Published in final edited form as:

J Pediatr. 2013 February ; 162(2): 387–391. doi:10.1016/j.jpeds.2012.06.059.

Incidence and Acute Complications of Asymptomatic Central Venous Catheter–Related Deep Venous Thrombosis in Critically Ill Children

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Abstract

Objective—To determine the current incidence and acute complications of asymptomatic central venous catheter (CVC)-related deep venous thrombosis (DVT) in critically ill children.

Study design—We performed a prospective cohort study in 3 pediatric intensive care units. A total of 101 children with newly inserted untunneled CVC were included. CVC-related DVT was diagnosed using compression ultrasonography with color Doppler.

Results—Asymptomatic CVC-related DVT was diagnosed in 16 (15.8%) children, which equated to 24.7 cases per 1000 CVC-days. Age was independently associated with DVT. Compared with children aged <1 year, children aged >13 years had significantly higher odds of DVT (aOR, 14.1, 95% CI, 1.9–105.8; $P = .01$). Other patient demographics, interventions (including anticoagulant use), and CVC characteristics did not differ between children with and without DVT. Mortality-adjusted duration of mechanical ventilation, a surrogate for pulmonary embolism, was statistically similar in the 2 groups (22 ± 9 days in children with DVT vs 23 ± 7 days in children without DVT; $P = .34$). Mortality-adjusted intensive care unit and hospital lengths of stay also were similar in the 2 groups.

Conclusion—Asymptomatic CVC-related DVT is common in critically ill children. However, the acute complications do not seem to differ between children with and without DVT. Larger studies are needed to confirm these results. Future studies should also investigate the chronic complications of asymptomatic CVC-related DVT.

Deep venous thrombosis (DVT) is a leading cause of excess mortality and morbidity in adults.¹ Although less is known about DVT in children, it is of growing concern among pediatricians owing to its potential complications.² Central venous catheters (CVCs) are the most significant risk factor for DVT in children.³ CVC-related DVT may be symptomatic, with signs of inflammation, venous obstruction, or CVC dysfunction, or asymptomatic, detected only by radiologic imaging. In adults, no distinction is made between symptomatic and asymptomatic DVT, given that either category carries the same risk of pulmonary embolism (PE).¹ Whether this also holds true in children is unknown; age-related differences in coagulation and cardiovascular status preclude extrapolation of adult findings to children.³

We recently reported that 2.9% of critically ill children with a CVC develop symptomatic CVC-related DVT. Similar to critically ill adults,⁴ DVT is associated with acute complications (eg, longer mortality-adjusted duration of mechanical ventilation and intensive care unit [ICU] stay), possibly due to unsuspected PE.⁵ The current incidence of asymptomatic CVC-related DVT^{6,7} in critically ill children is unclear. The most current incidence figures were reported in 1998, with 10.8% of children with CVC developing DVT.⁷ More recent changes in physician practices, such as in CVC placement technique⁸ and blood transfusion strategies,⁹ might have affected the incidence of asymptomatic CVC-related DVT. It is also unclear whether asymptomatic CVC-related DVT is associated with acute complications. In the present study, we examined the current incidence and acute complications of asymptomatic CVC-related DVT in critically ill children, important factors in the design of DVT prevention trials.

Methods

In this multicenter prospective cohort study, we screened children admitted in the ICU with newly inserted untunneled CVC for the presence of asymptomatic CVC-related DVT (ie, ultrasound-confirmed DVT at the CVC insertion site with no signs of inflammation, venous obstruction, or CVC dysfunction). Enrollment began at Yale-New Haven Children's Hospital in October 2009, then 3 months later at Connecticut Children's Medical Center, and finally 16 months later at Maria Fareri Children's Hospital. Enrollment was completed in July 2011. The Institutional Review Board of each participating center approved the study.

Children aged <18 years old were enrolled within 24 hours after insertion of an untunneled CVC. The untunneled CVC was typically inserted when the child was acutely ill. Other types of CVCs were excluded, because these could carry different risks of DVT.^{7,10} If a patient had multiple CVCs, only the first one inserted was included in the analysis, to facilitate comparison of acute complications with data from our previous study.⁵ We excluded children with any of the following: documented DVT at the CVC insertion site, previous enrollment in the study, ward of the state status, limitation of care orders, brain death, or <48-hour anticipated ICU stay. We also excluded children who developed symptomatic CVC-related DVT (ie, ultrasound-confirmed DVT with signs of obstruction or inflammation in the limb ipsilateral to the CVC insertion site, or CVC dysfunction with inability to draw blood or infuse fluids in any CVC port) after enrollment.

