

Radiofrequency ablation for colorectal liver metastases

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg327

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.

This guidance replaces IPG92.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of radiofrequency (RF) ablation for colorectal liver metastases is adequate to support the use of this procedure in patients unfit or otherwise unsuitable for hepatic resection, or in those who have previously had hepatic resection, provided that normal arrangements are in place for clinical governance, consent and audit.
- 1.2 Patient selection should be carried out by a hepatobiliary cancer multidisciplinary team.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Colorectal cancer is the second most common cancer in women and the third most common cancer in men in the UK. The liver is the most common site for metastases.
- 2.1.2 Curative treatment for patients with liver metastases from colorectal cancer may be provided by liver resection. However, fitness for surgery and the number, location and size of the metastases may dictate the use of alternative treatment options. These include systemic chemotherapy, radiotherapy, thermal ablation, chemoembolisation and selective internal radiation therapy. Radiofrequency (RF)

ablation may be indicated as the primary treatment for liver metastases if the patient is unfit for surgery or in the treatment of postresection recurrence. It may also be used as an adjunct to hepatic resection to ablate small-volume disease in the future remnant liver.

2.2 Outline of the procedure

- 2.2.1 A percutaneous or intraoperative approach may be used, with the patient under local or general anaesthesia. Needle electrodes are inserted into the target tumour area (or areas) using imaging guidance. A high-frequency alternating current is applied, resulting in heat generation, which causes localised coagulative necrosis and tissue destruction around the electrodes.
- 2.2.2 Several different types of RF electrodes are available.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

- 2.3.1 The selection criteria in the following studies means that patients who had RF ablation or RF ablation plus surgery could not have been treated by surgery alone.
- 2.3.2 A non-randomised controlled trial of 46 patients treated by RF ablation or surgical resection described in a systematic review reported that median survival after diagnosis of liver metastases was 44 months and 54 months, respectively (significance not stated). In the same systematic review, 6 case series reported survival ranging from 17% (1 out of 6) at 11-month follow-up to 88% (7 out of 8) at 2- to 6-month follow-up. A non-randomised controlled trial of 418 patients reported that patients treated by surgical resection had overall survival rates of 73%, 65% and 58% at 3-, 4- and 5-year follow-up, respectively. These rates were significantly higher than those from patients treated by RF ablation alone, or by

RF ablation plus resection (absolute figures not stated; $p < 0.0001$). In the same study, the difference in survival between patients treated by RF ablation alone and RF ablation plus surgical resection was not significant ($p = 0.36$). A non-randomised controlled trial of 258 patients reported that 3-year disease-free survival was significantly greater in patients treated by surgical resection alone (40%) than in those treated by RF ablation plus resection (34%; absolute figures not stated; $p = 0.01$).

2.3.3 A case series of 243 patients with unresectable metastases reported survival rates of 20% and 18% at 3- and 5-year follow-up, respectively (absolute figures not stated).

2.3.4 The non-randomised controlled trial of 418 patients reported that recurrence at any site occurred more often in the RF ablation group (84%) than in the surgical resection group (52%) at a median 21-month follow-up (absolute figures not stated; $p < 0.001$). The non-randomised controlled trial of 258 patients reported that recurrence at any site at 1-year follow-up was significantly lower in the surgical resection group (24%) than in the RF ablation plus resection group (61%) or the RF ablation alone group (66%; absolute figures not stated; $p < 0.001$).

2.3.5 The Specialist Advisers listed key efficacy outcomes as overall survival and local recurrence rate.

2.4 Safety

2.4.1 Haemorrhage requiring transfusion (required hospital stay of more than 72 hours) was reported in 1% (7 out of 617) of treatment sessions in a case series of 309 patients.

2.4.2 Three cases series described in the systematic review reported postoperative complication rates between 0% and 33%. The complications included bowel perforation, peritoneal seeding (metastasis), bile duct stricture, wound infection and postoperative bleeding (absolute figures not stated).

2.4.3 A case report of a patient previously treated by both surgical resection and cryoablation described cutaneous fistula formation between the site of electrode

insertion and the gastric antrum at 3-week follow-up. This had resolved at 6-month follow-up.

- 2.4.4 Visceral thermal injury (required hospital stay of more than 72 hours) was reported in less than 1% (4 out of 617) of treatment sessions in the case series of 309 patients.
- 2.4.5 A case series of 122 patients reported infected biloma development (requiring percutaneous drainage) in 1% (1 out of 122) of patients, and biliary dilation and cholangitis leading to biliobronchial fistula in 1% (1 out of 122) of patients. Minor complications (not requiring intervention) included development of a small haemoperitoneum in 2% (3 out of 122), biliary dilation in 3% (4 out of 122) and persistent pain (location not reported) in 2% (3 out of 122) of patients.
- 2.4.6 Another case report described a patient with pain and fever (40°C) at 5-day follow-up. Abdominal ultrasound revealed an intrahepatic abscess which required drainage. The patient recovered uneventfully.
- 2.4.7 The Specialist Advisers listed anecdotal adverse events as damage to the biliary tree and bradycardia. They considered theoretical adverse events to include injury to the bowel or diaphragm, and damage to the pleura or lungs.

2.5 Other comments

- 2.5.1 The Committee noted that the evidence was difficult to interpret because patient selection criteria and the use of concomitant treatments differed between the studies.

3 Further information

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](#).