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ORIGINAL ARTICLE

Transanal total mesorectal excision (TaTME): single-centre early experience in a selected population

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Abstract
Total mesorectal excision (TME) represents the key principle in the surgical treatment of rectal cancer. Transanal mesorectal excision was introduced as a complement to conventional surgery to overcome its technical difficulties. The aim of this study was to evaluate the early surgical results following the introduction of this novel technique at our Unit. Between January and May 2016, 12 patients diagnosed with mid-low rectal adenocarcinoma were enrolled into this study and evaluated with regards demography, histopathology, peri-operative data and postoperative complications. The tumor was located in the middle rectum in 6 patients (50%), in the lower rectum in 6 patients (50%). Mean operative time was 356.5 ± 76.2 min (range 240–494). Eleven out 12 patients (91.6%) had less than 200 mL of intraoperative blood loss. Mean hospital stay was 10.9 ± 4.6 days (range 5–19). No mortality was recorded. Intraoperative complications were recorded in 1, while early post-operative complications (< 30 days) were observed in 5 patients (41.6%). Histopathology showed in all cases an intact mesorectum. Mean number of lymphnodes harvested was 13.6 ± 6.6 (range 4–29). Distal and circumferential margin was, respectively, of 20.8 ± 14.2 mm (range 2–45 mm) and 16.1 ± 7.6 mm (range 3–30 mm). The comparative analysis showed significant differences concerning mean operative time ($p = 0.0473$) and estimated blood loss ($p = 0.0367$). This study confirms this technique is safe and feasible, but more evidence to support its use over conventional laparoscopic surgery is needed.

Keywords TME · Transanal surgery · Rectal cancer · Laparoscopy

Introduction

Total mesorectal excision (TME) represents the key principle in the surgical treatment of rectal cancer [1]. This technical innovation has embodied a real revolution in rectal cancer surgery and shows the relevance of the integrity of the mesorectal envelope in achieving excellent oncological outcomes, with less than 10% of local recurrence in some surgical series compared to the significantly higher rates seen with historical resectional technique [2].

In the last two decades minimally invasive surgery has shown major benefits compared to open technique in the treatment of colon cancer. Rectal cancer surgery is more technically demanding and the steep learning curve has made laparoscopic approach less commonly used.

Transanal mesorectal excision "*down-to-up*" was introduced as a complement to conventional surgery with the aim to overcome technical difficulties and simplify the dissection of distal rectal tumor.

Since its introduction, Transanal TME (TaTME) has gained popularity in the colorectal community and represents one of the most promising areas of research in the field of minimally invasive colorectal surgery.

The aim of this study was to evaluate the early surgical results following the introduction of this novel technique at our Unit.

Methods

Between January and May 2016, after institutional review board approval and informed consent acquisition, 12 patients affected by mid-low rectal adenocarcinoma

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histologically proven and suitable for resection were enrolled for this study.

Diagnosis and pre-operative staging were achieved by complete colonoscopy with biopsies and, where contraindicated or not feasible, with CT colonography.

Pelvic MRI with rectal cancer protocol was used for local staging and whole body CT scan for the evaluation of metastatic disease.

Endoscopic US and PET scan were used when CT scan did not show conclusive results in the evaluation of local or metastatic disease, respectively.

According to MDT panel, neoadjuvant CRT was given to all patients with good performance status and evidence of a resectable disease but at high risk of local recurrence.

Adjuvant treatment was reserved for II and III stage patients.

Demographic, histopathological, surgical morbidity/mortality and clinical outcome in all patients who underwent transanal resection of rectal cancer were retrospectively evaluated from a prospectively collected database.

Specimen characteristics were examined in operating room by the operating surgeon who assessed the distal margin and the mesorectal envelope integrity: the specimen was then sent to pathology service and the quality of mesorectum evaluated according to Quirke grading score [3], taking into account the worst grading in case of discrepancy.

