NICE National Institute for Health and Care Excellence

NICE guidance

Irreversible electroporation for treating renal cancer

HealthTech guidance
Published: 23 February 2013

www.nice.org.uk/guidance/htg303

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.

Contents

This guidance replaces IPG443.

1 Recommendations

More research is needed

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.

2.3 Efficacy

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.

2.3.1 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 out of 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 out of 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.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 443 has been migrated to HealthTech guidance 303. The recommendations and accompanying content remain unchanged.

ISBN 978-1-4731-8724-5

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.