

# Irreversible electroporation for treating prostate cancer

Interventional procedures guidance

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[www.nice.org.uk/guidance/ipg572](http://www.nice.org.uk/guidance/ipg572)

## 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 Recommendations

### 1.1 Current evidence on the safety and efficacy of irreversible electroporation for

treating prostate cancer is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. Studies should include randomised controlled trials comparing the procedure with current standards of care. They should report details of patient selection and short- and long-term outcomes, including patient-reported outcomes and the effect on any future prostate surgery.

## 2 Indications and current treatments

- 2.1 Prostate cancer is usually diagnosed after a blood test in primary care has shown elevated prostate-specific antigen (PSA) levels. A raised PSA is not diagnostic of prostate cancer and a prostate biopsy is required to confirm the diagnosis and further tests are required to stage the extent of the disease. A [NICE guideline](#) describes recommendations for the diagnosis and management of prostate cancer.
- 2.2 Most prostate cancers are either localised or locally advanced at diagnosis. Localised prostate cancer does not usually cause any symptoms, but some men might have some urinary problems or erectile dysfunction. Current treatments for localised disease include active surveillance, radical prostatectomy, external beam radiotherapy and brachytherapy. Hormone therapy (androgen deprivation or anti-androgens) is usually the primary treatment for metastatic prostate cancer, but is increasingly being used for locally advanced, non-metastatic disease.

## 3 The procedure

- 3.1 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 homeostatic mechanisms and leading to cell death.
- 3.2 The procedure is done with the patient under general anaesthesia. A neuromuscular blocking agent is essential to prevent uncontrolled severe muscle contractions caused by the electric current. A number of electrode needles (typically 3 to 5) are introduced percutaneously and inserted into, and adjacent to, the tumour using image guidance. A series of very short electrical

pulses is delivered over several minutes to ablate the tumour. The electrodes may be repositioned to extend the zone of electroporation until the entire tumour and an appropriate margin have been ablated.

- 3.3 Cardiac synchronisation is used to time delivery of the electrical pulse within the refractory period of the heart cycle, minimising the risk of arrhythmia.

## 4 Efficacy

This section describes efficacy 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 [interventional procedure overview](#).

- 4.1 In a case series of 25 patients treated by irreversible electroporation for prostate cancer, the ablated zone was histologically clear of disease in all of the men who had a 7-month follow-up biopsy (84% [21/25] of patients). Overall, 76% (16/21) of men were histologically clear of significant disease and 38% (8/21) of men were histologically clear of any cancer at all. One patient had a significant finding in the field outside the adjacent zone; the lesion had not been detected preoperatively or on his 6-month MRI. Of the 5 patients with significant disease on follow-up biopsy, 3 remain on active surveillance, 1 is awaiting repeat irreversible electroporation and 1 had a radical prostatectomy.
- 4.2 In a case series of 34 patients, suspicious residual disease was seen on multiparametric MRI in 18% (6/34) of patients during follow-up. In 2 of these patients, prostate-specific antigen (PSA) levels dropped significantly from baseline and they remain on surveillance. The other 4 patients had secondary treatment (1 irreversible electroporation, 2 high-intensity focused ultrasound, 1 radical prostatectomy). Only 1 patient had histological verification of treatment failure by transperineal targeted biopsy. In a second case series of 25 patients, 28% (7/25) of men had a template biopsy that was positive for prostate cancer at 6-month follow-up. Primary failure was reported in 16% (4/25) of patients: 3 patients subsequently had surgery.
- 4.3 In the first case series of 25 patients there were no statistically significant changes in urinary symptom score, urinary function score, sexual function score, bowel function score, SF-12 physical component score or SF-12 mental component score at 6-month follow-up (n=18). Pad-free continence rates were

100%, 94%, 94% and 100% and leak-free continence rates were 67%, 53%, 65% and 67% at baseline, 6-week, 3-month and 6-month follow-up respectively. The proportion of men with erections sufficient for penetration were 44%, 38%, 47% and 56% at baseline, 6-week, 3-month and 6-month follow-up respectively. In the case series of 34 patients, potency was preserved in 95% (19/20) of men who were potent before treatment. All men who were continent before treatment were still continent afterwards (24/24). In the second case series of 25 patients, 77% (17/22), 81% (13/16) and 88% (15/17) of patients had normal urinary function at baseline, 6-month and 12-month follow-up respectively. Of the 17 patients with normal urinary function at baseline, 2 reported a decrease in score to below normal at 6-month and 1 at 12-month follow-up. At 12-month follow-up, 1 patient with normal erectile function at baseline reported new difficulty with potency. Use of incontinence pads was reported in 1 and 2 men at 6-month and 12-month follow-up respectively.

