



## Review

## What is the evidence for chemical thromboprophylaxis in foot and ankle surgery? Systematic review of the English literature



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## ABSTRACT

Venous thromboembolism (VTE) is a well documented complication following lower limb trauma and surgery. The incidence of VTE in hip and knee surgery has been well studied, whereas the incidence in foot and ankle surgery is less clear. There is debate as to which cases require prophylaxis and what is the most effective means by which this is achieved.

We performed a systematic review of the published English literature on VTE prophylaxis in foot and ankle surgery using MEDLINE, EMBASE, CINAHL, Cochrane Library, without date restrictions up to December 2012. From 988 citations, 25 papers fulfilled the inclusion criteria. Conclusions were drawn on the incidence (symptomatic and asymptomatic VTE), location (distal vs. proximal), associated risk factors, timing of VTE, role of mechanical and pharmacological prophylaxis and cost effectiveness of the treatment.

Our review showed that the overall incidence of symptomatic VTE in foot and ankle surgery is low (0–0.55%). There is increased incidence in foot and ankle trauma patients with the highest incidence reported in tendo-achilles surgery. The reported risk factors include previous history of VTE, immobilisation, high BMI, age, co morbidities, contraceptive pill, and air-travel. There is a cumulative effect resulting in higher risk when two or more risk factors are present.

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## Contents

1. Introduction .....	174
2. Materials and methodology .....	174
3. Results .....	174
3.1. Incidence .....	174
3.1.1. Elective foot and ankle surgery .....	174
3.1.2. Trauma of the foot and ankle .....	174
3.1.3. Metatarsal fractures .....	174
3.2. Symptomatic vs. asymptomatic VTE .....	174
3.2.1. Elective foot and ankle surgery .....	174
3.2.2. Trauma foot and ankle surgery .....	175
3.2.3. Timing of DVT post-op .....	175

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3.2.4.	Effect of pharmacological prophylaxis on the incidence of DVT and PE .....	175
3.2.5.	Cost effectiveness .....	176
4.	Discussion .....	176
4.1.	Diagnosis of DVT .....	176
4.2.	Incidence .....	176
4.3.	Risk factors .....	176
4.4.	Thromboprophylaxis .....	176
5.	Conclusions .....	177
5.1.	Definite advice .....	177
	References .....	177

## 1. Introduction

The incidence of venous thromboembolism (VTE) in the general population is estimated to be 0.00048% [1]. Although uncommon, VTE in foot and ankle surgery can be a potentially fatal complication. There is controversy regarding efficacy of pharmacological prevention and whether it is required routinely.

NICE guidelines (published in January 2010) on the prevention of VTE recommend the use of pharmacological thromboprophylaxis in all patients with lower limb trauma and/or surgery who are immobilised in a plaster cast along with other indications. A survey of the current practice in the United Kingdom has questioned the suitability of these guidelines and their application in the NHS today [2]. Another survey showed variation in individual practices as regards VTE prophylaxis [3].

The purpose of this systematic review is to perform a qualitative synthesis of the best available evidence on VTE in foot and ankle surgery in order to address some of the controversies and identify areas for developing future research in this highly debated topic. We aimed to evaluate if there is any reported difference in the rates of VTE between elective and trauma surgery to the foot and ankle and also if there is evidence to suggest chemical thromboprophylaxis can reduce this risk.

## 2. Materials and methodology

We undertook a literature search utilising the following electronic bibliographic databases: MEDLINE (Medical Literature Analysis and Retrieval Online, Bethesda, MD), CINAHL (Cumulative index to Nursing and Allied Health Literature, Ipswich, MA) and EMBASE (Excerpta Medica Database, Amsterdam, Netherlands) the Cochrane library without date restriction up to 1st December 2012. To avoid missing any unpublished studies on the subject, Google Scholar search engine was also used. The key words and medical subject heading (Mesh) terms used were: foot OR feet OR ankle; DVT OR thrombo\*; surgery OR surgical). Only English language papers were considered; giving a total of 988 Medline results, 1 Cochrane review and 131 CINAHL results. No papers were found in the EMBASE database.

