

Risk Assessment and Management of Venous Thromboembolism for patients in Lower Limb Plaster of Paris (PoP) or non-weight bearing

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

Introduction

The purpose of this document is to outline the recommendations for the prescription of thromboprophylaxis for adult patients requiring lower limb immobilisation following injury, to reduce the risk of venous thromboembolism.

It is not applicable to patients who are admitted as they will be assessed via the Trust's venous thromboembolism (VTE) risk assessment.

This guideline is for use by the following staff groups :

All qualified healthcare professionals involved in risk assessing and prescribing or administering thromboprophylaxis

Lead Clinician(s)

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Consultant A&E
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Approved by Medicines Safety Committee on:

3rd December 2018

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3rd December 2020

This is the most current document and should be used until a revised version is in place:

Key amendments to this guideline

Date	Amendment	Approved by:
3 rd December 2018	New document approved at Medicines Safety Committee	MSC

Risk Assessment and Management of Venous Thromboembolism for patients in Lower Limb Plaster of Paris (PoP) or non-weight bearing

Introduction

The relationship between temporary limb immobilisation and VTE has been documented since 1944¹. This link persists despite modern medical care, with lower-limb immobilisation recently implicated as an aetiological factor in approximately 1.5 -3% of all VTE events^{2,3}.

The incidence of DVT in patients who were not given thromboprophylaxis ranges from 4.3–40 %⁴. When compared to an annual VTE incidence of 0.12-0.18% in a normal undifferentiated population, these figures serve as a stark reminder of risk⁹⁻¹¹. When indicated, thromboprophylaxis reduces the incidence of VTE in ambulatory patients with lower limb immobilisation (odds ratio 0.49 95% CI 0.34 to 0.72)⁴.

The use of low molecular weight (LMWH) thromboprophylaxis is associated with very low rates of major bleeding when used in ambulatory patients with plaster cast immobilisation (0.3%)⁴. Recent studies have shown reduced bleeding risk when comparing rivaroxaban with LMWH⁽⁷⁻¹⁵⁾.

Evidence supports the use of oral factor Xa inhibitor prophylaxis in other settings such as post operative thromboprophylaxis. NICE guidance supports the use of LMWH in this setting but due to limited evidence with the new direct oral anticoagulants, has not been able to comment on their use⁶.

It is worth noting that using either LMWH or rivaroxaban in this setting is outside the terms of the product license.

The risks of providing pharmacological thromboprophylaxis for patients without contraindications are minimal. Given the significant risk of deep vein thrombosis (DVT), the potential impact of VTE and the very low risk associated with prophylaxis, this guideline recommends the prescription of VTE prophylaxis to all adult patients requiring lower limb immobilisation with an additional VTE risk factor in whom it is not contraindicated.

Inclusion Criteria

This guideline is for use in all patients >18 years of age presenting to the emergency departments and minor injury units of Worcestershire Royal Hospital NHS Trust with a lower limb injury who are discharged home with temporary limb immobilisation. Subsequent application of the guideline will be by the trauma and orthopaedics team as required to follow up these patients.

It is designed to support and expand on the guidance provided in the NICE treatment pathway on reducing venous thromboembolism in hospital patients⁶ and Royal College of Emergency Medicine guidance on thromboprophylaxis in ambulatory trauma patients requiring temporary limb immobilisation⁵.

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- Patients >18 years of age
AND
- Rigid immobilisation (above or below knee) / Non-weight bearing status/ Acute severe injury (dislocation, fracture or complete tendon rupture)
AND
- Admission not required

Risk assessment and Prescribing Guidance

- Patient should be risk assessed using the proforma in appendix 1 and the completed form filed in the notes.
- Please note oral contraceptive pills containing oestrogen should be discontinued and alternative contraceptive methods used for the entire duration that the limb is immobilised however no thromboprophylaxis is required as long as no other risk factors are present.
- If the patient has a risk factor for VTE but thromboprophylaxis is contraindicated, the case should be discussed with a senior doctor and advice from a haematologist may be considered.
- If patients are eligible for thromboprophylaxis either enoxaparin or rivaroxaban may be used. Discuss the treatment options with the patient and provide a patient advice leaflet (appendix 3).
- If there are contraindications to rivaroxaban, enoxaparin should be used.
- Please check no other anticoagulants are taken and if on Warfarin that the INR is >2.
- Once commenced, thromboprophylaxis should be continued for the duration of the immobilisation⁵, unless the patient is scheduled for surgery in which case it should be stopped 24 hours prior to the procedure. The thromboprophylaxis should be reviewed by the fracture clinic and duration of thromboprophylaxis confirmed with the patient.
- Blood tests are not required for all patients. Request FBC, U&E's and LFT's only if known or suspicious of renal disease or bleeding disorder.
- Discuss the risks and symptoms of VTE and risks and benefits of thromboprophylaxis with the patient and provide with a DVT/PE prevention leaflet (appendix 2).
- Prescribe the TTO thromboprophylaxis on an outpatient prescription or an FP10
- TTO packs of rivaroxaban and enoxaparin can be found in the emergency departments at WRH and the Alexandra Hospitals.

