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ORIGINAL ARTICLE

Transanal total mesorectal excision for rectal cancer: a multicentric cohort study

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Abstract

Background: Transanal total mesorectal excision (taTME) has recently emerged as a promising novel surgical procedure for rectal cancer. It is believed to hold the potential advantage of providing better access to mobilize the distal rectum and achieving better pathologic results. This study aimed to evaluate the feasibility of taTME for rectal cancer and summarize the preliminary experience in 10 Chinese hospitals.
Methods: A total of 211 patients were enrolled in this study. Variables for evaluation of safety, feasibility, and oncologic outcomes were retrospectively collected and analysed.
Results: The median distance between the tumor and the anal verge was 5.9 cm (range, 1.5–12 cm). The median operating time was 280 min (range, 70–600 min) and the median estimated intra-operative blood loss was 50 mL (range, 10–1,500 mL).

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The overall rate of complication was 27.9%. Among the 211 patients, 175 (82.9%) had complete TME and 33 (15.6%) had near complete TME. The circumferential resection margin was negative in 97.7% of patients. The patients were followed for a median of 35 months (range, 2–86 months). There was 7.6% (16) mortality, 6.2% (13) had local recurrence, and 12.8% (27) had systemic recurrence. Kaplan–Meier survival analysis showed that 1-, 2-, and 3-year disease-free survival rates were 94.8%, 89.3%, and 80.2%, respectively, and 1-, 2-, and 3-year OS rates were 97.4%, 95.7%, and 92.9%, respectively.
Conclusions: Although limited by its retrospective nature, taTME was safe and feasible in selected patients. Future work with rigorous data recording is warranted.

Key words: rectal cancer; laparoscopic; transanal; total mesorectal excision; multicentric

Introduction

Over the last decade, there have been advances in the treatment of rectal cancer. Neoadjuvant therapy has reduced the local-recurrence rate of rectal cancer. While the use of transanal local excision in highly selected tumors may be justified, patients with a complete pathological response have been offered 'watch and wait' as an alternative to proctectomy [1]. Nevertheless, being less invasive has become an important trend in the treatment of rectal cancer. However, currently, only a small portion of rectal cancers are detected in very early stages. Therefore, invasive radical surgery to resect the tumor still acts as the keystone for most patients.

The laparoscopic approach for rectal cancer has been shown to decrease the length of hospital stay and wound complications and increase favorable short-term clinical outcomes when compared with open surgery. In addition, several important randomized–controlled trials showed that laparoscopic surgery could achieve equivalent pathological and oncologic outcomes compared with open surgery [2–4]. However, before a definite conclusion can be safely drawn, two updated randomized clinical trials—the ACOSOG Z6051 and the ALaCaRT studies [5, 6]—recently failed to show the non-inferiority of laparoscopic surgery compared with open resection. From the perspective of surgical technique, it is argued that the increased difficulty in the deep pelvis is to be blamed, especially in challenging cases such as bulky mesorectums, enlarged prostates, and irradiated pelvises. Some assumed that the utility of wristed instruments in the robotic system may to some extent relieve such situations [7]; however, the high costs undoubtedly limit its widespread application. In such circumstances, transanal total mesorectal excision (taTME) has emerged as an alternative 'down-to-up' solution in recent years. Since more and more studies have proven the feasibility and advantage of taTME, it has become a hot topic in the field of colorectal surgery [8, 9].

However, taTME is still in the early stages. Despite many pilot, single-institutional reports, studies of higher-level evidence, i.e. with a large sample size, being compared with conventional surgery, and multicentric design, are strikingly lacking. Herein, based on the preliminary experience of performing taTME by pioneer colorectal surgeons in China, we conducted this multicenter cohort study in 10 hospitals and analysed the data of more than 200 taTME cases.

Patients and methods

taTME workshop and training

Before July 2014, taTME was performed in the First Affiliated Hospital of Guangzhou Medical University and Dongguan Kanghua Hospital (Guangdong, China). Then, the Sixth Affiliated Hospital of Sun Yat-sen University (Guangdong, China) developed workshops for training surgeons in taTME techniques.

Patient population

CT scan of the chest, abdomen, and pelvis as well as a rectal-cancer protocol-staging MRI was used to evaluate the preoperative stage of the patients. Decisions for neoadjuvant chemoradiotherapy were made by the multidisciplinary team of discussion on rectal cancer in each center. Inclusion criteria were (i) patients with cT1-T4NxM0-1 rectal carcinoma (with/without neoadjuvant therapy) and (ii) patients undergoing taTME assisted by laparoscopy (hybrid taTME) or without assistance (pure taTME). Patients with obstructed or perforated disease were excluded.