The senior authors reviewed the titles, abstracts and full texts of relevant articles for their eligibility. Our agreed selection criteria are shown in Fig. 1. The references of inclusive studies were screened and a further three full text articles were identified.

Inclusion	Exclusion
Randomised studies	Case series <20 patients
Retrospective, observational studies	Review articles
Controlled clinical studies	Studies not on foot and ankle VTE
Meta analysis	Abstract only

Fig. 1. Inclusion and exclusion criteria.

Any doubts regarding the eligibility of data were resolved by discussion amongst the senior authors (JM, MC, DW) and each study was reviewed for the quality of its methodology. 25 journal articles were deemed to have met the inclusion criteria. Their publication dates ranged from 1979 to 2012. These articles were then rated based on their scientific methodology and robustness using a modified Colman Methodology Score system on a scale of 0–100. 23 of the 25 journal articles included in this review achieved a Colman Score of 70 or greater. The two remaining papers that scored less than 70 were included on the basis of their clinical relevance (Figs. 2 and 3).

## 3. Results

### 3.1. Incidence

The incidence of symptomatic VTE in patients undergoing foot and ankle surgery is low. There is a higher incidence of VTE events in trauma of the foot and ankle compared to elective reconstructive foot and ankle surgery.

#### 3.1.1. Elective foot and ankle surgery

Of note the study by Jameson et al. reported rates of PE in first ray surgery, hindfoot fusion and total ankle replacements as 0.02%, 0.11% and 0.06% respectively [4]. In another large prospective multi-centre study incidence of PE was 0.15% [5].

The incidence of asymptomatic DVT ranges from 0% [10] to 3.5% [11] and 4.0% [12].

Patients undergoing total ankle arthroplasty reported a symptomatic VTE incidence of 3.9% [13] and a 0.06% risk of PE [4].

With the exception of Jameson et al., no other paper reported any case of mortality resulting from a VTE event in elective foot and ankle surgery.

#### 3.1.2. Trauma of the foot and ankle

Fig. 4 shows a summary of VTE incidences in lower limb trauma patients and also whether the studies looked at chemical VTE prophylaxis use.

Tendo Achilles injuries are associated with higher rates of VTE [19,22]. Lapidus et al. study showed no significant difference in VTE rates between chemical thromboprophylaxis and placebo groups, however, they did feel that the relative risk of a VTE event was increased in the high risk patient with or without prophylaxis [22].

#### 3.1.3. Metatarsal fractures

Soohoo et al. reporting a 0.2% incidence of PE, with no DVTs. [23]. However, this study only captured readmissions for a VTE event, which may explain why no DVT's were reported (as these may not require admission). No risk factors were assessed in the study.

## 3.2. Symptomatic vs. asymptomatic VTE

### 3.2.1. Elective foot and ankle surgery

There is a difference in rates between symptomatic and asymptomatic VTE in elective foot and ankle surgery. Solis et al.



Fig. 2. Flow chart showing numbers of full-text articles meeting inclusion.

Study	Numbers in study	DVT incidence
Jameson Metatarsal [4]	33,626	0.01%
Jameson Hindfoot [4]	7033	0.03%
Mizel [5]	2733	0.22%
Wukich [6]	1000	0.40%
Felcher [7]	16,804	0.30%
Hanslow [8]	602	3.5%
Solis [11]	201	4%
Radl [12]	100	4%

Fig. 3. Incidence of DVT following elective foot and ankle surgery (see refs. [4–8,11,12]).

prospectively undertook duplex ultrasound scans to assess for VTE in the post-operative period for a variety of foot and ankle procedures. They reported a 3.5% asymptomatic DVT rate with no symptomatic patients. No further treatment was provided to positive scan patients and they showed no evidence of progression in subsequent scans. Radl et al. scanned their patients with ascending phlebography at 4 weeks and had a 4% DVT rate, all of whom were asymptomatic. Only asymptomatic distal occlusions were found in all patients with DVT in two prospective studies for elective foot and ankle surgery [11,12].

