

Extracorporeal membrane oxygenation for severe acute respiratory failure in adults

This document replaces previous guidance on extracorporeal membrane oxygenation in adults (interventional procedure guidance 39).

1 Guidance

- 1.1 Evidence on the safety of extracorporeal membrane oxygenation (ECMO) for severe acute respiratory failure in adults is adequate but shows that there is a risk of serious side effects. Evidence on its efficacy is inadequate to draw firm conclusions: data from the recent CESAR (Conventional ventilation or extracorporeal membrane oxygenation for severe adult respiratory failure) trial were difficult to interpret because different management strategies were applied among many different hospitals in the control group and a single centre was used for the ECMO treatment group. Therefore this procedure should only be used with special arrangements for clinical governance, consent and research.
- 1.2 Clinicians wishing to undertake ECMO for severe acute respiratory failure in adults should take the following actions.
- Inform the clinical governance leads in their Trusts.
 - Whenever possible, ensure that patients and their carers understand the uncertainty about the procedure's efficacy and its risks and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/guidance/IPG391/publicinfo).
- 1.3 Extracorporeal membrane oxygenation for severe acute respiratory failure in adults should only be carried out by clinical teams with specific training and expertise in the procedure.
- 1.4 Clinicians are encouraged to submit data on all adults undergoing ECMO for severe acute respiratory failure to the international

Extracorporeal Life Support Organization register (www.else.med.umich.edu).

- 1.5 NICE encourages further research into the use of innovative technologies for the management of severe acute respiratory failure, and may review this guidance on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Extracorporeal membrane oxygenation is a supportive therapy for adults with severe acute respiratory failure from a potentially reversible cause. Extracorporeal membrane systems mimic gas exchange in the lungs by eliminating some carbon dioxide from the blood and adding oxygen.
- 2.1.2 There are many causes of severe acute respiratory failure, including acute respiratory distress syndrome, pneumonia, and chest trauma.
- 2.1.3 Conventional treatment involves maximum medical support, including mechanical ventilation. Arteriovenous extracorporeal membrane carbon dioxide removal, also known as pumpless extracorporeal lung assist, can also be used to support gas exchange.

2.2 Outline of the procedure

- 2.2.1 Extracorporeal membrane oxygenation for severe acute respiratory failure in adults aims to reduce ventilator-induced lung injuries and improve patient outcomes.
- 2.2.2 There are two main types of ECMO: venovenous ECMO (for respiratory support) and venoarterial ECMO (for cardiac and mixed cardiac and respiratory support). In venovenous ECMO

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This guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

This guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by NHS QIS for implementation by NHSScotland.

desaturated blood is withdrawn from the venae cavae and pumped through an oxygenator, where gas exchange of oxygen and carbon dioxide takes place. The oxygenated blood is then returned to the venous system. In venoarterial ECMO, blood is withdrawn via the venous system and returned to the arterial system. In both systems patients are given a continuous infusion of an anticoagulant, usually heparin, to prevent blood clotting in the external system.

Sections 2.3 and 2.4 describe efficacy and 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, available at

www.nice.org.uk/guidance/IP/29a/overview

2.3 Efficacy

- 2.3.1 A randomised controlled trial (RCT) of 180 patients treated by ECMO or conventional management reported death or severe disability in 37% (33/90) and 53% (46/87; there was no information about 3 patients) of patients respectively at 6-month follow-up (relative risk [RR] 0.69, 95% confidence interval [CI] 0.05 to 0.97).
- 2.3.2 A non-randomised comparative study of 245 patients treated by ECMO or conventional treatment reported survival to hospital discharge in 55% (34/62) and 61% (absolute figures not stated) of patients respectively ($p =$ not significant). A non-randomised comparative study of 150 patients treated by ECMO or conventional treatment reported survival rates of 53% (17/32) and 71% (84/118) respectively ($p = 0.06$). All patients in these studies treated by ECMO had more severe disease than controls.
- 2.3.3 The RCT of 180 patients treated by ECMO or conventional management reported similar levels of overall health status scores in both groups at 6 months (67.9 versus 65.9; measured on a visual analogue scale from 0 to 100, where a higher score indicates a better health status).
- 2.3.4 The Specialist Advisers listed key efficacy outcomes as successful weaning from ECMO, successful weaning from ventilation, improved survival and quality of life.

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This guidance represents the view of NICE, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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2.4 Safety

- 2.4.1 The non-randomised comparative study of 245 patients and the case series of 255 patients both reported that 5% of patients (3/62 in the comparative study, no actual figures were given for the case series) developed disseminated intravascular coagulation.
- 2.4.2 Vessel perforation during cannulation contributed to the death of 1 patient out of 68 treated by ECMO in the RCT of 180 patients.
- 2.4.3 Difficulties and/or injuries during cannulation were reported in 8% (5/62) of patients in the non-randomised comparative study of 245 patients; 1 patient required surgical intervention to repair an injury to the carotid artery.
- 2.4.4 The non-randomised comparative study of 245 patients and case series of 1473 and 255 patients reported rupture of the ECMO tubing system in 5% (3/62), 4% (64/1473) and 3% (actual numbers not stated) of patients respectively. Of the patients in the non-randomised comparative study, brain death was diagnosed in 1 patient after resuscitation and reinstatement of ECMO.
- 2.4.5 The Specialist Advisers listed anecdotal adverse events as air embolism, thromboembolic events, sepsis, multi-organ failure and mechanical failure.

2.5 Other comments

- 2.5.1 The Committee recognised the importance of the CESAR trial and the reasons for its pragmatic design.

3 Further information

- 3.1 NHS Specialised Services has developed 'Standards for Nationally Designated Centres for Extracorporeal Membrane Oxygenation (ECMO) for Adults with Severe Potentially Reversible Respiratory Failure'.
- 3.2 For related NICE guidance see www.nice.org.uk

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See

www.nice.org.uk/guidance/IPG391/publicinfo