

IAEM Clinical Guideline

Thromboprophylaxis for lower limb immobilisation

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DISCLAIMER

IAEM recognises that patients, their situations, Emergency Departments and staff all vary. These guidelines cannot cover all clinical scenarios. The ultimate responsibility for the interpretation and application of these guidelines, the use of current information and a patient's overall care and wellbeing resides with the treating clinician.

GLOSSARY OF TERMS

DOACs Direct Oral Anticoagulants, including rivaroxaban, apixaban

and dabigatran

EB Evidence Based

EBM Evidence Based Medicine

Immobilisation Any clinical decision taken to prevent normal weight bearing

and/or use of that limb

LMWH Low Molecular Weight Heparin

Permanent risk Ongoing risk factor with no definitive time period of association

or clear cessation date

RCEM Royal College of Emergency Medicine

RCT Randomised Controlled Trial

Temporary risk Provoking factor with definitive temporal association

VTE Venous Thromboembolism. Composite outcome including

distal DVT, proximal DVT, central venous thrombosis and PE

Thromboprophylaxis Any anticoagulant administered by any route at a dose

considered to be prophylactic, rather than therapeutic, for the

patient concerned

Severe lower limb trauma Fracture of either the tibia or the fibula or an achilles tendon

rupture requiring immobilisation

Thromboprophylaxis for lower limb immobilisation

INTRODUCTION

The relationship between temporary limb immobilisation and VTE has been well documented; however, evidence for the benefit of routine prophylactic anticoagulation for this patient population has been less clear.

The annual incidence of VTE in the general population is estimated to be 0.12-0.18%. The increased incidence of VTE for patients is estimated to be somewhere between 5-39%. This wide range of increased risk appears to be linked not just to variations in the method of immobilisation across different studies but largely to underlying individual patient risk factors. Whereas there have been several studies that have identified risk factors and prediction models for VTE in the general population, there has been far less data focusing on patients requiring lower limb immobilisation and further risk stratification.

A further area of contention is that of the clinical significance of this increased noted incidence of VTE. Temporary limb immobilisation is implicated as a causative factor in 1.5-3% of all VTE events. While there is a significantly increased documented risk of VTE, the risk of actual symptomatic PE amongst this cohort is considerably lower at 0.5%.

VTE prophylaxis for lower limb immobilisation is now part of national guidelines in several countries, including France, Germany and the UK. Prior to the introduction of the UK guideline 2012, 60% of departments did not routinely use VTE prophylaxis. Internationally there remains discordance in practice. The ACCP (American College of Chest Physicians) advice against giving routine prophylaxis, stating that it is uncertain whether or not it reduced clinically

significant DVT or whether or not it is cost effective. The ICS (the Cardiovascular Disease Educational and research Trust) guidelines advise in favor of anticoagulation if risk factors are present. No specific Australasian or Canadian national guidelines were identified for this particular subject.

Given the lack of consensus internationally, these IAEM guidelines have been developed to act as an up-to-date resource for medical and nursing staff in Ireland as well as other members of the multidisciplinary ED team, to help to decide which patients may require VTE prophylaxis. These guidelines are not intended to replace clinical judgment, but should help to guide local practice guidelines.

Target Population

This guideline encompasses:

- Adult patients with
- Lower limb trauma who are
- Ambulatory and
- Suitable for outpatient conservative management with
- Temporary lower limb immobilisation.

METHODOLOGY

A short-cut systematic review was carried out for a series of clinical questions. These questions were based around a similar structure and search strategy used for the Royal College of Emergency Medicine Guidelines 2012.

Levels of evidence and grading of recommendations

Level 1 evidence: well-designed RCTs

Level 2: large cohort studies or poorly designed RCTs

Level 3: small cohort studies or case control studies

Level 4: experimental studies, case series or case studies

Suffix "a": systematic review or meta-analysis

Suffix "b" original research

Grade A: based on multiple level 1 papers

Grade B: based on individual level 1 papers, or multiple 2 papers

Grade C: based on individual level 2 papers or multiple level 3 papers

Grade D: based on individual level 3 or level 4 papers

Grade E: based on consensus guidelines or studies of expert opinion

Evidence for Recommendations

1. The risk of VTE in lower limb immobilisation:

There is good evidence to suggest an increased risk of VTE in ambulatory patients with isolated injury who are temporarily immobilised.

Grade A

2. Assessing individual risk in the ED

Any ambulatory patients with lower limb immobilisation and any of the following should be considered to be at increased risk of venous thromboembolic disease:

Rigid immobilisation and/or not weight bearing and/or an acute severe injury (i.e. dislocation, fracture or complete tendon rupture)

Grade C

A combination of "general population"/"permanent" risk factors increases the risk of developing VTE.

