

New approach in minimally invasive surgery for treatment of rectal cancer: Transanal laparoscopic surgery

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Summary

Objective: To prospectively evaluate the short-term outcomes of transanal total mesorectal excision (TaTME) for rectal cancer. **Subject and method:** 56 patients with middle and low rectal cancer who underwent TaTME in Gastrointestinal Surgery Department, 108 Military Central Hospital from July 2017 to December 2018 were included in this study. The data of preoperative staging, tumor's location, operative morbidity, macropic quality of mesorectal specimen, circumferential resection margin, anal sphincter function were collected. The method popularized by Quirke, Kirwan's classification was used to assess to quality of mesorectal specimen, the sphincter function respectively. Patients were followed in the outpatient clinic 2 weeks after the surgery and then every 3 months in the first year. Statistical analysis was performed using SPSS 20.0. **Result:** The mean age of patients was 65.45 ± 11.18 years, the mean BMI was $20.5 \pm 2.6 \text{ kg/m}^2$. The mean operative time was 147.8 ± 22.2 minutes. Operative morbidity rate was 28.6%, there was no operative mortality. The quality of mesorectal specimen was complete in 80.4%, nearly complete in 16.1%. The circumferential resection margin (CRM) was negative in 94.6%; The mean harvested lymph nodes was 8.24 ± 3.17 . The mean follow-up time was 10.0 ± 3.9 months, one patient (1.8%) developed local and distant recurrence, disease-free survival and overall survival rates were 98.2% and 100% respectively. The sphincter function at 12 months postoperation assessed by Kirwan was Kirwan I in 58.5% and Kirwan II in 41.2%. **Conclusion:** The TaTME technique is safe and feasible with acceptable results, especially in the quality of mesorectal specimen and sphincter function.

Keywords: Transanal total mesorectal excision, laparoscopic surgery, rectal cancer.

1. Background

The conventional up-to-down approach of total mesorectal excision (TME) is more technically demanding, especially in mid and low rectal cancer [1]. Risk factors for a positive CRM were increased in the patient with advanced stage, male and bulky tumor [4]. In addition, the difficulty to see the lower limit of the tumor clearly and poor ergonomics for

staplers to enter the pelvis distally from the tumor leads to poor distal margins and multiple firings which leads to the risk of leakage.

Many benefits of TaTME have been reported by the authors: It can provide empty pelvic views of the presacral and the perirectal planes; tissue distention using CO₂ and pneumodissection can be performed effectively during the procedure; the TaTME enables the easy dissection of the distal part of the TME in a narrow pelvis with clear circumferential and distal resection margins for oncological safety; with the

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TaTME, specimens can be extracted transanally without the need for an additional abdominal incision [3], [4], [9].

In this study, we investigated the short-term outcomes of laparoscopic TaTME for the of middle and low rectal cancer.

2. Subject and method

Patients

Fifty-six patients with middle or low rectal cancer underwent TaTME in Gastrointestinal Surgery Department, 108 Military Central Hospital from July 2017 to December 2018.

Tumor characteristics and staging

Staging and classification of the tumor were performed before the neoadjuvant treatment according to the Union International Control on

Cancer (UICC) criteria and by means of CT scan of the chest, abdomen and pelvis, endorectal ultrasound, and MRI.

Surgical procedures

A standardized surgical procedure was performed by an experienced rectal cancer team. Patients were placed in the Lloyd Davies position. The abdominal laparoscopy is performed to initially assess distant metastasis or peritoneal dissemination.

The procedure commenced with the perineal phase, the rectum was irrigated with iodine solution, a Lone Star Retractor System (Cooper Surgical Inc., Trumbull, Connecticut, USA) was used. For tumours located within 1cm from the anal verge, a hand-sewn purse-string around the anus was performed (Figure 1A). The plane dissection was extended cranially up between intersphincteric space to the level of the puborectal sling (Figure 1B).