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Thromboprophylaxis options

Enoxaparin

- Use 40mg daily in patients with CrCl >30ml/minute
- Use 20mg daily in patients with CrCl 15-29ml/minute
- Consider larger doses e.g. 40mg BD in patients weighing >100kg
- Give the patient the information leaflet for enoxaparin and how to inject
- Advise the patient how to inject the enoxaparin daily and show them
- Prescribe the TTO enoxaparin on an outpatient prescription or FP10
- Give patients a TTO Sharps Bin

Rivaroxaban

- 10mg once daily (creatinine clearance >30ml/minute)
- Creatinine clearance 15-29ml/minute use enoxaparin 20mg daily
- Creatinine clearance less than 15ml/minute discuss with haematology

Known medication interactions for rivaroxaban

- Ketoconazole, itraconazole, voriconazole, posaconazole
- HIV protease inhibitors (atazanavir, darunavir, fosamprenavir, indinavir, lopinavir, nelfinavir, ritonavir and saquinavir).
- Cobicistat
- Dronadarone
- CYP3A4 inducers (including rifampicin, phenytoin, carbamazepine, phenobarbital or St Johns Wort)

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Monitoring Tool

This should include realistic goals, timeframes and measurable outcomes.

Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: <i>(Responsible for also ensuring actions are developed to address any areas of non-compliance)</i>	Frequency of reporting:
WHAT?	HOW?	WHEN?	WHO?	WHERE?	WHEN?
100% patients >16 years old and attending ED/MIU with lower limb immobilisation are risk assessed with the VTE proforma	Patient first record audit	Once a year	Clinical Lead for ED/MIU	ED Governance Committee	Once a year
A thromboprophylaxis patient information leaflet is to be provided to each relevant patient provided with enoxaparin or rivaroxaban in the ED/MIU	Patient first audit	Once a year	Clinical lead for ED/MIU	ED governance committee	Once a year
Thromboprophylaxis is to be prescribed in accordance with the standards set out in this document.	Patient first, note review	Once a year	Clinical lead for ED/MIU	ED governance committee	Once a year

References

1. Bauer G. Thrombosis following leg injuries. *Acta Chir Scand.* 1944;90(1):229-49.
2. Bertolotti L, Righini M, Bounameaux H, Lopez-Jimenez L, Tiraferri E, Visona A, et al. Acute venous thromboembolism after non-major orthopaedic surgery or post-traumatic limb immobilisation. Findings from the RIETE registry. *Thromb Haemost.* 2011 Apr;105(4):739-41.
3. Clarke AM, Winson IG. Does plaster immobilization predispose to pulmonary embolism? *Injury.* 1992;23(8):533-4.
4. Testroote M, Stifter W, Jansenn L, Janzing H. Low molecular weight heparin for the prevention of venous thromboembolism in patients with lower-leg immobilization (Review), The Cochrane Collaboration. The Cochrane Library, 2014.
5. College of Emergency Medicine Guideline for the use of thromboprophylaxis in ambulatory trauma patients requiring temporary limb immobilisation. Guidelines in Emergency medicine network, GEMNet, October 2012.
6. NICE guidance. Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism. March 2018. Accessed via <https://www.nice.org.uk/Guidance/NG89>
7. Lassen, Rivaroxaban versus Enoxaparin for Thromboprophylaxis after Total Knee Arthroplasty. *The New England Journal of Medicine.* June 2008
8. Wasserlauf. Meta-analysis of rivaroxaban and bleeding risk. *American Journal of Cardiology.* May 2013
9. Caldeira. Intracranial haemorrhage risk with the new oral anticoagulants: a systematic review and metaanalysis. *Journal of Neurology.* August 2014
10. Levitan. Benefit-risk assessment of rivaroxaban versus enoxaparin for the prevention of venous thrombo-embolism after total hip or knee arthroplasty. *Vascular Health and Risk Management.* March 2014
11. Goodman. Insights from the ROCKET AF Trial (Rivaroxaban once-daily oral direct factor Xa inhibition compared with vitamin K antagonism for prevention of stroke and embolism trial in Atrial Fibrillation). *Journal of the American College of Cardiology.* March 2015
12. Prediction of venous thrombosis risk after cast immobilization of the lower extremity. Nemeth B, le Cessie S, van Hylckama V, Bucciarelle P, Martinelli I, Baglin T, Rosendaal F, Cannegieter S. Department of Clinical Epidemiology, Leiden University Medical Center, 2014.
13. Holster. New oral anticoagulants increase risk for gastrointestinal bleeding: A systematic review and meta-analysis. *Gastroenterology* 2013.
14. Eriksson Rivaroxaban versus enoxaparin for thromboprophylaxis after hip arthroplasty. *The New England Journal of Medicine.* June 2008.
15. Miller. Meta-analysis of efficacy and safety of new oral anticoagulants (dabigatran rivaroxaban apixaban) versus warfarin in patients with atrial fibrillation. *American Journal of Cardiology.* 2012
16. Healy B, Beasley R, Weatherall M. Venous thromboembolism following prolonged cast immobilisation for injury to the tendo Achillis. *J Bone Joint Surg Br.* 2010 May;92(5):646-50.