The study period began in May 2010, when the group at the First Affiliated Hospital of Guangzhou Medical University (Guangdong, China) performed their first case, and ended in April 2016. Ten centers across China participated in this study and contributed to 211 cases; the number of patients from each center ranged from 2 to 67. The Sixth Affiliated Hospital of Sun Yat-sen University contributed to the most cases (Table 1).

Surgical technique

The technical approach of the pure or hybrid taTME was previously described [10–14]. Regardless of its sequence, the surgical procedure can be mainly divided into two categories: the transabdominal approach and the taTME.

The transabdominal approach is the standard laparoscopic procedure using between one and five trocars (diameter 5 or 12 mm). The procedure through the multi-channel single-port in the planned ileostomy site was more technically demanding [15] and required selected patients. Goals of the transabdominal procedure included separation of the inferior mesenteric vessels (IMV), mobilization of the left colon (the splenic flexure was mobilized as needed), and total mesorectal excision to the level of peritoneal reflection in most cases. All cases were routinely ligated at the root of the IMV.

The taTME portion was performed with the anal canal dilated and exposed with the lone star retractor in an extended lithotomic position, which involved the following key steps: (i) utilization of the purse string to occlude the rectal lumen; (ii) full-thickness dissection of the rectal wall and perirectal fat until the mesorectal plane was identified; (iii) setting-up of the transanal multi-channel working platform and establishing the pneumo-anorectum by insufflating CO_2; (iv) carefully approaching the 'Holy plane' identified in step 2 circumferentially and cephalically until the peritoneal cavity was entered; (v) mobilization of the left colon and division of the IMA/IMV transanally after the rectum was reversed (in pure taTME);

Table 1. Pre-operative characteristic of patients and tumors

Characteristic	Data
Sex	
Male/female	124/87
Age, mean ± SE (years)	58.6 ± 13.6
BMI, mean ± SE (kg/m^2)	22.9 ± 3.1
ASA classification	
I	35 (16.6%)
II	154 (73.0%)
III/IV	22 (10.4%)
Previous abdominal surgery	22 (10.4%)
DAV, mean ± SE (cm)	5.9 ± 2.0
Lower rectum (DAV ≤6 cm)	143 (67.7%)
Middle and upper rectum (DAV >6 cm)	68 (32.2%)
Pre-operative T category, n (%)	
T1	11 (5.2%)
T2	56 (26.5%)
T3	106 (50.2%)
T4	29 (13.7%)
Missing data or not assessed	9 (4.3%)
Pre-operative N category, *n* (%)	
N–	157 (74.4%)
N+	43 (20.4%)
Missing data or not assessed	11 (5.2%)
Pre-operative M category, *n* (%)	
M0	202 (95.7%)
M1	9 (4.3%)
Received neoadjuvant therapy[a]	58 (27.5%)

SE, standard error of the mean; BMI, body mass index; ASA, American Society of Anesthesiologists; DAV, distance from anal verge; N–, lymph node negative; N+, lymph node positive.

[a]Including concurrent chemoradiotherapy and chemotherapy alone.

and (vi) dissociation of the splenic flexure was determined by the length of the proximal colon during operation. If an intersphincteric resection was required for a tumor located <5 cm from the anal verge, the sequence of steps 1 and 2 might be switched. For a middle rectal tumor, step 3 was performed prior to steps 1 and 2. During step 4, attention should be paid not to injure the vagina, urethra, presacral vessel, or the autonomic and parasympathetic nerve plexus.

The specimen was extracted either transabdominally or transanally with a preference for the hybrid taTME when the tumor was not too bulky. End-to-end stapled anastomosis with a diameter of 29 mm was routinely constructed. Hand-sewn sutures were added for reinforcement if considered necessary. No end-to-side anastomoses, coloplasty, or colonic J-pouch was employed. A protective ileostomy was preferred in patients with a high risk of anastomotic leak, i.e. low rectal cancer after long-course chemoradiation. Fluorescence microscopy has not been widely used in the early development of taTME, so fluorescence angiography with indocyanine green has not been used in the cases included in this study. Anastomoses test mainly depended on direct visualization of the donuts and blood supply by surgeons.

The selection of platforms was not identical in different centers. Self-made wrist-shape proctoscopes or customized three-channel adapted to Procedure for Prolapse and Hemorrhoids anoscopes were utilized by some early adaptors [10, 16]. Commercial products, such as the *SILS port* (Covidien, Mansfield, MA, USA) and Transanal Endoscopic Microsurgery (TEM) (Karl Storz, Tuttlingen, Germany), were also used.

