NICE National Institute for Health and Care Excellence

NICE guidance

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

HealthTech 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.

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1 Recommendation

1.1 Percutaneous insertion of a catheter-based left ventricular 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.

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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.

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 the procedure's safety and efficacy, 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. 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. Regularly review the data on outcomes and safety.

Who should be involved with the procedure

This procedure should only be done in primary percutaneous coronary intervention centres with on-site intensive care expertise and by healthcare professionals with specific training in this procedure.

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What evidence generation is needed

Healthcare professionals must collect data specifically around the safety and efficacy of this procedure.

This includes:

- 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. The trial had a lot of very specific requirements about who could take part, which would be challenging to use in practice. More evidence is needed to know if the benefit observed in this subgroup will also apply to the broader cardiogenic shock population. There is also evidence from several large retrospective observational studies, but the populations in these varied and the efficacy results 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.

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2 Information about the procedure

2.1 Catheter-based left ventricular 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 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 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 HealthTech 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 HealthTech guidance on percutaneous insertion of a temporary heart pump for left ventricular haemodynamic support in high-risk percutaneous coronary interventions.

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3 Committee discussion

The interventional procedures advisory committee considered evidence on percutaneous insertion of a catheter-based left ventricular microaxial flow pump for cardiogenic shock from several sources. This included evidence submitted by 1 company, a review of efficacy and safety evidence and responses from stakeholders. Full details are available in the project documents for this guidance.

The condition

3.1 Acute heart failure is a complex clinical syndrome of signs and symptoms 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, interventions to reverse the underlying cause may be used. These include revascularisation using bypass surgery or percutaneous coronary intervention. If symptoms do not improve, a heart transplant or implantation of a durable left ventricular assist device may be options.

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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 for the heart to recover, or for bridging to a heart transplant or implantation of a durable left ventricular assist device.

The evidence

3.4 NICE did a rapid review of the literature on the efficacy and safety of this procedure. The prioritised evidence included 1 randomised controlled trial, 1 individual patient data meta-analysis, 5 systematic reviews and meta-analyses, 1 network meta-analysis, 1 propensity score matched database study and 4 registry studies. It is presented in the summary of key evidence section in the interventional procedures assessment report. Other relevant literature is in the appendix of the assessment report. Several different devices were used in the studies informing this guidance.

3.5 The professional experts and the committee considered the key efficacy outcomes to be:

- short-term survival
- bridging to heart transplant or durable left ventricular device
- longer-term outcomes, including survival and health-related quality of life.

3.6 The professional experts and the committee considered the key safety outcomes to be:

- pain
- bleeding
- haemolysis
- stroke

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- pump failure
- limb ischaemia
- acute kidney injury
- sepsis
- 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.

3.10 Centres that do the procedure should have a bleeding management protocol in place.

Equality considerations

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

3.12 There is a lack of evidence in women.

3.13 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.

3.14 People with heart failure may be covered by the Equality Act 2010 under disability

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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.

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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.

Chairs

Rick Body
Chair, interventional procedures advisory committee

Tom Clutton-Brock
Former 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, consultant clinical advisers, a project manager and an associate director.

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