### 3.2.2. Trauma foot and ankle surgery

Goel et al. reported an overall incidence of 11% VTE in patients with lower limb trauma below the knee. None of these patients were symptomatic. Bartil et al. reported an overall 5% incidence of DVT in patients with stable ankle fractures treated non-operatively. All patients were asymptomatic.

The incidence of proximal DVT (above the knee) is rare. In a meta-analysis, only eight such events were noted in a total of 614 patients who received LMWH (incidences 0–4%). There were 20 patients with proximal DVTs out of 603 in the control groups (incidence ranging from 0.9 to 6.4%) [24]. Proximal DVT incidences of 3% in Dalteparin and 4% in the placebo group were found in the studies by Lapidus et al. [16,22].

### 3.2.3. Timing of DVT post-op

The attribution of a VTE event in relation to the injury or surgery has been reported as ranging from as early as 3 days to 70 days after the event [5,6]. Other authors who performed routine DVT screening post-operatively in their studies, diagnosed DVTs in the first post-operative week [11], this may indicate that figures may be falsely low.

### 3.2.4. Effect of pharmacological prophylaxis on the incidence of DVT and PE

Pharmacological prophylaxis did not statistically reduce the risk of DVT or PE with the use of dalteparin or tinzaparin in four randomised studies [15,16,22,25]. Three studies established that LMWH (reviparin, fraxiparin) reduced the incidence of DVT significantly in trauma patients [26–28]. A meta-analysis undertaken by Testroote et al. showed that administration of LMWH led to a decreased rate of DVT in lower-limb trauma requiring immobilisation, both with and without surgical intervention [24]. A retrospective study showed no difference in VTE rates in elective foot and ankle surgery with the use of anti-platelet therapy (aspirin) [9].

No randomised controlled studies assessed the effect of thromboprophylaxis on the incidence of VTE in elective foot and ankle surgery.

One study found an increased incidence of DVT in higher risk patients (prior history of DVT, malignancy, oral contraceptive use and obesity), despite having had chemical prophylaxis. These patients received prophylaxis for an average of 2.8 days yet their risk of DVT was not diminished [8].

In many of the studies there were no reported complications related to pharmacological prophylaxis [8,16,22,25,26,28]. Of 438 patients evaluated for drug safety taking Avairy, 14 patients in the Raviparin group and 12 patients in the placebo group experienced a bleeding event [27].

None of the studies reported heparin induced thrombocytopenia (HIT). No deaths were recorded in any study related to PE events either with or without prophylaxis with the exception of the paper from Jameson et al. [4].

Study	Trauma	Numbers in Study	Incidence of VTE event	Chemical Prophylaxis
Patil [14]	Ankle	100	5%	No
Goel [15]	Lower limb	127	8.7%	Yes - LMWH
Goel [15]	Lower limb	111	12.6%	No
Lapidus [16]	Ankle	136	21%	Yes - LMWH
Lapidus [16]	Ankle	136	28%	No
Sooahoo [17]	Ankle	57,183	0.05%	Unsure
Pelet [18]	Ankle	1540	2.99%	Mixed
Healy [19]	TendoAchilles	208	6.30%	No
Persson [20]	TendoAchilles	20	10%	No
Speck [21]	TendoAchilles	20	5%	Yes - LMWH
Lapidus [22]	TendoAchilles	47	34%	Yes - LMWH
Lapidus [22]	Tendoachilles	44	36%	No

Fig. 4. A summary of VTE incidences in lower limb trauma patients and also whether the studies looked at chemical VTE prophylaxis use (see refs. [14–22]).

### 3.2.5. Cost effectiveness

Mizel et al. discussed the cost of investigations, pharmaceuticals and monitoring for each patient undergoing foot and ankle surgery to give prophylaxis against DVT. Their estimate suggested that total costs per patient would exceed US \$165 once the full cost of treatment is taken into consideration [5]. However, this study was based in America and the costs were calculated in 1998.

## 4. Discussion

### 4.1. Diagnosis of DVT

The gold standard of diagnosing DVT is by venography; however duplex ultrasound has a reported sensitivity and specificity of over 90% [24]. All papers in this systematic review used either venography or duplex ultrasound to diagnose DVT in conservative and operative patient groups.