Assessment and definition

The data of all patients included in this study were collected and analysed. Operative time included the duration of the transanal operation and/or transabdominal operation (for hybrid taTME). Post-operative morbidity was measured by the Calvien–Dindo system. Anastomotic leak was diagnosed based on clinical manifestations and/or radiological evidences. Divert surgery was performed when anastomotic leakage occurred and local irrigation was not effective, abdominal pain, abdominal distension was obvious, or there was a risk of septic shock for the patient. Urinary retention was defined by prolonged duration of catheterization or when re-catheterization was required after discontinuation of the catheter.

In this study, completeness of mesorectum specimens was independently assessed by the pathologists who grossly graded the mesorectum as complete, near complete, and incomplete, as described by Nagtegaal *et al.* [17]. Patients were closely monitored and treated according to the NCCN guidelines for rectal cancer. The diagnosis of local and distal recurrence was established by radiological and/or pathological findings.

Statistical analysis

Data were collected and recorded in a database. Parametric data are presented as means with standard deviations (SDs) and non-parametric data are presented as medians with the corresponding ranges. Probability of survival was calculated according to Kaplan–Meier analysis. Data were analysed with IBM SPSS Statistics for Windows, version 18.0 (IBM Corp; Armonk, NY, USA).

Ethics and informed consent

All the research centers involved in this study have passed the approval of the ethics committee of their hospitals. The new technology has been fully informed of the potential risks and benefits of patients and informed consent of patients.

Results

Pre-operative characteristics

A total of 211 patients from 10 independent centers across China who underwent taTME between May 2010 and April 2016 were included in this study (Supplementary Table 1). The patients' characteristics are shown in Table 1. The median distance between the tumors and the anal verges was 5.9 cm (range, 1.5–12 cm); the tumor was located in the lower third of the rectum in 143 patients (67.8%). Fifty-eight patients (27.5%), whose tumors were pre-operatively staged as locally advanced diseases, had received neoadjuvant therapy (chemoradiation or chemotherapy alone).

Perioperative results

Fifty-three patients (25.1%) underwent a pure taTME without laparoscopic assistance, whereas the remaining 158 patients (74.9%) underwent hybrid taTME. The duration of the taTME and transabdominal portion were not recorded separately. It took a median of 280 min (range, 70–600 min) to complete the whole procedure. Median estimated blood loss was 50 mL (range, 10–1,500 mL) with massive bleeding (>500 mL) in five cases. Perioperative transfusion was needed for 11 patients (5.2%). Protective ileostomy was constructed in 78 patients (37.0%). As shown in Table 2, the overall occurrence rate of

Table 2. Perioperative results of 211 patients with rectal cancer who underwent transanal total mesorectal excision (taTME)

Characteristic	Data
Pure taTME	53 (25.1%)
Hybrid taTME	158 (74.9%)
OT, mean ± SE (min)	280.0 ± 109.8
EBL, mean ± SE (mL)	107.7 ± 169.1
Perioperative transfusion	
Yes	11 (5.2%)
No	200 (94.8%)
Ileostomy or colostomy	
Yes	78 (37.0%)
No	133 (63.0%)
Overall morbidity	59 (27.9%)
Intra-operative complications	
Presacral bleeding	1 (0.5%)
Urethra injury	1 (0.5%)
Ureteric injury	1 (0.5%)
Rectal perforation	1 (0.5%)
Massive bleeding (>500 mL)	5 (2.4%)
Conversion to open surgery	2 (0.9%)
Post-operative complications	
Anastomotic leak	17 (8.1%)
Operative treatment (required ostomy)	7 (3.3%)
Conservative treatment	10 (4.8%)
Anastomotic bleeding	4 (1.9%)
Anastomotic stricture	3 (1.4%)
Pelvic abscess	2 (0.9%)
Bleeding in peritoneal cavity	1 (0.5%)
Urinary retention	14 (6.6%)
Ileus	7 (3.3%)
Ileostomy necrosis	1 (0.5%)
Pulmonary infection	6 (2.8%)
Acute myocardial infarction	1 (0.5%)
Deep-vein thrombosis	1 (0.5%)
Clavien–Dindo classification	
Dindo I–II	44 (20.8%)
Dindo III–IV	15 (7.1%)
Dindo IV	0
Required re-intervention in OR	14 (6.6%)
Readmission within 30 days	4 (1.9%)
Death within 30 days	0

