NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

VA ECMO for postcardiotomy cardiogenic shock in adults

Postcardiotomy refers to the period immediately after open-heart surgery. Postcardiotomy cardiogenic shock (PCS) is a rare but life-threatening situation that happens when the heart cannot pump blood well enough to meet the body's needs.

Venoarterial extracorporeal membrane oxygenation (VA ECMO) is when blood is taken out of the body and put through an artificial lung located outside of the body (extracorporeal). The ECMO machine adds oxygen to the blood (oxygenation), removes carbon dioxide and pumps the blood around the body. This is done over days or weeks. Tubes take blood out of the major veins in the groin, neck, or both, and return it through tubes into a large artery (venoarterial).

VA ECMO aims to do the work of the heart to provide oxygenated blood to the body while the heart recovers or as a bridge to a treatment.

Guidance development process

NICE interventional procedures guidance evaluates procedures used for treatment or diagnosis. It provides evidence-based recommendations about how safe and effective these procedures are. 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 VA ECMO for postcardiotomy cardiogenic shock in the NHS in England. 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:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical effectiveness 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 VA ECMO for postcardiotomy 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: 21 May 2025

Second committee meeting: 10 July 2025

1 Recommendations

1.1 More research is needed on venoarterial extracorporeal membrane oxygenation (VA ECMO) to manage postcardiotomy cardiogenic shock (PCS) before it can be used in the NHS.

1.2 This procedure should only be done as part of formal research and an NHS research ethics committee needs to have approved its use.

What research is needed

More research is needed on:

- patient selection
- short- and long-term survival outcomes.

What this means in practice

There is not enough evidence to know if this procedure is effective. VA ECMO to manage PCS should only be done as part of formal research.

Auditing of outcomes

Clinicians doing this procedure should collect data on safety and outcomes of the procedure. Enter details about everyone having this procedure into

the Extracorporeal Life Support Organization registry 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 with specific training in this procedure, in centres that specialise in managing postcardiotomy cardiogenic shock.

Why the committee made these recommendations

Evidence from observational studies suggests that some people with PCS, who would not survive being taken off a cardiopulmonary bypass machine after cardiac surgery, may survive if VA ECMO is used, but it is limited.

There is some evidence that some people may benefit more from VA ECMO than others. More research is needed on survival outcomes with VA ECMO, so it should only be used in research.

2 Information about the procedure

2.1 Extracorporeal membrane oxygenation (ECMO) can be used to manage postcardiotomy cardiogenic shock immediately after heart surgery, or to help separation from cardiopulmonary bypass.

2.2 In venoarterial ECMO, blood is taken from the venous system (usually from the femoral vein or the right atrium) and pumped through an oxygenator, where oxygen and carbon dioxide are exchanged. It is then returned to the arterial system (usually through the femoral or axillary artery or ascending aorta). People are given a continuous infusion of an anticoagulant, usually heparin, to prevent blood clotting in the extracorporeal system. For people with poor kidney function, a haemofiltration unit may be added to the circuit.

3 Committee discussion

The condition

3.1 Postcardiotomy refers to the period immediately after open-heart surgery. Postcardiotomy cardiogenic shock (PCS) is a rare but life-threatening situation that happens when the efficiency of the heart as a pump is impaired and is unable to meet the body's tissue demands. This means a person may be unable to be separated from cardiopulmonary bypass after open-heart surgery. Persistent cardiogenic shock cannot be managed with pharmacological treatments alone.

Current practice

3.2 Treatment for PCS involves pharmacological treatments, including diuretics and inotropic agents, and mechanical circulatory support, including intra-aortic balloon pumps. Without using mechanical circulatory support PCS has a very high risk of death, with mortality reported as high as 76%.

Unmet need

3.3 VA ECMO is used to provide cardiac and respiratory support for people with cardiogenic shock after cardiac surgery. Unlike a heart–lung (cardiopulmonary) bypass machine, it tends to be used for days to weeks and not hours during surgery, allowing the heart time to recover. ECMO provides circulatory support and allows time for other treatments to promote recovery, or may be a bridge to a long-term mechanical solution or transplant. It aims to improve patient outcomes.

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 4 systematic reviews, 2 retrospective registry studies, 1 multicentre retrospective study and 3 single centre retrospective 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: restoration of organ function and bridging to recovery, transplant or long-term support.

3.6 The professional experts and the committee considered the key safety outcomes to be: bleeding, leg ischaemia, stroke, infection, renal failure and circuit-related complications.

3.7 Patient commentary was sought but none was received.

Committee comments

3.8 Clinical experts advised that some centres are providing elective VA ECMO for people who are more likely to have cardiogenic shock after cardiac surgery.

3.9 Clinical experts advised that VA ECMO can be done either peripherally or centrally. After cardiac surgery it is common to use central VA ECMO.

3.10 The committee noted that it would be difficult to do randomised controlled trials in people with PCS, and that other study designs could be useful.

3.11 The committee noted that the recommendations in this guidance include the use of ECMO during pregnancy or in the post-partum period.

Equality considerations

3.12 Not all cardiac surgery centres specialise in using VA ECMO in the UK. So, people in some areas may not have access to this intervention.

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 consultant clinical adviser, a project manager and an associate director.

Jessica Wilcock and Helen Gallo
Technical leads

Alan Ashworth
Consultant clinical adviser

Corrina Purdue
Project manager

Anastasia Chalkidou and Emily Eaton-Turner

Associate directors

ISBN: [to be added at publication]