NICE guidance

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

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg752

This guidance replaces IPG590.

## 1 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 The procedure should only be done by clinicians with training in and experience of transperineal interventional procedures.

1.5 Further research could be in the form of randomised controlled trials or observational data studies including registry studies and real-world evidence. It should report details of patient selection, choice of radiotherapy technique and device used, improvement in quality of life, and long-term efficacy and safety. It should also 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 guideline on prostate cancer: diagnosis and management).

2.3 Radiation therapy is an established curative treatment and can be either external-beam radiotherapy or brachytherapy (also called interstitial radiotherapy). Brachytherapy can be given at 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 acic 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 can be done with the patient under general, spinal or local anaesthesia using transrectal ultrasound guidance. The patient is placed in the dorsal lithotomy position. For gel injection, a needle is advanced

percutaneously via a transperineal approach into the space between the prostate and the rectum. Hydrodissection with saline may be used to separate the prostate and the rectum for some gels, but is not always necessary. After confirming the correct positioning of the needle, the gel is injected, filling the perirectal space. Some of the gels may polymerise to form a soft mass and some do not. The biodegradable gel absorbs slowly over several months. Some gels are reversible and can be dissolved using enzymes. 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, 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, as well as a submission from a patient organisation representing people who have had this procedure.

## 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. This includes those with inflammatory bowel disease or 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, and these may reduce the need for MRI scanning.

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# Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

# Accreditation