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Descriptive Epidemiology of Venous Thromboembolism in Pediatric Orthopedic Patients

A National, Multicenter Study

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This investigation performed at Boston Children's Hospital, Boston, MA

Background: Consensus regarding which children within orthopedics would benefit from venous thromboembolism (VTE) prophylaxis is lacking. Our objective was to explore the incidence and epidemiology of VTE within pediatric orthopedics through a multicenter review across the United States.

Methods: Encompassing 13 pediatric centers nationwide, VTE incidence rates with 95% confidence interval (CIs) were determined for all pediatric nonorthopedic patients (PNOPs) in general (age 0-18 years) and compared with pediatric orthopedic patients (POPs) from both inpatient and outpatient settings between 2014 and 2017. Demographics, risk factors, presence of prophylaxis, treatment, and outcomes for POP VTEs were analyzed using descriptive statistics.

Results: Of 10,040,937 total unique patients, the overall 4-year VTE incidence for PNOPs was 2.1 per 10,000 patients (CI 2.01-2.19). Of 141,545 POPs, the VTE incidence was 8.0 per 10,000 patients (CI 6.61-9.63). The weighted median age for POP VTEs was higher than that for PNOP VTEs (11.5 vs. 8.0 years, $p = 0.001$). Of the 113 POP VTEs, 97 eligible patients (median age 13.3 years, 56% male) with complete data were further analyzed: 85% (82/97) underwent orthopedic surgery for trauma, infection, or an elective procedure. Orthopedic procedures (49%), bacteremia (46%), central venous catheters (38%), and trauma (28%) were the most common risk factors associated with VTE development, mostly occurring during the initial hospitalization (65%). Thirty-four percent (33/97) of VTE cases had received prophylaxis, predominantly pharmacological (26/33, 79%), administered postoperatively. Ninety-seven percent (94/97) of POP VTEs were treated with anticoagulation, most frequently low-molecular-weight heparin (79%). Twenty-two percent of POP VTEs experienced complications, 2 (2%) of which were deaths, with one having received postoperative VTE prophylaxis.

Conclusions: Although relatively rare, the true incidence of pediatric orthopedic-related VTE may be greater than that of nonpediatric orthopedic VTE, with child mortality occurring in a small minority of cases. In children diagnosed with VTE, one third had received VTE prophylaxis. Identifying at-risk children undergoing orthopedic surgery and establishing best practice safety protocols for VTE prevention are critical to prevent associated morbidity and mortality.

Level of Evidence: Level III—Retrospective comparative study. See Instructions for Authors for a complete description of levels of evidence.

Introduction

Compared with adults, venous thromboembolism (VTE) in children is rare¹⁻⁴. The incidence of VTE in children, encompassing both deep vein thrombosis (DVT) and pulmonary embolism (PE), is low at the population level—estimated

at 0.07 to 0.14 per 10,000 children¹⁻⁴. Hospitalized children, however, are believed to have much higher rates of VTE⁵, with recent national and international studies suggesting a dramatically increased incidence over the past 2 decades from 34 to 58 cases per 10,000 pediatric hospital admissions⁵⁻⁷. Reported risk

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (<http://links.lww.com/JBJSOA/A762>).

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factors associated with development of VTE include the presence of a CVC, malignancy, comorbid chronic inflammatory diseases, infection or sepsis, trauma, surgery, and prolonged hospitalization⁵⁻¹⁰. VTE is bimodally distributed, disproportionately affecting neonates 0 to 1 year old and adolescents 15 to 17 years old¹¹. Currently, the optimal management and prophylactic strategy for pediatric VTE are yet to be fully established by the American Society of Hematology, with current pediatric prophylaxis protocols extrapolated from adults¹².

In 2016, the first study on VTE in children undergoing elective orthopedic surgery reported an incidence of 5.1 per 10,000 orthopedic admissions or 6.3 per 10,000 orthopedic patients¹³. These findings were drawn from the Pediatric Hospital Information System (PHIS), a large database containing discharge information from 44 large pediatric hospitals across the United States. While useful, PHIS relies on International Classification of Disease 9th Revision discharge codes, which are less sensitive and specific, particularly if VTE occurrence is not coded as the primary discharge diagnosis¹⁴. *A more recent study investigated pediatric VTE cases following orthopedic surgery or orthopedic trauma within one large tertiary referral center and reported an incidence rate of 1.48 per 10,000 orthopedic-related cases, compared with 5.55 per 10,000 non-orthopedic-related cases, illustrating a wide variation across the literature*¹⁵.