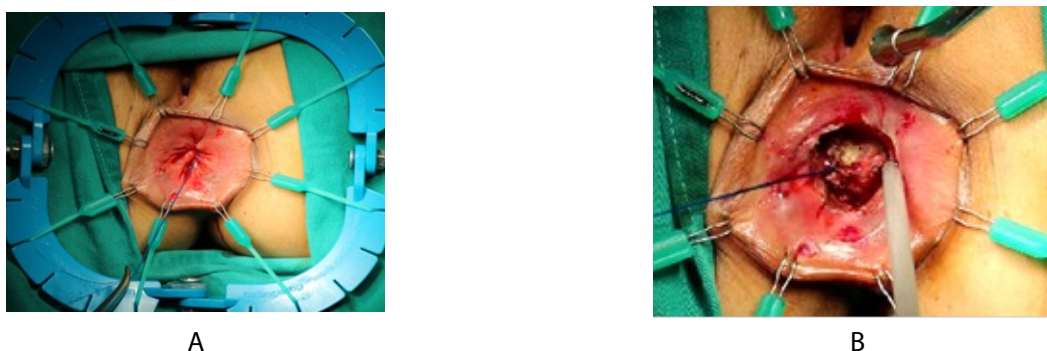


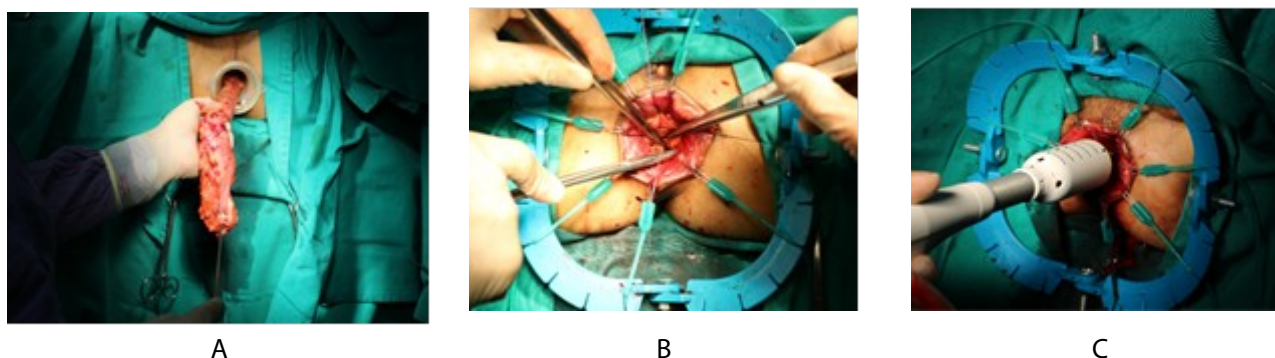
Figure 1. Purse-string and the initial resection

For higher tumours, the rectum was occluded below the tumour 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 10 - 12mmHg. 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 initial dissection in the posterior plane before being extended to the lateral and anterior aspects (Figure 2).



Figure 2. Down to up resection

The abdominal phase was done as routinely TME. TME was carried out up to down along the avascular space while automatic nerve plexus was preserved. All the cases, the specimen was extracted transanally, the proximal margin was marked and divided at the anal verge level (Figure 3A). Hand-sewn coloanal anastomosis was performed for patients with the lower rectal tumors (Figure 3B) while those with middle rectal cancer, stapled anastomosis was done (Figure 3C). A protective ileostomy at right lower quadrant was performed in some initial cases.

**Figure 3.** Withdraw the specimen (A). The han-sewn (B) and the stapler anastomosis (C)

Statistics

Early postoperative complications were defined and recorded as complications occurring within 30 days after surgery and were categorized according to the Clavien-Dindo (CD) classification for surgical complications [6].

Anastomotic leakage was defined according to the International Study Group of Rectal Cancer (ISGRC) classification, which grades the severity based on its impact on patients' clinical management [2].

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 and colleagues [7].

Proximal margin resection was defined as the distance from sigmoid resection margin to the upper edge of tumor, distal resection margin was defined as the distance from lower edge of tumor to rectal resection margin. Fecal incontinence was evaluated using the Kirwan's classification [8]. We obtained the patients' clinical data from their medical records and performed statistical analysis using the Statistical Package for the Social Sciences (SPSS, version 20.0).

3. Result

3.1. Patient characteristics

Table 1. Characteristics of patients

Characteristic	Data
Age, year, mean \pm SD (range)	65.45 \pm 11.18 (45 - 86)
Sex, n (%)	
Male	38 (67.9)
Female	18 (32.1)
BMI, kg/m ² , mean \pm SD (range)	20.5 \pm 2.6 (16 - 27)
ASA classification, n (%)	
I	8 (14.3)

II	42 (75)
III	6 (10.7)

Table 1. Characteristics of patients (Next)

Characteristic	Data
Previous abdominal open surgery, n (%)	9 (16.1)
Tumor location, n (%)	
Middle rectum	33 (58.9)
Lower rectum	23 (41.1)
Distance from anal verge by MRI, cm, mean \pm SD (ranger)	4.6 \pm 1.6 (1.5 - 8.2)
Preoperative assessment of tumor, n (%)	
cT2	5 (8.9)
cT3	40 (71.4)
cT4a	5 (8.9)
Not assessed*	6 (10.7)
Preoperative assessment of lymph node, n (%)	
cN+	42 (75)
cN -	11 (19.6)
Not assessed*	3 (5.4)
Preoperative assessment of distant metastasis, n (%)	
M0	54 (96.4)
M1	2 (3.6)
Neoadjuvant therapy, n (%)	
Chemoradiation	18 (32.1)
Chemotherapy	1 (1.8)
Radiation therapy	26 (46.4)

*MRI can not identify rectal cancer or metastatic lymph nodes postoperative chemoradiation; BMI, Body Mass Index; ASA, American Society of Anesthesiologists.

