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Original Research

A Prospective Cohort Study of Symptomatic Venous Thromboembolic Events in Foot and Ankle Trauma: The Need for Stratification in Thromboprophylaxis?

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ABSTRACT

The incidence of venous thromboembolic (VTE) events (deep vein thrombophlebitis [DVT] or pulmonary embolism [PE]) in foot and ankle trauma has been low, and the risk/benefit ratio associated with chemoprophylaxis is controversial. We compared the 90-day incidence of VTE events in 3 cohorts: group 1, tendo-Achillis (TA) ruptures managed with full weightbearing in a walker boot; group 2, ankle fractures immobilized non-weightbearing in a below-the-knee cast; and group 3, ankle fractures managed surgically, followed by non-weightbearing in a below-the-knee cast. Data were extracted from 2 prospectively collected trust databases for acute TA ruptures and ankle fractures. VTE risk was assessed using a U.K. national assessment tool. Chemoprophylaxis was prescribed for high-risk patients. The 90-day incidence of symptomatic VTE events was drawn from a trust-wide radiology database. In group 1 (n = 291), the incidence of VTE events was 4.8% (11 [3.8%] DVT, 3 [1.0%] PE) at a mean of 16.1 ± 6.8 days. In group 2 (n = 227), the incidence of VTE events was 2.2% (5 [2.2%] DVT) at a mean of 33.4 ± 11.3 days. In group 3 (n = 199), the incidence of VTE events was 3.0% (5 [2.5%] DVT, 1 [0.5%] PE) at a mean of 37.2 ± 14.2 days. Patients with symptomatic VTE events presented significantly earlier after acute TA rupture compared with after ankle fracture ($p = .002$). We found the overall incidence of VTE events in foot and ankle trauma was low, with a relatively greater incidence of symptomatic VTE events, which occurred earlier, in acute TA ruptures compared with ankle fractures.

Venous thromboembolic (VTE) disease is a well-known cause of morbidity and mortality in lower limb surgery and immobilization (1). Published series have mainly focused on VTE in hip and knee arthroplasty (2–9). The incidence and risk of VTE in foot and ankle pathology is less clear (10).

Symptomatic VTE risk in elective foot and ankle surgery has been shown to be ~0.1% (11,12). Asymptomatic VTE rates of <4% have been reported, with little apparent risk of clot progression (13,14). Trauma patients have a proinflammatory status (15), and in some cases combined with a surgical insult, the incidence of VTE could be expected to be greater. Multiple studies have shown an increased risk of symptomatic and asymptomatic VTE events in foot and ankle trauma, 5% and 13%, respectively (16,17), with a particularly high risk, ≤35%, in tendo-Achillis (TA) ruptures, presumably due to dysfunction of the calf muscle pump (18).

Although national guidelines have made recommendations, their evidence base has not been robust (19–21). In addition, evidence has shown that the adherence to the guidelines is poor, with a wide variation in practice demonstrated (22,23). In an effort to establish the 90-day incidence of VTE in 3 different groups of foot and ankle trauma patients and to inform the decision-making process for chemical thromboprophylaxis for these patients, we undertook a retrospective cohort study of patients who had sustained either a TA rupture or an ankle fracture.

Patients and Methods

The following information was collected from 2 prospective databases, 1 for all ankle fractures and 1 for TA ruptures. Consecutive patients presenting to the Leicester Royal Infirmary Fracture clinic were included in each database. The patients were seen and assessed by supervised trainees and consultant surgeons in general fracture clinics and

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Table 1
Summary of NICE guidelines for venous thromboembolic assessment

Risk Factors
VTE
Active cancer or cancer treatment
Age >60 y
Critical care admission
Dehydration
Known thrombophilia
Obesity (BMI >30 kg/m^2)
≥1 Significant medical comorbidities (e.g., heart disease; metabolic, endocrine, or respiratory pathologic features; acute infectious diseases; inflammatory conditions)
Personal history or first-degree relative with a history of VTE event
Use of hormonal replacement therapy
Use of estrogen-containing contraceptive therapy
Varicose veins with phlebitis
Bleeding
Active bleeding
Acquired bleeding disorders (e.g., acute liver failure)
Concurrent use of anticoagulants known to increase bleeding risk (e.g., warfarin with INR >2)
Lumbar puncture/epidural/spinal anesthesia expected within next 12 hr
Lumbar puncture or epidural or spinal anesthesia within previous 4 hr
Acute stroke
Thrombocytopenia (platelet count <75 × 10^9/L)
Uncontrolled systolic hypertension (≥230/≥120 mm Hg)
Untreated inherited bleeding disorders (e.g., hemophilia and von Willebrand disease)

Abbreviations: BMI, body mass index; INR, international normalized ratio; VTE, venous thromboembolic.

a dedicated TA rupture clinic. VTE assessments were performed by the plaster technicians at the application of a boot or cast and supervised by 1 of us (G.S.). The database was compiled, data were extracted, and statistical analysis was performed by 1 of us (J.B.). Surgically treated ankle fractures were operated on by supervised trainees, general orthopedic surgeons, and specialist foot and ankle surgeons.

The patients were divided into 3 groups. Group 1 included patients with a TA rupture managed with a full weightbearing (FWB), functional, walker boot protocol for 8 weeks. The protocol involved 4 weeks in full equinus, followed by sequential removal of 1.2-cm heel wedges weekly until the patient walked plantigrade in the boot. Group 2 included patients with ankle fractures managed nonoperatively in a non-weightbearing (NWB) below-the-knee cast for 6 weeks. Finally, group 3 included patients with unstable or displaced ankle fractures managed with surgery and a NWB below-the-knee cast for 6 weeks. None of the TA ruptures were treated surgically; however, the ankle fractures were treated either nonsurgically or surgically.