The goal of this multicenter study was to investigate VTE incidence rates for all general pediatric nonorthopedic patients (PNOPs) compared with pediatric orthopedic patients (POPs) and identify the associated risk factors within POPs nationally. Children included were undergoing treatment for orthopedic trauma, orthopedic infection, and elective orthopedic procedures. Secondary outcomes involved identification of risk factors and high-risk patient populations.

Materials and Methods

Study Population

After Institutional Review Board approval, 13 pediatric medical and academic centers across the United States who were members of the CORTICES Study Group identified all symptomatic patients (aged 0-18 years) between January 1, 2014, and December 31, 2017, who were diagnosed with a VTE in either the inpatient or outpatient setting after review of ultrasound or computed tomography. *No VTEs were diagnosed by screening or clinical examination alone, and all VTEs were associated with classic signs and symptoms.* All data were collected at individual institutions and sent to a central RedCap Database according to signed Data Use Agreements.

VTEs in POPs were defined as being within 30 days¹⁶ of an elective orthopedic surgery (e.g., sports, foot and ankle, hip, neuromuscular, spine, oncology surgery), orthopedic trauma (e.g., lower extremity long bone fracture, pelvic fracture, spinal cord injury), or orthopedic infection (e.g., septic bursitis, septic arthritis, pyomyositis, osteomyelitis, necrotizing fasciitis, cellulitis, myositis, superficial abscess, subperiosteal abscess). Non-orthopedic VTEs encompassed all remaining VTEs in PNOPs attributed to nonorthopedic conditions. Patients were excluded

for pre-existing VTE or history of chronic VTE, VTE diagnosed at a nonparticipating hospital, incomplete medical documentation, sinus thrombosis, renal thrombosis, mesenteric thrombosis, or other thrombus associated with visceral organs. Thrombi in superficial veins distal to the brachial or popliteal vein were also excluded.

Incidence

The total number of VTEs from January 1, 2014, to December 31, 2017, was collected to calculate incidence, along with demographic differences between POP and PNOP VTEs. Each hospital also shared the total number of unique patients (inpatient and outpatient) seen during the study period, in addition to the total number of pediatric orthopedic surgeries performed, which were used to calculate incidence rates.

VTEs in POPs

Demographics including age at VTE diagnosis, patient sex, VTE timing (during hospitalization or after discharge), VTE type (DVT, PE, or both), and DVT location were gathered retrospectively from the medical records for POPs. Race and ethnicity data were not available. Using the Cincinnati Children's Hospital's Best Evidence Statement for VTE in children and adolescents, we collected data on risk factors such as bacteremia or placement of a CVC¹⁷. Similarly, patient history of venous thrombosis, hyperosmolar state, inflammatory disease, medications (asparaginase or estrogen use), obesity (body mass index at or above the 95th percentile), oncological diagnosis, orthopedic procedure/immobility, nephrotic syndrome, thrombophilia, and/or trauma was collected. For POP VTEs, additional details on etiology (orthopedic trauma, surgery, and infection), VTE prophylaxis, treatment, and complications were gathered for a total of 2 years after the index VTE event.

Statistical Analyses

Incidence and demographic data were described for both POP and PNOP cases of VTE. For the POP VTE cohort, additional details regarding surgery characteristics, VTE management, and outcomes were described. Continuous variables were captured by median and interquartile range (IQR), whereas categorical variables were summarized by frequency and percent. From January 1, 2014, to December 31, 2017, overall PNOP VTE incidence and POP VTE incidence with 95% confidence intervals (CIs) were calculated for all 13 hospitals. A weighted median was calculated for age at diagnosis for both POP and PNOP VTEs, and a weighted Mann-Whitney *U*-test was performed to determine if there was a significant difference between the 2 groups. Tests were 2-sided, and *p* values < 0.05 were considered significant.

