Int J Colorectal Dis (2016) 31:359–363
DOI 10.1007/s00384-015-2418-0

ORIGINAL ARTICLE

Is transanal total mesorectal excision a reproducible and oncologically adequate technique? A pilot study in a single center

Is transanal TME a safe procedure?

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Accepted: 14 October 2015 / Published online: 21 October 2015

Abstract
Purpose An oncologically effective total mesorectal excision (TME) still represents a technical challenge, especially in the presence of a low rectal cancer and anatomical restraints such as obesity or narrow pelvis. Recently, few reports have shown that transanal TME was feasible and associated with good outcomes. Nevertheless, a widespread employment of the technique has yet to happen due to the doubts about the reproducibility of the results outside a tertiary specialized center.
Methods Between February 2014 and June 2015, patients with low rectal cancer underwent a transanal TME with laparoscopic assistance. The end points included the oncologic adequacy of the mesorectal excision and the perioperative outcomes.
Results Eleven patients (9 male, median age 70.5 years) with proven low rectal cancer were enrolled in the study. The median distance of the tumor from the anal verge was 5 cm (2–7). Four patients (36.4 %) received preoperative chemoradiation. The median operative time was 360 min (275–445). Postoperative morbidity (36.4 %) included one (9.1 %) anastomotic leak requiring a reoperation. The median length of hospital stay was 8 days (3–28). The median distance from the circumferential and distal resection margins were, respectively, 5 (1–20) and 10 (5–20)mm, and the mean number of harvested lymph nodes was 21.7 (11–50). All cases had a complete or nearly complete mesorectal plane of surgery.
Conclusions Although technically challenging, the initial results suggest that transanal TME could be a feasible, oncologically safe, and reproducible operation. However, more robust studies are required to assess the short- and long-term outcomes.

Keywords Transanal · TME · NOTES · Laparoscopic · Rectal cancer · Surgery

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Introduction

The paramount relevance of total mesorectal excision (TME) in rectal cancer surgery was described 30 years ago by Heald et al., and since then, the adherence to this surgical paradigm has led to a single-digit rate of local recurrences [1].

Subsequently, other authors highlighted a strong correlation between local relapse and tumor involvement of the mesorectal circumferential, rather than the distal margin [2, 3]. Further studies identified the importance of the integrity of the mesorectal fascia to predict local recurrence following a total mesorectal excision, even in absence of a tumor infiltration of the radial margin [4].

The use of minimally invasive surgery in the treatment of rectal cancer has been accepted in the scientific community despite the initial doubts regarding the feasibility of an oncologically acceptable complete mesorectal excision, and while the long-term results of the large multicentric trials have not been published yet, single-center studies show oncologic results after laparoscopic TME at least similar to those achieved with an open approach [5, 6].

However, the technical challenges of rectal mobilization, preservation of important pelvic neurovascular bundles, and formation of ultra-low anastomosis are well known and

particularly pronounced in the presence of a difficult pelvic and abdominal anatomy, as observed in the narrow male pelvis or in obese patients [7–9].

Recently, a novel approach to TME using a transanal minimally invasive surgery (TAMIS) platform has been described by some authors, ideally as a way to overcome those difficulties and perform a state-of-the-art total mesorectal excision.

The transanal TME is an evolving technique using a transanal single-port and laparoscopic instruments for mobilization of the distal rectum in a "down to up" approach, usually employed with laparoscopic assistance to mobilize the left colon and the proximal mesorectum transabdominally. While the first reports from the specialized centers showed positive short-term outcomes and an acceptable adherence to the oncologic principle of TME [7, 10–12], it is still unclear whether the technique could be widely embraced.

Materials and methods

From February 2014, unselected adult patients with histologically proven adenocarcinoma of the middle or low rectum were prospectively enrolled in the study.

The preoperative assessment included a full colonoscopy, pelvic magnetic resonance imaging (MRI), and computing tomography (CT) of the chest and abdomen. All patients were managed through a multidisciplinary team, gave consent for the procedure, and underwent appropriate perioperative counseling.

Patients requiring neoadjuvant chemoradiation underwent a laparoscopic defunctioning ileostomy formation prior to therapy and a subsequent restaging with pelvic MRI and CT. In those cases, surgery was scheduled 6–8 weeks after completion of the chemoradiation.

Exclusion criteria were metastatic disease, infiltration of the anal sphincters, stage T4 cancer, and contraindications to laparoscopy.

The data were collected prospectively. Demographic and patient characteristics, oncologic and perioperative data, and follow-up were recorded.

The primary end point of the study was the oncologic adequacy of the TME, including the rate of tumor infiltration of the surgical margins and the plane of surgery. The secondary end points included the intraoperative and postoperative outcomes. The variables were presented as number (%) or median (range).

Surgical technique

A full mechanical bowel preparation was given to all patients.

The transanal operations were performed by two experienced laparoscopic colorectal consultants, while the abdominal team included two senior surgical fellows as first operators.

In the last three cases, the abdominal and transanal approaches were performed simultaneously.

The patient was placed in lithotomy position after general anesthesia, and a digital examination or rigid sigmoidoscopy was performed to confirm the location of the tumor.

A 12-mm umbilical port was inserted under direct vision, and further trocars were positioned in right iliac fossa (12 mm), suprapubic area (12 mm), left iliac fossa (12 mm), left upper quadrant (5 mm), and epigastric area (5 mm).

The pneumoperitoneum and the pneumoperineum were established using an AirSeal device (SurgiQuest, Milford, CT, USA).

A harmonic scalpel (Ethicon Endo-Surgery, Cincinnati, OH, USA) was used both in abdominal and transanal excision.

The splenic flexure and descending colon were mobilized, and the gastrocolic ligament was divided to give adequate length for a tension-free anastomosis. The left ureter and gonadal vessels were always identified and preserved allowing the IMA pedicle to be safely taken at the origin using a 60-mm vascular cartridge Power Echelon (Ethicon Endo-Surgery, Cincinnati, OH, USA). The lateral attachments were released, and the upper mesorectum was mobilized from above to join the dissection plane obtained through the transanal approach.

For the transanal TME, a GelPOINT path TAMIS platform (Applied Medical, Rancho Santa Margarita, CA) port was secured in the anus. In the event of a tumor with a distal margin at 3 cm or less from the anal verge, the transanal insertion of the port might be difficult or not feasible in the first instance. In those cases (two in the present series), a Lone Star Retractor (Lone Star Medical Products, Houston, Texas, USA) was employed in order to proceed with a full thickness rectal resection distally to the tumor followed by the insertion of the transanal port.

The rectal wall was therefore incised circumferentially and closed using a purse-string suture, and a washout of the perineal cavity with povidone-iodine solution as cytocidal agent was performed.

The rectal space was therefore insufflated, and the mesorectal plane was dissected from below-up using diathermy and the harmonic scalpel, starting posteriorly and proceeding cephalad in the avascular presacral plane, and subsequently extending laterally and finally anteriorly.

During the dissection, particular attention was given to avoid injuries to the neurovascular bundles, such as the inferior rectal plexus, located laterally in the pelvic side wall above the level of the levator ani muscle, and the inferior hypogastric plexus, found in the posterolateral edge of the prostate (or the vagina). In those key areas, the dissection was performed adherent to the mesorectal fascia by holding a constant lateral to medial traction on the mesorectum in order to obtain a satisfactory plane of dissection.

After the high TME plane developed transabdominally was reached and opened circumferentially from below, the completely mobilized colorectum was pulled through the anal retractor, the colon was divided at the level of the proximal sigmoid, and a coloanal anastomosis was performed using the Lone Star Retractor and interrupted 2-0 absorbable sutures. In three cases, a double purse-string stapled anastomosis was performed.

Results

Between February 2014 and June 2015, 11 unselected patients (9 males), with a median age of 70.5 years, underwent a transanal TME for rectal cancer. Median BMI was 29 kg/m^2. All patients had histologically proven adenocarcinoma in the middle or low rectum. The median distance from the anal verge was 5 cm (range 2–7). Four patients (36.4 %) underwent neoadjuvant chemoradiation (Table 1).

The perioperative findings are summarized in Table 2. The median operating time was 360 min (275–445). This included the time necessary to change the position of the patient and a pause requested by the anaesthetist to reduce the Trendelenburg position.

A hand-sewn anastomosis was performed in seven cases. No intraoperative complications occurred.

Postoperatively, the median time to full oral intake was 1.5 days and the median length of hospital stay was 8 days.

The 30-day postoperative surgical complications included one anastomotic leak, which required a reoperation and formation of an end colostomy, one presacral collection that was treated conservatively, and two cases of ileus.

The median tumor size was 50 (10–70)mm, and the median distance of the tumor from distal and circumferential resection margins were 10 (5–20) and 5 (1–20)mm, respectively. In one case (9.1 %), the tumor was at 1 mm from the circumferential resection margin. The mean number of lymph nodes was 21.7 (11–50). Five patients (45.5 %) had evidence of extramural vascular invasion. The mesorectal fascia was intact in eight cases (72.7 %), while in the other three patients, the surgical dissection involved the intramesorectal plane. The histological examination confirmed an American Joint Committee of Cancer (AJCC) stage 3 in eight (72.7 %) and a stage 2 in three (27.3 %) patients (Table 3).

Table 1 Preoperative characteristics

Age (years)	70.5 (58–77)
Male gender	9 (81.8 %)
BMI	29 (24.3–32.8)
ASA score 2	11 (100 %)
Distance from anal verge (cm)	5 (2–7)
Neoadjuvant chemoradiation	4 (36.4 %)

BMI body mass index, *ASA* American Society of Anesthesiologists

Table 2 Perioperative outcome

Operative time (minutes)	360 (275–445)
Intraoperative complications	0
Hand-sewn anastomosis	7 (63.6 %)
Time to full oral intake (days)	1.5 (1–2)
LOS (days)	8 (3–28)
Postoperative complications	4 (36.4 %)

LOS length of stay

Discussion

The ultimate goals of rectal cancer surgery are the performance of an oncologically radical resection of the rectum and mesorectal tissue in order to prolong survival by reducing local recurrences, in addition to maintaining the patient's quality of life by performing a nerve sparing technique. Local recurrence rates have dramatically improved in the last decades, largely due to the adherence to the principle of TME and the extensive use of preoperative chemoradiation [13].

Despite the initial resistance to the routine use in clinical practice due to doubts about oncologic adequacy [14], laparoscopy in rectal surgery has been proven to be associated with at least equivalent morbidity and short-term oncologic outcomes when compared to open surgery [6, 8, 9, 15]. However, a low TME can be particularly challenging, due to the limited exposure and the difficulty to reach a clear margin distally to the tumor. This, associated with a higher chance of conversion and intraoperative complications, could potentially compromise the quality of the oncologic resection and increase the risk of injury to the sphincters and nerves [6, 11].

These constraints, together with the availability of surgical platforms such as the natural orifice transanal endoscopic surgery (NOTES), the transanal endoscopic microsurgery (TEM), and the single-port laparoscopic surgery, have led to the development of a novel approach for the treatment of low rectal cancer. In 2010, Sylla et al. published the first case of

Table 3 Histological characteristics

Tumor size (mm)	50 (10–70)
CRM (mm)	5 (1–20)
DRM (mm)	10 (5–20)
Extramural vascular invasion	5 (45.5 %)
Number of lymph nodes	21.7 (11–50)
Complete or nearly complete surgical plane	11 (100 %)
AJCC stage 3	8 (72.7 %)

CRM circumferential resection margin, *DRM* distal resection margin, *AJCC* American Joint Committee on Cancer

laparoscopic-assisted transanal TME using a TEM platform, demonstrating the feasibility of a down to up mesorectal excision, which was presumed to overcome the shortcomings of the standard transabdominal approach to the pelvis. Subsequently, other authors demonstrated the technique to be feasible using a transanal single port for access, either performed with a hybrid transabdominal laparoscopic assistance or through a pure transanal approach [7–12, 16–19]. The advantages of the technique were immediately clear, especially in difficult cases such as obese patients, male narrow pelvis, or locally advanced distal tumors.

Ideally, a retrograde TME considerably reduces the risk of breaching the distal resection margin (as the rectum is divided under vision with a clear margin), and the transanal pneumodissection simplifies the opening of the "holy plane" of the TME [8]. In our experience, no tumor involvement of the distal resection margin was identified, and the median distance was 10 mm from the tumor. Taking into account that all cases had a low advanced rectal cancer, and that nine patients were male, a standard transabdominal TME would have been challenging and associated with a higher risk of tumor infiltration.

While a clear distal margin is essential to achieve an acceptable rate of tumor recurrence, the crucial impact of a tumor-free circumferential margin on the long-term outcomes has been strongly emphasized in the last years [20]. Moreover, it was observed that a less than optimal plane of surgery was also associated with a significantly higher rate of local recurrence, even in presence of a clear margin [21]. In particular, a review from Bosch et al. showed that a muscularis propria resection plane was associated with a higher risk of local (RR 2.72) and distant (RR 2.00) recurrence compared to a mesorectal or intramesorectal plane of surgery and that the incidence of a poor surgical plane was up to 15 % in the meta-analysis [22].

In our experience, all patients had a mesorectal (72.7 %) or an intramesorectal (27.3 %) plane of surgery. No incomplete resection plane was detected at the histological examination.

These encouraging results are comparable to those presented in a recent review which showed a range of complete or nearly complete mesorectal surgical plane between 89.5 and 100 % after transanal TME [23]. More interestingly, a subsequent case–control study reported a significantly higher rate of completeness of the mesorectum with transanal rather than laparoscopic TME (96 vs. 72 %, $p<0.05$) [11].

In this series, one case (9.1 %) had a 1-mm circumferential resection margin (CRM) and was considered as a positive margin, based on the evidence that when the CRM is ≤2 mm, a higher rate of recurrence is reported. The patient had a technically challenging resection due to a bulky tumor and dense adhesions related to neoadjuvant radiation. The final AJCC pathology stage was T3N2; the patient received postoperative chemotherapy and was disease-free at a 10-month follow-up.

Similarly, other authors reported a low incidence of CRM involvement after transanal TME [23].

The mean number of harvested lymph nodes was 20 in the present study. Three patients (27.2 %), all undergoing preoperative chemoradiation, had less than 15 lymph nodes removed, confirming previous reports of a lower lymph node harvest after neoadjuvant radiation [24].

In the last six cases of the series, a two-team approach was employed. While proved by other authors [17], a shorter operative time was not shown in this series, likely due to the low number of patients and the fact that the learning curve was still increasing.

However, additional advantages of this approach were acknowledged. It is known that the transanal dissection of the anterolateral mesorectal plane at the level of the prostate could be particularly challenging, often due to unclear anatomical planes. Such difficulty can be overcome by relying on the simultaneous dissection of the same mesorectal plane from opposite directions.

While no intraoperative complication was detected, the 30-day postoperative morbidity included one case of anastomotic leak which required an urgent laparotomy and formation of an end colostomy. Two patients experienced prolonged ileus, and one case was complicated by a pelvic collection treated with transcutaneous drainage. The overall complication rate was therefore 36.4 %, comparable to that presented in other reports of outcomes after low anterior resection [25].

Only few studies have been published in the last years regarding the outcomes of transanal TME, all by well-known innovators and recognized referral centers for laparoscopic surgery [23]. Reasonably, other authors claimed caution, as the technique was not proven to be reproducible and the results could have been significantly worse when applied to a widespread use [26]. As already stated, an advanced expertise in laparoscopic single-port surgery and a well-proven knowledge of the transanal anatomy are required to approach this novel technique. Nevertheless, despite the inclusion of non-selected cases with locally advanced low rectal cancer in this series, our initial experience is cautiously encouraging and shows that the transanal TME might be a reproducible and oncologically safe technique in the treatment of the tumors of the distal rectum.

Conclusion

Transanal TME has the potential to revolutionize rectal cancer surgery from both a technical and a clinical point of view. Approaching distal and mid rectal cancers transanally may in the future improve the quality of TME specimens, particularly in cases where patient's factors and anatomic constraints can make surgery challenging. Robust clinical trials are now

required to evaluate the long-term and oncologic outcomes and the impact on the patient's quality of life.

Compliance with ethical standards

Conflict of interest Drs. Rottoli, Hanna, Kukreja, Pancholi, and Wegstapel have no relevant financial interests to disclose.

Human and animal rights and informed consent Informed consent was obtained from all individual participants included in the study.

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