

Evaluation of laparoscopic-assisted transanal total mesorectal excision (Ta-TME) for locally advanced distal rectal cancer in men with difficult pelvic conditions after neoadjuvant chemoradiation therapy

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Research article

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Abstract

Background: To evaluate the use of laparoscopic-assisted transanal and total mesorectal excision (Ta-TME) in men with difficult pelvic anatomy in an attempt to optimize anal sphincteric preservation, determine the completeness of TME, and determine postoperative morbidity and mortality.

Methods: Twenty male patients (TA group) with difficult pelvic anatomy (narrow pelvis) who were diagnosed with rectal cancer underwent Ta-TME surgery from January 2017 to January 2018 at Peking University Cancer Hospital. We matched these 20 patients with 2 other groups of patients who underwent either a laparoscopic transabdominal TME (LA group) or an open transabdominal TME (OP group) according to age, sex, BMI, distance of tumour from the anal verge, and diameter of the tumour. All 3 groups of patients had undergone preoperative neoadjuvant chemoradiation therapy. The efficacy and safety of Ta-TME were evaluated according to operative time, blood loss, postoperative hospital stay, and postoperative complications. Outcomes of Ta-TME were evaluated by comparing the rate of a positive circumferential resection margin, the integrity of the TME, and the rate of sphincter preservation among the 3 groups.

Results: When comparing Ta-TME (TA group), laparoscopic transabdominal TME (LA group), and open transabdominal TME (OP group), the respective mean blood loss (100 mL, 100 mL, 100 mL, $p=0.335$), postoperative hospital stay (9 days, 9 days, 7 days), number of harvested lymph nodes (7, 6, 7), positive circumferential resection margin rate (0%, 0%, 5%), rate of pathologic complete response (5%, 10%, 10%), and integrity of TME showed no significant differences across groups ($p>0.5$ for all). In contrast, there were significant differences in operation time (302 min, 253 min, 135 min), rate of preservation of the anal sphincter (100%, 30%, 45%), and the creation of a protective diverting ileostomy (100%, 30%, 45%, $p<0.05$ for all).

Conclusion: The rate of anal sphincter preservation in the Ta-TME group was considerably greater than that in the other groups, but the safety of the operation did not differ among the 3 groups. Ta-TME required a diverting ileostomy in all cases, and the total operation time for Ta-TME was greater than that of laparoscopic and open transabdominal TME.

Background

It is estimated that there will be approximately 43,000 new cases of rectal cancer in the US in 2018, of which as many as 26,000 are likely to occur in males [1]. Operative resection following the principle of total mesorectal excision (TME) is the mainstay of treatment for patients with rectal cancer to minimize local recurrence. With TME, the rates of local recurrence (LR) have greatly decreased from nearly 33% to less than 10% [2]. Recently, laparoscopic surgery has been used widely in clinical practice and often provides better visualization and potentially better functional outcomes than open surgery. In the traditional “up-to-down” laparoscopic and open transabdominal approach when performing TME, surgeons may find it difficult to perform TME in certain clinical scenarios, including in male patients with

a narrow pelvis, patients with a high body mass index (BMI), or patients with oedema and/or fibrosis after preoperative chemoradiation, especially those with bulky middle to distal rectal tumours [3]; in these situations, the exposure and dissection of the distal margin of either the rectal wall or the mesorectum might be compromised without clear exposure. Additionally, conversion from laparoscopic to open surgery occurs in 10–30% of patients, often leading to longer operation times and adverse intraoperative events [4-6]. Therefore, a new technical approach that facilitates exposure of the distal part of the resection/dissection is greatly needed.

Combined transabdominal–transanal surgery (TATA) was introduced by Marks in the 1990s to preserve the sphincter through the distal to proximal approach [7]. This concept, even with the open surgery approach, lays a good foundation for later improvements, but few surgeons have adopted this approach as a technique for patients with a narrow pelvis and poor visualization. The feasibility of dissection from the distal side proximally has been demonstrated. We wondered if a transanal approach might eliminate the difficulties of visualization and dissection of patients with a narrow or otherwise difficult rectal pelvic anatomy encountered during open and laparoscopic rectal surgery. Fortunately, natural orifice transluminal endoscopic surgery (NOTES), integrating TATA and transanal endoscopic microsurgery (TEM), demonstrated that TME can be completed via a transanal approach and has the advantage of no scar. The first case of transanal total mesorectal excision (Ta-TME) was performed by Sylla et al. in 2010 [12]; then, the multiluminal, single port strategy initiated by Atallah et al established a more technically appealing approach to Ta-TME [13]. Available data have demonstrated the noninferiority of Ta-TME compared to laparoscopic surgery in terms of the distal margin, circumferential resection margin (CRM), and integrity of the specimen [14]. Regarding long-term outcomes, most importantly, the local recurrence rate was 7.4% among 373 patients with a median follow-up of 5.5 years, distant metastasis occurred in 19.5%, and the 5-year overall survival was 90%[15].

Most studies enrolled patients with either middle or low rectal cancer. Thus, there was little evidence to compare the outcomes of locally advanced, bulky distal rectal cancer in patients with a narrow pelvis. Most locally advanced rectal cancers are also treated with neoadjuvant chemoradiation, which makes surgery even more difficult. Therefore, we evaluated the short-term outcomes of Ta-TME in this subgroup of male patients with a narrow pelvis who had undergone neoadjuvant chemoradiation therapy compared to patients undergoing the more classic laparoscopic or open transabdominal dissection. All operations in the Ta-TME group were performed by 2 experienced senior surgeons (Wu AW, Wang L) trained in the UK and the Netherlands.

Methods

A prospective database was established for this Ta-TME programme at Peking University Cancer Hospital from June 2017 to January 2018. Only patients matching all the following criteria were included for analysis: males with biopsy-proven distal rectal adenocarcinoma (less than 5 cm from the distal margin of the mass to the anal verge); with locally advanced rectal cancer having undergone neoadjuvant chemoradiation; and with tumour diameters of less than 4 cm, a narrow pelvis (interischial tuberosity

distance of less than 10 cm), and a BMI greater than 26 kg/m². This study was approved by the ethics committee of Peking University Cancer Hospital (approval no. 2017YJZ42-GZ01).

Informed written consent was obtained from all patients. Patients with a prior history of other malignancies, recurrent or metastatic lesions, KPS \leq 60, poor anal function, concomitant inflammatory bowel disease, familial adenomatous polyposis or multiple colorectal polyps were excluded from analysis. Cases of open and laparoscopic surgery were matched from the database by age, sex, BMI, distance between the interischial tuberosity, and neoadjuvant chemoradiation.

Ta-TME Technique

All patients in the three groups received bowel preparation the day before the operation, and intravenous antibiotics were prophylactically administered perioperatively.

Laparoscopic-assisted Ta-TME: Patients were placed in the lithotomy position; the skin was prepared and draped to allow access to both the perineum and abdomen. First, rectal dissociation was performed under laparoscopy in accordance with the TME principle. Low ligation of the inferior mesenteric artery and preservation of the left colonic artery were usually performed, but complete mobilization of the splenic flexure was not routine. No rectal dissection was performed before the transanal dissection. After digital dilation of the anal sphincter, the port was inserted transanally, and sometimes dissection of the installed rectum and purse-stringing were performed under direct vision. The instruments included either a transanal endoscopic operation (TEO) device (Karl Storz GmbH&Co. KG, Tuttlingen, Germany) or Star port (Shin aide Co., Xiamen, China) after exposure of the anal canal. Distal rectal dissection, including the TME, was begun posteriorly in most cases, followed by symmetrical bilateral dissection and finally anterior dissection. Once the peritoneal reflection was opened, the abdominal group then assisted in freeing to allow removal of the specimen through the anus, occasionally from a small incision when the tumour was too large. The colorectostomy anastomosis was performed either by hand sewing or with a stapler VIA. A protective loop ileostomy was constructed in all cases of T-TME.

Transabdominal TME: Laparoscopic and open surgery were performed routinely following the principles of the TME resection principle. Surgeons decided whether to use a protective stoma; these stomas were generally closed 3–6 months after the operation. Postoperative complications were graded according to the Dhindo-Clavien classification[16].