- 4.4 In a case series of 16 patients, statistically significant differences were seen in 1 domain in the Expanded Prostate Cancer Index Composite (EPIC) questionnaire: quality of life concerning urinary function decreased ( $p=0.01$ ) at 1-week and 4-week follow-up. Quality of life concerning sexual function, hormonal function and bowel habits did not significantly decrease during follow-up.
- 4.5 The specialist advisers listed cancer control and cancer-related survival as the key efficacy outcomes.

## 5 Safety

This section describes 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 [interventional procedure overview](#).

- 5.1 Urinary retention was reported in 6% (2/34), 10% (3/30), 20% (5/25), 22% (6/27), and 38% (6/16) of patients in 5 case series of 34, 30, 25, 27 and 16 patients respectively.
- 5.2 Intermittent haematuria was reported in 24% (6/25) of patients in the case series of 25 patients (all resolved by 6 months). Debris or haematuria was reported in 18% (6/34) of patients in the case series of 34 patients. Haematuria

was reported in 15% (4/27) of patients at 30-day follow-up in the case series of 27 patients (all resolved by 90 days). Mild haematuria was reported in 31% (5/16) of patients in the case series of 16 patients (resolved spontaneously in all patients within 1 to 27 days).

- 5.3 Dysuria was reported in 3% (3/103), 4% (1/27), 15% (5/34), and 20% (5/25) of patients in the case series of 103, 27, 34, and 25 patients respectively. Painful micturition during 4-week follow-up was reported in 13% (2/16) of patients in the case series of 16 patients.
- 5.4 Urinary tract infection was reported in 6% (1/16), 7% (2/27), and 15% (5/34) of patients in the case series of 16, 27, and 34 patients respectively.
- 5.5 Postoperative infection (cystitis, epididymo-orchitis, or other infection) was reported in 3% (3/103) of patients in a case series of 103 patients. Urosepsis was reported in 1 patient in the case series of 16 patients. The patient was admitted to hospital for 6 days and treated with intravenous antibiotics.
- 5.6 Epididymitis was reported in 7% (2/27) of patients in the case series of 27 patients. In 1 of the patients, epididymitis led to abscess formation, which was treated by simple orchiectomy. Epididymitis (grade 3) was reported in 1 patient in the case series of 30 patients.
- 5.7 Urgency and frequency (Common Terminology Criteria for Adverse Events [CTCAE] grade 2) were each reported in 13% (2/16) of patients in the case series of 16 patients. Transient urgency was reported in 4% (4/103) of patients in the case series of 103 patients. Transient incontinence was reported in 12% (12/103) of patients in the case series of 103 patients.
- 5.8 Dysejaculation was reported in 5% (5/103) of patients in the case series of 103 patients.
- 5.9 Urethral stricture (grade 3) was reported in 1 patient in the case series of 30 patients.
- 5.10 Recto-urethral fistula was reported in 1 patient in the case series of 103 patients.

- 5.11 A temporary reduction in potency (less than 9 months) was reported in 10% (10/103) of patients and complete reduction in potency (more than 3 years) in 2% (2/103) of patients in a case series of 103 patients.
- 5.12 Self-resolving tachycardia during the procedure was reported in 1 patient in the case series of 34 patients.
- 5.13 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers did not report any anecdotal adverse events. They considered that the following were theoretical adverse events: damage to the urethra, bladder, urethral sphincter and rectum.

## 6 Committee comments

- 6.1 The Committee noted that this procedure uses new technology, which has also been used to treat cancer in organs other than the prostate.

## 7 Further information

- 7.1 Patient commentary was sought but none was received.
- 7.2 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.

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## Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).

## Accreditation

