

Transanal total mesorectal excision for rectal carcinoma: short-term outcomes and experience after 80 cases

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Abstract

Background Low anterior resection for distal and mid-rectal cancer is associated with high positive resection margins. Transanal total mesorectal excision (TaTME) is a new treatment in which the rectum is dissected transanally according to TME principles. The short-term results and oncological follow-up of the first 80 patients were described.

Methods Between June 2012 and September 2014, all patients in the Gelderse Vallei Hospital and the VU University Medical Center with histologically proven distal or mid-rectal carcinomas without evidence of distant metastases underwent TaTME. Patients with T4 tumors were excluded. Transanal mobilization was performed with the aid of a single port and endoscopic instruments according to TME criteria.

Results Eighty patients were operated in a period of 2 years. Laparotomy was recommended and performed in four patients. Postoperative morbidity was 39 %. Ten (12 %) complications were graded as severe (Clavien–Dindo grade 3, 4 and 5) and needed re-intervention. Median operative time was 204 min (range 91–447). Median hospital stay was 8 days (range 3–41). Specimens were graded as complete in 88 % of the patients, nearly complete in 9 % and incomplete in 3 %. A positive

circumferential resection margin (<2 mm) was observed in two patients. During the two and half years study period, a local recurrence was observed in two patients.

Conclusion TaTME is a safe alternative to standard laparoscopic TME in selected low-risk patients with rectal carcinoma when treated by an experienced colorectal team. In the future, randomized trials are necessary to prove its oncological safety.

Keywords Colorectal · Cancer · G-I · Endoscopy

Rectal cancer management and rectal cancer surgery are in progress, and new techniques aiming for better functional results and better oncological outcomes are being developed. Ever since Heald et al. stressed the importance of the quality of surgery in reducing the number of local recurrences, a significant reduction in the local recurrence rate has been achieved [1, 2].

Results from the Dutch TME trial further stressed the importance of the technical quality [3, 4]. Increased risk of local tumor recurrence has been reported for patients who underwent a potentially curative procedure, but had an incomplete or damaged specimen [5].

Even though progress has been made, total mesorectal excision (TME) surgery can still be improved. Bondeven et al. [6] evaluated the completeness of the mesorectal excision by postoperative magnetic resonance imaging (MRI) and showed residual mesorectum in 36 % of patients who should have had complete excision based on the height of the tumor. Furthermore, low anterior resections for mid- and distal rectal cancer are associated with relatively high circumferential margin involvement. Laparoscopic techniques were expected to improve the quality of surgery, by improving visualization of the pelvic

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cavity and therefore facilitating mobilization of the rectum. However, until now, evidence for oncological superiority is lacking [7].

Transanal TME (TaTME) is a new treatment option, which is expected to revolutionize the surgical treatment of rectal cancer. During TaTME, the rectum is dissected transanally according to TME principles with the use of endoscopic instruments, the so-called down-to-up TME. An important advantage of this new technique is that a sufficient distal margin can be obtained under direct vision. Furthermore, the parts that are often considered the most difficult of the standard laparoscopic TME, the part ventral to the rectum and the most distal dorsal part, are much better visualized.

In this article, we describe our initial experience with the TaTME and report oncological follow-up.

Materials and methods

Between June 2012 and September 2014, all patients in the Gelderse Vallei Hospital and the VU University Medical Center (VUmc) with histologically proven distal or mid-rectal carcinomas (MRI 0–10 cm from dentate line) without evidence of distant metastases and eligible for elective laparoscopic TME were included and underwent TaTME. The Ethics Committee of the VUmc approved the protocol. Patients with T4 tumors or those with expected positive circumferential margins prior to neoadjuvant therapy were excluded. A margin of <2 mm was considered positive.

Perioperative assessment

The preoperative assessment included MRI for local staging and computed tomography (CT) of the thorax and abdomen to detect distant metastases. All patients were treated according to the Dutch guidelines for the treatment of rectal cancer. Patients with T2–3 N0–1 tumors underwent preoperative radiotherapy with a total dose of 25 Gy and a daily dose of 5 Gy. Surgery was performed in the week following cessation of radiotherapy. Patients with T2–3 N2 tumors underwent chemoradiotherapy with a total dose of 50 Gy and a daily dose of 2 Gy combined with 5-fluorouracil. In these cases, surgery was performed 6 weeks after the end of the neoadjuvant treatment. From 2014, we changed our national policy and patients with T1, T2 and small T3 have not been given neoadjuvant short-course radiotherapy. Patients received mechanical bowel preparation before surgery with Moviprep (Norgine, Amsterdam, The Netherlands). For postoperative pain control, they received epidural analgesia. Prophylactic antibiotics were administered according to the protocol. Patients were treated according to enhanced recovery after surgery (ERAS) guidelines.

