NICE guidance

Transanal total mesorectal excision for rectal cancer

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg713

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.

This guidance replaces IPG514.

1 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, including tumour type, 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.

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 enable 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 19 sources, which was discussed by the committee. The evidence included 4 systematic reviews, 2 registry reports, 3 non-randomised comparative studies (1 of which was also included in a systematic review), 4 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.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee noted that this is a highly challenging procedure so extensive training and mentorship is needed for it to be done safely.

3.6 The committee noted that the Association of Coloproctology of Great Britain and Ireland has published recommendations on this procedure.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.