NICE guidance

Extracorporeal whole liver perfusion for acute liver failure

Interventional procedures guidance
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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. However, 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.

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.

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 Evidence on the safety of extracorporeal whole liver perfusion for acute liver

failure shows serious, well-recognised complications. Evidence on efficacy is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 Clinicians and centres doing this procedure must follow the relevant regulatory and legal requirements of the Human Tissue Authority and the procedure should only be done in accordance with the policies of the NHS Blood and Transplant (NHSBT) Organ Donation and Transplantation Liver Advisory Group. Details of any patient who has a liver transplant after extracorporeal whole liver perfusion for acute liver failure should be entered into the NHSBT UK transplant registry, and clinical outcomes should be reviewed locally.

1.3 Further research should report details of patient selection, the exact protocol followed, the type of liver used, and long-term immunological and microbiological surveillance. Outcomes should be reported in a way that allows the procedure to be compared with other current treatments.

1.4 The procedure should only be done in centres specialising in treating acute liver failure and liver transplantation by a multidisciplinary team experienced in managing this condition.

2 The condition, current treatments and procedure

The condition

2.1 Acute liver failure is characterised by a rapid (typically in less than 4 weeks) decline in liver function. Causes include poisoning because of alcohol, pharmaceutical or recreational drugs, and viral infection. Less common causes are metabolic disease and acute fatty liver of pregnancy.

Current treatments

2.2 Untreated, acute liver failure can have a high mortality. Current treatment options include medication (to reverse poisoning and to prevent complications caused by acute liver failure), temporary liver support therapies (such as

haemodialysis or filtration, plasma exchange, and bioartificial liver support), hepatocyte transplantation and liver transplantation.

The procedure

2.3 In this procedure a veno-venous circuit is usually used to perfuse the patient's blood through an extracorporeal whole liver. The aim is to provide metabolic support and prolong survival, to allow time for the patient's liver function to recover or to find a suitable donor liver for transplantation.

2.4 Blood is pumped from a catheter inserted into the femoral vein through an oxygenator and the hepatic artery and portal vein of an extracorporeal whole liver. The liver may be a human liver not suitable for transplantation or a xenogeneic liver (typically a pig liver). Effluent blood from the extracorporeal liver, which is maintained at a normal temperature with a normal pH and electrolytes, is returned to the patient through a subclavian or jugular venous cannula. The literature describes modifications to the technique, such as isolating the patient's immune system from the extracorporeal liver and using different sites for venous access.

2.5 Extracorporeal perfusion is continued for up to 5 days until either the patient has a liver transplant or their liver function recovers.

3 Committee considerations

The evidence

3.1 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 7 sources, which was discussed by the committee. The evidence included 1 systematic review, 5 case series and 1 case report. It is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: survival, improvement in neurological outcomes and bridge to transplantation.

3.3 The professional experts and the committee considered the key safety outcomes to be: thrombotic events, hyperkalaemia causing cardiac arrhythmia and septicaemia.

3.4 No patient commentary was sought because it was not feasible for patients with acute liver failure to offer commentary for this procedure.

Committee comments

3.5 The committee noted that much of the evidence reviewed came from studies done some years ago.

3.6 Recent advances in the intensive care management of acute liver failure and liver transplantation have made the data on patient selection, safety and efficacy outcomes difficult to interpret in the context of current practice.

3.7 The committee was informed that, if clinically appropriate, patients having this procedure should be listed with NHS Blood and Transplant for an urgent transplant. But the committee noted that this procedure can also be used for patients who are unable to have, or do not need, liver transplantation.

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