All patients were followed up at 1 month postoperatively and then every 3 months for 2 years. Digital examination was performed routinely to assess the status of the anastomosis. Adjuvant chemotherapy was adopted according to the NCCN guidelines.

Statistics

The 8th AJCC/UICC TNM staging system was used [17]. A positive CRM was defined as a tumour less than 1 mm from the margin, and Nagtegaal's 3-scale grading was used to evaluate the quality of the

dissected specimen [18,19]. All analyses were performed using SPSS version 20.0 (SPSS, Inc., Chicago, IL). Independent, nonparametric Kruskal-Wallis tests were used to compare the groups, and t-tests were used for continuous parameters that were represented either as the mean values \pm standard deviations or as median values with the range; a p-value of less than 0.05 was used as the cut-off for statistical significance.

Results

From June 2016 to January 2018, 20 patients met the criteria and underwent Ta-TME. Another 2 groups of 20 patients each who had undergone a transabdominal TME via open and laparoscopic approaches during the same time interval with matched parameters were used as controls. All patients were male and received neoadjuvant chemoradiation. The median ages were 57 ± 11 , 59 ± 10 , and 61 ± 9 years in the Ta-TME, laparoscopic, and open groups, respectively. The median BMIs were 27.7 kg/m^2 , 27.8 kg/m^2 , and 28.4 kg/m^2 , respectively. Median distances from the anal verge to the distal border of the tumour were 4 cm, 4 cm, and 4 cm, respectively. The median distances between the 2 ischial tuberosities were 9.3 ± 0.53 cm, 9.1 ± 0.6 cm, and 9.3 ± 0.2 cm, respectively.

Table 1 presents the baseline information for the TA group. The mean blood loss was 100 mL (range 50 to 200 mL), and the operation time was 302 min (range 215–405 min). Ninety-five percent (19/20) of the patients were Stage III. A median of seven lymph nodes were harvested. At a median follow-up of 8.5 months (range 3 to 18), all patients in the Ta-TME group were alive and without disease, 1 was lost at follow-up, 18 had no evidence of disease, 1 had lymph node metastasis to the right supraclavicular area but was still alive, and 2 had undergone stoma closure; there were no local recurrences noted at the end of follow-up.

Table 2 shows the comparisons of the 3 groups. There were no significant differences among the 3 groups in terms of blood loss, postoperative hospital stays, number of lymph nodes harvested, positive lymph nodes, CRM positivity, rates of a complete pathologic response to neoadjuvant therapy, and the quality of TME specimens. There were, however, statistically significant differences found in operation time, the rate of anal sphincter preservation, and the use of a protective, proximal diverting stoma (ileostomy). The Ta-TME group had a much superior rate of intraoperative preservation of the anal sphincter (100% vs. 30% vs. 45%; $p<0.05$) but also had longer operation times (302 min vs. 253 min vs. 135 min; $p<0.05$) and a need for a protective proximal diverting stoma (100% vs. 30% vs. 45%; $p<0.05$). Postoperative complications occurred in 5 of the 20 cases in the Ta-TME group. Three had pelvic infections and were discharged after receiving intravenous antibiotics for 5 days (Grade II); One patient had anastomotic fracture, followed by Hartmann operation—another patient had postoperative ileus and recovered after conservative treatment being discharged on postoperative day. The laparoscopic group had 4 complications (3 grade II complications and 1 grade III anastomotic leakage necessitating a second laparotomy), while the OP group had 5 complications involving 5 infections all treated successfully with antibiotics (grade II).

Discussion

This study found that laparoscopic-assisted Ta-TME had great advantages over total laparoscopic and open transabdominal TME insphincter preservation, especially for patients with difficult operative conditions, such as bulky distal rectal carcinomas in male patients with a narrow pelvis or a high BMI who were treated with neoadjuvant chemoradiation therapy.

