

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Percutaneous thrombectomy for massive pulmonary embolism

A pulmonary embolism is a blockage in an artery in the lungs, usually caused by a blood clot (embolus) that travels to the lungs from deep veins in the leg. A 'massive' pulmonary embolism is a life-threatening condition, caused by a large clot in a major pulmonary artery. In this procedure a catheter (thin tube) is inserted into a large vein through the skin (percutaneous), usually in the groin. It is guided through the heart to the clot and used to remove it (thrombectomy). The aim is to rapidly remove the blockage, restore blood flow to reduce strain on the heart and avoid the bleeding risks of thrombolysis.

NICE is looking at percutaneous thrombectomy for massive pulmonary embolism.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

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

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation 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: 20/03/2023

Target date for publication of guidance: August 2023

1 Draft recommendations

- 1.1 Percutaneous thrombectomy for massive pulmonary embolism (PE) should be used only in research. Find out [what only in research means on the NICE interventional procedures guidance page](#).
- 1.2 Further research should be in the form of randomised controlled trials or registries.
- 1.3 Further research should report:
- patient selection
 - size and position of the clot
 - degree of right ventricular dysfunction
 - details of the procedure, including the device used
 - short-term and long-term outcomes, including patient-reported outcomes.

Why the committee made these recommendations

There is enough evidence that the procedure reduces clot burden but not enough evidence of improvement in short- and long-term outcomes. There is also not enough good quality evidence on safety. There is no data from randomised controlled trials and very little evidence of long-term follow up, particularly patient-reported outcomes. Although this procedure is being assessed for massive PE, most of the data is for sub-massive PE.

2 The condition, current treatments and procedure

The condition

- 2.1 A pulmonary embolism (PE) is when a pulmonary artery is obstructed, usually by an embolus 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 massive PE (also known as high-risk PE) is defined by sustained systemic hypotension or shock. A sub-massive PE (also known as intermediate-risk PE) involves right ventricular dysfunction or myocardial injury without haemodynamic compromise. Massive 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 anticoagulants. Systemic thrombolysis may be used for massive or sub-massive PE and, rarely, open surgical embolectomy. Catheter-directed therapies may also be used, including catheter-directed thrombolysis and percutaneous thrombectomy. Percutaneous thrombectomy is usually used if someone has had a massive PE and they cannot have surgery, and when thrombolysis is contraindicated or has failed.

The procedure

- 2.4 In this endovascular procedure, a catheter is inserted percutaneously into the peripheral vasculature (usually via 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. 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 5 sources, which was discussed by the committee. The evidence included 2 single-arm trials (1 trial included with its sub-study), 1 safety database review, 1 retrospective comparative study and 1 prospective registry. 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.

Committee comments

- 3.4 The committee noted that more than 1 device can be used for this procedure. Devices vary in the size of the introducer and their mechanism and are at different stages of development.

Tom Clutton-Brock

Chair, interventional procedures advisory committee

March 2023

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