

Microwave ablation for the treatment of metastases in the liver

1 Guidance

- 1.1 Current evidence on the safety and efficacy of microwave ablation for the treatment of metastases in the liver does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to use microwave ablation for the treatment of metastases in the liver 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 and provide them with clear written information, including about other treatment options. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG220publicinfo).
 - Audit and review clinical outcomes of all patients having microwave ablation for the treatment of metastases in the liver (see section 3.1).
- 1.3 Patient selection should be carried out by a multidisciplinary team that includes a hepatobiliary surgeon.
- 1.4 The procedure should be performed under appropriate imaging guidance.
- 1.5 As a number of devices are available, and there is some uncertainty about the energy levels that should be used, any adverse events relating to this procedure should be reported to the Medicines and Healthcare products Regulatory Agency.
- 1.6 Further research on the procedure would be useful. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

- 2.1.1 The procedure is used to ablate liver metastases which have spread from primary cancers in other organs, most commonly colorectal cancer.
- 2.1.2 Surgical resection of colorectal liver metastases with curative intent is possible in a minority of patients, with 5-year survival rates of 25–39%. Metastatic disease from other primary sites may also be operable. However, most patients are not candidates for surgical resection because of the number or distribution of tumours, and/or the presence of extra-hepatic metastases. Treatment options, which can be used with palliative and sometimes curative intent, include hepatic artery infusion chemotherapy, trans-arterial chemoembolisation, percutaneous ethanol injection, cryoablation, laser ablation and radiofrequency ablation.

2.2 Outline of the procedure

- 2.2.1 Microwave ablation is a technique that destroys tumours using heat, resulting in localised areas of necrosis and tissue destruction. The procedure can be performed under local or general anaesthesia. Needle electrodes, connected to a generator, are advanced into the liver tumour(s) either during laparotomy or laparoscopy, or percutaneously under image guidance. The targeted tumour(s) are then ablated. Multiple pulses of energy may be delivered during one session and multiple needle electrodes can be used to treat larger tumours. Several types of microwave needle electrodes and generators are available.

2.3 Efficacy

- 2.3.1 Data on the efficacy of microwave ablation for liver metastases were available from one randomised controlled trial and three case series.

Interventional procedure guidance 220

This guidance is written in the following context

This guidance represents the view of the Institute, which 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.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

Statistical methods employed to calculate survival varied between studies, making interpretation of the evidence difficult. One randomised controlled trial of 30 patients (14 undergoing microwave ablation) reported that the mean survival was 27 months following microwave ablation and 25 months following liver resection ($p = 0.83$). Disease-free survival was also similar between the groups, being 11.3 and 13.3 months, respectively ($p = 0.47$).

- 2.3.2 One case series reported that the mean survival period following microwave ablation was 22 months, and disease-free survival to final follow-up (25 months) was achieved in 35% (26/74) of patients. A second case series of 22 patients with liver metastases treated with microwave ablation reported no tumour recurrence during 17 months' follow-up in 32% (7/22) of patients, with 72% (16/22) of patients surviving to 17 months' follow-up. In the above series the primary tumours were of mixed origin. For more details, refer to the 'Sources of evidence' section.
- 2.3.3 The Specialist Advisers considered that there are some uncertainties about the efficacy of the procedure. There are currently no data on long-term survival and tumours may recur if less than complete tumour cell death is achieved.

2.4 Safety

- 2.4.1 One randomised controlled trial of 30 patients (14 undergoing microwave ablation) reported that there were no intraoperative deaths in either group. Two case series of 74 and 22 patients reported that there were no severe complications, such as massive bleeding or pneumothorax, following microwave ablation procedures.
- 2.4.2 Among the 14 patients in the microwave ablation arm of the randomised controlled trial and in one case series of 29 patients, the rate of bile duct fistula formation was reported to be 7% (1/14 and 2/29, respectively). The rate of hepatic abscess formation following microwave ablation was 7% (1/14 and 2/29, respectively).
- 2.4.3 Other complications reported following microwave ablation of liver metastases include minor to moderate pleural effusions in 9% (7/74) of patients, and minor subcapsular bleeding which

resolved without transfusion in 3% (2/74) of patients. For more details, refer to the 'Sources of evidence' section.

- 2.4.4 The Specialist Advisers stated that theoretical adverse events resulting from the procedure include liver abscess, intraperitoneal haemorrhage, neoplastic seeding, biliary peritonitis, bowel perforation and thrombosis of adjacent blood vessels.

3 Further information

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. The Institute has identified relevant audit criteria and developed an audit tool (which is for use at local discretion), available from www.nice.org.uk/IPG220
- 3.2 The Institute has issued guidance on radiofrequency ablation for the treatment of colorectal metastases in the liver (www.nice.org.uk/IPG092), selective internal radiation therapy for colorectal metastases in the liver (www.nice.org.uk/IPG093) and microwave ablation for hepatocellular carcinoma (www.nice.org.uk/IPG214).

Andrew Dillon
Chief Executive
May 2007

Information for patients

NICE has produced information describing its guidance on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG220publicinfo

Sources of evidence

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

'Interventional procedure overview of microwave ablation for the treatment of metastases of the liver,'
November 2006.

Available from: www.nice.org.uk/ip381overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1261. 'Understanding NICE guidance' can be obtained by quoting reference number N1262.

The distribution list for this guidance is available at www.nice.org.uk/IPG220distributionlist

Published by the National Institute for Health and Clinical Excellence, May 2007; ISBN 1-84629-418-5

Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

© National Institute for Health and Clinical Excellence, May 2007. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the express written permission of the Institute.