

Irreversible electroporation for primary liver cancer

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg664

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 IPG444.

1 Recommendations

- 1.1 Evidence on the safety of irreversible electroporation for primary liver cancer shows serious but infrequent and well-recognised complications. Evidence on its efficacy is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.
- 1.2 Patient selection should be done by a multidisciplinary team.
- 1.3 The procedure should only be done in specialist centres by clinicians with experience and specific training.
- 1.4 Further research could be in the form of case series or registry-based research. It should include: details of patient selection; tumour position and size; long-term outcomes including overall survival, progression-free survival and tumour regression; and patient-reported outcomes including quality of life.

2 The condition, current treatments and procedure

The condition

- 2.1 The most common primary liver cancers are hepatocellular carcinoma and cholangiocarcinoma.

Current treatments

- 2.2 Treatment for primary liver cancer depends on several factors, including the exact location and stage of the cancer, the patient's liver function and any patient-related comorbidities. For most patients, treatment with curative intent is not possible. The treatment options include surgical excision, chemotherapy (either systemic or local hepatic artery infusion), transarterial chemoembolisation, percutaneous ethanol injection, and thermal ablation techniques such as cryotherapy, radiofrequency and microwave ablation. Liver transplantation (with curative intent) may be appropriate for some patients.

The procedure

- 2.3 The aim of irreversible electroporation (IRE) is to destroy cancerous cells by subjecting them to short pulses of high-voltage direct current. This creates multiple holes in the cell membrane, irreversibly damaging the cell's homeostasis mechanisms and leading to cell death.
- 2.4 IRE for primary liver cancer is done with the patient under general anaesthesia. A neuromuscular blocking agent is used to prevent muscle spasms. Needle-like electrodes are introduced percutaneously into the tumour under imaging guidance (either CT or, less commonly, ultrasound). The distance between the electrodes is confirmed by imaging. This is to ensure that the electrodes are correctly placed parallel to each other, and that enough current flow would be

generated to ensure IRE. The procedure may also be done through an open surgical or laparoscopic approach, although the percutaneous route is the most common.

- 2.5 Electrodes are repositioned under imaging guidance to extend the zone of electroporation until the entire tumour and an appropriate margin have been ablated. The number of ablations is determined by the volume of the target tumour. When the ablation procedure is completed, further imaging may be done to confirm the extent of the ablation.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 11 sources, which was discussed by the committee. The evidence included 3 non-randomised comparative studies (1 of which was a conference abstract included for safety data only), 7 case series and 1 case report. It is presented in [table 2 of the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: tumour ablation, progression-free survival, overall survival and quality of life.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: damage to adjacent structures, bleeding, cardiac arrhythmias and tumour seeding.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee was informed that the procedure may have a particular role for small tumours (that is, under 3 cm) next to blood vessels or the biliary tree, which may not be suitable for ablation by other techniques.
- 3.6 The committee was informed that the positioning and alignment of needles is critical to the success of the procedure.

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Endorsing organisation

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