The patients underwent 3 follow-up reviews within 6 weeks. Data for group 1 were collected from March 2010 to December 2014 and the data for groups 2 and 3 from October 2013 to April 2014. Data were extracted on patient demographics. Also, all the patients underwent a risk assessment with a national VTE risk assessment tool based on the National Institute for Health and Clinical Excellence guidelines (available at: www.nice.org.uk/guidance/CG92) (19). High-risk patients, as defined by the criteria (Table 1), were treated with the low-molecular-weight heparin (LMWH) dalteparin until no longer immobilized and/or non-weightbearing. Patients were given information leaflets (available electronically) and advised regarding the importance of regular calf exercises, mobility as able, and maintaining good hydration. Patients were advised to return to the clinic if they noticed any signs or symptoms of VTE events, and they were clinically reviewed in accordance with the study protocol. Overview of patient management in the fracture clinic was performed by 2 of us (G.S., J.M.).

If the clinician suspected a VTE event, appropriate imaging was obtained, and treatment dose anticoagulants were started in line with the United Hospitals of Leicester Trust policy. This trust is based in the East Midlands of the United Kingdom and serves a population of approximately 1.5 million. Superficial or low-risk thrombi, defined as below the knee and isolated to the peroneal, muscular veins or posterior and anterior tibial veins, were not treated. All patients were subsequently checked against a multisite, hospital-wide database of radiologic results. The data for this database are collected in real time and consist of every radiologic investigation performed within the United Hospitals of Leicester Trust. It documents the nature of the request, the clinical indications for requesting the service, and the result. All computed tomography, nuclear medicine, and ultrasound scans performed within 90 days of the index trauma were reviewed for the purposes of our investigation. We also reviewed the medical records for complications related to VTE prophylaxis, including hemorrhage, heparin-induced thrombocytopenia, and mortality. Hemorrhage was defined as the patient presenting to the orthopedic clinic, outside of a routine appointment, with symptoms of bleeding within 90 days of diagnosis. Mortality was similarly measured at ≤90 days after diagnosis. Heparin-induced thrombocytopenia is a serious complication that was defined in our study as a 4T score (24) >5 or the presence of heparin-PF4 complex antibodies in symptomatic patients.

Patients were classified as having either DVT or PE according to their radiology outcome. Patients presenting with a clinical findings suspicious for DVT were sent for Doppler scanning. Those presenting with signs and symptoms of PE were sent for computed tomography pulmonary angiography. Some patients might, in fact, have had both pathologic entities; however, in the present study, we only classified them according to their clinical presentation and positive radiology investigation findings.

The Student unpaired t test was used to compare the mean time of VTE presentation among the groups. The incidence of VTE by treatment group was compared using a χ^2 test. For the purposes of analysis, $p \leq .05$ was considered statistically significant. The analyses were conducted by 1 of us (J.B.) using SPSS, release 2009, and PASW Statistics for Windows, version 18.0 (IBM, Armonk, NY).

Results

We assessed a total of 709 patients and observed an overall incidence of VTE events of 3.5% (Table 2). The Fig. shows the maximum, minimum, median, and quartile ranges of the interval to the development of a VTE event after injury.

In the group of TA rupture patients (n = 291), we observed an incidence of VTE events of 4.81% (14 patients) at a mean of 16.1 ± 6.8 (range 5 to 33) days (Table 2). Of these, 11 (3.8%) experienced DVT and 3 (1.0%) experienced PE. Of the TA rupture patients, 3 (1.0%) were stratified as being at high risk for the development of VTE. These 3 patients received LMWH VTE prophylaxis. Despite receiving prophylaxis, 1 of these 3 patients (33%) developed a VTE event.

In the group of nonsurgically managed ankle fracture patients (n = 227), we observed an incidence of VTE of 2.2% (5 patients) at a mean of 33.4 ± 11.3 (range 16 to 48) days. Of these patients, 5 (2.2%) experienced DVT but none developed PE. Of the nonsurgically treated ankle fracture patients, 7 (3.1%) were stratified as being at high risk for the development of VTE, and they received LMWH VTE prophylaxis. Despite receiving prophylaxis, 1 patient (14.3%) developed DVT.

In the group of surgically managed ankle fracture patients (n = 199), we observed an incidence of VTE of 3.02% (6 patients) at a mean of 37.2 ± 14.2 (range 13 to 58) days. Of these patients, 5 (2.5%) experienced DVT and 1 (0.5%) experienced PE. Of these patients, 4 (2.0%) were stratified as being at high risk for the development of VTE and

Table 2
Summary of results (N = 709 patients)

Group	Trauma Type	Patients (n)	Total VTE Events (n)	PE (n)	DVT (n)	Rate (%) VTE	Mean Time to Positive Radiologic Findings (days)
1	TA rupture	283	14 (4.95)	3 (1.06)	11 (3.88)	4.9*	16.1†
2	Conservative ankle	227	5 (2.2)	0	5 (2.2)	2.2‡	33.4†
3	ORIF ankle	199	6 (3.02)	1 (0.5)	5 (2.51)	3‡	37.2†
All	All patients	709	25 (3.52)	4 (0.56)	21 (2.96)	3.5	24.6

Abbreviations: DVT, deep vein thrombophlebitis; ORIF, open reduction and internal fixation; PE, pulmonary embolism; TA, tendo-Achillis; VTE, venous thromboembolic.
* No statistically significant difference in VTE rate for each group ($p = .197$).
† No statistically significant difference in how soon VTE presented after injury ($p = .002$).
‡ No statistically significant difference in VTE rate between conservatively and surgically treated ankle fractures ($p = .37$).