

TRANSANAL TOTAL MESORECTAL EXCISION LAPAROSCOPIC SURGERY FOR RECTAL CANCER TREATMENT: SHORT-TERM OUTCOMES IN 57 PATIENTS

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SUMMARY

Objectives: To assess the short-term outcomes of transanal total mesorectal excision (TaTME) laparoscopic surgery for treatment of the mid and distal rectal cancer. **Subjects and methods:** Clinical intervention, prospective, follow-up study without comparison in 57 patients with mid and distal rectal cancer who underwent TaTME in Gastrointestinal Surgery Department, Military Central Hospital 108, from July 2017 to December 2019. **Results:** During the study period, there was a total of 57 patients undergoing TaTME. The median tumour distance from the anal verge was 4.96 (2.0 - 8.0) cm. The macroscopic quality assessment of the resected specimen was complete in 89.47% and the positive circumferential resection margin was noted in 1.75%. The median lymph node yield was 13.75 (3 - 23). The postoperative morbidity rate was 31.58%. The median length of stay was 11.26 (4 - 29) days. The median Wexner score in the 12 and 24 months after surgery was 4.05 and 2.15, respectively. The median follow-up was 26.35 (13 - 38) months; 2 patients (3.51%) developed a local recurrence and 8 patients (14.55%) developed distant recurrence. Overall survival and disease-free survival rates were 87.72% and 88.89%, respectively. **Conclusion:** These data suggest that TaTME for rectal cancer is feasible with an acceptable pathological outcome and morbidity profile.

* **Keywords:** Rectal cancer; Total mesorectal excision; Transanal surgery; TaTME.

INTRODUCTION

Total mesorectal excision (TME) is a gold standard for the management of rectal cancer [1]. Surgical quality has a direct impact on local control and survival. In the pathological assessment of rectal cancer specimens, the circumferential resection margin (CRM) and the plane of surgery achieved have been demonstrated to be an independent predictor of local recurrence [2]. Despite the advances in operative approach and neoadjuvant treatment, current CRM positivity rates have reached a nadir of approximately

10% [3]. Risk factors for a positive CRM include advanced T stage, male sex and large tumour size [4]. In the setting of laparoscopic proctectomy for rectal cancer, male gender, high body mass index (BMI), visceral obesity and a narrow pelvis predict intra-operative difficulty, which in turn is associated with local recurrence [4, 5]. In 2010, a study by Sylla et al demonstrated the advantages of a new cancer surgery approach, known as transanal total mesorectal excision (TaTME), where two access lines from the bottom of the anus (down-to-up) are combined with the up-down approach,

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Date received: 20/12/2020

Date accepted: 25/02/2021

which may represent a new solution for overcoming the limitations associated with conventional total mesorectal excision (TME) surgery [6]. In recent years, many studies have demonstrated this technique to be feasible and safe, the abdominal-transanal approach may improve quality of the specimens, including good CRM and distal margins, and oncologic outcomes [4, 5]. This study aims: *To focus on the short-term and oncological outcomes of laparoscopic TME for rectal cancer.*

SUBJECTS AND METHODS

1. Subjects

A total of 57 patients with middle or low rectal cancer, who underwent laparoscopic TaTME in the Digestive Surgery Department, Military Central Hospital 108, from July 2017 to December 2019, were enrolled in this study.

2. Methods

* *Design study:* Clinical intervention, prospective study

* *Diagnostic tool:*

Rectal cancer was diagnosed based on the results of colonoscopy, biopsy, 3.0 Tesla magnetic resonance imaging (MRI, Discovery 3.0 Tesla MR750, GE Healthcare, US), and computed tomography (CT, Brivo 385, with 16 slices, GE Healthcare, US).

* *Procedure:*

Neoadjuvant chemoradiation was performed in all patients with T3-T4N0 or T1-T4, N+ tumors, according to the preoperative staging guidelines. The protocol included a total dose of 50.4 Gy, with a daily dose of 1.8 Gy, administered five days each week, and chemotherapy was administered, in the form of a continuous capecitabine infusion at 225 mg/m²/day, five days each week, concomitant with

radiation therapy. Patients were re-examined at 6, 12 and 24 months after surgery. Postoperative complications, sphincter function, recurrence, and metastasis were detected through clinical examinations and CT and MRI scans.

* *Tumor characteristics and staging*

The staging and classification of the tumor were performed before the neoadjuvant treatment, by performing CT-scan of the chest, abdomen, and pelvis, endorectal ultrasound, and pelvic MRI. The tumor was reclassified after surgery, according to the 7th American Joint Committee on Cancer (AJCC) classification. A pelvic MRI was used to measure tumor height and to predict the circumferential resection margin (CRM), which was defined as the shortest distance between the rectal tumor and the mesorectal fascia.

* *Surgical technique:*

A standardized surgical procedure was performed by a team of experienced rectal surgeons. Patients were placed in the Lloyd Davies position. Abdominal laparoscopy was performed to assess distant metastasis or peritoneal dissemination. The TaTME procedure commenced with the perineal phase. The rectum was irrigated with an iodine solution, and a Lone Star Retractor System (Cooper Surgical Inc., Trumbull, Connecticut, USA) was used. For tumors located ≤ 4 cm from the anal verge, a hand-sewn purse-string around the anus was performed. The plane dissection was extended cranially, up between the intersphincteric space, to the level of the puborectal sling. For higher tumors, rectums were occluded below the tumor with an endoluminal purse-string. The GelPOINT Path Transanal Access Platform (Applied Medical, Inc., Rancho Santa

Margarita, California, USA) was inserted. The pelvic cavity was insufflated with CO₂, to a pressure of 6 - 10 mmHg. After the full thickness circumferential division of the rectal wall, the 'holy' plane was identified posteriorly, in the 5 or 7 o'clock position, allowing the initial dissection in the posterior plane, before being extended to the lateral and anterior aspects.

At the abdominal phase, we used a 30-degree scope at the umbilicus with 10 mm, and 5 mm ports at the lower right quadrant and a 5 mm port at the lower left quadrant. In some cases, a fifth suprapubic port was used to lift the uterus. After the division of the inferior mesenteric artery and vein, the left colon was completely mobilized and the splenic flexure was

mobilized. TME was performed top-down, along the avascular space, preserving the automatic nerve plexus. The specimen was extracted transanally or through abdominal incision, and the proximal margin was marked and divided. The early operative complications were defined and recorded as those occurring within 30 days after surgery and were categorized according to the Clavien-Dindo classification [7]. Late postoperative complications were defined as any complication occurring more than 30 days after the operation [4]. The quality of the mesorectum excision was assessed by the surgeon in the operative room and by the pathologist, according to the grading described by Quirke et al [2].

RESULTS

1. Patient characteristics

Table 1: Characteristics of patients.

Characteristics		Data
Gender (n, %)	Male	39 (68.42)
	Female	18 (31.58)
Age (years) ($\bar{X} \pm SD$)		62.44 \pm 12.48 (min 28 - max 86)
BMI (kg/m ²) ($\bar{X} \pm SD$)		21.09 \pm 3.09 (min 16 - max 28.1)
American Society of Anesthesiologists score (n, %)	I	2 (3.51)
	II	16 (28.07)
	III	39 (68.42)
Tumor location (n, %)	Middle rectum	28 (49.12)
	Lower rectum	28 (49.12)
	Not assessed	1 (1.76)
Distance from anal verge (cm) ($\bar{X} \pm SD$)		4.96 \pm 1.49 (2 - 8.2)
Preoperative T stage (n, %)	cTx	4 (7.02)
	cT1	0 (0.00)
	cT2	10 (17.54)
	cT3	37 (64.91)
	cT4a	6 (10.53)
Preoperative N stage (n, %)	cN-	16 (28.07)
	cN+	31 (71.93)

The majority of patients was male (68.42%), the median BMI was 21.09 kg/m² (16 - 28.1), median distance from the tumour to the anal verge was 4.96 cm (2 - 8.2).

2. Postoperative outcomes

Table 2: Postoperative outcomes.

Characteristics		n (%)	Clavien-Dindo
Early postoperative morbidity (≤ 30 days)	Urinary retention	7 (12.28)	I
	Anastomotic leak	1 (1.75)	IIIb
	Bowel obstruction	1 (1.75)	II
Late postoperative morbidity (> 30 days)	Anastomotic stricture	6 (10.53)	IIIb
	Anastomotic leak	1 (1.75)	IIIb
	Bowel obstruction	1 (1.75)	II
	Anal sphincter dysfunction	1 (1.75)	IIIb
Postoperative hospital stay (days) ($\bar{X} \pm SD$)		11.26 ± 5.41 (4 - 29)	

The median postoperative hospital stay was 11.26 days (2 - 29), the rates of early and late complications are equal (15.79%). Major postoperative morbidity (Clavien - Dindo IIIb) was observed in 15.79%.

3. Histopathology outcomes

Table 3: Histopathologic characteristics of surgical specimens.

Characteristics	Data	
Tumor size (cm) ($\bar{X} \pm SD$)	3.03 ± 1.50 (min 1 - max 8)	
Proximal margin (cm) ($\bar{X} \pm SD$)	13.75 ± 6.02 (min 5 - max 38.6)	
Distal margin (cm) ($\bar{X} \pm SD$)	2.33 ± 0.58 (min 1.4 - max 3.7)	
Circumferential resection margin (n, %)	CRM -	56 (98.25)
	CRM +	1 (1.75)
Lymph nodes yield ($\bar{X} \pm SD$)	13.75 ± 4.45	
Quality of mesorectum (n, %)	Grade 3: Complete	51 (89.47)
	Grade 2: Nearly complete	5 (8.77)
	Grade 1: Incomplete	1 (1.75)
pT staging (n, %)	T0	5 (8.77)
	T1	4 (7.02)
	T2	21 (36.84)
	T3	27 (47.37)
	T4	0 (0.00)
pN staging (n, %)	N0	40 (70.18)
	N1	13 (22.80)
	N2	4 (7.02)

A complete TME specimen was observed in 89.47% of cases. The majority of specimens were T3 (47.37%) and N positive (29.82%). The median number of harvested lymph nodes was 13.75. The median distal margin was 2.33 cm and 1 patient of CRM (1.75%) was positive.

4. Functional outcomes

Among 57 patients who underwent TaTME surgery, 53 patients were assessed anal sphincter function (4 patients not having stoma closed were excluded). Result at the post-operative timepoints of 6 months, 12 months and 24 months, the average Wexner score was 8.48, 4.05 and 2.15, respectively. The mean score of erectile function was 15.36 ± 4.20 points. 7 patients (12.28%) developed postoperative urinary retention.

5. Oncologic outcomes.

Table 4: Oncologic outcomes.

Outcome	Data
Follow-up (months) ($\bar{X} \pm SD$)	26.35 \pm 6.99 (min 13 - max 38)
Dead (n, %)	7 (12.28)
Local recurrence (n, %)	2 (3.51)
Distant recurrence (n, %)	8 (14.55)
Overall survival (n, %)	50 (87.72)
Disease-free survival (n, %)	48 (88.89)

Median follow-up was 26,35 months (IQR 7.1 to 20.7, local recurrence was observed in 2 patients (3.51%). 2 patients who had metastasis before surgery were excluded, distant recurrence observed in 8 patients (14.55%). Rate of overall survival and disease-free survival were 87.72 and 88.99%, respectively.

DISCUSSION

During the study period, there was a total of 57 patients with mid and low rectal cancer, who underwent laparoscopic TaTME.

It can be seen from table 1 that male patients were present in 68.42%, the median BMI of patients was 21.09 kg/m² (16.0 - 28.1), median distance from the tumour to the anal verge was 4.96 cm (2.0 - 8.0). With good experience in endoscopic surgery for rectal cancer, we found that high BMI, narrow pelvis and bulky tumour were predictive factors of the difficulties. The reasons for conversion in the COLOR II trial were a narrow pelvis in 22%, obesity in 10%, fixation of the tumor in 9%, technical anatomic difficulties in 6%, poor vision in 5%, large tumor in 4%, and fibrosis in 4% of patients [3]. None of these challenges to open and to laparoscopic TME prevented successful taTME.

The postoperative morbidity rate of 31.58% (including 15.79% the 30-days morbidity and 15.79% major morbidity) is comparable to that in other trials which were 34.2%, after TaTME [4] and 40% after laparoscopic TME [3]. Two patients (3.51%) had overall anastomotic leakage, this result is comparable to the rate observed in Lacy's trial (8.6%) [4] and in Burke's trial (6%) [8].

Theoretically, improved access can result in improved visualization, which then directly translates into the ability to more completely excise the rectum and mesorectum. As a result, it has been suggested that TaTME could represent a solution to the "Achilles' heel" of rectal cancer surgery [9]. It has been shown that laparoscopy, due to improved visualization, enhances the CRM positivity rate in

lower-third rectal cancers (9% vs. 22%), which translates into a recurrence-free survival advantage [3]. Circumferential resection margin is the main prognostic factor in rectal cancer surgery and, accordingly, obtaining a complete TME is mandatory. Mesorectal integrity has been shown to be one of the most important factors in both local and systemic tumor relapse, so it has been the objective with the highest priority throughout [2]. In the COLOR II trial [3], macroscopically complete resected specimens were recorded in 88% of the laparoscopic group and 92% of the open group. In our trial, pathologic analysis showed the mesorectum was complete in 89.47%, nearly complete in 8.77%, and incomplete in 1.75%. Macroscopic quality assessment of the resected specimen in Lacy's trial [4] was complete in 97.1%, nearly complete in 2.1% and incomplete in 0.7%. The CRM in the COLOR II trial resulted in free margins in 93% after laparoscopic resection and 91% after open surgery [3]. In our trial, 98.5% of patients had a negative CRM. One patient (1.75%) had CRM positive, that was associated with large-sized tumor in stage T4. Lacy et al [4] showed all 9 patients (6.4%) in whom the CRM was positive had a complete mesorectal specimen, and all of the positive margins were correctly predicted by MRI rate of CRM positivity in other trials: 5.3% [5] and 2% [8]. The 1 to 2cm distal resection "rule" is much less important than obtaining tumor-free CRMs and complete TMEs, especially after preoperative therapy [2]. One major advantage of the transanal

approach is that placement of a transanal purse-string suture below the tumor under direct vision helps guarantee an oncologically adequate distal margin. In addition, the purse-string and washout minimizes the risk of tumor spillage [4]. The mean distal margin in our series (2.33 ± 0.58 cm) is comparable to that in Lacy' trial (2.8 ± 2.1 cm) [4] and higher than Tuech's findings (1.0 cm) [5]. The median lymph node harvest achieved in our series was 13.75, this result is comparable to that in other trial in 14.7 [4].

Many factors have been related to bowel dysfunction such as reduced capacity of the neorectum, damage to the bowel innervation and to the anal sphincter muscles and pudendal nerves, or loss of the rectoanal inhibitory reflex. The level of anastomosis also plays a significant role while lower anastomosis, particularly colo-anal anastomosis and intersphincteric resections, can lead to a higher risk. Genitourinary function impairment is mainly related to nerve injury during pelvic dissection. After laparoscopic or open TME, the reported incidence of urinary dysfunction, including incontinence, retention and dysuria, ranges between 0% and 26% [10]. Our study, as a result at the post-operative time-points: 6 months, 12 months and 24 months, the average Wexner score was 8.48, 4.05 and 2.15, respectively. One patient (1.75%) required a colostomy because of severe fecal incontinence after intersphincteric resection. 11 patients under 60 years of age were assessed for sexual function. The mean

score of erectile function was 15.36 ± 4.20 points. The rates of patients without erectile dysfunction, incomplete erectile dysfunction and complete erectile dysfunction were 27.27%, 63.64% and 9.09% respectively. Seven patients (12.28%) developed postoperative urinary retention; all were treated by temporary urethral catheterization. At 4 months, all patients reported normal urinary function with no incontinence, increase voiding frequency, nor urinary retention.

An incomplete mesorectal specimen results in an increased risk of local and distant recurrence, but there is no appreciable difference in distant or local failure among nearly complete and complete specimens [2]. Oncologic outcomes are shown in *table 4*, the mean follow-up period was 26.35 months. There were two patients (3.51%) developing a local recurrence and 8 out of 55 patients (14.55%) who did not have metastatic disease at presentation developed a distant recurrence. The liver was the most common site of distant failure. Both local and distant recurrence rates in other series was 4.1% local recurrence and 9% distant metastases at 18 months of follow-up [4]. Rate of overall survival and disease-free survival were 87.72 and 88.99%, respectively. In the Tuech' trial [5], the overall survival rate was 96.4% and leading to a 5-year estimate disease-free survival rate of 94.2%.

While these results are acceptable for mid and low rectal cancers, but it is not a

randomized controlled trial and long-term follow-up is necessary to assess these data more accurately and validate oncological outcomes.

CONCLUSIONS

The TaTME technique is feasible and can result in a high-quality rectal cancer (specimen was complete in 89.47% and circumferential resection margin negative in 98.25%), which is the most important prognostic factor in rectal cancer. The postoperative morbidity rate was 31.58%. The median Wexner score in the 12 and 24 months after surgery were 4.05 and 2.15, respectively. The rate of local recurrence and distant recurrence were 3.51% and 14.55%, respectively. Rate of overall survival and disease-free survival rates were 87.72% and 88.89%, respectively. These data suggest that TaTME for rectal cancer is feasible with an acceptable pathological outcome and morbidity profile. Further data on long-term oncological and is needed.

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