all 3 risk score categories (0.92, \(P \leq .001\); 0.74, \(P \leq .001\); 1.00, \(P \leq .001\)).

A \(\chi^2\) test (with Yates continuity correction) and direct logistic regression were performed to assess the tool’s reliability, assessing the correlation between risk scores and the likelihood of a VTE developing. Variables included specific risk scores of 1, 2, and 3, sex, and age.

**Results**

**Demographic Data**

A total of 1001 patients were assessed on admission for risk of VTE. Demographic characteristics are summarized in Table 1. More than 50% of the patients assessed were less than 5 years old. The mean age of the patients assessed was 6.91 years: 7.29 years for male patients and 6.64 years for male patients.

**Table 1**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, No. (%) of patients</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>581 (58)</td>
</tr>
<tr>
<td>Female</td>
<td>420 (42)</td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>6.91 (6.26)</td>
</tr>
<tr>
<td>Female</td>
<td>6.63 (6.14)</td>
</tr>
<tr>
<td>Female</td>
<td>7.29 (6.40)</td>
</tr>
<tr>
<td>Age range, No. (%) of patients</td>
<td></td>
</tr>
<tr>
<td>0-5 y</td>
<td>525 (52.5)</td>
</tr>
<tr>
<td>6-11 y</td>
<td>171 (17.1)</td>
</tr>
<tr>
<td>12-20 y</td>
<td>305 (30.5)</td>
</tr>
</tbody>
</table>

**Table 2**

<table>
<thead>
<tr>
<th>Venous thromboembolism</th>
<th>Absent</th>
<th>Present</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>406 (96.7)</td>
<td>14 (3.3)</td>
<td>420</td>
</tr>
<tr>
<td>Male</td>
<td>575 (99.0)</td>
<td>6 (1.0)</td>
<td>581</td>
</tr>
<tr>
<td>Total</td>
<td>981</td>
<td>20</td>
<td>1001</td>
</tr>
</tbody>
</table>

**Association of VTE With Age and Sex**

Of the 1001 patients assessed, 981 patients (98% of patients surveyed) did not have a diagnosis of VTE (indicated by 0) and 20 patients (2%) had VTE (indicated by 1). Phi and Cramér’s V were calculated in order to evaluate the effect size, with both results being identical. Based on these results, it can be concluded that the effect size is irrelevant (Cramér’s V = \(\phi = \sqrt{6.59/1001} = 0.081\)).

Of the 20 patients (2%) with venous thromboembolism, 14 or 70% were female, indicating a relationship between female sex and VTE (Table 2). Results were statistically significant (\(\chi^2 \mid n = 1001 \mid = 6.6, P = .01\)). As this was a 2 × 2 table, Yates correction for continuity was used, which was statistically significant (\(P = .02\)). Table 3 shows that most of the patients at risk for VTE were between the ages of 13 and 17 years.

**Correlation of VTE and Risk Score**

The trend of the risk scores in Table 4 suggests a significant association between the risk score and the incidence of VTE (\(\chi^2 \mid n = 1001 \mid = 340.7, P \leq .001\)). Because only 20 patients had VTE diagnosed, multiple cells in Table 4 have fewer than the expected count.
Use of Direct Logistic Regression to Predict VTE in Children

Direct logistic regression was used to predict the probability of the occurrence of VTE on the basis of specific identified risk factors, which were categorized according to level of risk. Other variables included the patient’s age and sex. Results indicate that female sex is a strong predictor of VTE occurrence, with an odds ratio of 7.047. Table 5 suggests that patients with risk scores of 3 were 4.8 times more likely to have VTE develop. There was an adequate sample size (n = 1001) of reviewed charts; however, only 20 (2%) were positive for VTE, which may explain the close association in predictability in risk scores, suggesting that more charts of patients with a diagnosis of VTE should be explored.

The model was statistically significant ($\chi^2_{[n = 1001]} = 100.6, P < .001$), indicating the ability to distinguish those patients who would be positive for VTE according to the assessment tool.

Future Research

Approval has been obtained from the institutional review board for a logistic regression analysis in order to assess the tool concurrently with patients admitted.