TaTME

The technique we used during the various procedures changed and evolved to a standardized technique. The transanal phase and the abdominal phase were performed in sequence and not synchronous with two teams. In the first patients, we started with the transanal phase of the procedure as described previously. The sequence was changed to a ‘transabdominal phase first technique’ because of complicating pneumatosis of the retroperitoneum, beginning with standard laparoscopic mobilization of the sigmoid and the splenic flexure. The technique that was used for the laparoscopic mobilization is either a four-trocar medial-to-lateral approach or a single-port approach, with the single-incision laparoscopic surgery (SILS) port at the future ileostomy site, described previously by Van den Boezem et al. [8]. During the transabdominal phase, the proximal rectum was mobilized to localize the hypogastric nerves by opening the peritoneal reflection on both sides. We consider it important to leave the anterior part of the peritoneal reflection unopened because it helps to maintain a stable pneumoretroperitoneum during the transanal phase.

The technique used for the transanal phase depended on the height of the tumor. For distal tumors, an intersphincteric dissection was performed with the use of a Scott retractor. This dissection was continued as high up as possible in an open fashion. The rectal stump was then closed with a purse string suture to prevent spillage of tumor cells and bacteria. After closure of the rectal stump, the cavity was rinsed with a povidone-iodine solution as a cytotoxic agent. Then, the transanal port was introduced.

In case of more proximal tumors, the rectal stump was closed with a purse string suture either endoscopically or in an open fashion. To secure a total removal of the mesorectum, the purse string is situated 3–4 cm from the dentate line. A full-thickness endoscopic transection of the mucosa was performed using the diathermic hook (Fig. 1A–C). The full-thickness transection circumferentially is essential for optimal use of the pneumorectum and entering the right layer. If not, there is the risk of getting lost in the submucosal plane with the possibility of perforating the rectum.

In the first patients, a SILS Port (Covidien) was used for the rectal dissection. Currently, we use two different ports. For more distal tumors, the SILS port is still used. This port can be sutured to the perineal skin allowing traction to the port to create more space. Furthermore, in case of intersphincteric dissection, suturing the trocars allows to create a pneumorectum, which is otherwise lost due to leakage.

In more proximal tumors, the GelPOINT Path Transanal Access Platform (Applied Medical, Rancho Santa Margarita, California, USA) is used, ergonomically a more

