NICE guidance

Extracorporeal albumin dialysis for acute liver failure

Interventional procedures guidance
Published: 23 September 2009

www.nice.org.uk/guidance/ipg316

This guidance replaces IPG45.

1 Guidance

This guidance replaces previous guidance on extracorporeal albumin dialysis for acute-on-chronic liver failure (interventional procedure guidance 45)

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 patients ('Understanding NICE guidance') 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.

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 Efficacy

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 (6/8 and 5/8 patients who had albumin dialysis by 2 different systems, and 3/6 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% [17/33]) than after standard medical therapy (17% [8/46]) (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% [85/113]) and patients treated with standard medical therapy (61% [28/46]) (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% (9/30) of patients developed positive blood cultures 2–17 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 2027 extracorporeal albumin dialysis sessions reported transitory hypotension in 14% (292/2027) of treatments. Transitory hypoglycaemia requiring medical management occurred in 17% (335/2027) of treatments, all in patients with Model for End-stage Liver Disease (MELD) scores of 30–40 (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).

3.2 For related NICE guidance see our website.

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.

4 About this guidance

NICE interventional procedure 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. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

It updates and replaces NICE interventional procedure guidance 45.

This guidance has been incorporated into the NICE pathway on alcohol use disorders, along with other related guidance and products.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes since publication

6 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and 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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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation