

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Irreversible electroporation for primary liver cancer

Primary liver cancer starts in the liver, unlike secondary cancer that has spread from another part of the body. In this procedure, single-use needles are inserted into the liver. Short electrical pulses of high-voltage current are passed between the needles to create tiny holes (pores) in the cancer cells (irreversible electroporation). The aim is to kill the cancer cells without damaging the structure of the liver.

NICE is looking at irreversible electroporation for primary liver cancer. This is a review of NICE's interventional procedures guidance on [irreversible electroporation for treating primary liver cancer](#).

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of specialist advisers, who are consultants with knowledge of the procedure.

This document contains the draft guidance for [consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

- prepare a second draft, which will go through a [resolution](#) process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 17 July 2019

Target date for publication of guidance: October 2019

1 Draft recommendations

- 1.1 Evidence on the safety of irreversible electroporation for primary liver cancer shows serious but 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](#).
- 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 9 sources, which was discussed by the committee. The evidence included 2 non-randomised comparative studies (1 of which was a conference abstract included for safety data only) and 7 case series. 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.

Committee comments

- 3.4 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.
- 3.5 The committee was informed that the positioning and alignment of needles is critical to the success of the procedure.

NICE interventional procedures consultation document, June 2019

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Chair, interventional procedures advisory committee

June 2019

ISBN: