NICE guidance

Ex-vivo hepatic resection and reimplantation for liver cancer

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, 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.

1 Guidance

1.1 Current evidence on ex-vivo hepatic resection and reimplantation for liver cancer raises concerns about the safety and efficacy of the procedure. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. It should only be used for patients who would otherwise not survive and for whom other treatment options have failed or are inappropriate.

1.2 Clinicians wishing to undertake ex-vivo hepatic resection and reimplantation for liver cancer should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy; specifically the risks of death or serious morbidity, and the possible need for liver transplantation. Clear written information should be provided. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having ex-vivo hepatic resection and reimplantation for liver cancer (see section 3.1).

2 The procedure

2.1 Indications and current treatments

2.1.1 This procedure can be carried out in patients with primary or secondary

(metastatic) liver cancer.

2.1.2 Treatment strategies for patients with liver cancer depend on tumour type, location, number and size. Most patients with liver cancer cannot benefit from surgical treatment and are treated with palliative intent. For some patients, liver resection surgery, either on its own or in combination with other treatments, may be beneficial.

2.2 Outline of the procedure

2.2.1 The procedure is carried out with the patient under general anaesthesia. The liver is removed through an abdominal incision and is perfused with a preservative solution. A bloodless resection of the diseased hepatic parenchyma is then performed, allowing complex reconstruction of the hepatic and portal vein structures, and the liver is reimplanted into the patient. The procedure can be performed with or without venovenous bypass.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3.1 In a case series of 24 patients (22 with cancer) treated by ex-vivo hepatic resection and reimplantation, it was possible to resect and reimplant the liver in 91% (20 out of 22) of the patients with cancer. In the case series of 24 patients (22 with cancer), 59% (13 out of 22) survived the procedure and were discharged. Of the 13 patients who survived the procedure, 77% (10 out of 13) died of tumour recurrence at between 12-month and 36-month follow-up. In a case series of 8 patients with liver metastases from colorectal cancer, 4 patients were treated by ex-vivo resection, of whom 2 were alive at 5-month follow-up (1 patient with tumour recurrence in the bone). The third patient died after 30 months and the fourth died 15 days after the operation. In a case series of 16 patients treated by liver resection with hepatic vein reconstruction, 2 patients

were treated by ex-vivo resection. One of the 2 patients, with hepatocellular carcinoma, was alive and disease free at 52-month follow-up. The other patient, with colorectal metastases, was free of hepatic involvement at death following small bowel perforation after 4 months of follow-up. A case report of a single patient with hepatocellular carcinoma reported that the patient was alive with no recurrence 1 year after ex-vivo hepatic resection.

2.3.2 In the case series of 24 patients (22 with cancer), the mean operative time was 13.54 hours, and the mean anhepatic phase was 6.67 hours.

2.3.3 The Specialist Advisers stated that the key efficacy outcome of this procedure is survival.

2.4 Safety

2.4.1 Of the 22 patients with cancer in the case series of 24 patients treated by ex-vivo liver resection, 41% (9 out of 22) died postoperatively during the same admission episode as the operation (exact timing of death not stated). In the same study, 32% of patients (7 out of 22) required donor liver transplantation either immediately (2 patients) or at a subsequent procedure (5 patients; exact timing of transplantation not stated).

2.4.2 In the case series of 8 patients, of the 4 patients undergoing ex-vivo resection, 1 patient died after 15 days from respiratory failure, renal failure and haemopneumothorax; and 1 patient developed inferior vena caval obstruction requiring stenting and pleural effusion requiring drainage.

2.4.3 The Specialist Advisers stated that adverse events (reported in the literature or anecdotally) include mortality, liver failure and bleeding/requirement for blood transfusion. The Specialist Advisers also commented that the procedure may increase the demand for donor livers.

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 audit support (which is for use at local discretion).

3.2 NICE has published interventional procedures guidance on radiofrequency ablation for colorectal liver metastases, selective internal radiation therapy for unresectable colorectal metastases in the liver, microwave ablation for treating liver metastases, radiofrequency-assisted liver resection, living-donor liver transplantation, laparoscopic liver resection and radiofrequency ablation of hepatocellular carcinoma.

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.