

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Extracorporeal whole liver perfusion for acute liver failure

Acute liver failure is when the liver stops working within days or weeks. The patient often dies if they do not get a liver transplant. In this procedure blood is diverted from a large vein, usually in the leg, to a whole liver (perfusion) outside the body (extracorporeal) and returned to the patient through another large vein, usually in the neck. The liver may be a donor human liver that is unsuitable for transplantation or from an animal such as a pig. The aim is to keep the patient alive until their liver starts working again or they get a liver transplant.

NICE is looking at extracorporeal whole liver perfusion for acute liver failure.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 22 October 2020

Target date for publication of guidance: March 2021

1 Draft recommendations

- 1.1 Evidence on the safety of extracorporeal whole liver perfusion for acute liver failure shows serious but 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 and the type of liver used. 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 septicemia.
- 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.

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Vice chair, interventional procedures advisory committee
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