Results

Incidence

Data from 2014 to 2017 for 13 hospitals were analyzed, which included 10,040,937 total unique PNOPs and 141,545 POPs. The 4-year VTE incidence was 2.1 per 10,000 PNOPs (95% CI = 2.01-2.19) and 8.0 per 10,000 POPs (95%

TABLE I Incidence From 2014 to 2017 (N = 13 Hospitals) *

Category	VTE Patients	Total Patients	Incidence Rate (Per 10,000)	95% CI
Pediatric nonorthopedic	2,111	10,040,937	2.1	2.01-2.19
Pediatric orthopedic	113	141,545	8.0	6.61-9.63

*CI = confidence interval, and VTE = venous thromboembolism.

CI = 6.61-9.63) (Table I). Regional variations in VTE incidence rates across the 13 included sites are depicted in Table II and Figures 1 and 2; see Supplement 1. The weighted median age at diagnosis for POP VTEs (11.5 years) was significantly higher than that for PNOP VTEs (8.0 years; $p = 0.001$).

Pediatric Orthopedic-Related VTEs

Of the 113 POP VTEs identified across 13 participating hospitals, 97 eligible patients with complete data were included for further analysis, of which 82 underwent surgery (Table III). The median age of this cohort was 13.3 years (IQR, 6.79-15.52 years), and 56% were male (54/97). Age distribution was bimodal (Fig. 3), peaking at 3.8 and 14.9 years. These patients were seen in pediatric orthopedics for trauma (20/97, 21%),

infection (47/97, 48%), and elective surgery (30/97, 31%). The most common injuries in trauma were lower extremity long bone fracture (9/20, 45%) and spinal cord injury (6/20, 30%), and most (13/20, 65%) underwent surgery. Osteomyelitis (41/47, 87%) was the most frequent infection subtype although 81% (38/47) had more than one infection subtype. Most children presenting with infection also underwent surgery (39/47, 83%). For the elective procedures included in our cohort, sports reconstruction surgeries comprised the largest volume (12/30, 40%), followed by spine surgery (6/30, 20%), hip surgery (5/30, 17%), and sports arthroscopy (5/30, 17%).

Seventy-eight percent of patients had a DVT (76/97), 10% had a PE (10/97), and 11% had both (11/97) (Table III). More than half had more than one risk factor (66/97; 68%), most frequently orthopedic surgery (49%) and bacteremia (46%) (Table IV). Most of the VTEs developed during the initial hospitalization (63/97; 65%), and most of the outpatient VTEs were the result of elective orthopedic surgeries (30/34, 88%). Prophylaxis (pharmacological, mechanical, or both) was administered to 33 orthopedic patients who developed a VTE (33/97, 34%; Table V). The majority who did not receive prophylaxis had a diagnosis of infection.

Most of the POP VTE cohort was treated with anti-coagulation (94/97, 97%); the remaining 3 patients either did not have any treatment or required further hospitalization or an additional procedure. Low-molecular-weight heparin (LMWH) was most frequently used (79%, 74/94). Seventy-eight percent of patients did not experience any complications secondary to their VTE (76/97). The most common complications (Table VI) included acute respiratory distress syndrome (4/97; 4%), post-thrombotic phlebitis (6/97; 6%), and septic emboli (8/97, 8%). Two died of complications related to their VTE (2/97; 2%): one was a polytrauma 3-year-old female with occlusive thrombus of the lower extremity after multiple pelvic and spinal fractures with CVC use and orthopedic surgery for hip reconstruction, who received VTE prophylaxis. The second was a 17-year-old male with chondroblastic osteosarcoma status postsurgical resection with PE, who did not receive VTE prophylaxis.