Another opportunity for future pediatric VTE research is to assess the tool concurrently with patients admitted. Multiple opportunities exist for future pediatric VTE research. Anecdotal evidence accrued while collecting data suggests that children with inflammatory bowel disease and deficiency of factors C and S may have a higher incidence of thrombotic events. In order to assess these patients accurately, interdisciplinary education will be performed. Revisions of the tool will be discussed with the team to possibly amend the level 3 risk factor category to ensure that these patients are identified as being at risk.

Pediatric inpatients experiencing extended stays pose another opportunity, as these patients may warrant reassessment of risk on the basis of changes in their condition. Another area worthy of research as identified in the literature review is the assessment of VTE risk in neonates. Because few cases of pediatric VTE have been reported, further studies must be conducted in this area with a much larger sample size in order to assess the reliability and validity of the tool better.

Conclusions

In summary, we verified the reliability and validity of the tool for assessing risk for VTE in children. Most patients at risk for VTE were between 13 and 17 years of age, with females having more than 7 times more risk than males. Data suggest that the

<table>
<thead>
<tr>
<th>Table 3 Association between venous thromboembolism and age</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Venous thromboembolism</strong></td>
</tr>
<tr>
<td><strong>0</strong></td>
</tr>
<tr>
<td><strong>1</strong></td>
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<tr>
<td><strong>2</strong></td>
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<td><strong>3</strong></td>
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<tr>
<td><strong>4</strong></td>
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<td><strong>19</strong></td>
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<tr>
<td><strong>20</strong></td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
</tbody>
</table>

*Values are number (percentage) of patients.*

<table>
<thead>
<tr>
<th>Table 4 Cross-tabulation of risk score vs venous thromboembolism</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Risk score</strong></td>
</tr>
<tr>
<td><strong>0</strong></td>
</tr>
<tr>
<td><strong>1</strong></td>
</tr>
<tr>
<td><strong>2</strong></td>
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<tr>
<td><strong>3</strong></td>
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<tr>
<td><strong>4</strong></td>
</tr>
<tr>
<td><strong>5</strong></td>
</tr>
<tr>
<td><strong>6</strong></td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
</tbody>
</table>

*Values are number (percentage) of patients.*
higher the identified risk score, the greater the risk of VTE, demonstrating a significant relationship between the risk score and incidence of VTE.

These preliminary results demonstrate that broad use of this risk assessment tool is beneficial for patients with a history and clinical criteria suggestive of the probability of VTE developing. Implementation of the risk assessment tool could reduce the morbidity and mortality associated with thrombotic events.

ACKNOWLEDGMENT
Mario Cardona, statistician at Baptist Hospital, is acknowledged for his assistance with the statistical analysis.

FINANCIAL DISCLOSURES
None reported.

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REFERENCES

Table 5
Logistic regression predicting venous thromboembolism by using the pediatric risk assessment tool in 1001 inpatient chart reviews

<table>
<thead>
<tr>
<th>Predictor from step 1</th>
<th>Variables in the equationa</th>
<th>B</th>
<th>SE</th>
<th>Wald</th>
<th>P</th>
<th>Exp (B) odds ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk score 1</td>
<td></td>
<td>1.487</td>
<td>0.435</td>
<td>11.656</td>
<td>.001</td>
<td>4.422</td>
</tr>
<tr>
<td>Risk score 2</td>
<td></td>
<td>1.034</td>
<td>0.218</td>
<td>22.589</td>
<td>&lt;.001</td>
<td>2.813</td>
</tr>
<tr>
<td>Risk score 3</td>
<td></td>
<td>1.575</td>
<td>0.292</td>
<td>29.014</td>
<td>&lt;.001</td>
<td>4.832</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td>1.953</td>
<td>0.738</td>
<td>6.998</td>
<td>.008</td>
<td>7.047</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td>0.100</td>
<td>0.065</td>
<td>2.402</td>
<td>.12</td>
<td>1.105</td>
</tr>
<tr>
<td>Constant</td>
<td></td>
<td>-7.938</td>
<td>1.081</td>
<td>53.958</td>
<td>&lt;.001</td>
<td>0.000</td>
</tr>
</tbody>
</table>

a Statistics for the overall model: $\chi^2 = 100.557$, df = 5, $P < .001$.
b All comparisons had 1 degree of freedom.


