

Microwave ablation of hepatocellular carcinoma

1 Guidance

- 1.1 Current evidence on the safety and efficacy of microwave ablation of hepatocellular carcinoma appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.
- 1.2 Patient selection should be carried out by a multidisciplinary team that includes a hepatobiliary surgeon.
- 1.3 The procedure should be performed under appropriate imaging guidance.
- 1.4 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.
- 1.5 Further research on long-term survival outcomes and comparisons of microwave ablation with other ablative techniques will be useful.

2 The procedure

2.1 Indications

- 2.1.1 Hepatocellular carcinoma is the most common type of primary liver cancer. For most patients, treatment with curative intent is not possible. The treatment options include surgical excision, hepatic artery infusion chemotherapy, trans-arterial chemoembolisation, percutaneous ethanol injection, cryoablation and radiofrequency ablation. Liver transplantation (with curative intent) may be appropriate for some patients.

2.2 Outline of the procedure

- 2.2.1 Microwave ablation destroys tumour cells by heat, resulting in localised areas of necrosis and tissue destruction. The procedure can be performed under local or general anaesthesia.
- 2.2.2 Under appropriate imaging guidance, needle electrodes are advanced into the liver tumour(s) during laparotomy or laparoscopy, or percutaneously, and are attached to a microwave generator. Microwave energy is then delivered to destroy areas of the tumour(s). Multiple pulses of energy can be delivered during one session, and multiple-needle electrodes can be used to treat larger tumours.

2.3 Efficacy

- 2.3.1 A non-randomised controlled study of 89 patients found that overall survival was similar in patients treated with microwave ablation or liver resection at 25 months' follow-up; local recurrence occurred in 8% of patients treated with microwave ablation (3/38) or resection (4/51). In another non-randomised controlled trial of 43 patients with well-differentiated liver tumours, overall 5-year survival was similar after microwave ablation (70% in 23 patients) or percutaneous ethanol injection (78% in 20 patients). In the same study, 5-year survival in patients with moderately or poorly differentiated tumours was significantly higher after microwave ablation (78% in 25 patients) than after percutaneous ethanol injection (35% in 20 patients) ($p = 0.03$). One case series of 288 patients who received microwave ablation reported overall survival of 51% at 5 years.

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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.

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

2.3.2 In contrast, a further non-randomised controlled study reported that overall survival rates following radiofrequency ablation were 96% at 1 year, 92% at 2 years and 77% at 3 years (absolute figures not presented) which were significantly higher than survival rates following microwave ablation (rates not presented) ($p = 0.041$). This study also found that local recurrence following radiofrequency ablation occurred in 5% of patients at 1 year, 15% at 2 years and 15% at 3 years (absolute figures not presented) which was significantly lower than following microwave ablation (rates not presented) ($p = 0.042$).

2.3.3 In a non-randomised controlled study of 102 patients, the mean duration of disease-free survival was 15.5 months in patients treated with microwave ablation (95% confidence interval [CI] 11.3 to 20.0 months) compared with 16.5 months (95% CI 10.1 to 19.2 months) in those receiving radiofrequency ablation. The difference was not statistically significant ($p = 0.53$).

2.3.4 The Specialist Advisers stated that this is a novel procedure, but there are no major concerns about efficacy. They noted that data on long-term survival are limited.

2.4 Safety

2.4.1 A non-randomised controlled trial of 89 patients found no difference in the incidence of intra-abdominal bleeding, gastrointestinal bleeding, biliary stenosis and wound dehiscence between patients treated with microwave ablation via laparotomy and those treated with liver resection.

2.4.2 Another non-randomised controlled trial reported that major complications (not otherwise described) occurred in 8% (4/49) of patients treated with microwave ablation and 6% (3/53) of patients treated with radiofrequency ablation ($p = 0.71$). A case series reported that acute respiratory distress syndrome occurred in 19% (4/21) of patients treated with open microwave ablation.

2.4.3 A further non-randomised controlled trial found that there was a significantly greater proportion of patients with postoperative pain following microwave ablation, 16% (11/70), than following radiofrequency ablation, 4% (2/48) ($p = 0.049$).

There was also a higher rate in the microwave ablation group than in the radiofrequency group of patients with bile duct injury, 16% (11/70) versus 4% (2/48) ($p = 0.049$), and postoperative ascites, 10% (7/70) versus 0% ($p = 0.024$). However, there were no statistically significant differences in the rates of skin burns, vagovagal reflex, liver abscess, bleeding, hepatic infarction, portal thrombus or biliary peritonitis between treatment groups.

2.4.4 The Specialist Advisers listed the theoretical adverse events as including liver abscess, intraperitoneal haemorrhage, neoplastic seeding, biliary peritonitis, bowel perforation, adjacent vessel thrombosis and the potential for collateral thermal injury.

3 Further information

3.1 The Institute has issued interventional procedures guidance on radiofrequency ablation of hepatocellular carcinoma (www.nice.org.uk/IPG002) and laparoscopic liver resection (www.nice.org.uk/IPG135). The Institute is developing guidance on the use of microwave ablation for metastases in the liver (www.nice.org.uk/IP_381).

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Chief Executive
March 2007

Information for patients

The Institute has produced information describing its guidance on this procedure for patients ('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/IPG214publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document. 'Interventional procedure overview of microwave ablation of hepatocellular carcinoma', August 2006.

Available from: www.nice.org.uk/IP370overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1224. 'Understanding NICE guidance' can be obtained by quoting reference number N1225.

The distribution list for this guidance is available at www.nice.org.uk/IPG214distributionlist

Published by the National Institute for Health and Clinical Excellence, March 2007; ISBN 1-84629-387-1

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