Discussion

Understanding the epidemiology of pediatric orthopedic VTEs will help generate clinical practice guidelines to aid screening, prophylaxis, and management. In this multicenter study, the ***Blinded*** Study Group aimed to establish an incidence rate of pediatric orthopedic VTEs. The overall PNOP

TABLE II Incidence of VTE Per 10,000 Patients by Site (N = 13) *

Location	PNOP VTE Incidence (95% CI)	POP VTE Incidence (95% CI)
Northeast	3.0 (2.68-3.27)	6.8 (4.48-10.34)
Blinded Institution 1	5.6 (4.97-6.26)	5.4 (2.75-10.30)
Blinded Institution 2	1.3 (1.02-1.50)	8.4 (4.80-14.51)
Southeast	2.9 (2.69-3.19)	7.2 (4.87-10.69)
Blinded Institution 3	2.9 (2.60-3.29)	7.3 (4.38-11.92)
Blinded Institution 4	2.0 (1.53-2.38)	12.5 (5.83-25.74)
Blinded Institution 5	3.7 (3.18-4.26)	2.7 (0.46-10.69)
West	5.6 (4.82-6.47)	11.1 (5.17-22.86)
Blinded Institution 6	5.6 (4.82-6.47)	11.1 (5.17-22.86)
Midwest	2.1 (1.96-2.34)	8.4 (5.45-12.81)
Blinded Institution 7	1.6 (1.35-1.82)	7.0 (3.26-14.42)
Blinded Institution 8	1.3 (1.02-1.64)	3.3 (0.57-13.32)
Blinded Institution 9	3.6 (3.18-4.08)	13.1 (7.26-22.96)
North	3.2 (2.66-3.82)	6.2 (2.89-12.79)
Blinded Institution 10	1.4 (0.36-2.43)	1.7 (0.09-11.10)
Blinded Institution 11	3.5 (2.83-4.09)	10.0 (4.38-21.56)
South	1.0 (0.88-1.08)	10.6 (6.88-16.18)
Blinded Institution 12	1.1 (0.94-1.19)	14.3 (8.46-23.77)
Blinded Institution 13	0.8 (0.60-0.92)	6.7 (2.92-14.39)

*CI = confidence interval, VTE = venous thromboembolism, PNOP = pediatric nonorthopedic patient, and POP = pediatric orthopedic patient.

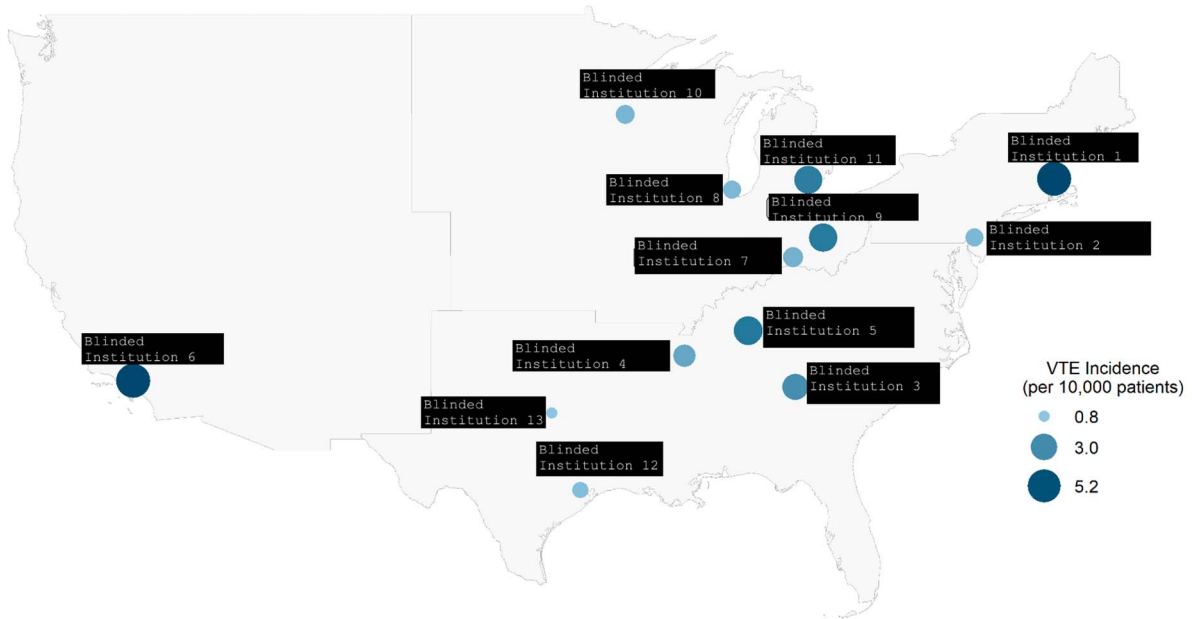


Fig. 1 Map of regional variation of VTE incidence for general pediatric nonorthopedic patients (PNOPs) per 10,000 patients by site (N = 13). VTE = venous thromboembolism.