Grade C

A number of non-externally validated clinical risk prediction scores exist, including the L-TRIP (cast) score (Leiden-Thrombosis Risk prediction for patients with cast immobilization score) derived from known risk factors.

Grade C

3. Who benefits from thromboprophylaxis

There is no evidence that ambulatory patients with lower limb injuries immobilised in splints or bandages are at increased risk of venous thromboembolism.

In ambulatory patients with acute lower extremity injury requiring temporary immobilisation with below knee plaster cast, prophylactic dose anticoagulation with LMWH reduces the risk of VTE 90 day incidence.

Grade A

In ambulatory patients with acute lower extremity injury requiring temporary immobilisation with above knee plaster cast, prophylactic dose anticoagulation with LMWH reduces the risk of VTE 90 day incidence.

Grade C

4. Types and duration of thromboprophylaxis

LMWH

LMWH in prophylactic doses is effective at reducing incidence of VTE.

Grade A

Oral thromboprophylaxis:

Aspirin is effective as thromboprophylaxis post-surgery for primary arthroplasty (Hip and Knee) and is associated with a reduced incidence of VTE and death.

Grade C

While limited trial data indicates an association with reduced VTE incidence in patients with lower limb injury on aspirin, there is currently insufficient evidence to support the use of aspirin as the sole agent for thromboprophylaxis in non-surgical patients requiring temporary lower limb immobilisation.

Direct Oral Anticoagulants are effective as thromboprophylaxis for primary arthroplasty (Hip and Knee) and are associated with a reduced incidence of VTE post-surgery.

Grade C

One retrospective case series indicated a non-inferiority of Rivaroxaban to LMWH.

There is currently insufficient evidence to support the use of Rivaroxaban for thromboprophylaxis in non-surgical patients requiring temporary lower limb immobilisation.

In ambulatory patients with temporary lower limb immobilisation, the optimum **duration** of thromboprophylaxis is considered to be the duration of plaster immobilisation.

Grade E

5. Risks associated with VTE prophylaxis

Use of LMWH associated with low rates of heparin induced thrombocytopenia and major bleeding in ambulatory patients requiring temporary lower limb immobilisation.

Grade A

DISCUSSION

While patients who are immobilised for lower limb trauma have been noted to be at increased risk of thromboembolic complications this incidence is low. The studies examined here are heterogenous, and are underpowered due to the low incidence of DVT/PE in the cohorts. There is also a lack of consensus as to the definition used to diagnose VTE. (e.g. Above knee +/-Below Knee, Thrombophlebitis, ultrasound positive for symptomatic vs asymptomatic DVT).

It is not yet clear for what categories patients may benefit from thromboprophylaxis.

The ideal situation would be to be able to identify characteristics of the patients, injury patterns and types of immobilisation that increase the risk so that the correct patients are offered thromboprophylaxis while not exposing the others to the inconvenience, cost and risk of bleeding unnecessarily. There are at present no validated risk scoring systems for this purpose. There is also no validated risk score for bleeding risk in this patient cohort.

The Royal College of Emergency Medicine is currently undertaking to look at the available evidence and seek expert opinion to try and define the risk and the patient cohort as to who should receive thromboprophylaxis (TiLLI). This is a three part project: Systematic review, Delphi consensus and Decision Analysis Modelling.

A Prospective multicentre study to assess the risk factors that contribute to Thrombosis in patients with Lower Limb Injuries Requiring Immobilisation to identify group of patients with a high predicted VTE risk. (TiLLIRI study) has commenced recruitment in Ireland.

We are closely watching for the results of these projects and will review this guideline once they are published.

RECOMMENDATIONS

All patients immobilised for lower limb trauma should be given written advice on their increased risk of developing VTE, the signs and symptoms of DVT/PE, and what to do if they develop any of them.

A low threshold to consider thromboprophylaxis should be considered for patients with cancer, previous history of thromboembolic events or pregnancy requiring immobilization for lower limb trauma. While there is no clear evidence of benefit for these patients, there is unlikely to be ethical approval given the high clinical risk to include this cohort in future studies.

While the overall incidence of VTE is low, there does appear to be an as yet undefined subgroup of patients who appear to be at increased risk of VTE following lower limb injury and immobilization. A discussion should be had with these patients about the potential risk/benefit ratio and shared decision making employed.

COMPANION DOCUMENT

Patient information leaflet