NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Transanal total mesorectal excision for rectal cancer

Rectal cancer affects the end part of the bowel (rectum). In this procedure, the whole rectum is removed (total mesorectal excision). This is done using instruments introduced through the anus (transanal) and by keyhole surgery through the abdomen. The aim is to remove all the cancer.

NICE is looking at transanal total mesorectal excision for rectal cancer. This is a review of NICE's interventional procedures guidance on transanal total mesorectal excision of the rectum.

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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.

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After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 19 August 2021

Target date for publication of guidance: December 2021

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1 Draft recommendations

1.1 Evidence on the efficacy of transanal total mesorectal excision of the rectum is adequate. Evidence on its safety is inconsistent. It also shows the potential for major safety concerns, including damage to adjacent structures and seeding of malignancy. 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, which could be randomised controlled trials or registry data, should report details of patient selection, use of neoadjuvant chemoradiotherapy and all complications, including malignancy dissemination.

2 The condition, current treatments and procedure

The condition

2.1 The incidence of rectal cancer rises sharply with age. Symptoms include rectal bleeding and change in bowel habit, although the early stages may be asymptomatic.

Current treatments

2.2 The management of rectal cancer is described in NICE's guideline on colorectal cancer. The main treatment is surgery. It involves resecting the affected part of the rectum with anus preservation or, when anus preservation is not technically possible, colostomy formation. Adjunctive radiotherapy and chemotherapy may also be used to reduce the risk of local recurrence and prevent metastatic disease.

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The procedure

2.3 The aim of transanal total mesorectal excision is to improve the clinical outcome of rectal resection, and to reduce length of hospital stay and morbidity after surgery. It may facilitate proctectomy (removal of all or part of the rectum) that would be difficult by an open or laparoscopic approach. This could be in people with a narrow pelvis or high body mass index, or where the position of the tumour is low in the rectum.

2.4 Before surgery, the patient has bowel preparation and prophylactic antibiotics. Using general anaesthesia, and with the patient in the lithotomy position, standard abdominal laparoscopic mobilisation of the left colon and upper rectum is done. After inserting an operating platform into the anus, the lower rectum including the total mesorectum is mobilised. At the start of the transanal part of the procedure, a purse-string suture is put in to close the rectal lumen. This is followed by a full thickness rectotomy. After identifying the total mesorectal excision plane, the dissection progresses proximally until it connects with the dissection from above. The specimen can be removed through the transanal platform or, if the tumour is large, through the abdomen using a small incision. Anastomosis to connect the colon and the anus can be done using sutures (hand-sewn technique) or staples, and a temporary ileostomy is usually created. When anastomosis is not possible, a permanent stoma is created.

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 15 sources, which was discussed by the committee. The evidence

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included 2 systematic reviews, 2 registry reports, 2 non-randomised comparative studies (1 of which was also included in a systematic review), 3 cohort studies, 3 randomised controlled trials, 1 case series and 2 case reports. 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: disease-free survival, functional outcome scores, quality of life and preservation of sexual function.

3.3 The professional experts and the committee considered the key safety outcomes to be: local or regional recurrence including malignancy dissemination, urethral injury, carbon dioxide embolus, anastomotic leak and rectal prolapse.

Committee comments

3.4 The committee noted that this is a highly challenging procedure that needs extensive training and mentorship to be done safely.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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