VTE incidence from 2014 to 2017 was 2.1 per 10,000 patients, whereas the POP VTE incidence was significantly higher at 8.0 per 10,000 patients.

The median age for POP VTE was also significantly higher compared with that for PNOP VTEs (11.5 vs. 8.0 years). Of the 97 POP VTE cases, the median age was 13.3 years, of which the

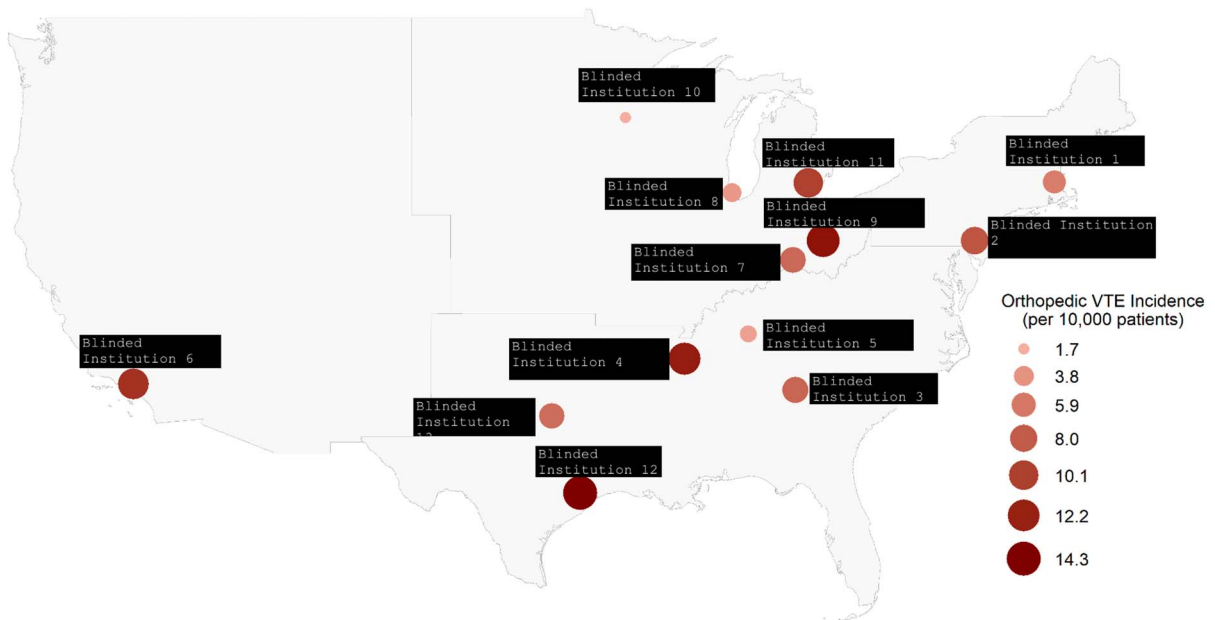


Fig. 2 Map of regional variation of VTE incidence for pediatric orthopedic patients (POPs) per 10,000 patients by site (N = 13). VTE = venous thromboembolism.

TABLE III Pediatric Orthopedic Patient VTE Demographics (N = 97)

Characteristic	Freq (%)
Age, yrs, median (IQR)	13.3 (6.79-15.52)
Sex (% male)	54 (56)
Trauma	20 (21)
More than one trauma	5 (25)
Lower extremity long bone	
Fracture	9 (45)
Pelvic fracture	5 (25)
Spinal cord injury	6 (30)
Other	5 (25)
Underwent surgery	13 (65)
Elective surgery	30 (31)
Sports (arthroscopy)	5 (17)
Sports (reconstruction)	12 (40)
Foot and ankle	1 (3)
Hip	5 (17)
Neuromuscular	1 (3)
Spine	6 (20)
Infection	47 (48)
More than one infection	38 (81)
Osteomyelitis	41 (87)
Underwent surgery	39 (83)
VTE type	
DVT	76 (78)
PE	10 (10)
DVT/PE	11 (11)
VTE timing	
During hospitalization	63 (65)
After discharge	32 (33)
Other	2 (2)
DVT location (n = 87)*	
Lower extremity	66 (68)
Upper extremity	17 (18)
Trunk	4 (4)
Neck	3 (3)
Unknown	0 (0)

*The number in parentheses represents the number of cases with available data for the given characteristic. IQR = interquartile range.

majority experienced an isolated DVT involving their lower extremity. The top 5 risk factors for developing an orthopedic-related VTE were orthopedic surgery, bacteremia, CVC, trauma, and obesity. One third of orthopedic-related VTE patients received prophylaxis, whereas nearly all received anticoagulation after their VTE event. Two patients in this cohort died because of their VTE.

Despite having a lower incidence compared with adults, pediatric VTE has been increasing over the past several decades,

which is believed to be due to a combination of greater recognition, longer life expectancy of children with chronic diseases, and increased frequency of interventions such as CVCs^{5,7}. Because of scarce research on this topic, it is unknown if the incidence of POP VTEs is increasing at a commensurate rate¹⁵. Compared with recent literature in pediatric orthopedics, our calculated VTE incidence is slightly higher^{13,15}. We believe that our results may be more accurate given our sample size of over 10 million patients and our methodology of using ultrasound or computed tomography to confirm the VTE diagnosis.

To our knowledge, little has also been published on the regional variation associated with POP VTEs. Regional variation in the incidence of VTEs in POPs was appreciated in our study but did not follow a pattern. The highest rates of VTEs in POPs were in Houston, Texas; Los Angeles, California; Columbus, Ohio; and Memphis, Tennessee, and the lowest rates were in Nashville, Tennessee, and St. Paul, Minnesota (Fig. 2). It is hard to speculate if these variations are due to regional differences in demographics vs. surgery and practice patterns.

The pathophysiology and risk factors of VTE are very different in children compared with adults. In children undergoing orthopedic surgery, one study found that increased age, metabolic syndrome, obesity, and surgery were significant predictors of VTE development¹³, whereas another identified immobility, trauma, and surgery¹⁵. This multicenter study found that orthopedic surgery (and presumably immobility), bacteremia, trauma, and obesity were frequently associated with POP VTEs. Infections are a known risk factor as they stimulate the blood coagulation cascade and typically result in further immobility, compounding the risk^{18,19}. The presence of a CVC has been found to be one of the greatest risk factors for VTE in POPs²⁰ and was a top 3 risk factor in this study, along with bacteremia. These findings should inform pediatric orthopedic surgeons and encourage consideration of VTE prophylaxis when caring for children with systemic musculoskeletal infections and indwelling vascular access.

While VTE prophylaxis is a well-established practice in adult orthopedics, tremendous variation exists within the pediatric orthopedic literature²¹. The few studies in this area have focused solely on patients with pediatric trauma and found that LMWH is the most commonly administered pharmacological VTE prophylactic agent, though not officially approved by the Food and Drug Administration for pediatric use^{22,23}. Further investigation into other forms of anticoagulation such as unfractionated heparin, novel oral anticoagulants, and mechanical VTE prophylaxis like sequential compression devices in children is still underway²⁴⁻²⁶.

In our study, one third of all POP VTEs received prophylaxis. Half of these VTE cases came from infectious etiologies, and almost none received VTE prophylaxis, highlighting the importance of considering prophylaxis in children presenting with multisystem dysfunction in the setting of musculoskeletal infection. While clarifying prophylaxis patterns related to POPs is important, our results should be interpreted with caution. We have only captured prophylaxis data on those