Fifty-six patients with middle and low rectal cancer treated by TaTME were included in the study, as described in Table 1. Laparoscopic procedures were performed in all patients (100%). The majority were male patients (68.9%). The mean distance from a tumor to the anal verge was 4.6cm. On pretreatment MRI, the majority of patients (71.4%) had T3 disease and positive lymph node (75%).

3.2. Perioperative outcomes

Table 2. Perioperative data in patients undergoing transanal total mesorectal excision for rectal cancer

Characteristic	Data
Laparoscopic produres, n (%)	56 (100)
Internal sphincteric resection (ISR), n (%)	
Total ISR	16 (28.6)
Subtotal ISR	6 (10.7)
Ileostomy, n (%)	35 (62.5)
Anastomosis, n (%)	
Hand sewn	45 (80.4)
Stapled	11 (19.6)

Operative time, minute, mean \pm SD (range)	147.8 \pm 22.2 (100 - 195)
EBL*, ml, mean \pm SD (range)	73.4 \pm 39.2 (30 - 225)

Table 2. Perioperative data in patients undergoing transanal total mesorectal excision for rectal cancer (Next)

Characteristic	Data
Specimen extraction site, n (%)	56 (100)
Transanal	
Intra-operative morbidity, n (%)	2 (3.6)
Bleeding	1 (1.8)
Rectal perforation	1 (1.8)
Postoperative complications, n (%), Clavien-Dindo classification	14 (25)
Urinary retention	7 (12.5) I
Bowel obstruction	2 (3.6) II
Anastomotic leakage and stenosis	1 (1.8) IIIb
Anastomotic leakage	2 (3.6) IIIa
Rectovaginal fistula	1 (1.8) IIIb
Anastomotic bleeding	1 (1.8) I
Reoperation, n (%)	3 (5.4)

*EBL, estimated blood loss.

As shown in Table 2, fifty six (100%) patients underwent laparoscopic TME. The specimen was extracted transanally in all the cases. Most patients had a hand-sewn coloanal anastomosis (80.4%). The protective ileostomy was performed in 35 patients (62.5%). Two patients intra-operative complications occurred (3.6%).

Overall, 14 patients (25%) had postoperative complications, most of them are urinary retention. Most (17.85%) were Clavien - Dindo grade I or II, 3 patients (5.4%) had major complications (Clavien -Dindo grade IIIb) underwent a reoperation: 1 anastomosis leakage, 1 rectovaginal leakage, 1 anastomosis combined stenosis and leakage required a permanent transverse colostomy and 1 patient who had anastomotic leakage was performed by transanal reinforcing stitches.

3.3. Histopathological results

Table 3. Histopathologic characteristics of surgical specimens

Characteristic	Data
Quality of mesorectum, n (%)	
Grade 3: Complete	45 (80.4)
Grade 2: Nearly complete	9 (16.1)
Grade 1: Incomplete	2 (3.6)
T	
pT0	3 (5.4)
pT1	2 (3.6)
pT2	15 (26.8)
T3	31 (55.4)
T4	5 (8.9)
N	

N0	37 (66.1)
N1	13 (23.2)
N2	6 (10.7)

Table 3. Histopathologic characteristics of surgical specimens (Next)

Characteristic	Data
Number of lymph nodes, mean \pm SD	8.24 \pm 3.17
Tumour size, cm, mean \pm SD	3.14 \pm 1.6
Distal margins, mm, mean \pm SD	2.3 \pm 0.76
Positive	0
Proximal margin, cm, mean \pm SD	13.11 \pm 6.9
Positive	0
CRM positive*	3 (5.4%)

*CRM, circumferential resection margin

Pathological data are reported in Table 3. A complete TME specimen was in 45 patients (80.4%). Most patients had a pT2 or a pT3 tumor (81.4%). The mean number of harvested lymph nodes was 8.24 \pm 3.17. CRM positivity rate was 5.4%.

3.4. Oncological outcomes

Table 4. Oncologic outcomes

Outcome	Data
Follow-up, month, mean \pm SD	10.0 \pm 3.9
Recurrence, n (%)	
Disease free survival	55/56 (98.2)
Local and systemic recurrence	1 (1.8)
Port site recurrence	0 (0)
Survival, n (%)	
Alive	56 (100)
Dead	0 (0)

As shown in Table 4, the mean follow-up time was 10.0 \pm 3.9 months. There were 1 patient had simultaneously local recurrence and dissemination in the abdomen at 6 months after the initial surgery and required chemotherapy. There were no port-site recurrences. At the end of follow-up, no patients had died.

