

Extracorporeal membrane oxygenation (ECMO) for acute heart failure in adults

Interventional procedures guidance

Published: 27 March 2014

www.nice.org.uk/guidance/ipg482

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

- 1.1 The evidence on the efficacy of extracorporeal membrane oxygenation (ECMO) for acute heart failure in adults is adequate but there is uncertainty about which patients are likely to benefit from this procedure, and the evidence on safety shows a high incidence of serious complications. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake ECMO for acute heart failure in adults should take the following actions.
 - Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
 - Submit data on all adults undergoing ECMO for acute heart failure to the international Extracorporeal Life Support Organization register.
- 1.3 ECMO for acute heart failure in adults should only be carried out by clinical teams with specific training and expertise in the procedure.
- 1.4 NICE encourages further research into ECMO for acute heart failure. This should include clear documentation of patient selection and indications for the use of ECMO. Outcome measures should include survival, quality of life and neurological status.

2 Indications and current treatments

- 2.1 Heart failure is a complex clinical syndrome of symptoms and signs that occurs when the efficiency of the heart as a pump is impaired. It can lead to reduced blood flow to the body tissues and increased filling pressure in the heart, which causes congestion and oedema in the lungs (causing breathlessness) and/or the body (causing swelling of the legs). Other symptoms include reduced exercise tolerance, fatigue and malaise.
- 2.2 Treatment for acute heart failure (specifically, sudden significant deterioration in people with known cardiac dysfunction or new onset of symptoms in people without previous cardiac dysfunction) involves pharmacological therapies, including diuretics and inotropic agents. Invasive therapies include electrophysiological interventions such as pacemakers or implantable cardioverter-defibrillators, revascularisation procedures such as percutaneous coronary intervention, valve replacement or repair, and temporary use of intra-aortic balloon pumps or ventricular assist devices.

3 The procedure

- 3.1 Extracorporeal membrane oxygenation (ECMO) for acute heart failure in adults can be used after heart surgery to assist in the transition from cardiopulmonary bypass to ventilation. It can also be used as a bridge to myocardial recovery, cardiac transplantation or implantation of a left ventricular assist device.
- 3.2 There are 2 main types of ECMO – venovenous and venoarterial. For acute heart failure in adults, the venoarterial method is used. Blood is withdrawn via the venous system (usually the femoral vein or right atrium) and pumped through an oxygenator, where gas exchange of oxygen and carbon dioxide takes place. It is then returned to the arterial system (usually the femoral artery or ascending aorta). Patients are given a continuous infusion of an anticoagulant, usually heparin, to prevent blood clotting in the external system. For patients with renal insufficiency, a haemofiltration unit may be integrated into the circuit.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

- 4.1 A register including 3,065 adult cardiac failure and cardiopulmonary resuscitation (CPR) patients reported survival to discharge or transfer in 39% (891 out of 2,312) of cardiac failure patients and in 27% (207 out of 753) of CPR patients. A non-randomised comparative study of 79 patients (61 treated by extracorporeal membrane oxygenation [ECMO] compared with 18 treated by miniaturised percutaneous ventricular assist device [mp-VAD]) reported in-hospital survival in 49% (30 out of 61) of ECMO patients and 50% (9 out of 18, $p>0.999$) of mp-VAD patients. Three case series of 81 patients (with acute refractory cardiogenic shock), 295 patients (treated by ECMO-supported CPR), 219 patients (with refractory postcardiotomy cardiogenic shock) and 1 systematic review of case series of 1,150 patients (with cardiogenic shock postcardiotomy) reported survival to discharge in 42% (34 out of 81), 27% (79 out of 295), 24% (52 out of 219) and 34% (386 out of 1,150) of patients respectively.
- 4.2 A case series of 47 patients with refractory postcardiotomy cardiogenic shock who were discharged from hospital after ECMO reported an overall survival rate of 59% at 10 years.
- 4.3 A non-randomised comparative study of 79 patients (61 ECMO compared with 18 mp-VAD) reported 31% (19 out of 61) of the ECMO group and 28% (5 out of 18, $p>0.999$) of the mp-VAD group were successfully bridged to long-term support or transplant. A systematic review of case series of 800 patients reported that 4% (29 out of 800) were bridged to transplant. Seventy-six per cent (22 out of 29) of these patients survived to discharge. The case series of 219 patients reported that 4% (8 out of 219) of patients were bridged to a long-term ventricular assist device. Five patients subsequently died, 2 had a successful transplant and 1 was successfully weaned from ECMO.
- 4.4 The case series of 81 patients (28 patients available for quality-of-life evaluation) reported significantly better scores in physical component ($p=0.0001$), general health ($p=0.01$) and vitality ($p=0.02$) domains of SF-36 quality-of-life scores in

14 patients who were followed up for 325 days or more than 14 patients who were followed up for fewer than 325 days.

