NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Irreversible electroporation for treating prostate cancer

Prostate cancer is often diagnosed before symptoms develop, but it may present with problems in passing urine or difficulties with sexual function. In this procedure, needles are inserted into the prostate and short electrical pulses of high-voltage current are passed through to create tiny holes in the cancer cells. The aim is to kill the cancer cells without damaging the structure of the prostate.

NICE is looking at irreversible electroporation for treating prostate cancer.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 23 September 2022

Target date for publication of guidance: February 2023

1 Draft recommendations

1.1 Evidence on the safety of irreversible electroporation for treating prostate cancer is limited. Evidence on its efficacy is inadequate. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 Further research should preferably be in the form of suitably powered randomised controlled trials with an appropriate comparator. It should include details of patient selection, details of the procedure (including imaging) and short- and long-term outcomes.

2 The condition, current treatments and procedure

The condition

2.1 Prostate cancer is the most common cancer in men in the UK, with 50% of diagnoses in people aged 70 years and over. 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 some 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 clinical 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. A number of 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 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, to minimise the risk of arrhythmia.

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 7 sources, which was discussed by the committee. The evidence included 1 systematic review, 1 non-randomised comparative study and 5 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.

Committee comments

3.4 The committee noted that detection, investigation, and management of prostate cancer now involves an increased use of MRI scanning and the published evidence does not reflect this change in practice.

3.5 The committee was pleased to receive a large number of patient commentaries and a submission from a patient organisation, and this supported the need for further research.

3.6 The committee was informed that using MRI ultrasound fusion imaging may be of value in this procedure.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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