Consent and assent, when applicable, were obtained from the parent and the child, respectively. Compression ultrasonography with color Doppler was used to assess the central vein of CVC insertion.⁷ Trained members of the research teams who regularly used the technology performed the ultrasound exams. The following SonoSite ultrasound machines (SonoSite, Bothell, Washington) were used in each center: M-Turbo at Yale-New Haven Children's Hospital, S Series at Connecticut Children's Medical Center, and Micro-

maxx at Maria Fareri Children's Hospital. To identify symptomatic cases of CVC-related DVT, research personnel blinded to the ultrasonography findings examined the limb ipsilateral to the CVC for signs of inflammation or venous obstruction.⁷ Ultrasonography and physical examination were performed on the day of enrollment, the day of study exit (ie, either immediately before or after CVC removal depending on the timing of patient care activities, day 28 after CVC insertion if the CVC was still in place by that time, day of ICU discharge, or before death), and when CVC-related DVT was suspected by the clinical team.¹¹ The CVC was also assessed daily for dysfunction. In all of the ICUs, it was standard practice to infuse unfractionated heparin (UFH) at 0.5–1 U/mL at a rate of 1.5–3 mL/hour in ports used for pressure monitoring, to maintain CVC patency. The clinical team was informed of the ultrasonography findings and devised the subsequent management strategy.

We collected data on patient demographics, interventions received at any time while the CVC was in place, and CVC characteristics. Because the risk of DVT in children is bimodal, with peaks during infancy and adolescence, the children were divided into 3 age categories: <1 year, 1–13 years, and >13 years.⁵ Anticoagulant use included any dose of UFH, low molecular weight heparin, aspirin, or warfarin.

Outcome Measures

The incidence of asymptomatic CVC-related DVT, expressed as percentage of children with DVT and rate of DVT relative to CVC-days, was the primary outcome measure. DVT was diagnosed when at least 2 of the following were present: intravenous echogenic filling defect, noncompressibility of the vein, or abnormal color Doppler pattern in the vein.⁷ Two experienced radiologists (C.S. and K.B.) blinded to the children's history and physical examination results independently read all ultrasound images. A third radiologist (T.G.) resolved discordant readings. The main acute complication of DVT was ventilator-free days, a mortality-adjusted duration of mechanical ventilation, defined as the number of days within 28 days from study enrollment that the child was alive and breathing without invasive ventilator support.⁵ We also monitored ICU- and hospital-free days.⁵

Statistical Analyses

We planned to enroll at least 100 children based on the projected enrollment rate at Yale-New Haven Children's Hospital. This sample size would yield a 95% CI of $\pm 6\%$ around the estimated 10.8% of children developing asymptomatic CVC-related DVT.⁷ Based on the mean of 20 ± 9 ventilator-free days in mechanically ventilated children in Yale-New Haven Children's Hospital, with 100 children, we would have 80% power at a 2-sided .05 significance level to detect 29% relatively fewer ventilator-free days in children with CVC-related DVT compared with the rest of the cohort.

Patient demographics, interventions, CVC characteristics, and outcome measures were compared using the Mann-Whitney and χ^2 tests, as appropriate. Patient demographic data, interventions, and CVC characteristics with $P < .25$ in the unadjusted analyses were entered in a multiple logistic regression model to assess their association with DVT in the presence of other variables. Multicollinearity was assessed using Spearman rank correlation. For collinear variables, the most biologically plausible variable was retained in the model. The use of anticoagulation was included in the model a priori because of its potential confounding effect. Given that the effect of UFH at doses used to maintain CVC patency on the incidence of DVT is unclear,¹² we developed 2 regression models in which UFH was either included or excluded as an anticoagulant. Adjusted ORs with 95% CIs were calculated.

Data are presented as mean $\pm$ SD, counts (%), rates (95% CI), and OR (95% CI). Unless specified otherwise, $P < .05$ was considered to indicate statistical significance for all tests. All statistical analyses were performed using SPSS 19.0 for Windows (IBM, Armonk, New York).

