

Microwave ablation of hepatocellular carcinoma

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 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, transarterial 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 out of 38) or resection (4 out of 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.
- 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 out of 49) of patients treated with microwave ablation and 6% (3 out of 53) of patients treated with radiofrequency ablation ($p=0.71$). A case series reported that acute respiratory distress syndrome occurred in 19% (4 out of 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 out of 70), than following radiofrequency ablation, 4% (2 out of 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 out of 70) versus 4% (2 out of 48; $p=0.049$), and postoperative ascites, 10% (7 out of 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 NICE has issued [interventional procedures guidance on radiofrequency ablation of hepatocellular carcinoma](#), [laparoscopic liver resection](#) and [microwave ablation for treating liver metastases](#).

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 decision made, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).