NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer

Radiotherapy to treat prostate cancer can damage the rectum (the end part of the bowel). This can cause side effects such as bleeding, diarrhoea and faecal incontinence. The aim of this procedure is to reduce the amount of radiation reaching the rectum during radiotherapy, which may reduce the damage. It is usually done under general anaesthesia about 1 week before radiotherapy starts. The rectum is pushed slightly away from the prostate by inserting a balloon or injecting a gel (spacer) between them. This stays in place during radiotherapy. It is biodegradable, which means it breaks down and is absorbed by the body after about 6 months.

NICE is looking at biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer. This is a review of NICE's interventional procedures guidance on biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants 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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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:

Issue date: August 2022

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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 and efficacy of biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer is limited in quality. Therefore, this procedure 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 biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer should:

- Inform the clinical governance leads in their healthcare organisation.
- Give people (and their families and carers as appropriate) clear written information to support shared decision making, including NICE's information for the public.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- 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 could be in the form of randomised controlled trials or registry data. It should report details of patient selection, choice of radiotherapy technique and device used, improvement in quality of life, long-term outcomes of efficacy and safety and identify high risk groups who might benefit.

2 The condition, current treatments and procedure

The condition

2.1 Prostate cancer is the most common cancer in men, and the second most common cancer in the UK. Most prostate cancers are either localised or locally advanced at diagnosis. Localised prostate cancer often does not 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 treatment options for localised or locally advanced prostate cancer include 'watchful waiting', active surveillance, radiotherapy, radical prostatectomy, transurethral resection of the prostate, cryotherapy, high-intensity focused ultrasound, androgen deprivation therapy and chemotherapy (as recommended in NICE's clinical guideline on prostate cancer: diagnosis and management).

2.3 Radiation therapy is an established curative treatment and can either be external-beam radiotherapy or brachytherapy (also called interstitial radiotherapy). Brachytherapy can be given at either low- or high-dose rates. Low-dose-rate brachytherapy may be used alone or with external-beam radiotherapy.

The procedure

2.4 Radiotherapy for prostate cancer can cause rectal damage because of the close proximity of the prostate and the rectum. Symptoms of rectal damage can include diarrhoea, incontinence, proctitis and ulceration of the rectal mucosa. Injecting a biodegradable substance (examples include polyethylene glycol hydrogel, hyaluronic acid, and human collagen), or inserting and inflating a biodegradable balloon spacer, in the space between the rectum and prostate is done to temporarily increase the distance between them. The aim is to reduce the amount of radiation delivered to the rectum and reduce the toxicity profile during prostate radiotherapy.

2.5 The procedure is usually done with the patient under general anaesthesia using transrectal ultrasound guidance, but it may also be done using local or spinal anaesthesia. The patient is placed in the dorsal lithotomy position. For gel injection, a needle is advanced via a transperineal approach into the space between the prostate and the rectum. Hydrodissection with saline is then used to separate the prostate and the rectum. After confirming the correct positioning of the needle, the hydrogel precursors are injected, filling the perirectal space. These then polymerise to form a soft mass. The biodegradable hydrogel absorbs slowly over several months. For balloon spacer insertion, a small perineal incision is typically used to insert a dilator and introducer sheath. The dilator is advanced towards the prostate base over the needle, which is then removed. A biodegradable balloon is introduced through the introducer sheath and is filled with saline and sealed with a biodegradable plug. The balloon spacer degrades over several months.

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 10 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial, 1 meta-analysis, 1 health technology assessment, 4 systematic reviews and 1 review, 1 case series and 1 commentary. 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: reduction in rectal toxicity, improvement in patient-reported outcome measures and quality of life.

3.3 The professional experts and the committee considered the key safety outcomes to be: pain, bleeding, infection, need for spacer removal, rectal perforation and spreading malignant disease.

3.4 Twenty-two commentaries from patients who have had this procedure were discussed by the committee. One patient organisation representing patients who have had this procedure provided submission and this was also discussed by the committee.

Committee comments

3.5 The committee was informed that there may be groups of patients who derive particular benefit from this procedure because they are at increased risk of developing severe symptoms of rectal toxicity after radiotherapy, including those with inflammatory bowel disease or those on anticoagulation treatment. However there was no

published evidence to indicate which groups of patients benefited from this procedure.

3.6 The committee was informed that the incidence of rectal toxicity after radiotherapy has decreased over time with improvements in radiotherapy techniques.

3.7 The committee noted that there was a considerable amount of information from unpublished audits. NICE encourages publication of such data to allow it to be considered in future updates of this guidance.

3.8 The committee was informed that some spacers are radio-opaque and can be seen on CT.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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