Results

A total of 499 children with a newly inserted CVC were screened, and 110 children were enrolled (Figure). Of these 110 children, 9 were subsequently excluded for various reasons. Of the 101 children included in the analysis, 61 (60.4%) received some form of anticoagulation (ie, UFH in 58 patients, low molecular weight heparin in 9, aspirin in 10, and warfarin in 1), and 18 (17.8%) received anticoagulation other than UFH (Table I).

A total of 16 (15.8%) children developed asymptomatic CVC-related DVT, for an incidence rate of 24.7 cases per 1000 CVC-days (95% CI, 14.7–38.9 cases per 1000 CVC-days). Of these, 5 DVT were occlusive. DVT was diagnosed on the day of study entry in 3 children, at CVC removal in 5 children, at ICU discharge in 7 children, and before death in 1 child. The majority of the DVTs (11 of 16; 68.8%) were diagnosed within 7 days after enrollment (median, 4 days; range, 1–16 days). The concordance rate between the 2 radiologists was 89%. The clinical team treated 1 child who developed asymptomatic DVT while receiving UFH at a dosage to maintain CVC patency with UFH.

In the unadjusted analysis, the children with DVT were older, weighed more, were more likely to have used mechanical thromboprophylaxis, were more likely to have the CVC placed in the internal jugular vein, and had a longer duration of CVC insertion (Table I). Older children weighed more (correlation coefficient [ρ] = 0.86; $P < .001$), had a longer duration of CVC insertion ($\rho = 0.60$; $P < .001$), and were more likely to have the CVC placed in the internal jugular vein ($\rho = 0.24$; $P = .02$). Weight was correlated with the use of mechanical thromboprophylaxis ($\rho = 0.25$; $P = .01$), given that these devices (ie, pneumatic compression devices) cannot be used in children weighing <30 kg. Mechanical ventilation was negatively correlated with postoperative status ($\rho = -0.39$; $P < .001$).

We included age category, race/ethnicity, use of mechanical ventilation, and use of anticoagulation in our multiple logistic regression model (Table II). Of these variables, only age category was independently associated with DVT ($P = .04$). Compared with children aged <1 year, those aged >13 years were more likely to have DVT (OR, 14.1; 95% CI, 1.9–105.8; $P = .01$). The use of anticoagulation, with UFH either included (OR, 1.1; 95% CI, 0.3–4.1; $P = .86$) or excluded (OR, 0.2; 95% CI, 0.02–2.0; $P = .18$), was not associated with DVT.

Ventilator-free days were statistically similar in children with DVT and those without DVT (Table III). Children with DVT had a mean of 22 ± 9 ventilator-free days, compared with 23 ± 7 ventilator-free days in children without DVT ($P = .24$). Duration of mechanical ventilation, number of ICU-free days, duration of ICU stay, number of hospital-free days, and duration of hospital stay were also similar in the 2 groups. A total of 3 children died, 1 with asymptomatic DVT and 2 with no DVT. None of the deaths was attributed to DVT. No child developed PE, embolic stroke, or catheter-associated bloodstream infection during the study period. No CVC was replaced owing to an asymptomatic DVT.

Discussion

In this study, asymptomatic CVC-related DVT is common in critically ill children with untunneled CVC. The incidence of DVT was highest in children aged >13 years. Acute complications of DVT, particularly ventilator-free days, were statistically similar in children

with DVT and those without DVT. The present study is the largest to date estimating the incidence of asymptomatic CVC-related DVT in critically ill children. This study examined prospectively mortality-adjusted durations of mechanical ventilation, ICU stay, and hospital stay as acute complications of CVC-related DVT in a general pediatric ICU population.

The 15.8% incidence of asymptomatic CVC-related DVT in the present study is within the 10.8%–30% range reported in previous studies.^{6,7} This suggests that the risk of DVT in a critically ill child has not changed significantly despite changes in ICU practices. The reported increase in DVT incidence² may reflect increased use of CVCs, but our study was not designed to test this hypothesis.

