

Percutaneous mechanical thrombectomy for acute deep vein thrombosis of the leg

Interventional procedures guidance

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 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. Find out what special arrangements mean on the NICE interventional procedures guidance page.
 - For distal DVT that does not extend into the common femoral vein, the evidence on efficacy is inconclusive, therefore this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.
- 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.
- 1.3 Clinicians should enter details of all patients who have the procedure onto the British Society of Interventional Radiology Venous Registry.

- 1.4 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 cerulea 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 anticoagulation. 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 that 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 or that increases the risk of recurrence.

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 14 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, 3 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.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee was informed that this can be a limb-saving procedure for patients with severe acute iliofemoral deep vein thrombosis (DVT).
- 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 DVT.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).