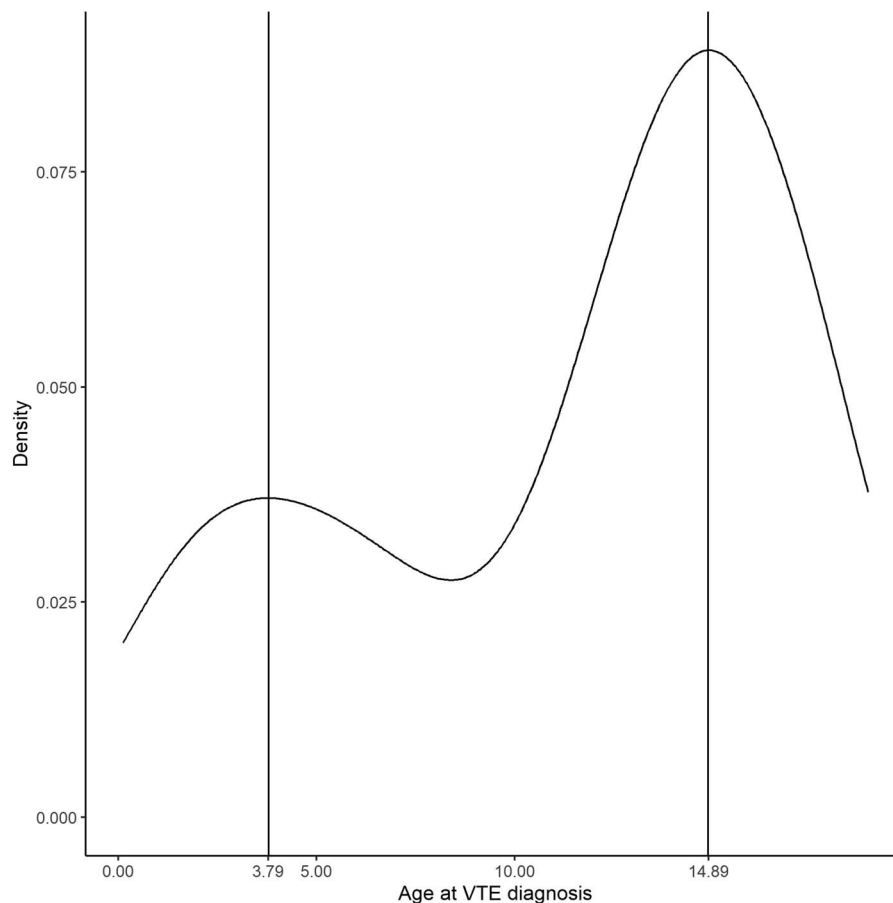


Fig. 3

Density plot demonstrating that the age distribution at diagnosis of pediatric orthopedic-related VTEs (N = 97) is bimodal, with peaks at 3.8 years and 14.9 years. VTE = venous thromboembolism.

POPs who developed a VTE. This gap in the literature calls for a more rigorous prospective multicenter study to help clarify which POPs would benefit most from pharmacological VTE prophylaxis and better understand the associated risks and benefits.

Mortality associated with pediatric VTEs has been reported in the literature and, fortunately, is rare. In one pediatric orthopedic study, 4 fatalities in 74 cases (5.4% mortality rate) were attributed to large VTEs or associated septic shock¹³. Another study reported a similar mortality rate affecting 2 of 46 (4.3%) orthopedic-related VTE events²⁷. In our study, while the overall VTE complication rate was quite low, 2 children died with the following risk factors: trauma, CVC, and orthopedic surgery for the first patient, who received postoperative VTE prophylaxis; and oncological diagnosis and orthopedic surgery for the second patient, who did not receive postoperative VTE prophylaxis. Identifying high-risk children will help mitigate the threat of this most feared complication.

The results of this study must be interpreted in light of several limitations. While multicenter, this study is retrospective and subject to selection bias, which may explain some VTE incidence variability across sites. Further institutional variability may be attributed to the types of surgical procedures and