Age was significantly associated with asymptomatic CVC-related DVT. Older children were more likely to develop DVT in our study cohort compared with the cohorts of Talbott et al⁶ and Beck et al,⁷ where younger children were at increased risk for DVT. Unfortunately, the age distribution of children enrolled in the other studies is not available to allow comparison of DVT risk according to age category. We also speculate that the higher percentage of subclavian CVC in children aged <1 year compared with those aged >13 years in our cohort (38% vs 20%) may partly explain the differences in DVT distribution. Ultrasonography has only fair sensitivity for diagnosing DVT in the subclavian veins.¹³

The majority of children in our study received UFH to maintain CVC patency. Excluding UFH, our pharmacologic thromboprophylaxis rate is comparable to that in an earlier study of critically ill children with a CVC.¹⁴ Our data suggest that anticoagulation therapy is not associated with DVT, which is consistent with a previous randomized trial in which anticoagulation failed to reduce the incidence of CVC-related DVT in children.³

The presence of asymptomatic CVC-related DVT was apparently not associated with any of the acute complications that we monitored. In contrast, in our previous study, children with symptomatic CVC-related DVT had fewer ventilator-free days and ICU-free days compared with a similar cohort of children with no DVT.⁵ We speculate that the difference in acute complications between critically ill children with symptomatic and asymptomatic CVC-related DVT is related to thrombus burden.¹⁵ Compared with children with symptomatic DVT, those with asymptomatic DVT have less thrombus to produce local symptoms and are less likely to produce clinically significant PE, with its associated effects on lung function. Alternatively, the acute complications that we monitored might not be appropriate outcome measures for DVT studies. This is less likely, based on our previous findings⁵ and the reported experience in critically ill adults.⁴ We also may have failed to detect smaller but clinically significant differences in our outcome measures owing to our sample size.

The present study has several strengths, including its multicenter nature and its use of outcome measures (ie, mortality-adjusted durations of mechanical ventilation, ICU stay, and hospital stay) that are easily quantifiable and accepted by critical care physicians.⁵ We used bedside portable ultrasound machines,⁸ which may provide significant financial savings in future DVT studies. All images were centrally adjudicated, which minimizes diagnostic bias.¹¹ Decisions to discontinue mechanical ventilation or to discharge the child from the ICU or the hospital were not part of the study protocol, increasing the generalizability of our results.⁵

Certain limitations of this study warrant mention. Detection of symptoms of DVT may be difficult.^{4,16} The research personnel who performed the physical examinations were blinded to the ultrasound results, to minimize bias. Although the risk period for DVT includes the first several days after CVC removal, the majority of CVC-related DVTs occur with the CVC still in place.⁷ The results of this study are applicable only to untunneled CVC in critically ill children. The type of CVC and the absence of critical illness may affect the incidence and

acute complications of DVT.^{10,11} We did not include catheter tip thrombi or fibrin sheaths, which may be important but are not typically categorized as CVC-related DVTs.¹⁶ Our sample size is not adequate to detect other potentially significant risk factors for asymptomatic CVC-related DVT. Finally, we did not test for congenital thrombophilia, which might affect the risk of DVT.¹⁰

Our findings do not appear to support the practice of routine pharmacologic prophylaxis against CVC-related DVT in critically ill children. A risk-stratified approach, including the use of markers of hypercoagulability,^{10,17} may be preferred in children. The potential differences in acute complications between symptomatic and asymptomatic CVC-related DVT in critically ill children also suggest that the use of the combined incidence of symptomatic and asymptomatic cases as the primary outcome measure, as done in DVT studies in adults,¹ might not be appropriate for studies in critically ill children. A larger study, particularly on the acute complications of asymptomatic CVC-related DVT, is needed to confirm our results. Chronic complications of asymptomatic DVT from untunneled CVC in critically ill children is another important area of study.^{16–18}

Acknowledgments

We thank the Northeast Pediatric Critical Care Research Consortium and the Blood Net of Pediatric Acute Lung Injury and Sepsis Investigators, which approved, but were not involved in, this study.

Supported by the National Center for Research Resources (UL1 RR024139 to E.V.F. and V.N.), a component of the National Institutes of Health (NIH) and NIH Roadmap for Medical Research.

Glossary

CVC	Central venous catheter
DVT	Deep venous thrombosis
ICU	Intensive care unit
PE	Pulmonary embolism
UFH	Unfractionated heparin

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Figure.
Consort diagram. *No exit ultrasonography.

