

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures

Patient Organisation Submission

Biodegradable spacer insertion to protect the rectum during radiotherapy for prostate cancer IP1316/2

Thank you for agreeing to give us your views on this procedure or operation and how it could be used in the NHS.

When we are developing interventional procedures guidance we are looking at how well a procedure or operation works and how safe it is for patients to have.

Patient and carer organisations can provide a unique perspective on conditions and their treatment that is not typically available from other sources. We are interested in hearing about:

- the experience of having the condition or caring for someone with the condition
- the experience of having the procedure or operation
- the outcomes of the procedure or operation that are important to patients or carers (which might differ from those measured in clinical studies, and including health-related quality of life)
- the impact of the procedure or operation on patients and carers. (What are the benefits to patients and their families, how does it affect quality of life, and what are the side effects after the procedure or operation.)
- the expectations about the risks and benefits of the procedure or operation.

To help you give your views, we have provided this template. You do not have to answer every question — they are there as prompts. The text boxes will expand as you type, the length of your response should not normally exceed 10 pages.

Please note, all submissions will be published on the NICE website alongside all evidence the committee reviewed. Identifiable information will be redacted.

| About you | |
|--|---|
| 1. Your name | XXXXXX |
| 2. Name of organisation | Tackle Prostate Cancer |
| 3. Job title or position | Patient Representative |
| 4. Brief description of the organisation (e.g. who funds the organisation? How many members does the organisation have?) | Tackle is a patient centred charitable organisation whose aims are to support men and their families whose lives are affected by prostate cancer. In addition we aim to represent the opinions of patients on any subject which is relevant to the diagnosis and treatment of prostate cancer. We also support local prostate cancer support groups around the UK. We represent over 100 support groups in UK and through them have 15,000 members - men and their families whose lives have been affected by prostate cancer. We are funded by a number of sources including unrestricted grants from the pharmaceutical industry. |
| 5. How did you gather the information about the experiences of patients and carers to help your submission? | |
| <p>We gain regular feedback from our members via face to face contact at local and national meetings, from direct contact by telephone from individuals and from the questions and queries of patients on our patient helpline. We have a medical advisory board who advise when and where necessary.</p> <p>As a patient I have not undergone radiotherapy myself but through my involvement with Tackle and also talking to members of and being involved with other Prostate Cancer Support Groups I have gained much knowledge of all therapies used and believe I can adequately represent those men on most occasions.</p> | |

Living with the condition

6. What is it like to live with the condition or what do carers experience when caring for someone with the condition?

Spacer devices are considered for use in men with prostate cancer (PCa) undergoing external beam radiotherapy or possibly brachytherapy. The devices are used to limit radiation damage to structures adjacent to the area being treated. With prostate cancer, the close proximity of the rectum to the prostate makes the rectum and damage to rectal mucosa the most vulnerable areas, although other parts of the large bowel can also be affected.

Whilst the disease process being treated here is 'cancer of the prostate', it is the potential damage to the rectum that is the main concern. 'The Condition' under discussion is the methodology and effectiveness of spacer devices to reduce collateral tissue damage.

The impact of a diagnosis of PCa on a patient and those around him is enormous. Depending on the stage, location and spread of the cancer the treatment options may include surgery, hormone therapy, chemotherapy and radiotherapy. These may be given in sequence or in combination. Many patients are fearful of radiotherapy – often because of lack of understanding. Considerable improvements have been made in radiotherapy techniques to provide more accurate, focussed treatment to reduce side effects, although these do still occur in varying degrees from one patient to another.

The consequences of radiotherapy can produce a significant impact – practically, emotionally and psychologically. Rectal pain, bowel dysfunction, rectal bleeding, and incontinence of urine/faeces are but a few of the problems that can occur. Many of these problems are often not immediately apparent during the treatment but become apparent many months afterwards.

Continence is a basic adult bodily function – it is not until this becomes a problem that one realises just how important it is to quality of life. Urinary incontinence is, arguably, the easiest type of incontinence to manage. Unpredictable rectal bleeding, leakage of liquid faeces or mucous/rectal secretions can be much more difficult problems to manage and may have devastating consequences on the lives of patients and, indeed, their families. Some men will need to constantly wear pads / protection to cope with the unpredictable nature of their post-radiation proctitis or other radiation-induced bowel symptoms. In simplistic terms this often requires the patient to constantly wear a pad / protective underwear. This may impact on all aspects of life – physical activity may be reduced, social activity can be affected. Depending on the patient's job, even their ability to work and gain financial income may be reduced. Simple daily tasks such as going shopping may need a degree of 'planning' to avoid accidents or social embarrassment.

The emotional impact can be immense. The elimination of bodily waste in adults can often be seen as 'dirty' and very unpleasant (although totally acceptable where babies and infants are concerned). The fear of having an accident in public because a lavatory may not be immediately available, the fear of having a bad smell around them, the unpredictability of a regular bowel

action, the inability to be naked and close to a loved one without wearing some form of protection – all of these can have a high priority in producing stress in a patient. It can often make a patient feel quite isolated.

Perhaps one of the more cruel aspects of radiation bowel damage is that, for many of these men, there may have been few side effects during the actual period of therapy. It can come as a bitter blow to find at a later stage that, although the radiotherapy may have been successful in controlling the cancer, the patient now has to face a very uncertain future of side effects that can be so very distressing.

Advantages of the procedure or operation

7. What do patients (or carers) think the advantages of the procedure or operation are?

Any procedure which reduces the incidence of such side effects will be of potential benefit to patients. Once established, treating the long-term problems associated with radiotherapy can be very difficult. It is undoubtedly true that *"prevention is better than cure"*. I have spoken with many men who would have taken the opportunity of having a rectal spacer device had it been available to them.

Improvements in radiotherapy techniques have played a large part in reducing side effects. For appropriate patients, the use of a rectal spacer can further improve outcomes.

A consequence of using a rectal spacer can be the ability to significantly shorten the number of treatment sessions required because dosages in each session can be increased without risk to the rectum / bowel. This can only come as good news to patients. A long course of daily treatments may be very inconvenient to the patient – particularly in more rural areas where the radiotherapy centre may be a long distance from where they live. Anything that reduces this length of treatment time would be greatly welcomed. Men who cope badly with psychological issues of treatment e.g. lying isolated in a treatment room, men with issues of early dementia or poor coping strategies – all would benefit from shorter treatment cycles. It is also this group of men who may well cope worse with any long-term side effects. Shorter treatment cycles would have the added benefit of freeing up more time on radiotherapy machines and allow an increased throughput of more patients.

Disadvantages of the procedure or operation

8. What do patients (or carers) think the disadvantages of the procedure or operation are?

This would add another invasive procedure to the treatment pathway, which some men may not find acceptable. The procedure can normally be done under local anaesthesia (with or without sedation if needed). In some circumstances a general anaesthetic may be required.

The downsides of using any new treatment are such things as the need for new equipment, the need for training healthcare staff in new techniques and the cost implications to implement this new technology. It is certainly not within the patient's remit to make comments on such problems – although one can foresee a greater demand on the time of certain staff and departments. However, equally it could reduce the need for long treatment schedules and thus free up time in other areas – e.g. being able to treat more patients in the radiotherapy department by freeing up time on radiotherapy machines already in high demand. Patient throughput could be increased.

Patient population

9. Are there any groups of patients who might benefit either more or less from the procedure or operation than others? If so, please describe them and explain why.

The greatest benefits will obviously be in those patients with the greatest risk of potential radiation-induced bowel damage. This will obviously depend on the site of the tumour within the prostate gland, the dose of radiation needed for treatment and the dose of radiation that will be produced outside of the main treatment field. None of these factors can be altered by the patient. However, what he will know is that by increasing the space between rectum and prostate the incidence of potential side effects can be significantly reduced or even abolished. Although the most common situation where such a technology could be used is external beam radiotherapy, there may also be an indication for the use of spacer devices in some patients undergoing brachytherapy.

For men whose sexual activity includes penetrative anal sex, the consequences of long-term damage to the rectal mucosa can be devastating. Reduction in such side effects will very positively impact on their lives.

To a patient it will be a simple decision – *not* “why should this technology be used?” but rather “why should this technology *not* be used?”. Currently patients do not even have the ability to make a choice as to whether to have this procedure pre-radiotherapy. The technology is not yet freely available to all. Tackle firmly believe that it should be.

Equality

10. Are there any potential [equality issues](#) that should be taken into account when considering this topic?

No equality issues with regard to age, ethnicity etc can be identified. As with any new treatment / procedure there is a need to ensure that such techniques are uniformly available to patients. The term ‘postcode lottery’ is, sadly still one that can exist for some treatments. New techniques will require provision and adequate training of relevant staff.

Other issues

11. Are there any other issues that you would like the Committee to consider?

Men are notoriously bad at discussing medical problems, particularly if they are of a personal nature. Men find it difficult to talk about urinary incontinence, even more so about sexual dysfunction and rarely ever discuss details of their bowel function, unless it is just to briefly mention diarrhoea or constipation. The very difficult problems of rectal bleeding, peri-anal abscesses, rectal incontinence and the like are very rarely discussed. It may be, therefore, that the incidence of some of the problems of radiotherapy induced bowel damage / post-radiation proctitis has been underestimated in the past.

Perhaps one of the best ways of expressing the opinions of patients is to use some quotes made by them:

“I sailed through my radiotherapy sessions but this.....now it’s a nightmare”

“I can cope with my rectal pain – it’s something I can sort of understand. But the bleeding at times can be really difficult”

“Anything that could shorten treatment times would great”

“I’m now like my little grand-daughter – we both have to wear ‘nappies’.....but she will eventually grow out of them. Will I?”

“It’s not rocket science – it’s a really simple principle. Why did we never think of it until now?”

“This seems like a ‘no-brainer’ to me. Let’s get on with implementing it”

“Dignity is a precious thing. My symptoms often rob me of this”

Key messages

12. In no more than 5 bullet points, please summarise the key messages of your submission.
1. For the patient, radiation-induced bowel damage can be one of the most difficult side effects from radiotherapy. The late onset of symptoms after relatively trouble-free radiotherapy can be particularly distressing.
 2. The side effects can have wide-ranging and disastrous impact on the quality of life of the patient and of those around them.
 3. This approach to reducing side effects is simple, uses a very novel technique and appears to have few adverse events.
 4. The technology may not be needed for every patient undergoing radiotherapy, but the onset of side effects can be difficult to predict in individual patients.
 5. Undoubtedly most patients would take a '*Better Safe than Sorry*' approach to any new technology that can produce potential improvement in quality of life during and after treatment with radiotherapy. Currently they do not even have a choice to make.

Thank you for your time.

Please return your completed submission to ip@nice.org.uk