### 4.2. Incidence

Although the reported incidence of VTE in foot and ankle surgery is low, there is inconsistency in the reporting methodology and timing of diagnosis and whether it was symptomatic or asymptomatic VTE. It is unclear whether such an event leads to long term morbidity and there is no long term data. However, it is clear that the VTE risk in trauma patients is higher than those undergoing elective foot and ankle surgery.

The relatively higher rate of PE over DVT in the Jameson et al. study may be related to methodology, as their study only utilised inpatient event coding [4].

In one study, patients with a prior history of DVT, despite prophylaxis, experienced a higher DVT rate [7]. The retrospective study by Griffiths et al. [9] gave an overall DVT rate of 0.27% and showed no significant reduction in VTE events with the use of aspirin in the low risk group. It however excluded all high VTE risk candidates from the study as they had a separate protocol for chemical prophylaxis.

The incidence of symptomatic DVT in total ankle replacement surgery reached 3.9% for patients taking LMWH [13]

Of note, with respect to Achilles ruptures, two papers that described early weightbearing in both treatment modalities [20,21] experienced low VTE complications compared to those papers where the patients remained non-weightbearing for a period of time [19,22]. However, these were two small studies with functional outcome being the main goal rather than complications and further research is needed on timing of conferring weight bearing status.

### 4.3. Risk factors

Risk factors identified in the studies reviewed are summarised in Fig. 5. Felcher et al. identified two or more risk factors (obesity, prior history, contraceptive pill) increased the rate of symptomatic DVT from 0.03% to approximately 1.13%. The risk increased to 4.6% for patients with a previous history of VTE and another risk factor, despite the use of chemical prophylaxis [7]. The majority of the studies considered previous history of DVT as a significant risk factor and prescribed thromboprophylaxis, often excluding these subjects from analysis. There is a variance in age cut off as a risk factor, ranging from 40 [25] to over 60 years [12] (Fig. 6).

Several studies have suggested that prolonged cast immobilisation with associated other risk factors can increase the risk of VTE (see Fig. 5). This seems particularly true in achilles tendon injuries [20,24]. The recent NICE guidance concerning lower limb plaster casts, recommend offering pharmacological VTE prophylaxis to patients with lower limb plaster casts after evaluating the

Risk Factor	No of studies	Authors
Age	4	Wukich, Radl, Jameson, Goel
Immobilisation	4	Wukich, Solis, Mizel, Hanslow
Non-WB	3	Wukich, Mizel, Hanslow
BMI	3	Wukich, Solis, Felcher
Co-morbidities	3	Hanslow, Jameson, Kujath
Prior history of DVT	2	Felcher, Hanslow
Contraceptive pill	1	Felcher
Air Travel	1	Hanslow
Tournique time/location	2	Solis, Simon

Fig. 5. Risk factors for DVT in elective foot and ankle surgery.

risks. They also suggest offering low molecular weight heparin until lower limb plaster cast removal [30].

Comorbidities identified as contributing factors to DVT included connective tissue disorders [8], and diabetes [4] [8].

Based on our review of these studies, we believe a cumulative risk assessment tool may be useful to assist clinicians in determining who may be considered for VTE prophylaxis. The Plymouth lower limb trauma assessment tool for cast immobilisation is one such published example. It has a weighted scoring system that has helped their NHS trust develop a standardised treatment algorithm. They provide low molecular weight heparin to patients scoring more than 3 points on the assessment form. Their internal auditing has shown that they have reduced their VTE events in orthopaedics from 2.3/month to <1.

Further research is required to establish if recent air travel (within 2 weeks of an operation) carries a VTE risk as not all studies looked at this variable. Tourniquet use and location does not appear to be a risk factor for VTE in foot and ankle surgery as reported by Simon et al. [10] and Solis [11]. A meta-analysis by Smith et al. looking at different risks of tourniquet use in foot and ankle surgery showed no statistically significant increase in VTE risk [31].

### 4.4. Thromboprophylaxis

When weighing the overall risk of VTE for foot and ankle surgery (3:1000) against the overall population rate (1:1000) [29], we agree with the statement made by Felcher et al. that chemical prophylaxis for patients with no known risk factors and who are normally ambulatory, is not required. This is also in line with the recommendations from the British Orthopaedic foot and ankle society guidelines from 2010.