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17. Nilsson-Helander K, Thurin A, Karlsson J, Eriksson BI. High incidence of deep venous thrombosis after Achilles tendon rupture: a prospective study. *Knee Surg Sports Traumatol Arthrosc.* 2009 Oct;17(10):1234-8.
18. Patil S, Gandhi J, Curzon I, Hui AC. Incidence of deep-vein thrombosis in patients with fractures of the ankle treated in a plaster cast. *J Bone Joint Surg Br.* 2007 Oct;89(10):1340-3.
19. Meek R, Tong RL. Venous thromboembolism in emergency department patients with rigid immobilization for lower leg injury: Incidence and risk factors. *Emerg Med Australas.* 2012 Jun;24(3):277-84.
20. Oger E. Incidence of venous thromboembolism: a community-based study in Western France. EPI-GETBP Study Group. Groupe d'Etude de la Thrombose de Bretagne Occidentale. *Thromb Haemost.* 2000 May;83(5):657-60.
21. Silverstein MD, Heit JA, Mohr DN, Petterson TM, O'Fallon WM, Melton LJ, 3rd. Trends in the incidence of deep vein thrombosis and pulmonary embolism: a 25-year population-based study. *Arch Intern Med.* 1998 Mar 23;158(6):585-93.
22. Spencer FA, Gore JM, Lessard D, Douketis JD, Emery C, Goldberg RJ. Patient outcomes after deep vein thrombosis and pulmonary embolism: the Worcester Venous Thromboembolism Study. *Arch Intern Med.* 2008 Feb 25;168(4):425-30.
23. Testroote M, Stigter W, de Visser DC, Janzing H. Low molecular weight heparin for prevention of venous thromboembolism in patients with lower-

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Contribution List

This key document has been circulated to the following individuals for consultation;

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This key document has been circulated to the chair(s) of the following committee's / groups for comments;

Committee
Venous Thromboembolism Review Group
Medicines Safety Committee

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Appendix 1 – VTE Risk Assessment



Appendix 1 - VTE
Risk Assessment.doc

Appendix 2 – DVT/PE Patient information leaflet

WRH Emergency Department Patient Information on Lower Limb Immobilisation and blood clot prevention

When the lower leg is put into a splint, plaster cast or similar it can increase the risk of a blood clot, often called a deep vein thrombosis (DVT) or pulmonary embolism (PE). All patients who require immobilisation of their lower leg due to injury are required to undergo risk assessment for potential blood clots. If you have been assessed to be at increased risk of a blood clot during the time you require immobilisation you will receive medication to help prevent this. In addition to medications there are things you can do to reduce your risk of blood clots further and these are recommended for all patients irrespective risk.

What else can I do to reduce the risk of developing a blood clot?

It is difficult to predict who will get a blood clot, and whilst medication may help there are steps that can be taken to try and reduce this risk further:

- Drink plenty of fluids.
- Mobilise as much as is comfortable.
- Stop smoking (if you smoke) - this will also help your bone to heal.
- Perform the exercises described below (perform 3 times per day).

Exercises for reducing the risk of DVT in lower limb casts whilst you have to wear a cast, any activity which promotes contraction of muscles and increased blood flow is helpful.

For any cast on the legs

Wiggle your toes while lying in bed or whilst sat up with your leg elevated. Try and do this for at least 10 seconds, and as often as you can. This promotes blood flow and can help reduce the risk of blood clotting. Inside the plaster cast, if it is safe to do so, try and move your ankle up and down. It will not move very much as the cast will stop it. Repeat 10 times.



For below knee casts only

Regularly bend your knee. Sit down on a chair, bend your knee and then straighten your knee. Repeat ten times.



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Lie on your tummy on the bed and bend your knee, bringing your heel towards your bottom. Slowly lower your foot back down to the bed, keeping the movement slow and controlled.



Lie on the bed or sitting up with your leg elevated. Keep your leg straight and brace your knee down by tightening the muscles on the front of your thigh.