In the Ta-TME group, intraoperative sphincter preservation was achieved in 100% of the 20 patients, in contrast to rates of sphincter preservation of only 30% and 45% of patients in the transabdominal TME laparoscopy and open surgery groups, respectively. Because one patient in the Ta-TME group required a permanent colostomy after developing an anastomotic leak, the ultimate rate of sphincter preservation was 95% to date. Nevertheless, the long-term rate of sphincter preservation was much greater with the Ta-TME approach than the other approaches. Transabdominal resection of the distal rectum, either open or laparoscopic, usually uses the double-stapler technique, which necessitates the ability to transect the distal rectum with the stapler. Unfortunately, this manoeuvre is difficult or even impossible with current surgical instruments when the pelvis is deep and narrow. In addition, anastomosis may be impossible under direct visualization. Most importantly, for patients with difficult pelvis conditions, the so-called distal margin is generally overestimated, and squeezing the tumour tissue during exposure is inevitable. Such operations do not conform to the principle of no tumour. Rouanet et al. reported on 30 men with advanced or recurrent low rectal tumours associated with unfavourable anatomic or tumour characteristics who underwent a sphincter-sparing, transanal endoscopic proctectomy[3]. Though the operated group included recurrent rectal cancer, 78% still had sphincter preservation at a median follow-up of 21 months. Local anatomy (deep narrow pelvis, fatty mesorectum), male sex, high BMI, and certain features of the tumour (anterior location and large tumours) are independent risk factors for conversion, operation time, morbidity, and noncurative resection. By overcoming existing restrictions, Ta-TME may make sphincter-preservation surgery both easier and more successful. Factors such as a narrow male pelvis and a high BMI may lead to an inevitable permanent colostomy after the conversion from laparoscopic to open surgery.

Although Ta-TME is technically feasible, the quality of surgical specimens—especially whether a complete excision of the mesorectum can be obtained and whether it might pose additional risks of local recurrence—has been questioned[19,20]. A positive CRM and its integrity are important factors in local recurrence [21]. Available data have shown that negative CRMs were present in 87.9–97.0% of open resections and 90.5–97.1% of laparoscopic resections [22,23]. Buchs et al. reported that traditional surgical approaches may lead to a greater rate of positive CRMs for tumours less than 3 cm from the dentate line [24]. In a study of 186 patients, Lacy found positive CRMs present in 8.1% of patients [25]. Theoretically, a more meticulous dissection as allowed because of better visualization by the Ta-TME approach may be very helpful for achieving a negative CRM for these distal rectal tumours; indeed, this was verified by Denost et al. in a randomized clinical trial [26]. That trial enrolled 100 patients between 2008 and 2012 with distal rectal cancers (<6 cm from the anal verge) otherwise suitable for sphincter preservation. The primary endpoint was the quality of the resection (rate of a positive CRM, the grade of

the integrity of the TME, and the ability to remove the local lymph nodes). The rate of positive CRM decreased markedly after transperineal dissection compared to transabdominal distal rectal dissection (4% versus 18%; $p=0.025$). In our cohort, all patients in the Ta-TME group achieved a negative CRM and complete specimens. Our ability to accomplish this success rate was unexpected because it was the first cohort of patients in whom we had performed this operation, and it might be attributable to either our prior extensive experience with dissection of distal rectal tumours or to the small sample size.

Safety is important for patients and surgeons when a new technique is introduced, especially during the period of the learning curve. This technique has drawn much attention, and various training courses have been introduced in Europe and the United States. In the study by Atallah and colleagues, the mean blood loss for 20 patients was 153 mL [27]. In a registry study of 720 cases, 61.2% of patients had blood loss of less than 100 mL, and only 1% of these patients had a blood loss of greater than 1 L [28]. Complications, such as ureteral injury or massive haemorrhage, are among the unique complications that could be countered during this kind of surgery. The need for a non-planned re-operation, a grade III complication, indicates a serious complication. Burke et al. reported an operation rate of 12% among the first 50 patients, mainly due to ileostomy dysfunction, anastomotic leakage, or pelvic collection [29]. In a study of 720 cases [28], however, postoperative mortality was generally quite low (approximately 0.5%). In our cohort, no deaths occurred. Current available data indicate that Ta-TME is a safe operative technique. Indeed, in our study, the median postoperative hospital stay was 9 days and comparable to those in the laparoscopic or open surgery groups. This result is consistent with the results reported by Araujo et al. for 150 patients [30].