- 4.5 The specialist advisers listed key efficacy outcomes as survival (to discharge from hospital, at 28 days, at 6 months, to definitive therapy, and long term), successful bridge to recovery, functional capacity and quality of life in the long term.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

- 5.1 Death during extracorporeal mechanical oxygenation (ECMO) support was reported in 40% (52 out of 131) of patients in a case series of 131 patients with cardiogenic shock; in 'most cases' this was because of multi-organ failure or sepsis.
- 5.2 Death within 30 days was reported in 76% (167 out of 219) of patients in the case series of 219 patients with refractory postcardiotomy cardiogenic shock; the main cause of death was low cardiac output syndrome secondary to refractory myocardial failure.
- 5.3 Intracranial haemorrhage was reported in 2% of patients in the register reporting on 2,312 cardiac failure patients (absolute numbers not reported; timing unclear).
- 5.4 Major or significant bleeding was reported to have a pooled incidence estimate of 41% (95% confidence interval [CI] 14.8% to 63.6%) in a systematic review of case series of 260 patients (5 studies).
- 5.5 Rethoracotomy for bleeding or tamponade was reported to have a pooled incidence estimate of 42% (95% CI 16.1% to 83.7%) in a systematic review of case series of 828 postcardiotomy patients (6 studies).
- 5.6 Stroke was reported in 9% (7 out of 81) of patients in the case series of 81

- patients (timing unclear). A pooled incidence estimate of 6% (95% CI 4.2% to 8.3%) was reported for stroke in a systematic review of case series of 630 patients (3 studies).
- 5.7 Femoral artery perforation (leading to uncontrollable bleeding and subsequent death) was reported in 2 patients in the case series of 131 patients. Inferior vena cava tear was reported in 2% (2 out of 92) of patients in a systematic review of case series of 92 patients (2 studies).
- 5.8 Lower extremity amputation was reported to have a pooled incidence estimate of 5% (95% CI 2.3% to 9.3%) in a systematic review of case series of 192 patients (5 studies).
- 5.9 Fasciotomy or compartment syndrome was reported to have a pooled estimate of 10% (95% CI 7.35% to 14.5%) in a systematic review of case series of 335 patients (5 studies).
- 5.10 Lower extremity ischaemia was reported to have a pooled estimate of 17% (95% CI 12.5% to 22.6%) in a systematic review of case series of 677 patients (13 studies). Lower limb ischaemia was reported in 13% (28 out of 219) of patients in the case series of 219 patients; fasciotomy for severe leg ischaemia was needed in 6% (13 out of 219) of patients (timing unclear).
- 5.11 Venous thrombus in either the femoral vein or the inferior vena cava was reported in 8% (18 out of 217) of patients (4 studies) and arterial thrombus in 7% (13 out of 192) of patients (3 studies) in a systematic review of case series.
- 5.12 Significant post-ECMO infection had a pooled incidence estimate of 30% (95% CI 13.7% to 64.5%) in a systematic review of case series of 992 patients (10 studies). Significant infection was defined as sepsis or suspected sepsis needing antibiotics, which occurred in 8 of the 10 studies. Ventilator-associated pneumonia (1 or more episode) was reported in 49% (40 out of 81) of patients, surgical wound infections in 17% (14 out of 81) of patients, bacteraemia in 14% (11 out of 81) of patients, and catheter-related infections in 6% (5 out of 81) of patients in the case series of 81 patients (timing unclear).
- 5.13 Mechanical complications, including oxygenator failure (15%; 36% of these

patients survived), cannula problems (4%; 27% survived), tubing rupture (less than 1%; none survived) and pump malfunction (less than 1%; 28% survived), were reported in cardiac failure patients (n=2,312) included in the register of patients treated by ECMO (absolute numbers not reported). Clots in the ECMO circuit were reported in 19% (56 out of 295) of patients and air embolus in 2% (5 out of 295) of patients in the case series of 295 patients.

- 5.14 Brachial plexus injury was reported in 2 case reports of patients treated with ECMO. One of these patients died 55 days later from multiple systemic complications. Symptoms improved at 4-month follow-up in the other patient.
- 5.15 The specialist advisers said that anoxic neurological complications were additional adverse events reported in the literature. They listed the following anecdotal adverse events: intrathoracic bleeding, left ventricular thrombus formation and acute pulmonary injury.

6 Committee comments

- 6.1 The Committee noted that the interpretation of evidence on extracorporeal membrane oxygenation (ECMO) for acute heart failure in adults was complicated by the different indications in published reports.
- 6.2 The Committee recognised that ECMO provides only short-term support, so it is important to have a strategy for management after ECMO before using the procedure. The Committee was advised that patient selection is fundamental to the success of ECMO, and that the procedure should only be used in patients whose condition is refractory to other treatments, and who have acute heart failure that is likely to recover spontaneously (for example, myocarditis) or for whom there is a clear plan for subsequent intervention (such as cardiac transplantation). The Committee was also advised that ECMO may need to be withdrawn for patients whose heart failure either will not recover or is not suitable for further treatment.
- 6.3 The Committee noted that the technology for this procedure is evolving.

7 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

ISBN: 978-1-4731-0494-5

Endorsing organisation

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