

Transanal total mesorectal excision of the rectum

Interventional procedures guidance

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[nice.org.uk/guidance/ipg514](https://www.nice.org.uk/guidance/ipg514)

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. However, 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.

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.

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 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](#) 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 malignancy or a benign indication) 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. If the procedure is used to treat malignancy, 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 on 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 do not 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 be difficult by an open or laparoscopic approach 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, standard laparoscopic mobilisation of the left colon and upper rectum is performed. After insertion of an operating platform into the anus, the lower rectum including the total mesorectum is mobilised in a reversed way using standard laparoscopic instruments.
- 3.3 The transanal part of this procedure starts with insertion of a purse-string suture to close the rectal lumen, followed by a full thickness rectotomy. After identification of the total mesorectal excision (TME) plane, the dissection progresses proximally until connection is made 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. When anastomosis is not possible, the patient is given a permanent stoma. 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](#).

- 4.1 A case series of 56 patients with low rectal cancer treated by transanal total mesorectal excision (TaTME) reported an overall survival rate of 96% (54/56) of

patients at 5-year follow-up (calculated using the Kaplan–Meier estimator); 2 patients with synchronous liver metastases died of metastatic evolution, 1 at 24 months and the other at 37 months after the procedure. The study reported a disease-free survival rate of 94% (53/56) at 5-year follow-up (Kaplan–Meier estimate); 2 patients developed metastases and 1 developed local recurrence.

- 4.2 The case series of 56 patients reported local recurrence in 1 patient at 24 months; the patient had a median circumferential resection margin of less than 1 mm. A case series of 30 patients reported locoregional or distant recurrence in 40% (12/30) of patients at 21-month follow-up.
- 4.3 A non-randomised comparative study of 74 patients treated by TaTME or laparoscopic total mesorectal excision (TME) reported that the quality of the mesorectal resection was not significantly different between the groups ($p=0.60$). In the TaTME group, resection was complete in 92% (34/37) of patients, almost complete in 5% (2/37) of patients and incomplete in 3% (1/37) of patients. In the laparoscopic TME group, resection was complete in 95% (35/37) of patients and almost complete in 5% (2/37) of patients. The patient from the TaTME group who had an incomplete resection had a total colectomy previously. A non-randomised comparative study of 50 patients treated by TaTME or laparoscopic 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 against 72% (18/25) of the specimens in the laparoscopic TME group ($p<0.05$). The case series of 30 patients and 1 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 74 patients treated by TaTME or laparoscopic TME reported no circumferential margin involvement in either group. The non-randomised comparative study of 50 patients reported circumferential resection margins of less than 2 mm in 1 patient of the TaTME group and in 8% (2/25) of patients in the laparoscopic TME group.
- 4.5 The case series of 56 patients reported conversion to laparotomy (in the group for whom the operation used laparoscopic assistance) in 7% (3/41) of patients; 1 because of adhesions from a previous operation, and 2 because of technical difficulties in obese patients. 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](#).

- 5.1 Anastomotic leakage was reported in 5% (2/37) of patients in the transanal total mesorectal excision (TaTME) group and in 11% (4/37) of patients in the laparoscopic total mesorectal excision (TME) group in a non-randomised comparative study of 74 patients ($p=0.39$; no further details provided). Anastomotic leakage was reported in 5% (3/56) of patients in a case series of 56 patients with low rectal cancer treated by TaTME; no reoperation was needed. 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 a 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 Acute urinary retention was reported in 3% (1/37) of patients in the TaTME group and in 11% (4/37) of patients in the laparoscopic TME group in the non-randomised comparative study of 74 patients ($p=0.16$; no further details provided). Transient urinary disorders were reported in 9% (5/56) of patients in the case series of 56 patients; all patients were treated by temporary urethral catheterisation. After 3 months, all patients reported normal urinary function.
- 5.7 Severe faecal incontinence after intersphincteric resection, needing a colostomy, was reported in 6% (3/52) of patients in the case series of 56 patients with low rectal cancer. Incontinence for liquid stools was reported in 15% of patients and for gas in 35% of patients, in the case series of 30 patients at 12 months after stoma closure (number of patients not reported).

Pelvic fluid collections were reported in 3% (1/37) of patients in the TaTME group and in 13% (5/37) of patients in the laparoscopic TME group in the non-randomised comparative study of 74 patients ($p=0.08$). The patient in the TaTME group was readmitted with fever: abdominal CT scans demonstrated the presence of fluid collections without gas. The patient was successfully treated with antibiotics.

Pelvic abscess was reported in 20% (4/20) of patients in the case series of 20 patients.

Sepsis within 30 days after the procedure was reported in 10% (3/30) of patients (2 had peritonitis and 1 had septic shock) in the case series of 30 patients. Peritonitis in 1 patient was secondary to a minor ileal wound, without a direct link with the procedure. The patient with septic shock had comorbidities including a lymphoma associated with chronic renal failure and diabetes and needed critical care (no further details provided).

- 5.8 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.
- 5.9 Ileus was reported in 11% (4/37) of patients in the TaTME group and in 5% (2/37) of patients in the laparoscopic TME group in the non-randomised comparative study of 74 patients ($p=0.39$). Bowel obstruction was reported in 7% (2/30) of patients in the case series of 30 patients; both patients recovered after medical treatment.
- 5.10 Impotence was reported in 11% (2/18) of the 18 sexually active male patients in the case series of 56 patients.
- 5.11 Blood transfusion after surgery was needed in 4% (2/56) of patients in the case series of 56 patients.
- 5.12 Incarcerated parastomal hernia was reported in 1 patient in the case series of 12 patients.
- 5.13 Reoperation rate within 30 days after the procedure was the same in the TaTME group and in the laparoscopic TME group (8% [3/37] of patients; $p=0.97$) in the non-randomised comparative study of 74 patients (no further details provided).
- 5.14 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse events: bleeding from the pelvic sidewall, pelvic haematoma, dissection in the incorrect plane into the pelvic sidewall and ascites. They considered that the following were theoretical adverse events: damage to specimens, poor cancer outcomes from increased local or distant recurrence and bowel dysfunction.

6 Committee comments

- 6.1 The Committee noted that if transanal total mesorectal excision (TaTME) is used for treating benign disease, the quality of mesorectal excision is not an

important issue and the outcome measures are different to those for treating malignancy.

7 Further information

7.1 For related NICE guidance, see the [NICE website](#).

Information for patients

NICE has produced information on this procedure for patients and carers ([information for the public](#)). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedures guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

This guidance was developed using the NICE [interventional procedures guidance process](#).

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence the guidance is based on is also [available](#).

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Endorsing organisation

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

Accreditation