Morbidity evaluation included all intraoperative, early post-operative (within 30 days) and late complications (> 30 days) and rated according to Clavien–Dindo classification [4].

Local recurrence was defined as tumor evidence, radiologically or histologically proven.

Distant recurrence was defined as radiologically distant tumor evidence. Anastomotic leakage definition was clinical: presence of pus or feaces from abdominal drain, pelvic abscess, peritonitis or pus discharge from anus.

A learning curve analysis was performed, comparing data on operative time, number of lymphnodes harvested and quality of surgical specimen, hospital stay, early and late complications in two groups, group A (first half of patients) and group B (second half of patients) operated sequentially from the beginning of experience.

All the procedures were performed by an expert single surgeon with advanced laparoscopic skills, but without formal hands-on training. However, preliminary physical model simulation of the procedure and observership at a referral centre were carried out prior to implementing TaTME.

A mean follow-up of 14.1 ± 6.9 months (range 3–21) was recorded.

All data are expressed as mean values $\pm$ DS and median when appropriate.

Statistical analysis was performed using *t* test, Chi square or Fisher test.

Statistical significance was considered for $p \leq 0.05$.

Surgical technique

After general anesthesia induction, patient was catheterized and put in lithotomic position with both arms along the body. A two-step approach was preferred, using the same surgical team for both operative phases.

Abdominal phase

Our preference is to start the abdominal phase with the induction of pneumoperitoneum with Veress needle technique in the right flank. In case of previous abdominal surgery or "complex abdomen", we opt for the use of Visiport or open transumbilical Hasson technique.

Once pneumoperitoneum is established with a CO2 pressure of 12 mmHg, 3 more ports are introduced under vision: 10–12 mm in the right iliac fossa, 5 mm in right hypocondrium and 5 mm in the left flank.

The patient is then put in the Trendelemburg position with left hand side up. The omentum is retracted cranially along with the transverse colon and the small bowel is sited in the right supramesocolic space. Mesocolon and mesosigmoid are thus exposed, together with sacral promontory and aortic plane.

The inferior mesenteric vessels are identified and tied and a complete mobilization of the distal transverse colon, splenic flexure and descending sigmoid colon is performed. The operation continues with the section of the peritoneum of the Douglas pouch and the dissection of the rectum and mesorectum caudally. The surgical plane to develop is the direct extension of the Toldt fascia plane already dissected. Rectal dissection is started posteriorly, dividing the parietal layer of pelvic fascia from the visceral one which covers the mesorectum. Attention should be kept not to breach this layer to achieve an adequate oncological resection.

Dissection is carried out anteriorly up to recto-vaginal septum in female and seminal vesicles in male. Pneumoperitoneum is thus released and the perineal phase of operation can start.

Transanal phase

Perianal phase is performed with TAMIS platform using a SILS port (Covidien, MA, USA). The patient is placed in Trendelenburg position with legs abducted and slightly flexed.

A Lone Star retractor is inserted and according to the distance of the lower edge of tumor from anal verge, the operation can start straight away with an intersphincteric resection or with the introduction of the port and the establishment of pneumorectum.

Once the tumor has been identified, a prolene 2/0 purse-string suture is placed through the rectal mucosa to tightly occlude the rectum 1–2 cm distal to the lower edge of the cancer. When the rectal lumen has been sealed a rectal washout is performed to remove debris and the potential implant of malignant cells.