How will I know if I have a DVT or PE?

When you have a DVT the blood flow in the vein is partially or completely blocked depending on the width of the clot. A calf vein is the common site for a DVT. A thigh vein is less commonly affected. Rarely, other deep veins in the body form clots.

The affected area of the blood clot may become swollen or painful, and possibly turn red or feel hot to touch as the flow of the blood is blocked. You may also develop swelling, which is the build-up of fluid in the skin tissues surrounding the clot. If the clot is somewhere other than in your leg, there may be no physical signs of DVT.

Sometimes bits of the clot can break up and lodge in the lungs causing a Pulmonary Embolism (PE) causing chest pain, difficulties with breathing and coughing up blood streaked sputum it may also cause sudden collapse.

Sometimes a DVT occurs for no apparent reason, and it becomes more common with age. Each year one in every 1,000 people in the UK is affected by DVT.

If you develop any of the signs or symptoms mentioned in this leaflet please seek medical attention. Should you develop severe shortness of breath, chest pain or sudden collapse you or the person you are with should dial 999 for an ambulance, should you experience leg pain, swelling redness or warmth of your leg you should contact your GP or NHS111.

Where can I find out more?

Please ask your doctor or nurse for more information. Alternatively, the NHS Choices website provides patient information on blood clots: www.nhs.uk

Appendix 3: Patient Advice leaflet on Thromboprophylaxis Choice



WRH Emergency Department Patient information on lower limb immobilisation and Rivaroxaban[®] and Clexane[®]

When the lower leg is put into a splint, plaster cast or similar it can increase the risk of a blood clot, often called a deep vein thrombosis (DVT) or pulmonary embolism (PE). All patients who require immobilisation of their lower leg due to injury are required to undergo risk assessment for potential blood clots. You have been assessed to be at increased risk of a blood clot during the time you require immobilisation and you therefore may benefit from having treatment to prevent a blood clot. Once you no longer require the splint or plaster cast, this risk will resolve and no further treatment should be required.

The treatment works to thin the blood and make it more difficult for the blood to clot. It is usually provided by either:

- Tablets called Rivaroxaban[®]. Taken once a day for the duration of the plaster cast or splint. Rivaroxaban works immediately and does not require any additional blood tests.
- Injections called Clexane[®]. These require an injection under the skin every day.

Research studies tell us that both treatments are equally effective and safe for the treatment of DVT and PE. For most patients, taking a tablet is less painful, easier and more convenient than having daily injections. Therefore Rivaroxaban is often the preferred option. However some people cannot take Rivaroxaban[®], these include:

- Children
- Pregnant and breast feeding ladies or recently given birth
- People with poor kidney function.
- People who have had a bleed from their gut
- People who have cancer or a receiving chemotherapy
- People with antiphospholipid syndrome
- People who have had a blood clot while on warfarin and need a higher level of blood thinning
- People who require warfarin for other reasons, except atrial fibrillation.

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Side Effects and Important Advice

Blood thinning treatment of any kind will make you more likely to bleed and bruise after simple bumps, cuts or scrapes. Simple first aid measures can be used in most cases by applying pressure to a bleeding area and elevating it if possible. Pressure should be firm, and in some cases may need to be applied for at least 20 minutes or longer.

If you happen to injure your head (eg. fall over) whilst taking either Clexane® or Rivaroxaban®, please seek medical advice from NHS111, your GP, local minor injuries unit or A&E department.

- **Clexane®** may cause bleeding and bruising under the skin as well as redness and irritation at the injection site. Clexane® has been used now for many years and there are no other long term side-effects.
- **Rivaroxaban®** may cause headaches, rashes and itches (a full list of side-effects can be found on the information leaflet in the box or by asking your doctor / nurse / pharmacist). Rivaroxaban® is a relatively new treatment and has only been in use for a few years; we therefore do not know if the drug has any other side-effects and we have less experience in using it for the prevention of clots in the lungs or legs compared to Clexane®.

After consideration of this advice, or at any other time, you may decide that you do not want to have any treatment; if this is the case, please discuss this with your doctor or nurse.

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of:	No	
	• Race		
	• Ethnic origins (including gypsies and travellers)		
	• Nationality		
	• Gender		
	• Culture		
	• Religion or belief		
	• Sexual orientation including lesbian, gay and bisexual people		
	• Age		
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	N/A	
4.	Is the impact of the policy/guidance likely to be negative?	No	
5.	If so can the impact be avoided?		
6.	What alternatives are there to achieving the policy/guidance without the impact?	N/A	
7.	Can we reduce the impact by taking different action?	N/A	

If you have identified a potential discriminatory impact of this key document, please refer it to Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact Human Resources.

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Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval.