NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Low-energy contact X-ray brachytherapy (the Papillon technique) for locally advanced rectal cancer

Locally advanced rectal cancer affects the end part of the bowel (rectum) and nearby tissues. Completely removing it using surgery can be difficult or impossible and some people cannot have it or choose not to have it.

In this procedure, an X-ray tube is inserted through the anus and placed in close contact with the cancer. It releases low-energy radiation into the cancer cells (brachytherapy). It may be done by itself or with other types of radiotherapy or chemotherapy. The aim is to kill the cancer cells while causing as little damage to surrounding healthy tissue as possible.

The National Institute for Health and Care Excellence (NICE) is looking at low-energy contact X-ray brachytherapy (the Papillon technique) for locally advanced rectal cancer. NICE's interventional procedures advisory committee has consider

ed the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

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

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

Issue date: February 2020

For further details, see the Interventional Procedures Programme process guide.

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

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

Closing date for comments: 25 March 2020

Target date for publication of guidance: June 2020

1 Draft recommendations

1.1 Current evidence on the safety and efficacy of low-energy contact X-ray brachytherapy (the Papillon technique) for locally advanced rectal cancer is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research.

1.2 Further research should include randomised controlled trials comparing this procedure with standard care and report details of patient selection (including tumour type and suitability for surgery), patient-reported outcomes, quality of life and long-term outcomes.

2 The condition, current treatments and procedure

The condition

2.1 Rectal cancer is a common form of bowel cancer. The likelihood of developing it rises sharply with age. Symptoms include rectal bleeding, obstruction, perforation, pain and discharge. Symptoms may also result from the tumour invading local structures (such as the bladder). Early stages of rectal cancer may be asymptomatic and between 5% and 10% of patients present with locally advanced disease (stage T3b to T4).

Current treatments

2.2 Surgery offers the best chance for cure in some patients with locally advanced rectal cancer. In patients who elect not to have surgery, or are not fit enough to have it, local surgical resection with systemic or radiation therapies, or both may be given. The aim is to reduce the tumour size, alleviate symptoms and improve the quality of life.

The procedure

2.3 Low-energy contact X-ray brachytherapy (CXB; the Papillion technique) for locally advanced rectal cancer may be given with external beam radiotherapy or chemotherapy, or both. It is usually delivered in a day-patient setting. The patient is given an enema before treatment to empty the rectum. With the patient in a knee-to-chest, prone jack-knife or supine position, local anaesthesia and glyceryl trinitrate are applied to the anal sphincter to numb the area and relax the sphincter muscles. A sigmoidoscope is inserted through the anal sphincter to ascertain the size and position of the tumour. Subsequently, a rigid endorectal treatment applicator is inserted and placed in contact with the tumour. A contact X-ray

tube is introduced into the applicator and treatment commences. This X-ray tube emits low-energy X-rays that penetrate tissue by only a few millimetres, minimising damage to deeper tissues.

3 Committee considerations

The evidence

3.1 To inform the committee, 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 randomised controlled trial and 6 case series, and is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: quality of life, functional outcomes (using scales such as the low anterior resection syndrome score), tumour regression or recurrence, and the need for further surgery.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: bleeding, rectal ulceration, rectal perforation, radiation proctitis and faecal incontinence.

3.4 Four commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee

February 2020