

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

Interventional procedures guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 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. Find out what only in research means on the NICE interventional procedures guidance page.
- 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 risk of developing it rises with age. Symptoms include rectal bleeding, obstruction, perforation, pain and discharge. Symptoms may result from the tumour invading organs near the rectum (such as the bladder). Early stages of rectal cancer may be asymptomatic and some patients present with locally advanced rectal cancer, commonly defined as T3 or T4 primary

tumours or nodal metastases, or stage 2 (T3 to T4, node negative) or stage 3 (T1 to T4, node positive).

Current treatments

- 2.2 There is variation in the clinical management and treatments offered for locally advanced rectal cancer. Radical surgery in the form of total mesorectal excision (TME) offers the best chance for cure in some patients. Patients who choose not to have surgery, or are not fit enough to have it, may have neoadjuvant chemoradiotherapy (such as external beam radiotherapy, with or without brachytherapy). The aim is to reduce the tumour size, alleviate symptoms, and improve survival and quality of life.

The procedure

- 2.3 Low-energy contact X-ray brachytherapy (CXB) is also known as the Papillon technique. It 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. Then a rigid endorectal treatment applicator is inserted and placed in contact with the tumour. A contact X-ray tube is introduced into the applicator. It 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 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 8 sources, which was

discussed by the committee. The evidence included 1 randomised controlled trial, 6 case series and 1 retrospective matched case control study, and 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 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 Sixty-one commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

Committee comments

- 3.5 The committee was pleased to receive a large number of patient commentaries, which were positive but also reported unpleasant short-term side effects.

Update information

December 2020: we withdrew this guidance in January 2020 to allow further consultation with stakeholders. We republished it unchanged on 2 December 2020.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).