NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

Percutaneous insertion of a catheter-based intravascular microaxial flow pump for cardiogenic shock

Cardiogenic shock is a life-threatening condition that happens when the heart cannot pump enough blood to meet the body's needs. In this procedure, a very small (microaxial) flow pump is temporarily used to pump blood out of the heart and restore blood flow. The pump is built into the tip of a tube (catheter). This is inserted through the skin (percutaneous) into an artery, usually in the groin. It is then pushed along the artery (intravascular) into the lower left chamber of the heart. The aim is to allow time for the heart to recover by reducing how hard it needs to work, or to help the heart while a person is waiting for a heart transplant or other treatment.

Guidance development process

NICE interventional procedures guidance evaluates procedures used for treatment or diagnosis. It provides evidence-based recommendations about the safety and efficacy of these procedures. The guidance supports healthcare professionals and commissioners to ensure that patients get the best possible care. By reviewing clinical evidence and considering patient outcomes, NICE aims to improve patient safety and treatment choices in the NHS.

Find out more on the NICE webpage on interventional procedures guidance.

NICE is producing this guidance on percutaneous insertion of a catheter-based intravascular microaxial flow pump for cardiogenic shock in the NHS.

Issue date: October 2025

The interventional procedures advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for consultation with the stakeholders. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the stakeholders for this evaluation and the public. This document should be read along with the evidence.

The committee is interested in receiving comments on the following:

- Is it appropriate to measure long-term complications for this procedure? If so, what would they be?
- Is it appropriate to measure long-term survival for this procedure?
- Has all of the relevant evidence been taken into account?
- Are the summaries of safety and efficacy reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?

After consultation:

- Based on the consultation comments received, the committee may meet again.
- If committee meets again it will consider the evidence, this evaluation consultation document and comments from stakeholders.
- The committee will then prepare the final draft guidance, which will go through a resolution process before the final guidance is agreed.

Note that this document is not NICE's final guidance on percutaneous insertion of a catheter-based intravascular microaxial flow pump for

cardiogenic shock. The recommendations in section 1 may change after consultation.

More details are available in NICE's interventional procedures programme manual.

Key dates:

Closing date for comments: 25 November 2025

Second committee meeting: 22 January 2026

1 Recommendation

1.1 Percutaneous insertion of a catheter-based intravascular microaxial flow pump can be used in the NHS during the evidence generation period as an option to manage cardiogenic shock. There must be enhanced informed consent and auditing of outcomes.

What this means in practice

There are uncertainties around the safety and efficacy of this procedure. It can be used if needed while more evidence is generated to check if it is safe and clinically effective.

After this, NICE will review this guidance and the recommendation may change.

Healthcare professionals do not have to offer this procedure and should always discuss the available options with the person with cardiogenic shock (and their family and carers as appropriate) before a joint decision is made, if possible.

Hospital trusts will have their own policies on funding procedures and monitoring results. NHS England may also have policies on funding of procedures.

Enhanced informed consent

Because there are uncertainties about whether this procedure is safe and effective, there must be an emphasis on informed consent. Healthcare professionals must make sure that people (and their families and carers as appropriate) understand the uncertainty and lack of evidence around a procedure's safety and efficacy using NICE's advice on shared decision making and NICE's information for the public. Healthcare professionals must also inform the clinical governance leads in their organisation if they want to do the procedure.

Auditing of outcomes

Healthcare professionals doing this procedure should collect data on safety and outcomes of the procedure and enter details about everyone having this procedure into an appropriate registry. If there is no data collection method already available, use NICE's interventional procedure outcomes audit tool and regularly review the data on outcomes and safety.

Who should be involved with the procedure

Patient selection should be done by a multidisciplinary team. This procedure should only be done in centres that specialise in managing cardiogenic shock and by healthcare professionals with specific training in this procedure.

What evidence generation is needed

Healthcare professionals must collect data specifically around the safety and efficacy of this procedure. This includes information on:

- patient selection
- the technique used, including device and access site
- short- and long-term complication rates
- short- and long-term survival outcomes

- quality of life.

Why the committee made this recommendation

Results from a high-quality randomised controlled trial suggest that this procedure improves survival compared with standard care alone in a subgroup of people with cardiogenic shock associated with heart attack. There is evidence from several large retrospective observational studies, but the trial populations in these varied and the results on efficacy are inconsistent.

The evidence shows that the procedure may be associated with complications such as bleeding, which can be serious. But because there are limited treatment options for people with cardiogenic shock, the procedure can be used as an option in the NHS while more evidence is generated.