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1. Which of the following is associated with the highest risk for pediatric deep vein thrombosis (DVT)?
   a. Patient age of less than 1 month and long-term central venous catheter use
   b. Patient age of less than 1 month and short-term central venous catheter use
   c. Patient age of 1 to 12 months and long-term central venous catheter use
   d. Patient age of 1 to 12 months and short-term central venous catheter use

2. Which of the following does the author cite as a reason for thromboembolic events being undiagnosed in pediatric patients?
   a. Venous thromboembolism (VTE) in patients younger than 18 years of age is too rare to justify routine assessment of every patient.
   b. Current regulations require assessment for VTE in adults only.
   c. Clinical criteria for diagnosis of VTE in patients younger than 18 years of age are significantly lacking.
   d. Children are frequently unable to report their symptoms.

3. Which of the following statements regarding the incidence of VTE in pediatric and adult patient populations is true?
   a. Incident rates in pediatric patients are similar to incident rates in adults, but the morbidity and mortality associated with them are significantly higher in the adult patients.
   b. Incident rates in pediatric patients are similar to incident rates in adults, but the morbidity and mortality associated with them are significantly higher in the pediatric patients.
   c. Incident rates in pediatric patients are lower than incident rates in adults, but the morbidity and mortality associated with them are similar for both groups.
   d. Incident rates in pediatric patients are lower than incident rates in adults, but the morbidity and mortality associated with them are significantly higher in the pediatric patients.

4. The health-related costs associated with VTE in children are disproportionately higher due to the expenses specifically related to which of the following?
   a. Lengthy hospitalizations
   b. Long-term complications
   c. Treatment of comorbidities, such as disseminated intravascular coagulation (DIC)
   d. Ongoing DVT prophylaxis

5. Which of the following was the mean length of stay for pediatric patients with a diagnosis of VTE compared to that of pediatric patients admitted to the hospital for other reasons?
   a. Between 2 and 3 times higher for VTE than for other reasons
   b. Between 3 and 4 times higher for VTE than for other reasons
   c. Between 4 and 5 times higher for VTE than for other reasons
   d. Between 5 and 6 times higher for VTE than for other reasons

6. According to the risk assessment tool for VTE in children, which of the following would be assigned a score of 3 points each?
   a. Sepsis and acute DIC
   b. Obesity and immobility
   c. Acquired abnormalities of anticoagulant factors and hereditary anticoagulation abnormalities
   d. Oral contraceptive use and family history of coagulopathy

7. Which of the following levels of risk would be assigned to a total score of 3 points on the risk assessment tool?
   a. Potential risk
   b. Low risk
   c. Medium risk
   d. High risk

8. Which of the following is thought to play a potentially large role in DVT formation in children?
   a. Congenital heart disease
   b. Systemic lupus
   c. Virulent staphylococcal infection
   d. Oncologic malignant growth(s)

9. Pretesting of the VTE risk assessment tool involved which of the following?
   a. Multiple nursing shifts and different pediatric inpatient units
   b. Multiple nursing shifts and 1 pediatric inpatient unit
   c. One specific nursing shift and different pediatric inpatient units
   d. One specific nursing shift and 1 pediatric inpatient unit

10. Of the 1001 patients who were assessed on admission for risk of VTE in the study, more than half of them were of which of the following ages?
    a. Younger than 3 years old
    b. Younger than 4 years old
    c. Younger than 5 years old
    d. Younger than 6 years old

11. Anecdotal evidence collected during this study suggests that children with which of the following conditions may have a higher incidence of thrombotic events?
    a. Deficiency of factors IV and XIII
    b. Deficiency of factors VII and VIII
    c. Gastric esophageal reflux disease
    d. Inflammatory bowel disease

12. At which of the following ages did VTE occur most often?
    a. 17 years
    b. 15 years
    c. 14 years
    d. 13 years

Program evaluation

Objective 1 was met
Objective 2 was met
Objective 3 was met
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My expectations were met
This method of CE is effective for this content
The level of difficulty of this test was:
   easy    medium    difficult
To complete this program, it took me ________ hours/minutes.

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