OT, operative time; EBL, estimated blood loss.

complications was 27.9%. Four specific intra-operative complications occurred, including presacral bleeding (one case), urethra injury (one case), ureteric injury (one case), and rectal perforation (one case). Conversion to open surgery was required for two patients (0.9%). Seventeen patients (8.1%) developed post-operative anastomotic leak according to clinical symptoms and/or radiologic diagnosis; among them, reoperations, to construct an ostomy with fecal diversion, were performed in 7 patients, whereas the remaining 10 patients were successfully treated conservatively, mainly with antibiotics and/or ultrasound-guided drainage (4 patients). In two patients (1.0%), pelvic abscesses were observed without significant evidence of leakage and recovered after conservative treatments. Other anastomotic complications included four cases of anastomotic bleeding (one required hemostasis by transanal operation) and three cases of anastomotic stricture (two required surgery to relieve stricture). Urinary retention was diagnosed in 14 patients (6.6%), with 2 patients requiring urinary operations. Mild ileus (ileus treated conservatively) was found in seven patients (3.3%) and did not require aggressive treatment. Other rare complications requiring re-operation included post-operative abdominal bleeding (one case) and ileostomy necrosis (one case). Medical comorbidity mainly included pulmonary infection (six cases), acute myocardial infarction (one case), and deep-vein thrombosis (one case).

Table 3. Pathologic results of 211 patients with rectal cancer who underwent transanal total mesorectal excision (taTME)

Characteristic	Data
LN harvest, mean ± SE	14.2 ± 7.3
LN less than 12	63 (29.8%)
Length of specimen, mean ± SE (cm)	14.4 ± 4.8
pTMN	
0 (tumor not found & Tis & complete response)	7 (3.3%)
I	85 (40.3%)
II	58 (27.5%)
III	52(24.6%)
IV	9 (4.3%)
Tumor size, mean ± SE (cm)	3.3 ± 1.5
Distal margin distance, mean ± SE (cm)	1.9 ± 0.9
Circumferential margin (CRM ≤1 mm)	5 (2.3 %)
Mesorectal resection quality	
Complete	175 (82.9%)
Near complete	33 (15.6%)
Incomplete	3 (1.4%)

LN, lymph node; pTMN, pathologic TMN stage; CRM, circumferential margin; Tis, carcinoma *in situ*.

Pathologic results and recovery

As shown in Table 3, the mean number of harvested lymph nodes was 14.2 ± 7.3 (range, 1–44). The mean diameter of the tumors was 3.3 ± 1.5 cm (range, 0–7.5 cm), and the mean distance of distal resection margins was 1.9 ± 0.9 cm (range, 0.5–5 cm). Five patients (2.3%) were found to have a positive circumferential resection margin (CRM). The integrity of the mesorectum was incomplete in 3 patients (1.4%), nearly complete in 33 patients (15.6%), and complete in 175 patients (82.9%).

Fifteen patients in the American Society of Anesthesiologists Physical Status Classification (ASA class) 3/4 categories were transferred to the intensive care unit for further post-operative recovery. The median time of flatus passage was 2.6 days (range, 1–16 days) and the median time of removal of the Foley catheter was 5.5 days (range, 1–62 days). The median time of post-operative hospital stay was 13 days (range, 3–65 days). The readmission rate within 30 days was 1.9% (four cases).

Local recurrence and overall survival

As shown in Table 4, the median follow-up time of the 211 patients was 35 months (range, 2–86 months). Local recurrence occurred in 13 cases (6.2%) and distant metastasis occurred in 27 cases (12.8%); 16 cases (7.6%) died. Kaplan–Meier survival analysis showed that 1-, 2-, and 3-year disease-free survival (DFS) rates were 94.8%, 89.3%, and 80.2%, respectively; 1-, 2-, and 3-year OS rates were 97.4%, 95.7%, and 92.9%, respectively.

Discussion

This study included 211 cases, with an average of more than 20 cases per center. The median operating time was 280 min and median estimated intra-operative blood loss was 50 mL.

Table 4. Oncologic outcome

Outcome	Data
Follow-up, months, median (IQR)	35 (2–86)
1-Year disease-free survival	94.8%
2-Year disease-free survival	89.3%
3-Year disease-free survival	80.2%
1-Year overall survival	97.4%
2-Year overall survival	95.7%
3-Year overall survival	92.9%

IQR, interquartile range.

The overall occurrence rate of complications was 27.9%, without any death among these patients during the perioperative period.

