NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Transanal total mesorectal excision of the rectum

This procedure is used for patients who need to have their whole rectum removed (for example, patients with rectal cancer or chronic inflammatory bowel disease that has not responded well enough to treatment). The rectum is removed using instruments introduced through the anus, combined with laparoscopic (keyhole) surgery through the abdomen, rather than through a long incision in the lower abdomen.

The National Institute for Health and Care Excellence (NICE) is examining transanal total mesorectal excision of the rectum and will publish guidance on its safety and efficacy to the NHS. NICE’s Interventional Procedures Advisory Committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The Advisory Committee has made provisional recommendations about transanal total mesorectal excision.

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE’s formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The Advisory Committee will meet again to consider the original evidence and its provisional recommendations in the light of the comments received during consultation.
- The Advisory Committee will then prepare draft guidance which will be the basis for NICE’s guidance on the use of the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide, which is available from the NICE website.
Through its guidance NICE is 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 the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would 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 NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 18 December 2014
Target date for publication of guidance: February 2015

1 Provisional recommendations

1.1 Current evidence on the safety and efficacy of transanal total mesorectal excision (TaTME) to remove the rectum is limited in both quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake TaTME should take the following actions.

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure’s safety and efficacy and provide them with clear written information. In addition, the use of NICE’s information for the public [[URL to be added at publication]] is recommended.
1.3 TaTME should only be done by surgeons who are experienced in laparoscopic and transanal rectal resection and who have had specific training in this procedure.

1.4 Clinicians should enter details about all patients undergoing TaTME (for both cancers and benign indications) onto the TaTME registry and review local clinical outcomes.

1.5 NICE encourages further research into TaTME of the rectum. Patient selection should be explicitly documented. Outcomes should include completeness of excision, recurrence rates, survival, quality of life outcomes and avoidance of the need for a stoma in the long term. All complications should be reported, specifically including incontinence.

2 Indications and current treatments

2.1 Transanal total mesorectal excision (TaTME) can be used to treat malignant or benign disease of the rectum.

2.2 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. Treatment of rectal cancer depends upon its stage. Surgery is the main treatment modality for patients with locally-confined disease. It involves resection of the affected part of the rectum, with or without preservation of the anus (and formation of a colostomy when preservation of the anus is not technically possible). Adjunctive radiotherapy and chemotherapy may also be used to reduce the risk of local recurrence and prevent metastatic disease.

2.3 Benign conditions that may lead to the need for resection of the rectum include ulcerative colitis and Crohn’s disease. Both are chronic conditions, characterised by periods of clinical relapse and remission. Treatment depends on the severity and extent of the disease and is aimed at reducing the frequency and severity of
recurrences. Drug therapy, including corticosteroids and immunosuppressive agents (such as azathioprine), usually controls the disease adequately. For more severe cases, treatment with a monoclonal antibody (such as infliximab) may be considered. Surgical removal of the affected areas may be necessary for severe cases that don’t respond to medical treatment.

3 The procedure

3.1 Transanal total mesorectal excision (TaTME) aims to improve the clinical outcome of rectal excision, and to reduce the length of stay in hospital and morbidity after surgery. It may facilitate proctectomy that would otherwise be difficult in people with a narrow pelvis or high body mass index or where the position of the tumour is low in the rectum.

3.2 Before surgery, the patient has bowel preparation and prophylactic antibiotics. With the patient under general anaesthesia and in the lithotomy position, an operating platform is inserted into the anus using endoscopic guidance. Laparoscopic instruments are usually inserted at this stage in order to assist with identification of the plane of excision for mesorectal dissection, mobilisation of the left colon and subsequent creation of an ileostomy.

3.3 Dissection of the rectum is done through the anal platform. A purse-string suture is used to close the rectal lumen and then full-thickness proctectomy is done. The specimen can be removed through the transanal platform or, if the tumour is large, through the abdomen using a laparoscope. Anastomosis to connect the colon and the anus can be done using sutures (hand-sewn technique) or staples. When anastomosis is not possible, the patient is given a temporary or permanent colostomy. When an anastomosis is done, a temporary ileostomy is usually created.
4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview [add URL].

4.1 A case series of 30 patients with rectal cancer treated by transanal endoscopic proctectomy reported an overall survival rate of 97% at 12 months (95% confidence intervals [CI] 78.0 to 99.5) and 81% at 24 months (95% CI 53.0 to 92.9) (rates calculated using the Kaplan–Meier estimator). The study reported a relapse-free survival rate of 93% at 12 months (95% CI 75.9 to 98.3) and 89% at 24 months (95% CI 69.0 to 96.3) (rates calculated using the Kaplan–Meier estimator). Cancer-related death was reported in 13% (4/30) of patients at 21 months (including 1 death caused by an isolated locoregional recurrence and 1 death caused by cirrhosis).

