

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Percutaneous mechanical thrombectomy for acute deep vein thrombosis of the leg

A blood clot (thrombus) in a vein is usually treated with anticoagulant drugs, which stop further clotting but do not dissolve the clot. Clots can be dissolved using clot-busting drugs but these can cause serious bleeding. In this procedure, a clot in the leg is broken up and sucked out using a mechanical device introduced through a tube inserted into the vein. The aim is to 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: 22 November 2018

Target date for publication of guidance: February 2019

1 Draft recommendations

- 1.1 Current evidence on the safety of percutaneous mechanical thrombectomy for acute deep vein thrombosis of the leg shows there are well-recognised but infrequent complications. Evidence on efficacy does not show benefit for most people. However there is evidence, limited in quality and quantity, which suggests a potential benefit for some people. Therefore, this procedure should only be used in the context of [research](#).
- 1.2 Further research should report the patient selection criteria, and identify the people who may benefit from this procedure.

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 from the leg vein it can travel to the lungs resulting in 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 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 in some cases 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 10 sources, which was discussed by the committee. The evidence included 2 randomised controlled trials,

2 registries, 2 non-randomised comparative studies and 4 case reports, 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 This procedure is used to remove clots from leg veins that are above the knee.
- 3.5 There are different devices and techniques used for this procedure.
- 3.6 Much of the evidence included in the overview is from a device that is no longer on the market.
- 3.7 Patient selection is important and patients should be assessed by a multidisciplinary team that includes a vascular surgeon, an interventional radiologist and a haematologist.
- 3.8 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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