Irreversible electroporation for treating primary liver cancer

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg444

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. However, 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.

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.

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 irreversible electroporation for treating primary liver cancer is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. In particular, studies should report the effect of the procedure on local tumour control and
2 The procedure

2.1 Indications and current treatments

2.1.1 The most common types of primary liver cancer are hepatocellular carcinoma (also known as hepatoma) and cholangiocarcinoma.

2.1.2 Treatment for primary liver cancer depends on a number of factors, including the location and stage of the cancer and how well liver function is preserved. Treatment options include surgical resection, thermal ablation, systemic chemotherapy, transarterial chemoembolisation and selective internal radiation therapy. Liver transplantation may be appropriate for some patients. For most patients, treatment with curative intent is not possible. Irreversible electroporation is a non-thermal cell-destruction technique, which is claimed to allow targeted destruction of cancerous cells with less damage to surrounding structures (such as major blood vessels and bile ducts) than other types of treatment.

2.2 Outline of the procedure

2.2.1 The aim of irreversible electroporation is to destroy cancerous cells by subjecting them to a series of short electrical pulses using high-voltage direct current. This creates multiple holes in the cell membrane, irreversibly damaging the cell’s homeostasis mechanisms and leading to cell death.

2.2.2 The procedure is performed with the patient under general anaesthesia. A neuromuscular blocking agent is essential to prevent uncontrolled severe muscle contractions caused by the electric current. Bipolar or unipolar electrode needles are introduced percutaneously (or by open surgical or laparoscopic approaches) and guided into place in and adjacent to the target tumour using imaging guidance. A series of very short electrical pulses is delivered over several minutes to ablate the tumour. The electrodes may then be repositioned to extend the zone of electroporation until the entire tumour and an appropriate margin have been ablated. Cardiac synchronisation is used to time delivery of the electrical pulse within the refractory period of the heart cycle, minimising the risk of arrhythmia.
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 Efficacy

2.3.1 A case series of 38 patients including 11 patients with primary liver cancer (22 tumours) reported a complete response in 64% (14/22) of these primary tumours, progressive disease in 14% (3/22) and stable disease in 23% (5/22) at 3-month follow-up, assessed by modified 'Response Evaluation Criteria in Solid Tumors' (modified RECIST). In patients with primary hepatocellular carcinoma, 82% (14/17) of targeted tumours were completely ablated at 3-month follow-up.

2.3.2 A case series of 44 patients (including 14 patients with hepatocellular carcinoma) reported local recurrence-free survival of 90% at 6 months and 50% at 12 months.

2.3.3 The Specialist Advisers listed key efficacy outcomes as completeness of tumour ablation, survival and relapse-free interval.

2.4 Safety

2.4.1 The case series of 38 patients reported transient cardiac arrhythmia in 6 patients (4 patients had ventricular tachycardia, 1 patient had supraventricular tachycardia and 1 patient had atrial fibrillation). Two of these patients had cardiac synchronisation and 4 did not. All of the arrhythmias resolved without treatment except for atrial fibrillation in 1 patient, which was treated by cardioversion.

2.4.2 A case series of 21 patients with primary or metastatic cancer (liver, kidney and lung) reported transient ventricular tachycardia during 25% (7/28) of procedures. In 4 of the 7 procedures, arterial blood pressure was 'markedly decreased' (not defined).

2.4.3 A case series of 49 patients with hepatocellular carcinoma or colorectal liver metastases reported pneumothorax in 4% (2/49) of patients. In the case series of 38 patients, 1 pneumothorax was related to liver ablation and a Heimlich
valve was inserted with resolution ‘in a few hours’. In the case series of 21 patients with primary or metastatic cancer, 1 pneumothorax occurred after transabdominal placement of electrodes in the liver and the other 2 were in patients having treatment for lung metastases. The case series of 21 patients with primary hepatocellular carcinoma reported pneumothorax in 1 patient, which was managed conservatively.

2.4.4 A case series of 26 patients with hepatocellular carcinoma reported haemothorax due to a needle puncture of an intercostal artery (treated by drainage) in 1 patient.

2.4.5 A case series of 44 patients with primary or metastatic liver cancer reported 1 patient with a neurogenic bladder, which resolved without treatment within 30 days.

2.4.6 The case series of 26 patients reported transient hepatic decompensation in 1 patient, which resolved without treatment.

2.4.7 The case series of 38 patients reported increases in alanine aminotransferase (ALT) level of between 19 and 1747 international units per litre 24 hours after 95% (40/42) of procedures (ALT levels available for 42 of 49 liver tumour ablation procedures). Levels returned to normal or baseline at 1-month follow-up after 98% (39/40) of the procedures.

2.4.8 The Specialist Advisers listed theoretical adverse events as tumour seeding along the needle tracks; injury to structures such as bile ducts, blood vessels, diaphragm and lung; nerve damage; portal vein thrombosis; and liver abscess.

2.5 Other comments

2.5.1 The Committee noted that most of the published studies included patients with different tumour types and that only a few patients had primary liver cancer.

2.5.2 The Committee noted the claim that this procedure may be associated with less damage to surrounding structures (such as major blood vessels and bile ducts) than other ablative techniques, but considered that more evidence is needed to support this.
3 Further information

3.1 For related NICE guidance see the NICE website.

Information for patients

NICE has produced information on this procedure for patients and carers (Information for the public). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedures guidance process.

We have produced a summary of this guidance for patients and carers.

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Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their 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.

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