4.2 The case series of 30 patients reported locoregional or distant recurrence in 40% (12/30) of patients at 21 months.

4.3 A non-randomised comparative study of 50 patients treated by transanal total mesorectal excision (TaTME) or laparoscopic total mesorectal excision (TME) reported that macroscopic evaluation of the completeness of mesorectal excision was significantly better for the TaTME group; 96% (24/25) of the specimens had a complete mesorectum compared with 72% (18/25) of the specimens in the laparoscopic TME group (p<0.05). The case series of 30 patients and 2 case series of 5 patients with rectal cancer treated by TaTME reported that the mesorectum had been completely excised in 100% of specimens.

4.4 The non-randomised comparative study of 50 patients reported circumferential resection margins of less than 2 mm in 1 patient of
4.5 The case series of 30 patients reported a conversion to open surgery in 7% (2/30) of patients because of the posterior fixation of the tumour.

4.6 The specialist advisers listed key efficacy outcomes as technical ease of dissecting the rectum low down in a narrow pelvis, quality of low rectal sealing and anastomotic healing, rate of conversion to open surgery, operative time, pain after surgery, quality of the TME specimen, length of stay in hospital, cosmetic outcome, patient-reported outcome measures, and urinary and sexual function after surgery.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview [add URL].

5.1 Anastomotic leakage was reported in 1 patient in a case series of 30 patients with rectal cancer treated by a combined transanal and laparoscopic approach (no further details provided). Anastomotic leakage was reported in 1 patient in a case series of 20 patients treated by a combined transanal and laparoscopic approach; the patient needed a further procedure to remove the coloanal anastomosis and construct a permanent end colostomy. This anastomotic leakage was secondary to ischaemia, most likely secondary to disruption of the blood supply to the proximal (descending) colon.

5.2 Colocutaneous fistula was reported in 1 patient in a case series of 12 patients with benign or malignant disease treated by transanal
endoscopic microsurgery proctectomy; the fistula was successfully treated by resection and creation of an ileostomy.

5.3 Asymptomatic anastomotic strictures noted on physical examination were reported in 20% (4/20) of patients in the case series of 20 patients; they were treated by manual dilatation.

5.4 Urethral injury was reported in 7% (2/30) of patients in the case series of 30 patients (1 urethral injury was caused by a difficult dissection of a large anterior tumour and the other by the presence of a concurrent prostatic carcinoma). Both were treated endoscopically with no subsequent complications (no further details provided).

5.5 Acute renal failure was reported in 1 patient in the case series of 20 patients (no further details provided).

5.6 Urinary retention was reported in 10% (2/20) of patients in a second case series of 20 patients treated by a combined transanal and laparoscopic approach (no further details provided).

5.7 Incontinence for liquid stools was reported in 15% of patients and for gas in 35% of patients, and 25% of patients had stool fragmentation, in the case series of 30 patients at 12 months after stoma closure (number of patients not reported).

5.8 Pelvic abscess was reported in 20% (4/20) of patients in the first case series of 20 patients. Sepsis was reported in 10% (3/30) of patients (2 had peritonitis and 1 had septic shock) in the case series of 30 patients.

5.9 Delayed healing of the perineal wound was reported in 33% (4/12) of patients in the case series of 12 patients and 50% (2/4) of these patients needed drainage of a perineal wound infection.

5.10 Prolonged ileus was reported in 20% (4/20) of patients in the first case series of 20 patients. Bowel obstruction was reported in 7%
(2/30) of patients in the case series of 30 patients; both patients recovered after medical treatment.

5.11 Extreme perioperative pneumatosis of the retroperitoneum and mesentery of the small bowel were reported in 1 patient in a case series of 5 patients. This complicated the laparoscopic mobilisation of the sigmoid colon during surgery.

5.12 Blood transfusion after surgery was needed in 20% (6/30) of patients in the case series of 30 patients.

5.13 Incarcerated parastomal hernia was reported in 1 patient in the case series of 12 patients.

5.14 Reoperation within 30 days of the procedure was reported in 7% (2/30) of patients in the case series of 30 patients (no further details provided).

5.15 The specialist advisers listed additional theoretical adverse events as damage to specimens, poor cancer outcomes from increased local or distant recurrence, bowel dysfunction and sexual dysfunction. The specialist advisers listed additional anecdotal adverse events as bleeding from the pelvic sidewall, pelvic haematoma, dissection in the incorrect plane into the pelvic sidewall and ascites.

6 Further information

6.1 For related NICE guidance, see the NICE website.

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