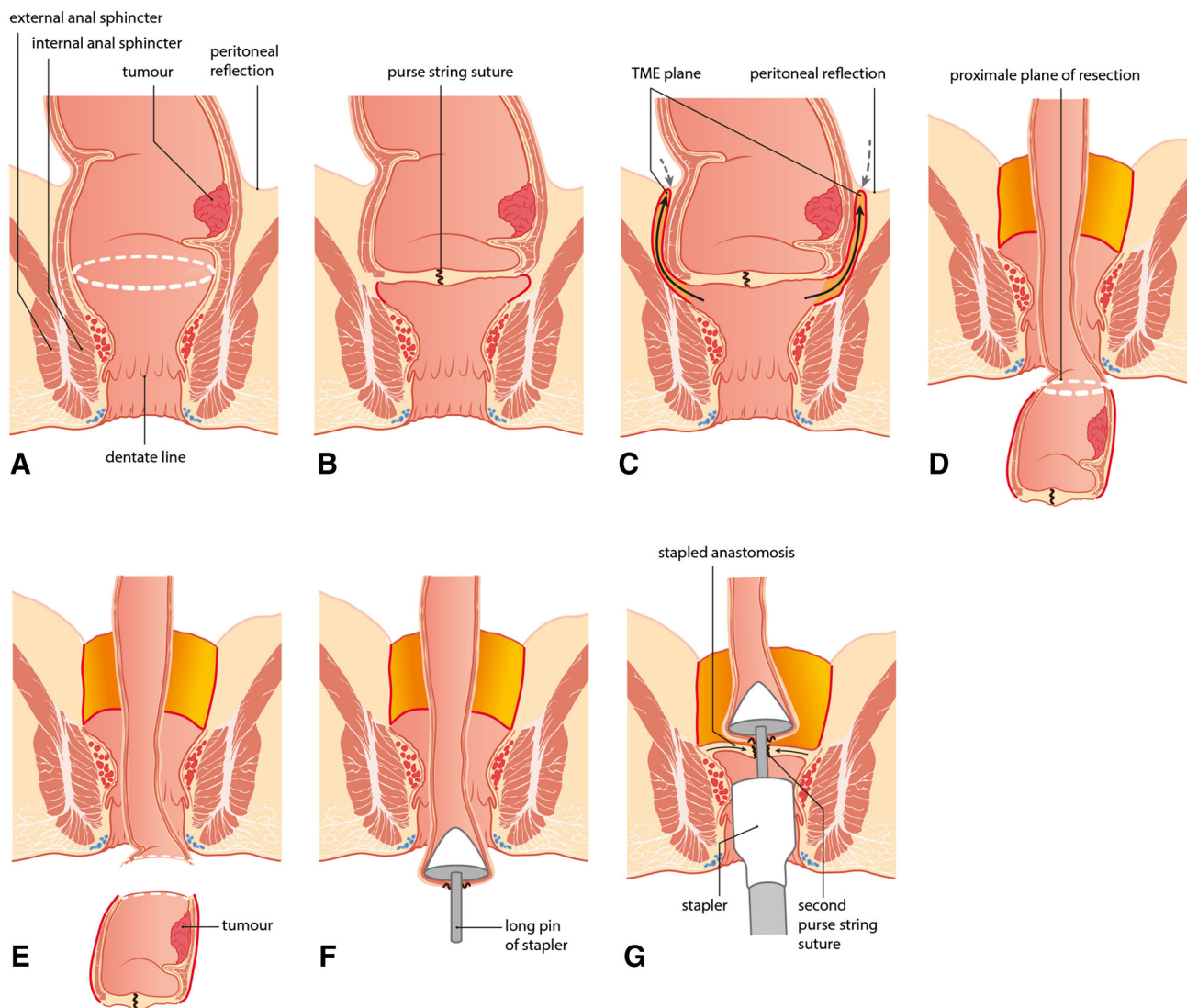


Fig. 1 Steps of TaTME. **A** Distal resection margin, **B** closure with a purse string suture and transection of the mucosa, **C** mobilization according to TME criteria, **D**, **E** transanal specimen removal, **F** suturing of stapler head, **G** second purse string and stapled anastomosis. The figure is published previously in NTVG

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pleasant trocar. However, the trocar can be too bulky for distal tumors. The GelPOINT Path has three 10-mm trocars and therefore gives more freedom in the decision which instruments to use. Furthermore, the GelPOINT Path consists of two parts, which are detachable. This allows easy access to the anal canal, making suturing and specimen retraction more accessible.

The pneumorectum was created with carbon dioxide at a pressure of 10–14 mmHg. Initially, the transanal phase was complicated by rhythmic contractions of the rectal wall caused by high flow. After reducing the flow of the carbon dioxide to less than 1 L/min, the contractions ceased.

The avascular dorsal plane was developed by sharp dissection with the diathermic hook. It is important to remember that the anal canal is at a steep angle with the pelvis floor and thereby with the TME plane. After dorsal dissection was continued as high up as possible, the dissection was continued ventrally. We used part blunt and part sharp dissection to find the correct plane.

One of the pitfalls of TaTME is dissecting lateral of the TME plane. This will occur when the pelvic floor or parietal fascia is followed from below during dissection, resulting in bleeding or damaging the nerves. Therefore, the dissection of the lateral sides was performed when both

the ventral and dorsal dissection was progressing and only the lateral pillar was left. After full TME mobilization, the peritoneum was opened and the specimen was pushed inside, showing the last remaining adhesions.

After the rectosigmoid was completely freed, the specimen is exteriorized transanally under direct visualization by using the camera in the abdominal port (Fig. 1D–E). If the specimen was too bulky, a small abdominal incision was used to extract the specimen.

In case of reconstructing continuity, the sigmoid was divided and the stapler head of the EEA Hemorrhoid stapler (Covidien, Mansfield, Massachusetts, USA) was introduced and the bowel was replaced into the abdomen. The long pin of the stapler is essential for manipulating the proximal bowel. The distal rectal stump was closed with a second purse string suture, and a stapled anastomosis was made after which an ileostomy was created routinely (Fig. 1F, G). In case of no reconstruction, the sigmoid was transected endoscopically. The specimen was removed transanally, and the colostomy was performed.

Results

Eighty consecutive patients were included in this study. Patient characteristics are depicted in Table 1.

All patients were staged as T2 or T3 carcinomas on preoperative MRI. Depending on preoperative T and N stage, 39 patients were treated with a short course of radiotherapy (5×5 gray), 26 patients were treated with chemoradiotherapy, and 15 patients received no adjuvant

therapy. The average distance from the tumor to the dentate line was 5.3 cm (range 1–10).

Tumor characteristics are depicted in Table 2. Macroscopic examination was graded as complete or nearly complete in 88 % of the specimen. Seven of the specimen had minor lacerations, and only two were scored as incomplete (according to the Quirke classification) [9]. Positive circumferential resection margins (<2 mm) were seen in two patients. Distal margins were all clear. The average length of the specimen was 19 cm (range 12–28). Average number of lymph nodes was 14 (range 6–30).

Laparotomy was recommended and performed in four patients: due to anterior fixation owing to previous radiotherapy for prostate carcinoma in the first patient, due to fixation to the bladder and the left ureter in the second patient, due to possible T4 carcinoma in the third patient and due to cardiac complications that warranted a quick finish of the procedure in the fourth patient.

Intraoperative complications were seen in five patients. Two bleedings occurred due to following the false plane on the lateral side. In three cases, a small perforation had to be sutured on the ventral side. In these three cases, the tumor was located on the dorsal side so none of these perforations resulted in a positive CRM. In seven patients, transanal extraction was not feasible due to the volume of the specimen and a small abdominal incision was necessary.

Postoperative complications were seen in 39 % of the patients. Of these complications, 10 (12 %) were graded as severe, Clavien–Dindo grade 3, 4 and 5 (Table 3).

Nine patients were re-operated: one patient because of anastomotic leakage and this patient died postoperatively due to septic complications. Reasons for re-operations in case of grade 4 complications were ischemia of the proximal limb of the colon, anastomotic leakage and small bowel laceration. Four patients with grade 3 complications were re-operated. Reasons were revision of a colostomy because of superficial necrosis, small bowel obstructions due to early adhesions, internal herniation and evacuation of a large hematoma.

One patient was readmitted 10 days after surgery with circular full-thickness ischemia of the mucosa distal of the anastomosis and in the anal canal, possibly caused by pressure necrosis due to the transanally placed trocar. The operative time of this procedure was 183 min.

Median operative time was 204 min, and these times varied considerably (range 91–447). No significant reduction in time was noticed with increased experience. Median hospital stay was 8 days (range 3–41).

Currently, two local recurrences have occurred. The patients were operated 18 and 24 months ago after chemoradiotherapy. Pathology reports showed T3N2 carcinoma in both patients, the specimen showed clear surgical margins in both patients distally, and one of these

Table 1 Patient characteristics

	Overall population ($n = 80$)
Gender	
Male	48
Female	32
Age (years), mean (range)	66.5 (42–86)
BMI (kg/m^2), mean (range)	27.5 (19.5–40)
ASA Classification	
ASA I	15
ASA II	53
ASA III	12
Type of resection	
LAR	65
APR	15
Neoadjuvant therapy	
None	15
Radiotherapy	39
Chemoradiotherapy	26

Table 2 Tumor characteristics

	Overall population (<i>n</i> = 80)
Tumor status (T)	
0	6
1	3
2	29
3	42
N status (N)	
0	44
1	21
2	15
Number of lymph nodes, mean (range)	14 (6–30)
Differentiation of carcinoma	
Well differentiated	27
Moderately differentiated	45
Poorly differentiated	8
Tumor size (cm), mean (range)	3.4 (1.2–11)
Length of resected specimen (cm), median (range)	19 (12–28)
Macroscopic completeness specimen (Quirke)	
Complete	71 (88 %)
Nearly complete	7 (9 %)
Incomplete	2 (3 %)
Circumferential resection margin involvement	
Positive (<2 mm)	2 (2.5 %)
Distal resection margin involvement	
Positive (<1 cm)	0 (0 %)

Table 3 Complications according to Clavien–Dindo

	Overall population (<i>n</i> = 80)
None	49
Grade 1	8
Grade 2	13
Grade 3	
3a	1
3b	5
Grade 4	
4a	3
4b	0
Grade 5	1

patients had a positive circumferential resection margin (being <2 mm).

Discussion

The laparoscopic approach for colorectal carcinoma is slowly becoming the standard. Short-term benefits are clear, but oncological superiority over open surgery has not been proven [7, 10–15].

With the use of neoadjuvant therapy, local recurrence rates in rectal cancer have reduced both in open and in laparoscopic surgery. However, most recent results leave room for improvement. The CLASICC trial showed high rates of local recurrence both in the open and in the laparoscopic group [13].

A recent report of the COLOR II trial shows a high percentage of patients with positive circumferential resection margins [12].

A further improvement probably warrants the introduction of a new approach. TaTME has been introduced as a supplement to existing laparoscopic techniques to improve results in complex patients. Expectations are high, but we should remember that only small case series have been published. Little is known about long-term functional and oncological results.

The critical words of Wexner and Berho [16] are justified. He correctly stated that we should be cautious not to lose the ground gained in recent decades with the introduction of a new approach.

TaTME was first described in 2011, after which various groups demonstrated feasibility in selected groups of patients. Our group started using the technique in 2012 in unselected patients with distal rectal carcinoma. Showing

feasibility, the technique evolved to the standard, currently used in all patients with mid- and distal rectal cancer.

After 80 procedures, our short-term results are comparable with those described in the literature for the standard laparoscopic approach [12, 15]. Morbidity and mortality rates conform the type of surgery and might decrease with increased experience. Hospital stay is comparable with standard laparoscopic TME for rectal cancer [12, 15]. These data are comparable with those reported in the literature. Fernandez-Hevia et al. [17] recently reported comparable short-term results between standard laparoscopic TME and TaTME from the Barcelona group. This experience did, however, report a reduction in surgical time and a reduced readmission rate.

However, these factors are of relative importance compared with the oncological results. Currently, two local recurrences have developed. It should be noted that follow-up is limited to 2 years. In these early days of TaTME, it is important to critically evaluate the completeness of the mesorectum, since it reflects the oncological quality of the procedure and may influence prognosis. Bosch and Nagtegaal [5] showed an increased risk of local and overall recurrence in patients with incomplete specimens. The specimens reported in this study were graded as complete or nearly complete in 97 % of the patients. A positive circumferential resection margin was only seen in two patients. However, patients staged as T4 tumors before neoadjuvant therapy were excluded.

Comparing quality of the specimens after traditional laparoscopic and TaTME, we previously demonstrated that TaTME seems to be associated with significantly higher rate of completeness of the mesorectum [18].

Various groups currently publish their first data in highly selected cases. Lacy et al. [19] published their first 20 cases, but their experience is currently more than 100. Emhoff et al. [20] recently reviewed all published experience. Overall intraoperative and postoperative complications rates of 8.3 and 27.8 %, respectively, are similar to laparoscopic TME. The reported mesorectal fascia was intact in all patients, and 94 % had negative margins. Other groups report no oncological recurrence in average-risk patients.

Rouanet et al. [21] are currently the only group who have reported the results in high-risk tumors. Thirty patients with advanced or recurrent low rectal cancer associated with unfavorable anatomical tumor characteristics underwent a sphincter sparing TaTME. They reported four patients with positive margins (87 %) compared with 95 % negative margins in low-risk patients who underwent laparoscopic TME during the same period. After 21 months, only 13 patients were free of disease. The short-term surgical results are nonetheless acceptable. The authors report no postoperative mortality and 30 % morbidity.

These results stress the importance of careful patient selection. The TaTME should first be introduced in low-risk patients with specialized teams. A long-term outcome has to be available before it can be accepted as a valid alternative to standard laparoscopic techniques. Furthermore, non-inferiority or superiority should be proven in randomized trials. Currently, the COLOR III trial, standard laparoscopic TME versus TaTME, is in preparation.

Before randomized trials can start, sufficient amounts of surgeons should be trained. We recently started workshops and proctoring programs for Dutch surgeons. Cadaver training is combined with proctoring in local hospitals.

Conclusion

TaTME is a safe alternative to standard laparoscopic TME in selected low-risk patients with rectal carcinoma when treated by an experienced colorectal team. In the future, randomized trials are necessary to prove oncological safety.

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