No clear consensus was established in any of the papers for the duration or type of thromboprophylaxis required for patients who had significant risk factors. There was variation between the RCT's with respect to exclusion criteria, pharmacological agents, doses, initiation of therapy and duration [15,16,22,26,27]. This may explain the large variation in incidence of VTE and the effectiveness of chemical prophylaxis.

Trauma of the foot and ankle has a higher incidence of VTE compared to elective foot and ankle surgery; however there remains controversy as to the benefit of thromboprophylaxis in the prevention of DVT especially in foot and ankle trauma. The studies investigating Achilles ruptures point to the possibility that early full weight bearing (24 h post-operatively) may be more effective in reducing the risk of VTE than thromboprophylaxis without increasing the potential risk of re-rupture. However numbers are small in

PATIENT DETAILS		Score
Age $\geq$ 60 years		1
Very overweight (BMI $\geq$ 30kg/m <sup>2</sup> )		2
Unable to walk before accident / injury		2
CURRENT MEDICATION		Score
Oral contraceptive pill (birth pill)		1
Hormone replacement therapy (HRT)		1
FAMILY HISTORY		Score
Known family history of leg vein clots (deep vein thrombosis) in close family (brother, sister, father, mother)		3
MEDICAL HISTORY		Score
Varicose veins		1
Heart disease / lung disease / bowel disease / hormone disease or other long term medical condition requiring treatment		1
Abdominal surgery (tummy) in last 6 weeks		2
Active cancer		3
Previous history of leg vein clots (deep vein thrombosis)		3
Previous history of lung clots (pulmonary embolus)		3
Pregnant or within 6 weeks of childbirth		3
Complex lower limb surgery or pelvic fracture in last 6 weeks and advised by surgeon to have prolonged DVT prophylaxis		3
Known blood clotting disease (Thrombophilia) Please discuss with Dr who may contact a haematologist		
<b>Total score:</b>		

Fig. 6. The Plymouth lower limb trauma assessment form.

these studies and it is difficult to apply them generally [21,22]. This controversy does not exist with patients having a previous history of VTE in either elective or trauma surgery.

## 5. Conclusions

### 5.1. Definite advice

The overall risk of a symptomatic VTE in the absence of risk factors for elective foot and ankle surgery, excluding total ankle replacement, lies between 0% and 0.3%. The risk of VTE increases to over 4% in the presence of previous VTE history and 2 or more of the following risk factors: obesity with a BMI greater than 30 kg/m<sup>2</sup>, age over 40, medical comorbidities, use of the contraceptive pill and immobilisation. Other possible risk factors include recent air travel within 2 weeks of any surgery. Surgically treated tendoachilles ruptures and ankle fractures carry a higher risk of VTE, which may reach up to 35%. However these are mainly asymptomatic DVT at distal sites whose exact significance is not very clear. Early weight bearing in Achilles ruptures, within 24 h of surgery may reduce the rate of VTE more effectively than with chemical thromboprophylaxis. There is no clear consensus that VTE events are reduced significantly with the use of chemical prophylaxis.

Until further randomised, multi-centre research is undertaken, we would therefore recommend the following from our review:

#### Elective foot and ankle surgery

- Patients with previous history of VTE should receive chemical thromboprophylaxis for their surgery and during any period of non-weight bearing mobilisation.

- Patients with 2 or less risk factors but no previous history of VTE, who are mobilised weight-bearing immediately post-operatively – No chemical prophylaxis
- Patients with 3 or more risk factors but no previous history, who are mobilised non-weight bearing – Chemical prophylaxis until weight bearing status conferred.

#### Trauma surgery (achilles ruptures, ORIF lower-leg, hind foot)

- Patients with previous history of VTE should receive chemical thromboprophylaxis for their surgery and during any period of non-weight bearing mobilisation
- Patients with 3 risk factors (but no previous VTE's) who are ambulatory – Chemical prophylaxis at time of surgery until weight bearing established.

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