Sufficient and appropriate lymph adenectomy is necessary for the accurate staging of rectal cancer and indicates the quality of the resection. Inadequate dissection of the mesorectum leads to a greater risk of residual disease and then an increased and unsatisfactory rate of local recurrence [31-34]. After neoadjuvant chemoradiation, patients have fewer lymph nodes [35], but in our study, the median number of lymph nodes harvested was not different between the 3 groups (7, 6, and 7 nodes per resection.).

Regarding operation time, the Ta-TME group had a significantly longer median operation time compared to the open and laparoscopic groups (302 min, 253 min, and 135 min; $p<0.001$). The shortest times for each of these groups were 215 min, 105 min, and 88 min, respectively. This finding could be related to the learning curve. There were 2 groups in the Ta-TME operations—the abdominal and perineal groups. The operation can be completed by 1 or 2 teams of surgeons, concurrently or sequentially. During the learning curve period, the choice of operational platform is of utmost importance. Moreover, the establishment of the pneumo-rectum with a conventional device or with a TEM platform or transanal minimally invasive surgery (Tamis) platform differed greatly in shortening operation times. The longest Ta-TME operation lasted 405 min, comparable to that reported by Araujo and colleagues [29,36]. The number of cases needed to complete the learning period has been estimated as 20–40, depending on the surgeon's prior experience and the operating room supportive team [24]. Optimization of protocols is necessary.

Our study had several limitations. First, although the sample size was small, all patients had a difficult anatomy. Second, all cases of Ta-TME were conducted within our learning-curve period. The longer operation times, complication patterns, and rates as well as the longer hospital stays might produce some bias. Third, this was a case-matched study that incorporated only certain factors that theoretically affected outcomes for rectal cancer patients. Some other parameters that might have made the 2 control groups either better matched or were indicative of poor matches might exist that were not included in the analysis. Finally, follow-up times were short and could not provide better long-term oncologic outcomes. Therefore, long-term follow-up is needed in terms of local recurrence, actual sphincter preservation after stoma closure, and patient-reported rectal function.

In conclusion, compared to a transabdominal open and laparoscopic approach, Ta-TME appears to result in superior insphincter preservation for patients with distal rectal cancer, especially when patients are male, have a narrow pelvis, have a high BMI and have had a course of neoadjuvant chemoradiation therapy. Our study strongly suggests that Ta-TME is a safe procedure in experienced hands that may benefit from structured training for shorter operation times. It is clear, however, that the value of Ta-TME still needs to be evaluated through larger randomized trials[2].

Abbreviations

TME: total mesorectal excision

Ta-TME: transanal total mesorectal excision

LA group: laparoscopic transabdominal TME

OP group: open transabdominal TME

LR: local recurrence

BMI: body mass index

TATA: transabdominal–transanal surgery

NOTES: natural orifice transluminal endoscopic surgery

TEM: transanal endoscopic microsurgery

CRM: circumferential resection margin

KPS: Karnofsky score

TEO: transanal endoscopic operation

Declarations

Ethics approval and consent to participate

The experimental protocol was established, according to the ethical guidelines of the Helsinki Declaration and was approved by the Human Ethics Committee of Peking University Cancer Hospital (approval no. 2017YJZ42-GZ201).

Ta-TME procedure is already approved for clinical use at the Peking University Cancer Hospital.

Written informed consent was obtained from individual or guardian participants.

Consent has been obtained for all forms of personally identifiable data including biomedical, clinical, and biometric data.

Consent for publication

Not applicable.

Competing interests

The authors have declared that no competing interests exist.

Availability of data and materials

All data generated or analysed during this study are included in this published article.

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Author Contributions

A.W.W.: conception and design of the study, draft and final approval of the manuscript; All operations were performed by Aiwen Wu; Y.J.L. and G.L.H.: collection of the data, drafting of the manuscript; L.W., Q.S.D., X.Z.L., J.H.L., X.Z., Y. Z., and Y.F.Y.: quality control of the study, especially the surgery part, acquisition of data; T.T.S.: study design and statistical analysis. All authors approved the final manuscript.

Conflict of interest declaration

The authors declare that they have no competing interests.

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Tables

Table 1. Basic information for patients in the Ta-TME group.