The rate of patients receiving neoadjuvant therapy was lower (27.5%) in this study when compared with an average of 72.3% in a recent systemic review [18]. Some studies only enrolled patients who received radiotherapy to perform a taTME [19, 20]. The low rate of neoadjuvant therapy might be partially explained by the earlier tumor staging in our study population [21]. Among the 211 patients, 157 (74.4%) had clinical stages I and II diseases. Operative time for this study was comparable to that reported in previous studies [18]. However, it was noted that there was a wide range of operative time, ranging from 70 to 600 min, and estimated blood loss ranged from 10 to 1,500 mL, which partially reflected the steep learning curve. It has been recognized by many authors that, for low rectal cancer, taTME was technically demanding and required expert hands with proficient experience in laparoscopic surgeries such as the transanal-transabdominal (TATA) procedure [22], Intersphincter Resection (ISR) [23], TEM [24], and Transanal Minimal Invasive Surgery (TAMIS) [25]. The overall rate of intra-operative complications in the present study was 4.2%. When compared with the rate of intra-operative complications in the COLOR II trial (12%) [26], our result was quite acceptable. Moreover, the rate of conversion to open surgery (0.9%) was lower in our series when compared with that (16%) in COLOR II trials.

Regarding post-operative comorbidity, anastomotic leak is of primary concern. The anastomotic leak rate of our study (8.1%) was comparable to that reported in a conventional surgery study [26] and other taTME studies [18]. However, since disastrous anastomotic leak remains unpredictable with a wide range of risk factors [27], construction of protective stoma in patients at high risk is still recommended. Continuous efforts are required to reduce anastomotic leak by variants of stapled technique [28]. Our pathological parameter results were satisfactory regarding the mean number of resected lymph nodes (14.2), positive resection margin (2.3%), and incomplete mesorectum (1.4%). Our results were also in accordance with those of other taTME studies [18], which also suggested an encouraging oncologic outcome. However, it should be noted that adequate follow-up is needed before we can draw a safe conclusion.

As a new technology launched in 2010, taTME still lacks long-term, large-sample-size, follow-up data, so it is not clear whether the advantages of taTME in the pathological quality of low rectal cancer can be translated into survival benefits. In the summary of 140 taTME cases published by Lacy *et al.* [12], the average follow-up period was 15 months. The local-recurrence rate was 2.3% and the distant-metastasis rate was 6.1%. In June 2017, Marks *et al.* [29] published, for the first time, the long-term survival results of rectal-cancer patients undergoing transanal TME. This single-center study included 373 cases of rectal cancer undergoing TATA surgery. Among these cases, 96% of the TME surgical specimens were evaluated as 'complete' and 'near complete', 94% were CRM-negative, and 98.6% were far-cut-negative; the 5-year local-recurrence rate was 7.4% and 5-year overall survival rate was 96%. The results showed that the quality of the transanal TME specimens was high and the long-term effect of taTME was good. In a case-matching study, Lelong *et al.* [30] compared 34 cases of transanal TME and 38 cases of transabdominal TME and did not find significant difference in 2-year DFS rates between the two groups (88% vs 86%, $P = 0.91$). In our study, the 2-year DFS and OS rates of taTME patients reached 89.3% and 95.7%, respectively, which were comparable to the results of the aforementioned studies; the 3-year DFS and OS rates reached 80.2% and 92.9%, respectively, indicating that taTME did not significantly compromise survival.

There were several limitations and methodological weaknesses in this study. First, data were collected retrospectively. Second, the assessment criteria of pathologic specimens were heterogeneous across centers. Third, variations of surgical techniques, such as different transanal platforms (including SILS, customized port and TEM platform) and different operating experiences, may have all contributed to inconsistencies between centers. Fourth, further insight of the learning curve and case-volume-effect analysis was not shown in this study. Fifth, data regarding function and quality of life were lacking, which prevented us from making any analyses in these aspects. These drawbacks together prevented us from drawing a firm and powerful conclusion and constrained the generalizability of our results.

As some authors have commented, taTME has not been 'ready for the prime time' [31], as we are currently promoting laparoscopic TME, mainly because of lack of higher grade of evidence. Hopefully, with the joint efforts of continuous teamwork and collaboration, such as the LOREC registry [32] and the COLOR III trial [33], we will be able to generate a higher level of evidence in the near future.

Conclusions

The present multicentric study suggests that taTME is both safe and feasible for selected patients.

Supplementary data

Supplementary data is available at *Gastroenterology Report* online.

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Conflicts of interest

The authors declare that there is no conflict of interest in this study.

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