patient demographics. It was also impossible to control for any site-to-site variation in the diagnosis, protocol, and documentation of pediatric VTEs, prophylaxis, and weight-bearing status, creating difficulty with standardization of our database. *Approximately one third of our cohort received preoperative VTE prophylaxis, but we cannot comment on the effectiveness of prophylaxis because we do not know the fate of those who did not receive prophylaxis; further prospective study may help answer questions regarding the effectiveness of preoperative VTE prophylaxis.* Furthermore, there is possibility that we are still under-reporting the true incidence of POP VTEs. While reviewing institutional imaging records might have improved our accuracy of VTE diagnosis, the documentation variability across medical sites was a barrier as many centers did not have an established database to capture VTEs prospectively, which might have led to missed cases. *With such small incidence numbers and the absence of controls for comparison, further investigation would better clarify indications for VTE prophylaxis.* Moreover, we were unable to report on race, ethnicity, and socioeconomic status. We did comment on complications in POPs after VTE, but not all patients participated in follow-up, and therefore, we might have under-reported the burden of complications. Finally, not all geographic regions of the United

TABLE IV Summary of POP VTE Risk Factors (N = 97)

Characteristic	Freq (%)
No. of risk factors per patient	
1	31 (32)
2	42 (43)
3	12 (12)
4	10 (10)
5	1 (1)
6	1 (1)
Type of risk factor	
Orthopedic surgery	47 (49)
Bacteremia*	45 (46)
Central venous catheter	37 (38)
Trauma (no surgery)	27 (28)
Obesity	20 (21)
Medications	8 (8)
Oncological diagnosis	5 (5)
Inflammatory disease	4 (4)
Hyperosmolar state	3 (3)
Thrombophilia	3 (3)
History of venous thrombosis	2 (2)
Nephrotic syndrome	1 (1)
None	0 (0)

*Diagnosed by positive blood cultures. POP = pediatric orthopedic patient.

States were equally represented in this study, potentially limiting generalizability.

Despite these limitations, we believe that important conclusions can be drawn. This represents the first multicenter study attempting to investigate the incidence and risk factors associated with VTE within pediatric orthopedics. *The incidence of VTE in patients with musculoskeletal infections is high enough to warrant more in-depth study or systematic review.* Pediatric orthopedic surgeons must be cognizant of these risk factors and consider prophylaxis of high-risk patients accordingly. *Based on the results of this study, we would recommend considering prophylaxis in older patients (>12 years of age), who are admitted for orthopedic trauma or infection and who receive a central line during their hospitalization.* This retrospective multicenter study can potentially form the template for generation of a risk calculator to guide diagnostics and prophylaxis; however, more data are needed on PNOPs to fully determine which patients are at high vs. low risk. *Additional multicenter prospective studies regarding the prevention and treatment of VTE in pediatric orthopedics are needed to clarify appropriate interventions for identified high-risk patients. While prospective randomized study represents the highest level of evidence-based medicine, this type of study design for a disease condition of such low incidence is challenging. We do believe that coordinated prospective multicenter studies can help answer*

TABLE V Summary of VTE Prophylaxis (N = 97) *

Characteristic	Freq (%)
Prophylaxis administered	33 (34)
Prophylaxis type (n = 33)	
Pharmacological	21 (64)
Mechanical	7 (21)
Both	5 (15)
Pharmacological administration (n = 26)	
Preoperative	2 (8)
Postoperative	17 (65)
Preoperative and intraoperative	1 (4)
Preoperative and postoperative	5 (19)
Intraoperative and postoperative	1 (4)
Mechanical administration (n = 12)	
Preoperative	4 (33)
Postoperative	6 (50)
Preoperative and postoperative	2 (17)

*VTE = venous thromboembolism.


TABLE VI Summary of VTE Complications (N = 97) *

Outcome	Freq (%)
At least one complication	21 (22)
Death	2 (2)
Acute respiratory distress syndrome	4 (4)
Multiple organ dysfunction syndrome	0 (0)
Post-thrombotic phlebitis	6 (6)
Long-term pain	1 (1)
Septic emboli	8 (8)
Stroke	1 (1)
Acute kidney injury	2 (2)

*VTE = venous thromboembolism.

questions regarding the utility of prophylaxis interventions and which high-risk patients benefit greatest from prophylaxis. We encourage additional investigation into this understudied topic.

Appendix

 Supporting material provided by the author is posted with the online version of this article as a data supplement at [jbjs.org \(http://links.lww.com/JBJSOA/A763\)](http://links.lww.com/JBJSOA/A763). This content has not been copyedited or verified. ■

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