No.	Age (y)	BMI	DAV (cm)	Clinical stage	IITD (mm)	Operation time (min)	Blood loss (mL)	Hospital stay (d)	Postoperative complication
1	40-59	31	5	T3N2bM0	99	274	100	7	none
2	70-79	36.	3	T4N + M0	94	405	100	10	none
3	50-59	27	2	T3N + M0	95	342	200	7	none
4	60-69	27	5	T3N + M0	91	290	100	9	none
5	30-39	26.	3	T3N + M0	91	283	100	12	none
6	60-69	27	5	T2N2M0	98	245	100	9	none
7	50-59	28	2	T3N2bM0	100	364	200	7	pelvic infection
8	50-59	27	4	T3N + M0	98	400	100	9	none
9	60-69	30	5	T3N2bM0	95	364	100	9	pelvic infection
10	60-69	27	4	T3N1M0	88	270	100	9	none
11	60-69	26	4	T3N + M0	91	262	50	12	none
12	50-59	28	5	T3N2M0	86	392	100	14	none
13	30-39	29	3	T3aN2bM0	91	266	100	5	none
14	40-49	28	5	T3N1M0	97	317	100	13	pelvic infection
15	40-49	28	4	T3N + M0	93	375	100	7	ileus
16	60-69	27	4	T3N2bM0	99	293	100	9	none
17	60-69	29	5	T4aN + M0	92	337	100	7	none
18	60-69	27	4	T3N1M0	91	271	100	7	none
19	70-79	29	5	T3N1M0	78	310	100	15	anastomosis leak
20	60-69	29	3	T3N0M0	90	215	50	9	none

Note: DAV: distance from the anal verge to the inferior border of the tumor; IITD: interischial tuberosity distance.

Table2. Comparison of patients in the Ta-TME, laparoscopic, and open surgery groups (n=20 patients in each group).

	Ta-TME[TA]	Laparoscopicgroup[LA]	Opengroup(OP)	cX ²	p-value
Age(year)*	57 ± 11	59 ± 10	61 ± 9	0.723	0.696*
BMI(kg/m ²)**	28 (26.2-36.4)	28 (26.8-31.6)	28 (26.1-31.6)	1.37	0.504*
IITD(mm)*	93 ± 5	92 ± 6	93 ± 3	0.568	0.753*
Preoperativechemoradiation(n)	20	20	20	--	--
DAV(cm)	4 (2-5)	4 (2-5)	4 (2-5)	1.13	0.568*
Operatingtime(min)**	302(215-405)	253(105-400)	135(88-420)	23.276	0.001*
Bloodloss(mL)	100(50-200)	100(20-180)	100(50-600)	2.189	0.335*
TMEgrading***				--	--
Grade1	0	0	0		
Grade2	0	0	0		
Grade3	20	20	20		
SPR	100% (20/20)	30% (6/20)	45% (9/20)	26.044	0.001*
Protectivestoma	100% (20/20)	30% (6/20)	45% (9/20)	26.044	0.001*
Hospitalstay(d)**	9(5-15)	9(6-16)	7(6-15)	2.707	0.258*
Postoperativecomplication	25% (5/20)	20% (4/20)	25% (5/20)	0.275	1.000\$
Lymphnodeharvested**	7 (2-13)	6 (2-12)	7 (2-13)	0.416	0.812*
CRMpositiverate	0% (0/20)	0% (0/20)	5% (1/20)	1.851	1.000\$
ypT				4.777	0.607\$
0	10% (2/20)	10% (2/20)	10% (2/20)		
1	10% (2/20)	25% (5/20)	15% (3/20)		
2	30% (6/20)	45% (9/20)	35% (7/20)		
3	50% (10/20)	20% (4/20)	40% (8/20)		
ypN				6.581	0.095\$
0	55% (11/20)	90% (18/20)	75% (15/20)		
1	40% (8/20)	10% (2/20)	20% (4/20)		
2	5% (1/20)	0% (0/20)	5% (1/20)		

IITD: interischial tuberosity distance; DAV:distance from the anal verge to the inferior border of the tumor;SPR:sphincter preservation rate;CRM:circumferential resection margin.

*Mean +/- Standard deviation

** Median (range)