2 Information about the procedure

2.1 Catheter-based intravascular microaxial flow pumps are temporary mechanical circulatory support devices. Percutaneous insertion is typically done through the femoral artery, under general anaesthetic or sedation with local anaesthesia. The microaxial flow pump catheter is advanced into the ascending aorta, across the aortic valve and into the left ventricle, guided by fluoroscopic or echocardiographic imaging. Once it is properly in position, the catheter-based pump delivers blood from the inlet area, which sits inside the left ventricle, through a cannula to the outlet opening in the ascending aorta. A wired console controls the pump speed and monitors its function and position. Different blood flow rates can be achieved, depending on the power of the pump that has been implanted.

2.2 The aim is to reduce ventricular work and provide the circulatory support needed to allow the heart time to recover from an acute injury. It can also be used as a bridge to other longer term

treatments, such as a heart transplant or implantation of a durable left ventricular assist device.

2.3 Some pumps can be surgically inserted using a graft cut-down technique through the axillary or subclavian artery, or through a direct aortic approach using a sternotomy or thoracotomy. This is covered by NICE's interventional procedures guidance on surgical insertion of a catheter-based microaxial flow pump for cardiogenic shock.

2.4 The procedure can also be used as support during high-risk percutaneous coronary intervention. This is covered by NICE's interventional procedures guidance on percutaneous insertion of a temporary heart pump for left ventricular haemodynamic support in high-risk percutaneous coronary interventions.

3 Committee discussion

The condition

3.1 Acute heart failure is a complex clinical syndrome of symptoms and signs that happen when the efficiency of the heart as a pump is impaired. It can lead to reduced blood flow to the body and increased filling pressures in the heart. Cardiogenic shock is the most severe form of acute heart failure, potentially leading to organ failure and death. It has multiple causes, including heart attack, chronic heart failure, sudden heart valve failure, cardiac arrhythmias, inflammation of the heart muscle, blood clots in the lungs, drug overdoses and poisoning. It can also happen after open heart surgery (postcardiotomy cardiogenic shock).

Current practice

3.2 Managing cardiogenic shock involves medicines, including diuretics and inotropic agents, and mechanical circulatory support devices, such as intra-aortic balloon pumps, venoarterial extracorporeal

membrane oxygenation and ventricular assist devices. Depending on the aetiology of the acute heart failure, once the initial symptoms of cardiogenic shock have been stabilised, revascularisation using bypass surgery or percutaneous coronary intervention may be used to improve the heart's function. If symptoms do not improve, a heart transplant or implantation of a durable left ventricular assist device may be options.

Unmet need

3.3 The procedure is used to provide temporary short-term cardiac support to people with cardiogenic shock when symptoms have not responded to other forms of treatment. It is used if there is the potential to recover from or be bridged to a heart transplant or implantation of a durable left ventricular assist device.

The evidence

3.4 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 1 randomised controlled trial, 1 individual patient data meta-analysis, 5 systematic reviews and meta-analyses and 3 registry studies. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.5 The professional experts and the committee considered the key efficacy outcomes to be: survival to recovery or bridge to heart transplant or durable left ventricular assist device, and quality of life.

3.6 The professional experts and the committee considered the key safety outcomes to be: pain, bleeding, stroke, pump failure, leg ischaemia, acute kidney injury, sepsis and cardiac perforation.

3.7 Three commentaries from people who had a catheter-based intravascular microaxial flow pump for cardiogenic shock inserted were discussed by the committee.

Committee comments

3.8 There are ongoing studies for this procedure.

3.9 Technology for this procedure has developed since the first studies were published, and newer models are available.

Equality considerations

3.10 The incidence of heart failure increases with age and it is more common in men.

3.11 Pregnancy and maternity are protected characteristics under the Equality Act (2010). Women, trans men and non-binary people with cardiogenic shock who are pregnant, or who have recently been pregnant, may need this intervention.

3.12 People with heart failure may be covered by the Equality Act 2010 under disability if their heart failure has had, or is likely to have, a substantial adverse impact on their usual day-to-day activities for over 12 months. People with heart failure often have multiple comorbidities.

4 Committee members and NICE project team

This topic was considered by NICE's interventional procedures advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Tom Clutton-Brock

Chair, interventional procedures advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

Helen Gallo

Technical lead

Evan Campbell

Technical adviser

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Consultant clinical adviser

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Project manager

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