3.5. Functional outcomes

The sphincter function was monitored and assessed monthly in patients not doing ileostomy and after the closure of ileostomy, that function was reassessed by Kirwan's classification. As shown in Table 5, the sphincter muscles recover in most patients at 6 to 9 months postoperatively (Kirwan I, II and III). 1 patient had Kirwan V required making colostomy.

Table 5. Sphincter function outcomes

According to Kirwan's classification, n (%)						
	Kirwan I	Kirwan II	Kirwan III	Kirwan IV	Kirwan V	Total
	(very good)	(good)	(rather)	(bad)	(very bad)	
1 month	0	0	6 (24)	19 (76)	0	25 (100)

3 months	0	3 (9.1)	25 (75.8)	5 (15.2)	0	33 (100)
9 months	6 (22.2)	17 (63)	3 (11.1)	0	1 (3.6)	27 (100)
> 12 months	1 (58.5)	7 (41.2)	0	0	0	17 (100)

4. Discussion

TaTME is especially attractive in patients with unfavourable anatomy including male gender, a narrow pelvis, obesity, or adverse tumour-related features including the location in the distal rectum, a bulky tumor or mesorectum or previous radiotherapy [9]. In this trial, most patients were male (67.9%), with a low tumor located at a mean of 4.6 ± 1.6 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 [1] showed that only 23% had preserved sphincter.

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 147.8 ± 22.2 minutes. Compared with other series of TaTME, the operative time in the present study was equivalent [3].

The quality of TME and the margins of the specimen especially the CRM, and which may influence the local recurrence rate. Quirke et al [7] 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% (intra mesorectal plane), and 13% (muscularis propria plane) ($p=0.0039$). Moreover, CRM-negative patients showed a 4% versus 12% local recurrence rate for mesorectal and muscularis propria plane respectively (HR 0.33 [95% CI: 0.15 - 0.74]). In our series, the mesorectum was complete in 80.4% or nearly complete in 16.1% of patients, these data are in accordance with Buchs et al [9] (97.5%). The CRM positivity rate was 6.7%. In TaTME series by Lacy et al [3], the CRM positivity rate was 6.4%.

TaTME may enhance distal rectal access and visualization, allowing optimal margins, adequate lymph node yield, and high-quality resection, even in the most difficult patient [3], [4], [9]. 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 minimize the risk of tumor spillage [10]. In our study found that negative distal margins were in all patients, with the mean distal margins was 2.3 ± 0.76 cm and the mean number of lymph nodes was 8.24 ± 3.17 . In a systematic review of TaTME, Penna et al [9] 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 rate of 3.6%, 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/m²). Immediately we performed the hole closure, washout the operating area with iodine solution and covered the rectum with the plastic bag. Postoperative complications rates were 28.6%, in which, the major complications were in 4 patients (25%) (Clavien-Dindo IIIb) included anastomotic leakage (3.6%) and rectovaginal fistula (1.8%), combined anastomotic stenosis and leakage (1.8%). Post-operative morbidity rate in some other studies was 34.2% [3] or 32.6% [9]. In our study, there were no conversions or mortality.

The mean follow-up time was 10.0 ± 3.9 months and no patient was lost to follow-up. With two patients had synchronous liver metastasis preoperative, among these 54 patients, we observed one patient (1.8%) (who had a rectal perforation) developed local and distant recurrence (at 6-month follow-up). Disease-free survival and overall survival rates were 98.2% and 100% respectively at the end of follow-up.

To evaluate the status of anorectal function, as shown in Table 6, the sphincter muscles recover in most patients at 6 months postoperatively (Kirwan I, Kirwan II and Kirwan III rate was 22.2%, 63%, and 11.1% 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 $3.7 \pm 0.6\text{mm}$ preoperatively to $3.5 \pm 0.3\text{mm}$ [$3.7 \pm 0.6\text{mm}$ vs $3.5 \pm 0.3\text{mm}$, $p=0.510$] at month 3 and then increased to $3.6 \pm 0.4\text{mm}$ [$3.7 \pm 0.6\text{mm}$ vs $3.6 \pm 0.4\text{mm}$, $p=0.123$] at month 6 after operation). In our study, seven patients (15.6%) developed postoperative urinary retention (Clavien-Dindo II), included three patients did not need a urethral catheterization and four patients were treated by temporary urethral catheterization. After 1 month, all patients reported normal urinary function.

5. Conclusion

TaTME is the future for treatment of mid to lower rectal cancer surgery. Short-term outcomes shown that safety and feasibility of TaTME. However, evaluations of the long-term functional and oncological outcomes are needed.

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