NICE guidance

Irreversible electroporation for treating primary lung cancer and metastases in the lung

Interventional procedures guidance
Published: 23 February 2013

www.nice.org.uk/guidance/ipg441

1 Guidance

1.1 Current evidence on the safety and efficacy of irreversible electroporation for treating primary lung cancer and metastases in the lung 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 patient survival.

2 The procedure

2.1 Indications and current treatments

2.1.1 Lung cancer is one of the most common cancers in the UK. The

symptoms often do not appear until the disease is at an advanced stage, and the prognosis is generally poor. The lung is also a common site for metastases from other primary cancers, such as breast and colon cancer.

2.1.2 The choice of treatment for primary lung cancer and metastases in the lung is influenced primarily by the type of tumour and stage of the disease. Treatments include surgical resection (open or thoracoscopic), chemotherapy, radiotherapy, photodynamic therapy or thermal ablation, or a combination of these. If the tumour protrudes into the major airways, interventional bronchoscopic treatments including diathermy, laser therapy, cryotherapy, brachytherapy or photodynamic therapy may be used. Irreversible electroporation is a non-thermal cell-destruction technique, which is claimed to allow targeted destruction of cancerous cells with less damage to supporting connective tissue (such as nearby blood vessels and nerves) than with 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 with a variety of tumours reported no satisfactory tumour response in any of the 4 patients treated for lung tumours, and all 4 patients had progressive disease when assessed by the modified 'Response Evaluation Criteria in Solid Tumors' at 3 months.

2.3.2 A case report of 2 patients with primary and metastatic lung tumours reported progression of disease (at 2 months after the procedure in 1 patient and at 6 months in the other patient).

2.3.3 The Specialist Advisers listed key efficacy outcomes as patient survival, tumour response on follow-up imaging, local tumour control, time to disease progression, improvement in health-related quality of life and reduction in tumour-related symptoms.

2.4 Safety

2.4.1 The case series of 38 patients reported 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 arrhythmias despite the use of cardiac synchronisation. All the arrhythmias resolved spontaneously except for the atrial fibrillation, 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 2 out of 3 procedures in patients with lung tumours.

2.4.3 A case series of 45 patients (12 lung lesions) reported pneumothorax in 14% (7/50) of procedures. The case series of 38 patients (4 patients with lung cancer) reported 2 cases of pneumothorax (50% incidence). The

case series of 21 patients (3 patients with lung cancer) reported 2 cases of pneumothorax (67% incidence).

2.4.4 The case series of 38 patients reported collapse of the right upper lobe in 1 patient with advanced lung cancer: the lobe re-expanded spontaneously.

2.4.5 The case report of 2 patients reported moderate parenchymal haemorrhage at the time of the procedure in 1 patient.

2.4.6 One Specialist Adviser reported an anecdotal adverse event of sepsis. The Specialist Advisers listed theoretical adverse events as tumour seeding, bronchopleural fistula, residual necrotic tissue and changes such as fibrosis.

2.5 Other comments

2.5.1 The Committee noted that most of the published studies included patients with a variety of different types of tumour, among whom there were few with primary lung cancer or metastases in the lung.

2.5.2 The Committee noted the claim that this procedure may cause less damage to surrounding structures (such as major blood vessels) than other types of ablative treatment for lung cancer, 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.

Your responsibility
This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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.

Contact NICE
National Institute for Health and Clinical Excellence

Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT

www.nice.org.uk

nice@nice.org.uk

0845 033 7780

ISBN 978-1-4731-0033-6

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation