NICE National Institute for Health and Care Excellence

NICE guidance

Extracorporeal albumin dialysis for acute liver failure

HealthTech guidance
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www.nice.org.uk/guidance/htg202

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.

Contents

This guidance replaces IPG316 and IPG45.

1 Recommendations

1.1 The evidence on extracorporeal albumin dialysis for acute liver failure raises no major safety concerns. However, current evidence on its efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake extracorporeal albumin dialysis for acute liver failure should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's efficacy and provide them with clear written information (subject to the requirement for an emergency procedure). In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having extracorporeal albumin dialysis for acute liver failure (see section 3.1).

1.3 NICE encourages further research into extracorporeal albumin dialysis for acute liver failure. This should describe clearly the indications for treatment. Short- and longer-term survival and the numbers of patients 'bridged to transplant' should be documented and compared with standard treatments. Further information about the utility of biochemical markers to guide the frequency of treatment would be helpful. NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 In acute liver failure there is rapid deterioration of liver function. It has a high mortality rate. Causes include poisoning due to alcohol, pharmaceutical or recreational drugs and viral infection. Less common causes are metabolic disease and acute fatty liver of pregnancy.

2.1.2 There are few treatment options for patients with diminishing liver function. Some patients recover liver function with supportive medical therapy including haemodialysis/filtration. Other patients need transplantation. However, there is a shortage of donor livers.

2.2 Outline of the procedure

2.2.1 This procedure aims to support the patient until either their own liver function recovers or a transplant becomes available. The procedure removes toxins bound to albumin in the blood in addition to the water-soluble toxins that can be removed by haemodialysis.

2.2.2 The blood is dialysed through a membrane against an albumin-rich dialysate. Toxic molecules bound to albumin in the blood pass through the membrane and bind onto the albumin molecules of the dialysate. The dialysate is then passed through an activated charcoal and an anion-exchange resin column (to remove toxins bound to albumin) and through a conventional filter (to remove water-soluble toxins). The dialysate is thus regenerated, and can be recirculated against the patient's blood.

2.2.3 A number of different systems are available for this procedure.

2.3 Efficacy

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.

2.3.1 A meta-analysis of 4 randomised controlled trials (RCTs) and 2 non-randomised controlled studies, which included 128 patients in total, reported no significant difference in 30-day all-cause mortality between patients who had extracorporeal albumin dialysis and those who had standard medical treatment (relative risk [RR] 0.56; 95% confidence interval [CI] 0.28 to 1.14; p=0.11). No significant differences in mortality were reported between treatment groups in the subgroups of patients with acute-on-chronic liver failure (RR 0.49; 95% CI 0.12 to 2.17; p=0.35) or those with acute liver failure (RR 0.49; 95% CI 0.15 to 1.58; p=0.23).

2.3.2 An RCT of 24 patients with cirrhosis of the liver treated by albumin dialysis or standard haemodialysis reported no significant difference in 6-month survival between 3 treatment groups (6 out of 8, and 5 out of 8 patients who had albumin dialysis by 2 different systems, and 3 out of 6 patients who had standard haemodialysis, survived; p=0.40).

2.3.3 A non-randomised controlled trial of 79 patients with acute alcoholic liver disease reported that survival at 3-year follow-up was significantly greater after extracorporeal albumin dialysis (52% [17 out of 33]) than after standard medical therapy (17% [8 out of 46]; p=0.0035). A non-randomised controlled trial of 159 patients reported no significant difference in overall survival at 6-month follow-up between patients treated by extracorporeal albumin dialysis (75% [85 out of 113]) and patients treated with standard medical therapy (61% [28 out of 46]; p=0.07).

2.3.4 The Specialist Advisers listed key efficacy outcomes as survival or successful bridge to transplant, reduced intracranial pressure/encephalopathy and improved haemodynamic stability.

2.4 Safety

2.4.1 A case series of 30 patients reported that 30% (9 out of 30) of patients developed positive blood cultures 2 to 17 days after extracorporeal albumin dialysis treatment. All 9 patients died.

2.4.2 A case report of 2 patients treated by albumin dialysis described severe pulmonary oedema in both patients. (Therapy was suspended in 1 patient.) In both patients the oedema resolved within 24 hours of aggressive medical treatment. One patient died at 9 days and the other at 201 days of follow-up.

2.4.3 A case series of 191 patients treated by 2,027 extracorporeal albumin dialysis sessions reported transitory hypotension in 14% (292 out of 2,027) of treatments. Transitory hypoglycaemia requiring medical management occurred in 17% (335 out of 2,027) of treatments, all in patients with Model for End-stage Liver Disease (MELD) scores of 30 to 40 (MELD scores range from 1 [least severe] to 40 [most severe]).

2.4.4 The Specialist Advisers listed adverse events as increased variceal bleeding and infection. They considered theoretical adverse events to include coagulopathy, shock, electrolyte abnormalities and thrombosis in the dialysis circuit.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 316 has been migrated to HealthTech guidance 202. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.