

Percutaneous thrombectomy for intermediate-risk or high-risk pulmonary embolism

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg778

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

High-risk pulmonary embolism (PE) when alternative treatments are not suitable

- 1.1 For high-risk PE in people who cannot have thrombolysis, or when there are no other suitable treatment options or alternative treatments have failed, percutaneous thrombectomy should only be used with special arrangements for clinical governance, informed consent and audit. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Clinicians wanting to do percutaneous thrombectomy for high-risk PE when alternative treatments are not suitable should:
 - Inform the clinical governance leads in their healthcare organisation.
 - Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
 - Take account of NICE's advice on shared decision making, including NICE's information for the public.
 - Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
 - Discuss the outcomes of the procedure during their annual appraisal to

reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

Intermediate-risk PE or high-risk PE when alternative treatments are suitable

1.4 For intermediate-risk PE or high-risk PE when alternative treatments are suitable, pulmonary thrombectomy should only be used in research. Find out [what only in research means on the NICE interventional procedures guidance page](#).

1.5 Further research should be in the form of randomised controlled trials or registries. It should report:

- patient selection
- size and position of the clot
- degree of right ventricular dysfunction
- details of the procedure, including the device used
- short- and long-term outcomes, including patient-reported outcomes.

Why the committee made these recommendations

There is enough evidence that the procedure reduces the extent of clot in the circulation but not enough evidence of improvement in short- and long-term outcomes. The evidence on safety does not raise any major concerns. Most of the evidence is for intermediate-risk PE. There is no evidence from randomised controlled trials and very little long-term follow-up evidence, particularly for patient-reported outcomes.

There is an unmet need for people with high-risk PE when alternative treatments are not suitable or have failed, and this procedure is the only treatment option. So, this procedure is recommended for use with special arrangements for this population.

Because of the lack of evidence, this procedure is only recommended for use in research for intermediate-risk PE, or high-risk PE when alternative treatments are suitable.

2 The condition, current treatments and procedure

The condition

- 2.1 A pulmonary embolism (PE) is when a pulmonary artery is obstructed by an embolus (usually a blood clot) that travels to the lungs from deep veins in the leg or pelvis. PE often causes shortness of breath, chest pain and cough. The symptoms and severity vary from no symptoms to cardiovascular collapse and death.
- 2.2 A high-risk PE (also known as massive PE) is defined by sustained systemic hypotension or shock. An intermediate-risk PE (also known as submassive PE) involves right ventricular dysfunction or myocardial injury without major haemodynamic compromise. High-risk PE accounts for less than 10% of acute PE cases and is a medical emergency with a high mortality rate.

Current treatments

- 2.3 The first-line treatment for PE is systemic or oral anticoagulants. For high- or intermediate-risk PE with haemodynamic compromise, systemic thrombolysis may be used or, rarely, open surgical embolectomy. Catheter-directed therapies may also be used, including catheter-directed thrombolysis and percutaneous thrombectomy. Catheter-directed therapies are usually used if someone has a high-risk PE and they cannot have surgery, or when systemic thrombolysis is contraindicated or has failed.

The procedure

- 2.4 In this endovascular procedure, a catheter is inserted percutaneously into the peripheral vasculature (usually by a common femoral vein) and advanced through the right side of the heart into the pulmonary arteries under image guidance. This procedure is usually done by interventional radiologists and interventional cardiologists. It is usually done using local anaesthesia with or without sedation.
- 2.5 There are several thrombectomy devices available with some variation in their mechanism of action. The thrombus may be fragmented before removal or not. There are several methods by which the thrombus can be removed: vacuum suction, aspiration with a syringe, mechanical removal with a clot removal device, or a combination of methods. It is a minimally invasive procedure that may be used alone or in combination with other treatment options for PE.
- 2.6 The aim of the procedure is to rapidly remove the obstruction and restore pulmonary circulation, reducing right ventricular strain, while avoiding the bleeding risks associated with thrombolysis.

3 Committee considerations

The evidence

- 3.1 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 12 sources, which was discussed by the committee. The evidence included 2 meta-analyses, 3 single-arm trials (1 trial included with its sub-study), 1 safety database review, 1 prospective non-randomised comparative study, 2 retrospective comparative studies, 1 prospective registry, 1 sub-set of the prospective registry and 1 case report. The evidence is presented in the [summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: clot removal, recovery of cardiac function, 30-day mortality or

survival, symptomatic relief, long-term patient-reported outcome measures, and quality of life.

- 3.3 The professional experts and the committee considered the key safety outcomes to be: pain, bleeding, damage to vessels and the heart, and worsening cardiac function.
- 3.4 One commentary from a person who had this procedure was received as part of consultation comments and was discussed by the committee. A submission from a patient organisation representing people who have had this procedure was also discussed.

Committee comments

- 3.5 The committee noted that more than 1 device is available for this procedure. Devices vary in the size of the introducer and their mechanism and are at different stages of development.
- 3.6 The committee noted that this is a complex procedure and requires a multidisciplinary team including clinicians with specific experience in managing pulmonary embolism.

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Endorsing organisation

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

Accreditation

