

Irreversible electroporation for treating prostate cancer

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg768

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.

This guidance replaces IPG572.

1 Recommendations

- 1.1 Irreversible electroporation for treating prostate cancer should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Clinicians wanting to do irreversible electroporation for treating prostate cancer should:
- Inform the clinical governance leads in their healthcare organisation.
 - Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
 - Take account of NICE's advice on shared decision making, including NICE's information for the public.
 - Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
 - Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.
- 1.3 Healthcare organisations should:
- Ensure systems are in place that support clinicians to collect and report data

on outcomes and safety for everyone having this procedure.

- Regularly review data on outcomes and safety for this procedure.

1.4 Further research should ideally be randomised controlled trials with an appropriate comparator. Further research could also include analysis of registry data or research databases. It should include details of patient selection, details of the procedure (including imaging) and short- and long-term outcomes.

Why the committee made these recommendations

There is enough evidence to suggest that the procedure works and does not raise any major safety concerns in the short- and medium term. The procedure can have complications and it is uncertain how well it works in the long term. It is also uncertain who would benefit most from the procedure and at what stage of their prostate cancer treatment it would be most effective. So, it can be used with special arrangements, and further data collection is needed.

2 The condition, current treatments and procedure

The condition

2.1 Prostate cancer is the most common cancer in men in the UK. Most prostate cancers are either localised or locally advanced at diagnosis. Localised prostate cancer does not usually cause any symptoms, but some people might have urinary problems or erectile dysfunction. Some people may not identify as men but may have a prostate.

Current treatments

2.2 Current treatments for localised prostate cancer include active surveillance, radical prostatectomy, external beam radiotherapy, brachytherapy, and ablation of the whole gland using cryotherapy or high-intensity focused ultrasound (as recommended in [NICE's guideline](#)

on prostate cancer: diagnosis and management). 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.

The procedure

- 2.3 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.
- 2.4 The procedure is done with the person under general anaesthesia. A neuromuscular blocking agent is essential to prevent uncontrolled severe muscle contractions caused by the electric current. Several electrode needles (typically 3 to 5) are introduced transperineally and inserted into, and adjacent to, the tumour in the prostate using image guidance. A series of 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.

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 11 sources, which was discussed by the committee. The evidence included 1 systematic review, 1 randomised controlled trial, 1 non-randomised comparative study, 1 single-arm trial and 7 case series. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: overall survival, recurrence-free survival, metastasis-free survival, improvement in quality of life, and need for subsequent intervention.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: pain, bleeding, infection, loss of sexual function, damage to adjacent structures, incontinence, urethral stricture and recurrence.
- 3.4 One patient organisation submission was received, and 101 commentaries from people who have had this procedure were discussed by the committee.

Committee comments

- 3.5 The committee noted that detection, investigation and management of prostate cancer now involves an increased use of MRI scanning.
- 3.6 The committee was pleased to receive a large number of patient commentaries and a submission from a patient organisation, and these supported the need for further research.
- 3.7 The committee was informed that using MRI and ultrasound fusion imaging may be of value in this procedure.
- 3.8 The committee noted that there will be an international registry which could be useful for collecting data on focal irreversible electroporation for prostate cancer, as recommended for further research (see [section 1.4](#)).
- 3.9 The committee was informed that this procedure is used for treating localised prostate cancer.

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Endorsing organisation

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