Table I

Characteristics of critically ill children included in the analysis

Characteristic	With DVT (n = 16)	No DVT (n = 85)	P value
Patient demographics			
Center, n (%)			.77
Yale-New Haven Children's Hospital	12 (75.0)	57 (67.1)	
Connecticut Children's Medical Center	1 (6.3)	10 (11.8)	
Maria Fareri Children's Hospital	3 (18.7)	18 (21.1)	
Age group, years, n (%)			.03
<1	3 (18.7)	39 (45.9)	
1–13	9 (56.3)	40 (47.1)	
>13	4 (25.0)	6 (7.0)	
Male sex, n (%)	11 (68.8)	56 (65.9)	.82
Weight, kg, mean $\pm$ SD	26.5 $\pm$ 17.2	15.4 $\pm$ 14.7	.02
Race/ethnicity, n (%)			.10
Non-Hispanic white	6 (37.5)	42 (49.4)	
African-American	1 (6.3)	13 (15.3)	
Hispanic	4 (25.0)	22 (25.9)	
Others	5 (31.2)	8 (9.4)	
PIM2 score, mean $\pm$ SD	0.10 $\pm$ 0.22	0.06 $\pm$ 0.13	.65
Diagnosis, n (%)			.75
Congenital heart disease	2 (12.5)	17 (20.0)	
Cancer	0 (0)	3 (3.5)	
Trauma	0 (0)	3 (3.5)	
Sepsis	6 (37.5)	27 (31.8)	
Others	8 (50.0)	35 (41.2)	
Personal history of thrombosis, n (%)	1 (6.3)	3 (3.5)	.50
Previous diagnosis of thrombophilia, n (%)	0 (0)	0 (0)	
Oral contraceptive use, n (%)	0 (0)	0 (0)	
Postoperative status, n (%)	5 (31.2)	44 (51.8)	.13
Interventions, n (%)			
Anticoagulation *	11 (68.8)	50 (58.8)	.46
Mechanical thromboprophylaxis	5 (31.2)	6 (7.0)	.004
Blood product transfusion	9 (56.3)	50 (58.8)	.85
Total parenteral nutrition	4 (25.0)	12 (14.1)	.28
Mechanical ventilation	13 (81.3)	52 (61.2)	.16
Renal replacement therapy	0 (0)	3 (3.5)	1.00
Vasopressor	8 (50.0)	35 (41.2)	.51
CVC characteristics			
Location, n (%)			.03
Internal jugular	11 (68.8)	30 (35.3)	
Femoral	4 (25.0)	32 (35.6)	

Characteristic	With DVT (n = 16)	No DVT (n = 85)	P value
Subclavian	1 (6.3)	23 (27.1)	
Laterality, n (%)			.25
Left	3 (18.7)	30 (35.3)	
Right	13 (81.3)	55 (64.7)	
Size, n (%)			.29
<5F	4 (25.0)	33 (38.8)	
5F	12 (75.0)	52 (61.2)	
Length, n (%)			.008
<12 cm	6 (37.5)	61 (71.8)	
12 cm	10 (62.5)	24 (28.2)	
CVC-days, mean $\pm$ SD	6 $\pm$ 5	6 $\pm$ 5	.63

PIM2, pediatric index of mortality 2.

* Includes UFH infusion to maintain CVC patency.

Table II

Multivariate regression analysis of characteristics associated with asymptomatic CVC-related DVT

Characteristic	OR (95% CI)	P value
Age group, years		.04
<1	Referent	
1–13	2.7 (0.6–11.9)	.18
>13	14.1 (1.9–105.8)	.01
Race/ethnicity		.11
Non-Hispanic white	Referent	
African-American	0.7 (0.1–7.6)	.78
Hispanic	1.8 (0.4–8.4)	.44
Other	6.3 (1.2–32.1)	.03
Mechanical ventilation	3.1 (0.7–13.2)	.12
Anticoagulation	1.1 (0.3–4.1)	.86

Table III

Acute complications of asymptomatic CVC-related DVT

Outcome measure	With DVT (n = 16)	No DVT (n = 85)	P value
Ventilator-free days	22 ± 9	23 ± 7	.34
Duration of mechanical ventilation, days	5 ± 8	5 ± 10	.24
ICU-free days	18 ± 8	19 ± 8	.43
Duration of ICU stay, days	9 ± 10	10 ± 13	.71
Hospital-free days	14 ± 9	15 ± 9	.65
Duration of hospital stay, days	14 ± 10	19 ± 31	.94

Values are expressed as mean ± SD.