NICE guidance

Irreversible electroporation for treating renal cancer

Interventional procedures guidance
Published: 23 February 2013

www.nice.org.uk/guidance/ipg443

1 Guidance

1.1 Current evidence on the safety and efficacy of irreversible electroporation for treating renal 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 patient survival.

2 The procedure

2.1 Indications and current treatments

2.1.1 The most common type of renal cancer in adults is renal cell carcinoma. Symptoms and signs may include pain and haematuria. Some patients are diagnosed during investigation with imaging for other disorders. Patients with certain genetic syndromes that predispose them to kidney

tumours may be diagnosed during routine imaging surveillance. Establishing the diagnosis and assessing the prognosis of some renal tumours can be difficult, and not all are actively treated.

2.1.2 Treatment options include laparoscopic (or open) partial or total nephrectomy, and ablation techniques including radiofrequency ablation and cryoablation. Drug therapy is commonly used for advanced renal cancer. 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 ducts).

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 7 patients with renal cancer (10 tumours) reported a complete response in 5 tumours and progressive disease in 5 tumours at 3-month follow-up, assessed by modified 'Response Evaluation Criteria in Solid Tumors' (modified RECIST). Computed tomography follow-up at 3 months confirmed ablation of the tumour in 5 of the 7 patients, although 2 patients needed a second irreversible electroporation procedure.

2.3.2 The Specialist Advisers listed key efficacy outcomes as local tumour control, time to progression, and patient survival.

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 the 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 or 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). The authors noted that a synchronisation device was used from early in the trial, but they had variable success with synchronisation. Intraoperative supraventricular extrasystole was reported in 1 patient in a case series of 6 patients. No electrocardiography-related changes were detected after the procedure or at follow-up (after 12 weeks).

2.4.3 The case series of 38 patients reported partial ureteric obstruction and increasing creatinine level in 1 patient with renal cancer (timing not reported). The patient's ureter had been damaged previously by radiofrequency ablation. The obstruction was treated by inserting a ureteric stent.

2.4.4 The case series of 21 patients with tumours in the liver, kidney or lung reported extreme increases in blood pressure during the procedure (up to 200/100 mmHg from a baseline of 140/60 mmHg) in 7% (2/28) of procedures (both patients were being treated for renal cancer). In 1 patient, the blood pressure increase lasted for more than a few minutes and medical treatment was needed. The position of the electrodes was subsequently checked, and thought to be in the adrenal gland. Transient increases in systolic blood pressure of approximately 20 to 30 mmHg after treatment cycles were reported for all patients in the same study.

2.4.5 The Specialist Advisers listed additional theoretical adverse effects as damage to surrounding organs, minor bleeding, sepsis and ureteric stricture.

2.5 Other comments

2.5.1 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 renal 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.

Yourresponsibility
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.

ContactNICE
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 978-1-4731-0037-4

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation