NEW APPROACH IN MINIMALLY INVASIVE SURGERY FOR TREATMENT OF RECTAL CANCER: TRANSANAL LAPAROSCOPIC SURGERY

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SUMMARY

Objectives: To assess results of transanal total mesorectal excision laparoscopic surgery for treatment of the middle and low rectal cancer. Subjects and method: Clinical intervention, prospective, follow-up study without comparison in 45 patients with middle and low rectal cancer underwent transanal total mesorectal excision in Gastrointestinal Surgery Department, 108 Millitary Central Hospital, from July 2017 to August 2018. Results: The mean operative time was 145.3 ± 22.5 minutes. Operative morbidity rate was 33.3%, no operative mortality. The macroscopic quality assessment of the resected specimen was complete in 77.8%, nearly complete in 17.8%. The mean number of harvested lymph nodes was 13.8 ± 6.7; the mean follow-up time was 7.47 ± 3.7 months, one patient (2.2%) developed local and distant recurrence, disease-free survival and overall survival rates was 97.7% and 100%, respectively. Conclusion: The transanal total mesorectal excision technique is feasible and safe, the good early outcomes, the high-quality of total mesorectal excision specimens for treatment in middle and low rectal cancer.

** Keywords: Rectal cancer; Transanal total mesorectal excision; Laparoscopic operation.*

INTRODUCTION

The oncologic outcome is the most important goal in surgery for treatment of rectal cancer, followed by the preservation of sphincter and patients without artificial anus. To achieve both goals are still big challenges for colorectal surgeons.

Total mesorectal excision (TME) was first described in 1982 by Heald et al [1] and since then it has been established as the gold standard treatment of middle and lower third rectal cancers. TME is based on the principle of excising the rectal tumour and the mesorectum en bloc, including its blood supply and lymphatic drainage, to optimize locoregional clearance.

The up to down approach of TME has not been satisfactory for oncologic outcomes in low rectal cancer [2]. Several technical challenges are associated with laparoscopic treatment of distal rectal tumors in patients with narrow pelvis or obesity. Limited visualization and insufficient maneuverability preclude safe dissections and the appropriate firing of laparoscopic staples leading to conversion to open surgery. Inadequate visualization, especially during the dissection of the anterior rectal wall may also lead to positive margins and poor oncological outcomes [3].

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The first transanal TME (TaTME) resection assisted by laparoscopy was published in 2010 [4]. Since then, there have been publications demonstrating how this technique can be performed safely and preserves oncological TME principles [3, 5, 6, 7].

In this study, we report results of 45 patients in which TaTME assisted by laparoscopy for the resection of middle and low rectal cancer.

SUBJECTS AND METHOD

1. Subjects.

Forty-five patients with middle and low rectal cancer underwent TaTME in Gastrointestinal Surgery Department, 108 Millitary Central Hospital, from July 2017 to August 2018 were diagnosed with Tesla MRI 3.0; colonoscopy and biopsy and computed tomography (CT) of the thorax, abdomen and pelvis for staging were operated by TaTME.

Neoadjuvant chemoradiation was done in all patients with T3-T4 N0 or T1-T4N1-N2 tumors according to the preoperative staging. The protocol included a total dose of 50.4 Gy, with a daily dose of 1.8 Gy administered 5 days each week, and chemotherapy with continuous capecitabin infusion, 225 mg/m^2/day, during 5 days, concomitantly with radiation therapy. Following neoadjuvant treatment, patients underwent repeat staging with MRI before surgery at 6 - 8 weeks after the completion of radiotherapy.

2. Methods.

Clinical intervention, prospective, follow-up study without comparison.

** Surgical technique:*

Patients were placed in the Lloyd Davies position. The rectum was irrigated with iodine solution immediately before surgery. The procedure commenced with the perineal phase, a Lone Star Retractor System (Cooper Surgical Inc., Trumbull, Connecticut, USA) was used. For tumours located within 1 cm of the puborectal sling, a variable intersphincteric dissection with a hand-sewn coloanal anastomosis was performed. The intersphincteric dissection was extended cranially up to the level of the puborectal sling and the rectum was closed with a prolen 2/0 purse-string suture. After a washout with iodine solution, the GelPOINT Path Transanal Access Platform (Applied Medical, Inc., Rancho Santa Margarita, California, USA) was inserted, 3 airtight access channels (two 5 mm and one 10 mm) and an air inlet tube, through which the pelvic cavity was insufflated with CO_2 to a pressure of 10 - 12 mmHg. After full thickness circumferential division of the rectal wall, the mesorectal plane was identified posteriorly in the 5 or 7 o'clock position allowing initial dissection in the posterior plane before being extended to the anterior and lateral aspects. Finally, the rectovaginal peritoneal reflection was identified and perforated to enter the peritoneal cavity.

We used 30-degree scope at the umbilicus with a 10-mm port, 12-mm and 5-mm ports at low right quadrant, 5-mm port at low left quadrant, and in some cases, a fifth port suprapubic. After division of the inferior mesenteric artery

and vein, the left colon was completely mobilized, the splenic flexure was mobilized as well. TME was carried out up to down, according to the key principles of a correct oncologic surgical procedure. All the cases, the specimen was extracted transanally, the proximal margin was checked and a proximal resection of the specimen was performed using a pair of scissors at the anal verge level. Hand-sewn coloanal anastomosis was performed for patients with the lower rectal tumors and some patients with middle rectal cancer; stapled anastomosis was undertaken for patients with middle rectal tumors. A protective lateral ileostomy was performed when considered necessary. In all patients, a suction drain was placed in the deep pelvis.

Data analyses were performed applying the Statistical Package for the Social Sciences (SPSS, version 20).

RESULTS

1. Patient characteristics.

Forty-five patients with middle and low rectal cancer treated by TaTME assisted by laparoscopy were included in the study.

Table 1: Characteristics of patients in the study.

Characteristics	Data
Age, year, mean ± SD (range)	64.6 ± 11.0 (45 - 82)
Sex, n (%)	
Male	31 (68.9)
Female	14 (31.1)
BMI, kg/m^2, mean ± SD (range)	20.5 ± 2.5 (16 - 26.2)
ASA score, n (%)	
I	10 (22.2)
II	31 (68.9)
III	4 (8.9)
Previous abdominal open surgery, n (%)	5 (11.1)
Tumor location, n (%)	
Middle rectum	18 (40)
Lower rectum	27 (60)
Distance from anal verge by MRI (cm), mean ± SD (ranger)	4.6 ± 1.4 (2.2 - 8.2)
Preoperative T stage, n (%)	
cT2	4 (8.9)
cT3	30 (66.7)
cT4a	5 (11.1)
Not assessed*	6 (13.3)
Preoperative N stage, n (%)	
cN+	33 (73.3)
cN -	9 (20)
Not assessed*	3 (6.7)
Preoperative M stage, n (%)	
M0	43 (95.6)
M1	2 (4.4)
Neoadjuvant therapy, n (%)	
Chemoradiation	15 (33.3)
Chemotherapy	1 (2.2)
Radiotherapy	23 (51.1)

(: MRI can not identify rectal cancer or metastatic lymph nodes postoperative chemoradiation; BMI: Body mass index; ASA: American Society of Anesthesiologists)*

2. Perioperative outcomes.

Table 2: Perioperative data in patients undergoing TaTME for rectal cancer.

Characteristics	Data
Abdominal access, n (%)	
Laparoscopic LAR†	45 (100)
Intersphincteric resection, n (%)	9 (20)
Ileostomy, n (%)	32 (71.1)
Anastomosis, n (%)	
Hand sewn	35 (77.8)
Stapled	10 (22.2)
Operative time (min), mean ± SD (range)	145.3 ± 22.5 (100 - 185)
EBL* (mL), mean ± SD (range)	72.7 ± 42.4 (30 - 225)
Specimen extraction site, n (%)	
Transanal	45 (100)
Intra-operative morbidity, n (%)	2 (4.4)
Bleeding	1 (2.2)
Rectal perforation	1 (2.2)
Postoperative complications, n (%), Clavien-Dindo classification	13 (28.9)
Urinary retention	7 (15.6) II
Bowel obstruction	2 (4.4) II
Anastomotic leakage	1 (2.2) IIIb
Rectovaginal fistula	2 (4.4) IIIb
Anastomotic bleeding	1 (2.2) I
Reoperation, n (%)	3 (6.7)
Length of stay (days), mean ± SD (range)	12.3 ± 6.1 (4 - 29)
Readmission, n (%)	6 (13.3)

(EBL: Estimated blood loss; LAR: Low anterior resection)

As shown in table 2, forty five patients (100%) underwent laparoscopic LAR with TME. The specimen was extracted transanally in all the cases. Most patients underwent a hand-sewn coloanal anastomosis (77.8%). Protective ileostomy was performed in 32 patients (71.1%). The mean operative time was 145.3 ± 22.5 minutes (ranged 100 to 185 minutes). Intra-operative complications occurred in two patients (4.4%), among which, one case involved in pelvic bleeding and one case had rectal perforation during the transanal dissection. There were no conversions and there was no perioperative mortality. Overall, 13 patients (28.9%) had postoperative complications.

Most patients (22.2%) were Clavien - Dindo grade I or II, 3 patients (6.7%) had major complications (Clavien - Dindo grade IIIb) underwent a reoperation, 2 patients had rectovaginal fistula required a permanent end colostomy and 1 patient (who had anastomotic leakage) was performed by transanal reinforcing stitches. The mean length of stay was 12.3 days and the readmission rate was 13.3%.

3. Histopathological results.

Table 3: Histopathologic characteristics of surgical specimens.

Characteristics	Data
Quality of mesorectum, n (%)	
Grade 3: complete	35 (77.8)
Grade 2: nearly complete	8 (17.8)
Grade 1: incomplete	2 (4.4)
T staging	
T0	3 (6.7)
T1	1 (2.2)
T2	14 (31.1)
T3	24 (53.3)
T4	3 (6.7)
N staging	
N0	30 (66.7)
N1	12 (26.6)
N2	3 (6.7%)
Number of lymph nodes, mean ± SD	13.8 ± 6.7
Tumour size (cm), mean ± SD	3.2 ± 1.7
Distal margins (mm), mean ± SD	23 ± 7
Positive	0
Proximal margin (cm), mean ± SD	11.9 ± 6.2
Positive	0
CRM positive	3 (6.7%)

(CRM: Circumferential resection margin)

A complete TME specimen was in 35 patients (77.8%). 2 patients (4.4%) were the TME incomplete. Most patients had a pT2 or pT3 tumour (84.4%). 15 patients (33.3%) had positive lymph nodes. The mean number of harvested lymph nodes was 13.8 ± 6.7. The mean distal margin was 23 ± 7 mm and none of distal margins were positive. CRM positivity rate was 8.9%.

4. Oncological outcomes.

Table 4:

Outcome	Data
Follow-up (month), mean ± SD	7.47 ± 3.7
Recurrence, n (%)	
Disease free survival	42/43 (97.7)
Local and systemic recurrence	1 (2.2)
Port site recurrence	0 (0)
Survival, n (%)	
Alive	45 (100)
Dead	0 (0)

There were no patients of local recurrence, 1 patient with distant metastasis at 6 months after the initial surgery. There were no port-site recurrences. At the end of follow-up, no patients died.

5. Functional outcomes.

Table 5: Sphincter function outcomes.

According to Kirwan's classification						
	Kirwan I (very good)	Kirwan II (good)	Kirwan III (fair)	Kirwan IV (bad)	Kirwan V (very bad)	Total
< 1 month	0	0	3 (18.8)	13 (81.2)	0	16 (100)
1 - < 3 months	0	1 (4.2)	18 (75)	5 (20.8)	0	24 (100)
3 - < 6 months	0	11 (50)	9 (40.9)	2 (9.1)	0	22 (100)
6 - < 9 months	6 (37.5)	7 (43.7)	3 (18.8)	0	0	16 (100)
9 - < 12 months	5 (71.4)	2 (28.6)	0	0	0	7 (100)
> 12 months		1 (100)	0	0	0	1 (100)

The sphincter function was monitored and assessed monthly in patients not receiving ileostomy or patients who had ileostomy closure. As shown in table 5, the sphincter muscles were recovered in most patients at 6 to 9 months postoperatively (Kirwan I, II and III). Seven patients (15.6%) developed postoperative urinary retention, of whom 3 patients did not need a urethral catheterization and 4 patients were treated by temporary urethral catheterization. After 1 month, all patients reported normal urinary function with no incontinence, increase voiding frequency, nor urinary retention.

DISCUSSION

Several technical challenges are associated with laparoscopic treatment of distal rectal tumors in patients with narrow pelvis or obesity. Limited visualization and insufficient maneuverability preclude safe dissections and the appropriate firing of laparoscopic staples leading to conversion to open surgery. Inadequate visualization, especially during the dissection of the anterior rectal wall may also lead to positive margins and poor oncological outcomes.

In this trial, most patients were male (68.9%), with a low tumour located at an average of 4.6 ± 1.4 cm from the anal verge, however, we did not have difficulty with TaTME in these patients. For the low rectal cancer group, the COLOR II trial [2] showed that only 23% had preserved sphincter.

TaTME can be a major change in the treatment strategy of low rectal cancer, contributing to increased sphincter preservation. Patient without permanent artificial anus, helping to improve the quality of life for patients is an important goal of the treatment of low rectal cancer.

The operative time depends on many factors, including the patient's characteristics, the level and experience of the surgeon, the number of surgical teams. The mean operative time was 145.3 ± 22.5 minutes. Compared with other series of TaTME, the operative time in the present study was equivalent when compared with Lacy et al's [3] but was lower than Burke et al's study [12]. The reason for this was that most patients in this trial had a lower BMI (20.5 vs. 25.2 and 26).

The quality of TME and the margins of the specimen especially the CRM which may explain partly local recurrences. Quirke et al [8] showed that the plane of surgery achieved was strongly associated with local recurrence, with a 3-year local recurrence rate of 4% (mesorectal plane), 7% (intramesorectal plane) and 13% (muscularis propria plane) (p = 0.0039). Moreover, CRM-negative patients showed a 4% versus 12% of local recurrence rate for mesorectal and muscularis propria plane respectively (HR 0.33 [95%CI: 0.15 - 0.74]). Xu et al recently reported a significant improvement in the quality of the TME specimen following TaTME with 90.5% of patients having a complete TME, compared with only 70.7% underwent a classical approach of transabdominal total mesorectal excision (p = 0.008). In our series, the mesorectum was complete in 77.8% or nearly complete in 17.8% of patients, these data are in accordance with Buchs et al [9] (97.5%). The CRM positivity rate was 6.7% of patients. In TaTME series by Lacy et al [3], Burke et al and Buchs et al CRM positivity rate was 6.4%, 4% and 2.5%, respectively.

TaTME may enhance distal rectal access and visualization, allowing optimal margins, adequate lymph node yield and high quality resection, even in the most difficult patients. 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 [3]. Hevia et al found that the distal margin was lower in the laparoscopy group than

in the transanal one (1.8 ± 1.2 mm vs. 2.7 ± 1.7 mm, respectively; p < 0.01). Our study found that negative distal margins were in all patients, the mean distal margins was 23 ± 7 mm and the mean number of lymph nodes was 13.8 ± 6.7. In a systematic review of TaTME, Simillis et al [6] found that positive distal margins were 0.3% of patients.

In this series, we have demonstrated that the use of this new approach led to intraoperative complications rates of 4.4%, one of whom had a rectal perforation (male with tumors T4a stage, tumor size 5.1 cm, distance from anal verge was 4.6 cm, BMI 18.8 kg/m^2). Immediately we performed the hole closure, washout the operating area with iodine solution and covered the rectum with plastic bag. In another study [6], also approaching rectal cancer by TaTME, intraoperative complication rate was < 1%. Population-based reports from Sweden, Norway, and Holland have shown a 3-fold increase in perforation rates after abdominoperineal excision compared with anterior resecsion (14 - 15% vs. 3 - 4%) and that perforation is a significant risk factor for adverse outcomes regarding local control and survival. Postoperative complications rates were 28.9%, in which, the major complications were in 3 patients (6.7%) (Clavien - Dindo IIIb) included anatomosis leakage (2.2%) and rectovaginal fistula (4.4%). Data were analysed from 66 registered units in 23 countries by Penna et al showed that anatomosis leakage rate was 6.3%. Post-operative morbidity rate in some other studies was 34.2% [10] or 32.6%. In our study, there were no conversions or mortality.

The mean follow-up time was 7.47 ± 3.7 months and no patients lost contact to follow-up. Without two patients had synchronous live preoperative recurrence, among these 43 patients, we observed one patient (2.2%) (who had a rectal perforation) developed local and distant recurrence (at 6-month follow-up). Disease free survival and overall survival rates were 97.7% and 100%, respectively at the end of follow-up.

To evaluate the status of anorectal function according to the Kirwan's classification [9], as shown in table 5, the sphincter muscles were recovered in most patients from 6 to 9 months postoperatively (Kirwan I, Kirwan II and Kirwan III rate was 37.5%, 43.7% and 18.8%, respectively). Zhang's study [10] found that with regard to the quality of life of patients who had multiple transanal endoscopic microsurgery procedures, at 6 months after operation, the physical and mental health status scores were not significant compared with the general population (external anal sphincter thickness decreased from 3.7 ± 0.6 mm preoperatively to 3.5 ± 0.3 mm [3.7 ± 0.6 mm vs 3.5 ± 0.3 mm, p = 0.510] at month 3 and then increased to 3.6 ± 0.4 mm [3.7 ± 0.6 mm vs. 3.6 ± 0.4 mm, p = 0.123] at month 6 after operation). Tuech et al [5] found that the postoperative function was good, with all patients continent to solid and liquid stool. However, prolonged anal dilatation with a 4 cm diameter rectoscope may induce fewer sphincter function problems. According to the Clavien - Dindo classification [11],

7 patients (15.6%) developed postoperative urinary retention (Clavien - Dindo II), of whom 3 patients did not need a urethral catheterization and 4 patiens were treated by temporary urethral catheterization. After 1 month, all patients were reported normal urinary function. In Tuech et al's study [5], 5 patients (8.9%) developed postoperative urinary retention, all were treated by temporary urethral catheterization. After 3 months, all patients reported normal urinary function.

CONCLUSIONS

Transanal total mesorectal excision opens to new future for treatment of middle to lower rectal cancer surgery. Short-term outcomes showed safety and feasibility of TaTME. However, evaluations of the long-term functional and oncological outcomes are required.

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