The rectal lumen is inflated with CO_2 to a pressure of 10–12 mmHg and the transection line is marked with hook diathermy, performing a full-thickness rectal transection. Transection is started at five o clock to avoid entering into the anococcygeal ligament and then extended circumferentially until the rectal wall is completely open and the perimesorectal space more easily defined by pneumorectum. The mesorectum is circumferentially dissected from down-to-up toward the anatomical landmarks of a 'good' taTME: the sacral promontory posteriorly, the Pouch of Douglas anteriorly and the iliac vessels laterally. Posteriorly, after sectioning the rectosacral fascia, the dissection follows the concavity of the sacrum and, once reached the holy plane, the mesorectum is mobilized and the dissection extends cranially in the presacral avascular plane according to TME principles. The anterior plane of dissection is conducted in front of or behind the Denonvillier's fascia according to the rectal cancer position until the connection with the transabdominally achieved dissection plane is joined. Lateral plane development is left as last step and particular attention must be paid to the inferior hypogastric plexus, keeping the dissection in close contact with the fascia of the mesorectum. When the lateral dissection is almost complete peritoneal cavity is accessed and last tissue bridges are cut to complete the dissection.

Specimen extraction can be done transanally or transabdominally through a small laparotomy.

In case of transanal extraction the recto-sigmoid segment is exteriorized and the section point is decided after having checked the presence of an adequate blood flow. Anastomotic technique is chosen according to the length of rectal stump. A handsewn anastomosis (laterotерminal when feasible) is performed for cancers located in the lower rectum, while a purse-string suture of the rectal stump by prolene 0 is performed and tied around the rod of the anvil in case of mid rectal cancer. The EEA™ 33 circular stapler (4.8-mm staples; Covidien) is inserted through the anorectal ring, linked to the rod, and then fired.

Anastomosis is performed under laparoscopic vision and checked with hydropneumatic test.

In case of transabdominal extraction, the same technical steps are performed proceeding to colon resection and pelvic transposition of the proximal stump, with or without the stapler anvil, according to mechanic or handsewn anastomosis confection.

A loop ileostomy is performed routinely and a perianastomotic drain is placed from the left flank 5 mm trocar site.

Results

Between January and May 2016, 12 patients affected by mid-low rectal adenocarcinoma suitable for surgical resection were operated on using the hybrid technique of laparoscopic anterior resection with TaTME; in all patients the operation was successfully completed laparoscopically.

Out of the total of patients, 8 were male (66.6%) and 4 female (33.3%) with a mean age of 64.6 years (range 43–77) and a mean BMI of 25.9 (range 19.2–34.5).

Two patients were overweight (16.6%) with a BMI ranging between 25 e 29.9 e 4 (33.3%) where obese with a BMI ≥ 30.

Cardiovascular comorbidities were present in 3 patients (25%; AF, ischaemic cardiopathy, hypertension); previous oncological disease in 2 patients (16.6%; prostate cancer); 1 patient suffered controlled type 2 diabetes, 1 patient had poorly controlled type I diabetes with end stage renal disease on dialysis.

According to the American Society of Anesthesiologists Classification 6 patients were categorized as ASA 1 (50%), 4 as ASA 2 (33.3%), 2 ASA 3 (16.6%).

Tumor was located in the middle rectum in 6 patients (50%), in the lower rectum in 6 patients (50%). No upper rectum cancer was selected for this approach.

Mean distance from anal verge was 6.25 cm $\pm$ SD 2.1 (range 3.5–10 cm).

In our experience indications for this surgical approach were a combination of difficult anatomic conditions such as narrow pelvis, bulky mesorectum, BMI ≥ 30 kg/m^2, previous prostatic surgery or radiotherapy or unfavorable tumor features like anterior development, circumferential margin highly suspected to be threatened on pelvic MRI.

Decision to perform TaTME was taken preoperatively on the basis of patient characteristics and tumor features on MRI, or following intraoperative findings of difficult anatomy of pelvis.

Pre-operative tumor and patients features are shown in Table 1.

Three patients (25%) underwent neoadjuvant treatment, 1 CRT, 1 RT, and 1 patient combined neoadjuvant CRT and adjuvant CT, respectively. We observed only one complete pathological response.

Three patients underwent adjuvant chemotherapy.

Tumor histology was adenocarcinoma in 100% cases.

Peri-operative data (Table 2)

TaTME was realized in all cases using the transanal platform SILS (Covidien, MA, USA).

