

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedures consultation document

# Percutaneous mechanical thrombectomy for acute deep vein thrombosis of the leg

A deep vein thrombosis (blood clot) in a leg is usually treated with anticoagulant drugs, which stop further clotting but do not dissolve the clot. It can be dissolved using clot-busting drugs but these can cause serious bleeding. In this procedure, the clot is broken up and sucked out using a mechanical device. This is introduced through a tube inserted into the vein through the skin (percutaneous). The aim is to reduce symptoms and prevent long-term problems such as swelling of the leg and ulceration.

The National Institute for Health and Care Excellence (NICE) is looking at percutaneous mechanical thrombectomy for acute deep vein thrombosis of the leg. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

**This is not our final guidance on this procedure. The recommendations may change after this consultation.**

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#).

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of

discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 21 February 2019

Target date for publication of guidance: May 2019

## 1 Draft recommendations

1.1 Current evidence on the safety of percutaneous mechanical thrombectomy for acute deep vein thrombosis (DVT) of the leg shows there are well-recognised but infrequent complications.

- For acute iliofemoral DVT the evidence on efficacy is limited in quality and quantity, therefore this procedure should only be used with [special arrangements](#) for clinical governance, consent, and audit or research.
- For distal DVT that does not extend proximal to the common femoral vein the evidence on efficacy is inconclusive, therefore this procedure should only be used in the context of [research](#).

1.2 Clinicians wishing to do percutaneous mechanical thrombectomy for acute iliofemoral DVT should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these. Provide them with clear written information to support [shared decision-making](#). In addition, the use of NICE's [information for the public](#) is recommended.
- Audit and review clinical outcomes of all patients having percutaneous mechanical thrombectomy for acute iliofemoral DVT. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion), which will be available when the guidance is published.

1.3 Further research should report the patient selection criteria including the site of the clot, symptom severity and age of patients.

## **2 The condition, current treatments and procedure**

### ***The condition***

- 2.1 Deep vein thrombosis (DVT) is a blood clot that develops within a deep vein, usually in the leg. It can cause pain, swelling, tenderness and red skin but sometimes there are no symptoms. Risk factors for DVT include surgery, immobility, malignancy, hypercoagulability, pregnancy and dehydration.
- 2.2 DVT may lead to complications because the blood flow in the leg is being affected. Chronic venous insufficiency can cause post-thrombotic syndrome in the affected leg with pain, swelling, and sometimes chronic ulceration. Raised venous pressure can rarely cause phlegmasia cerulean dolens with oedema of the leg, cyanosis, blistering and ischemia. If the clot becomes dislodged it can travel through the veins to the lungs and cause a pulmonary embolus, which is potentially life-threatening.

### ***Current treatments***

- 2.3 A DVT is usually treated with unfractionated or low molecular weight heparin, followed by oral anticoagulants (usually warfarin). Factor-X inhibitors may be used instead, without preliminary heparin. Extensive DVT is sometimes treated with systemic thrombolysis, or by endovascular interventions such as catheter-directed thrombolysis. Thrombolysis is associated with a risk of haemorrhagic complications including stroke. Surgical thrombectomy is an option when a DVT is refractory to thrombolytic therapy, or in people for whom thrombolysis is contraindicated, but it is rarely used.

### ***The procedure***

- 2.4 Percutaneous mechanical thrombectomy for acute DVT of the leg is usually done together with direct infusion of a thrombolytic drug into the thrombus. However, it can be done by itself if thrombolytic drugs are contraindicated. It can also be done before thrombolysis to reduce the size of the clot, or after thrombolysis if the thrombus persists.
- 2.5 The procedure is done using local anaesthesia. Imaging is used to determine the appropriate venous access, which is usually the popliteal or femoral vein. A catheter is advanced through the vein into the thrombus using fluoroscopic guidance. There are a range of mechanical thrombectomy devices which use different principles. The objective is mechanical disruption and aspiration of the thrombus. A temporary inferior vena cava filter may be used during the procedure to reduce the risk of pulmonary embolism from a displaced clot.
- 2.6 Anticoagulant drugs are usually taken for at least 3 months after the procedure and sometimes longer if clinically indicated, to

prevent recurrence. Early ambulation and use of compression stockings are advised.

- 2.7 Adjuvant angioplasty or stenting of the vein may be needed if thrombus removal reveals an anatomical lesion that contributed to the formation of the DVT.

### **3 Committee considerations**

#### ***The evidence***

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 13 sources, which was discussed by the committee. The evidence included 2 randomised controlled trials (1 of which also had a subgroup analysis published), 1 systematic review, 2 registries, 2 non-randomised comparative studies, 4 case reports and 1 conference abstract that reported safety data, and is presented in table 2 of the [interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: clot removal, reduction in post-thrombotic syndrome, patient-reported outcomes including quality of life scores, and reduction in pulmonary embolisation.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: bleeding, haemolysis, vessel damage including stenosis, clot embolisation, and rethrombosis.

#### ***Committee comments***

- 3.4 It would be helpful to have a national register of data for all patients having percutaneous mechanical thrombectomy for deep vein thrombosis.

- 3.5 The committee was informed that this can be a limb-saving procedure for patients with severe acute iliofemoral deep vein thrombosis.
- 3.6 There are different devices and techniques used for this procedure.
- 3.7 Much of the evidence included in the overview is from a device that is no longer on the market.
- 3.8 Patient selection is important and patients should be assessed by a multidisciplinary team that includes a vascular surgeon, an interventional radiologist and a haematologist.
- 3.9 The committee was informed that the procedure is likely to have a better outcome when it is done within 14 days of presentation with a deep vein thrombosis.

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Chairman, interventional procedures advisory committee

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