Table 1 Demographic features of patients and tumors

Demographic characteristics	No. ± DS	%
Male	8	66.6
Female	4	33.3
Total	12	
Age (mean)	64.6 ± 10.3 (43–77)	
ASA score		
ASA 1	6	50
ASA 2	4	33.3
ASA 3	2	16.6
Histology		
Adenocarcinoma	12	100
CRM involvement on MRI		
CRM < 1 mm	9	75
CRM > 1 mm	3	25
Rectal location		
High	0	
Medium	6	50
Low	6	50
Chemotherapy		
Neoadjuvant CRT	1	8.3
Neoadjuvant RT	1	8.3
No treatment	8	66.6
Adjuvant CT	3	25
Neoadjuvant CRT + adjuvant CT	1	8.3

Table 2 Peri-operative data

Operative data	No.	%	Range
TaTME indications			
Male patients	8	66.6	
Narrow pelvis	3	25	
BMI 30 kg/m^2	5	41.6	
Anterior-located tumor	8	66.6	
Previous radiotherapy	2	16.6	
Mean operative time (min)	356.5 ± 76.2		240–494
Laparotomy conversion	0		
Blood loss (ml)	175 ± 100		50–400
Anastomosis			
Handsewn	3	25	
Stapled	9	75	
Mean hospital stay (days)	10.9 ± 4.6		5–19

Mean operative time was 356.5 ± 76.2 min (range 240–494).

Laparoscopic abdominal phase was carried out with multiport technique with average use of 4.18 trocar (range 4–5). No conversion to laparotomy was observed.

Five out 12 patients (41.6%) underwent colo-anal anastomosis, 3 handsewn and 2 stapled. The remaining were stapled colorectal anastomoses.

All anastomoses were protected with a defunctioning ileostomy.

Eleven out 12 patients (91.6%) had less than 200 mL of intraoperative blood loss.

Mean hospital stay was 10.9 ± 4.6 days (range 5–19).

Morbidity and mortality

No mortality was recorded. Intraoperative complications were recorded in 1 case with the failed mechanical anastomosis which was resolved by placing additional interrupted stitches on the suture line.

Early post-operative complications (< 30 days) were observed in 5 patients (41.6%). According to Clavien-Dindo classification no severe complications were recorded. We observed 1 case of urinary retention, 1 of pneumonia, 2 skin infections and 2 post-operative ileus (grade I–II complications).

We did not record late post-operative complications (> 30 days).

Histopathology and follow-up (Table 3)

Histopathological examination of the specimen showed in all cases an intact mesorectum (grade 3 of Quirke classification). Mean number of lymphnodes harvested was 13.6 ± 6.6 (range 4–29).

Distal and circumferential margins were, respectively, of 20.8 ± 14.2 mm (range 2–45 mm) and 16.1 ± 7.6 mm (range: 3–30 mm). In all patients we recorded R0 resections.

According to TNM AJCC/UICC 7th 2010 classification 5 patients (41.6%) had stage I, 4 patients (33.3%) had stage IIA; 1 patient (8.3%) had stage IIIA; 2 patients (16.6%) had stage IIIC disease.

After a mean follow-up of 14.1 ± 6.9 months (range 3–21), we did not observe local recurrence. In two patients developing liver metastases we have observed one death due to progression of disease and one patient currently alive and disease-free after iterative hepatic surgery.

Ileostomy closure was performed 3 weeks after operation in 10 patients, in one patient after the resolution of skin infection, in 1 patient 8 weeks after conclusion of adjuvant treatment.

Twelve months after ileostomy closure in 7 patients mean Wexner score was 5 (range 3–9), with 1 report of mild fecal incontinence.

Table 3 Histopathology

Histopathology	No.	%
Anal margin distance (cm)[a]	6.25 (3.5–10)	
Tumor size (cm)[a]	3.2 (1–5)	
Tumor location		
Circumferential	2	16.6
Anterior	4	33.3
Antero-lateral	4	33.3
Posterior	1	8.3
Postero-lateral	1	8.3
TNM[43]		
pCR[b]	1	8.3
I	5	41.6
IIA	4	33.3
IIIA	1	8.3
IIIC	2	16.6
No. of lymphnodes examined (mean)	13.6 ± 6.6 (4–29)	
TME grading		
Quirke 3	12	100
Quirke 2	0	
Quirke 1	0	
Circumferential margin	16.1 ± 7.6 mm	
Distal margin	20.8 ± 14.2 mm	
R0	12	100

[a]Mean value

[b]Complete remission

Comparative analysis

The comparative analysis performed by dividing the patient sample in two groups according to chronology of operation (group A first half–group B second half) did not show significant differences in terms of: intraoperative complications ($p = 1$); early and late post-operative complications; ($p = 1$); hospital stay ($p = 0.2155$); mean number of lymphnodes retrieved ($p = 0.7430$); quality of mesorectum ($p = 1$); length of distal ($p = 0.9095$) and radial resection margin ($p = 1$); conversion to laparotomy ($p = 1$); we observed significant differences concerning mean operative time ($p = 0.0473$) and estimated blood loss ($p = 0.0367$).

Discussion

Minimally invasive surgery is in constant evolution with NOTES (Natural Orifice Transluminal Endoscopic Surgery) representing the further and probably conclusive step of this unstoppable progression. Advantages include reduction of postoperative pain, minor incision-related complications, such as hernia and wound infection, better cosmetic results and a quick recovery time [5].

Sylla et al. performed the first rectal resection with a transanal approach in a 76 y.o. female patient affected by a rectal cancer at 8 cm from anal verge [6].

Since this description transanal TME aroused great interest and, beyond the possibility of removing the specimen transanally, thus realizing "*scarless surgery*", perhaps the real importance of this novel technique rests in the fact that there is an opportunity to offer technical advantages compared to open and laparoscopic approaches in some situations considered "difficult" under normal circumstances.

Several conventional surgical studies report rectal resections with incomplete mesorectum [7], mainly in "high-risk" patients such as obese, with anterior tumor, narrow pelvis, bulky mesorectum or undergone neoadjuvant treatment [8, 9].

The laparoscopic approach offers the advantage of a better visualization of deep pelvic structures, but the risk of mesorectal tapering remains as a consequence of the limitations imposed by straight and long instruments, the difficulty to apply adequate traction and countertraction in a narrow space and by the limited angle of laparoscopic staplers [10].

The robotic approach can overcome several of the technical difficulties associated with traditional laparoscopic surgery; however, recent studies demonstrate similar clinical and oncological results between robotic and laparoscopic surgical procedures [11] and no real benefit of robotic over laparoscopic surgery seems to have been demonstrated.

TaTME was developed with the aim of overcoming these technical difficulties, mainly in middle-low cancers. Down-to-up dissection is safe and effective, allows formation of the purse-string below the distal margin of the tumor, makes the presacral plane more easily identifiable with the potential further advantage of nerve sparing. Moreover, in tumors located anteriorly, with an instrinsic high risk of positivity of the circumferential margin, the dissection of Denonvilliers fascia is made easier.

Soon after its introduction a number of series have been published in literature. [12–14] and, despite a remarkable heterogenity in terms of study design, inclusion criteria, surgical technique, instruments, selection and analysis of outcome, excellent oncological results have been reported, with a level of lymphnode harvesting and quality of surgical specimen comparable to conventional approach.

Our experience shows that the down-to-up approach allows an excellent quality of TME, with an intact mesorectal envelope in all cases. These results are of great interest since an intact mesorectum makes the probability of local recurrence, even with positive lymphnodes, significantly lower than with a threatened one and is around 7.5% [15].

Negativity of circumferential margin is another indicator of the quality of the rectal resection and in our series it was achieved in 100% of cases. Moreover, the ability to identify the distal margin of the tumor and to perform the rectal

transection under vision allowed us to achieve a negative distal margin in all cases.

Lymph node harvesting is in line with what was observed in laparoscopic series [16].

Early oncological results of our cases are in line with results obtained in previously published studies [17–19].

Beyond oncological outcome, morbidity also needs to be kept in consideration since it is generally considered higher in low-rectal cancers [20].

Preliminary results of our study showed an overall morbidity rate of 50%, with 1 intraoperative and 5 post-operative complications. None of those was deemed severe according to Clavien–Dindo classification. No cases of mortality were recorded. These results are consistent with mortality and morbidity rates reported in literature after rectal resection [21].

Despite some degree of technical difficulties, in all cases so far published patients showed a good tolerance of the procedure, with complications described generally as mild and transient.

Only the occurrence of urethral lesion could be considered an intraoperative complication strictly related to the technique [14].

Mean operative time was 356.5 ± 76.2 min (range 240–494), slightly longer compared to what was observed in other series, and we justify this data with the selection of patients with difficult anatomy and mainly because we performed the whole procedure with a single surgical equipe. Specifically, one operation on an obese patient lasted 494 min and contributed to raise remarkably the mean operative time, but, with the improvement of surgical experience and equipment, we registered a reduction of the operative time, as demonstrated by comparison of early with later cases.

Similar to other experiences [13, 14, 22], in our study post-operative functional results were satisfying, with all patients continent to solid and liquid stools. Only one patient complained of mild incontinence (post-operative Wexner score 9) but the slightness and heterogeneity of patients sample make difficult to express conclusive judgements about post-operative anorectal function.

Several controversies exist on the potential sphincteric impairment produced by the prolonged use of the operative anoscope, but in our study functional results and quality of life were not evaluated.

Kneist et al. tried to add some evidence on functional outcomes after taTME in patients with low rectal cancer and, despite a small sample size and confounding factors, data indicate that this technique has the potential to preserve continence, sufficient bowel function and urogenital function.

During follow-up evaluation no patients complained of urinary or genital disfunction, but these data are without statistical significance [23].

Comparing the early procedures with the last ones, despite the small sample, statistically significant benefits in terms of operative time and blood loss were demonstrated with the progression of the experience.

Post-operative complications, conversion rate and histopathology did not show statistically significant difference between two groups. In contrast, the mean hospital stay, despite not being statistically significant, was shorter in the first half of cases, as well as lymphnodes harvesting which was better in the first operations. This strengthens our opinion that this approach, despite deemed as a panacea, should be considered highly demanding even in the hands of very experienced surgeons. It is really promising, but an appropriate technical background, to date, is a necessary quality to become an expert.

Meta-analytic studies demonstrated that taTME can achieve comparable technical success in comparison with laparoscopic TME in the treatment of rectal cancer [24]. In addition, TaTME showed a better short-term clinical outcomes, such as a wider CRM with lower risk of positive margin, higher quality of TME rate and shorter operative duration [25].

Multicenter RCTs comparing taTME with conventional TME with long-term follow-up are required to validate the efficacy and safety of taTME as a therapeutic option for rectal cancer.

Conclusions

TaTME for rectal cancer has gained attention and popularity in the last few years. This study is in line with the available literature and confirms this technique is safe and feasible. To date, this approach is still a novel technique without enough evidence to support it over conventional laparoscopic surgery.

The multicentric randomized controlled trial COLOR III, designed to compare TaTME vs. Laparoscopic TME, is ongoing and will provide us with more reliable data concerning the oncological quality of surgery.

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Compliance with ethical standards

Conflict of interest Drs. Michele De Rosa, Fabio Rondelli, Marcello Boni, Fabio Ermili, Walter Bugiantella, Lorenzo Mariani, Graziano Ceccarelli and Antonio Giuliani have no conflicts of interest or financial ties to disclose.

Ethical approval All procedures performed were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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