



Transanal total mesorectal excision in selected patients with “difficult pelvis”: a case–control study of “difficult” rectal cancer patients

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Summary

Background Transanal total mesorectal excision (taTME) yields potential benefits for patients with a narrow pelvis and previous chemoradiotherapy by facilitating mobilization of the lower part of the mesorectum. The aim of this study was to investigate the role of taTME in patients with “difficult pelvis.”

Methods This single-institution retrospective non-randomized cohort study included patients with difficult pelvis who underwent either laparoscopic total mesorectal excision (lapTME) or taTME during 2013–2016. “Difficult pelvis” was defined as a combination of male gender, high body mass index (BMI; $\geq 25 \text{ mg/m}^2$), and previous chemoradiotherapy. Main outcome measures included TME quality, rate of stapling anastomoses, operative time, and postoperative complications.

Results In total, 26 patients underwent lapTME and 26 underwent taTME. The median BMI was 29.2 kg/m² and 28.3 kg/m² in the laparoscopic and transanal groups, respectively ($p=0.8$). The median operative time was 270 and 295 min, respectively ($p=0.2$). One (3.8%) patient died in the laparoscopic group, whereas no deaths occurred in the taTME group. The rate of grade III–IV complications was three (11.5%) vs. three (11.5%), respectively ($p=1.0$). Grade 1 TME was observed in four (17.4%) vs. four (16%) pa-

tients, respectively ($p=1.0$; per protocol). Stapling anastomosis was performed on 17 (68%) vs. 21 (84%) patients, respectively ($p=0.2$). The median follow-up was 28.2 months. There was one case (3.8%) of distant failure in each group and one (3.8%) patient in the laparoscopic group developed a local recurrence. **Conclusion** In rectal cancer patients with difficult pelvis, taTME may lead to higher rates of stapling anastomoses without compromising other surgical outcomes. We did not find any differences in specimen quality or other surgical outcomes between the two groups.

Keywords Rectal cancer · Transanal TME · Laparoscopic TME · Stapling anastomosis · TME quality

Main novel aspects

- Transanal TME results were studied in a selected patient group, i.e., in patients for whom it potentially has benefits over the standard laparoscopic or open approach. Only two studies have previously attempted to use restricted inclusion criteria to investigate taTME outcomes.
- We investigated the rate of stapling anastomoses as a potential benefit of taTME, which is often overlooked in other studies.

Introduction

Transanal total mesorectal excision (taTME) is a relatively new surgical technique. Its field of application is the subject of debate, with some authors claiming its superiority for all patients with low rectal cancer while others restrict it to “difficult pelvis” cases. The existing data come predominantly from nonrandomized trials with R0 resection varying from 88.2 to 100%

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and the grade 3 total mesorectal excision (TME) rate varying from 47.1 to 100% [1–3].

Some authors additionally describe technique-specific complications, such as urethral injury, which raises safety concerns [4, 5]. The results of the ongoing randomized COLOR III trial will probably shed light on most of these issues, but in the meantime additional data from selected patient groups are needed while the technique is being actively adopted in surgical clinics across the world [6].

Standard laparoscopic TME can give excellent results when performed by surgical teams with good experience [7, 8]. Thus, the need for a change may be evident only in selected difficult cases. The negative prognostic factors for rectal cancer surgery are well defined. These are high body mass index (BMI), male gender, bulky tumors, and previous chemoradiation [9, 10]. Besides the risk of achieving poor TME quality, surgery in patients with a “narrow pelvis” is associated with difficulty performing a double-stapling anastomosis, which eventually leads to a wider use of coloanal anastomoses, thus potentially compromising the functional outcomes.

The aim of this study was to investigate the role of taTME in patients with difficult pelvis.

Patients and methods

Data on T1-4aN0-2M0 rectal cancer patients with difficult pelvis who underwent transanal or laparoscopic TME during 2013–2017, were retrospectively reviewed from a prospectively maintained institutional database. “Difficult pelvis” was defined as a combination of male gender, high BMI (≥ 25 mg/m²), and previous chemoradiotherapy. Patients with synchronous and/or metachronous tumors, Eastern Cooperative Oncology Group (ECOG) status of >1 , and patients who underwent partial mesorectal excision were excluded. We identified patients who underwent laparoscopic or transanal TME and used case-matching of BMI, tumor height, and neoadjuvant treatment. Adjuvant chemotherapy was performed at the multidisciplinary team’s discretion. The study was approved by the local ethics committee and written informed consent was obtained from all patients.

Staging was based on pelvic magnetic resonance imaging (MRI) data. Other routine investigations included total colonoscopy, computed tomography, or ultrasound of the abdomen as well as chest radiographs.

The operative technique for both laparoscopic and transanal TME was described earlier [11]. Both a rigid operative rectoscope and a transanal flexible platform were used for the transanal stage of the surgery. The surgical team’s experience comprised more than 50 laparoscopic and 20 transanal TMEs prior to the initiation of this study.

Bowel preparation and perioperative antibiotic prophylaxis were used for all patients. TME quality was

assessed according to Quirke’s principles [12]. The TME quality was assessed by two independent pathologists, at least one of them among senior staff. In the case of discrepancies, the pathology report was consulted by a third specialist.

Statistical analysis and endpoints

The data were analyzed using SPSS 20.0 software (IBM, Armonk, NY, USA). Statistical significance was defined as $p < 0.05$. In the comparisons between the laparoscopic and transanal groups, the chi-square test was used for nominal and ordinal variables and the ANOVA test was used for continuous variables.

Primary endpoints were TME quality and rate of stapling anastomoses. Considering a small sample size in a highly selected patient group, we arbitrarily decided that $>15\%$ difference in grade 2–3 TME and $>15\%$ difference in the rate of stapling anastomoses would be considered sufficient evidence to further evaluate taTME in this patient group.

The other endpoint parameters were: circumferential resection margins, lymph node harvest, intraoperative blood loss, operative time, and postoperative complications (Clavien–Dindo classification; [13, 14]).

Results

We identified 147 patients who underwent lapTME and 66 patients who underwent taTME during the study period. Of these patients, 57 met the inclusion criteria for difficult pelvis, and 52 were included in this study after case-matching: 26 patients underwent lapTME and 26 underwent taTME. Patient characteristics are shown in Table 1.

The median BMI was around 29 kg/m² in both groups, all patients received neoadjuvant chemoradiotherapy. Patients in the laparoscopic group were younger ($p = 0.013$). There were no other significant differences between the groups.

Total mesorectal excision was performed on all patients. The procedure for one patient in each group was converted to open surgery (3.8% and 3.8%, $p = 1.0$); the procedure for two (7.7%) more patients in the taTME group was converted to the laparoscopic approach owing to difficulty in identifying the surgical plane from below. Stapling anastomosis was performed on 21 (84%) patients in the taTME group and on 17 (68%) patients in the laparoscopic group ($p = 0.2$). Hand-sewn coloanal anastomosis was performed for other patients.

The median operative time was 20 min longer in the taTME group, although the difference was not statistically significant (Table 2). One patient (3.8%) in the laparoscopic group died due to peritonitis, associated with an anastomotic leakage. There was no mortality in the taTME group. The anastomotic leakage rate was 1 (3.8%) vs. 4 (15.4%; $p = 0.35$) in the taTME and laparoscopic group, respectively. The

Table 1 Patient characteristics

	taTME, <i>n</i> =26	lapTME, <i>n</i> =26	<i>p</i>
BMI			
kg/m ² , median (min.–max.)	28.3 (25.4–36.4)	29.2 (25.2–35.1)	0.840
Age			
Years, median (min.–max.)	56.5 (25–68)	63.0 (38–78)	0.013
Tumor height			
cm, median (min.–max.)	7.0 (4–9)	7.0 (4–11)	0.370
0–5 cm, <i>n</i> (%)	5 (19.2)	5 (19.2)	1.0
cmrT			
T2, <i>n</i> (%)	0 (0)	4 (15.4)	0.111
T3, <i>n</i> (%)	18 (69.2)	16 (61.5)	
T4, <i>n</i> (%)	8 (30.8)	6 (23.1)	
cN+, <i>n</i> (%)	26 (100.0)	23 (88.5)	0.118

BMI/body mass index, taTME transanal mesorectal excision, lapTME laparoscopic mesorectal excision

Table 2 Operative outcome

	taTME, <i>n</i> =26	lapTME, <i>n</i> =26	<i>p</i>
Operative time			
min, median (min.–max.)	295 (205–420)	270 (170–435)	0.248
Blood loss			
ml, median (min.–max.)	50 (50–1000)	50 (50–1000)	0.210
Postoperative hospital stay			
Days, median (min.–max.)	7 (6–22)	7 (6–29)	0.618
Postoperative morbidity, Clavien–Dindo grade			
0, <i>n</i> (%)	17 (65.4)	20 (76.9)	0.403
I, <i>n</i> (%)	2 (7.7)	0	
II, <i>n</i> (%)	4 (15.4)	2 (7.7)	
IIIb, <i>n</i> (%)	3 (11.5)	2 (7.7)	
Iva, <i>n</i> (%)	0	1 (3.8)	
V, <i>n</i> (%)	0	1 (3.8)	

taTME transanal mesorectal excision, lapTME laparoscopic mesorectal excision

rate of grade III–IV complications was comparable (3 [11.5%] vs. 3 [11.5%], $p=1.0$) between the groups. The grade III–V complications in the taTME group were: one anastomotic leakage, one pelvic abscess, and one case of ileus, which required a diagnostic laparoscopy. All grade III–V complications in the laparoscopic group were associated with anastomotic leakage.

The circumferential resection margin (CRM) positivity rate was less in the taTME group (2 [7.7%] vs. 3 [11.5%]), but the difference did not reach statistical significance ($p=0.5$; Table 3). Both techniques allowed an adequate distal resection margin to be achieved, there was no difference in TME quality. The rate of grade 1 TME in the per-protocol analysis was 4 (17.4%) vs. 4 (16%) for taTME and lapTME, respectively ($p=1.0$).

The median follow-up was 28.2 months. During this time only one patient in the laparoscopic group experienced disease progression (liver metastases) and two patients in the taTME group also experi-

enced disease progression: one local relapse and one systemic recurrence.

Discussion

The benefits of taTME for patients with a difficult pelvis are often discussed in the literature [15, 16], although, to the best of our knowledge, only two studies used restricted specific inclusion criteria for difficult TME [5, 17] and only one of them was published in English. In this article, we reviewed our laparoscopic and transanal TME experience focusing on a highly selected patient group with multiple adverse surgical factors.

We decided to use very narrow inclusion criteria, thus sacrificing the potential group size in favor of better selection. Our groups were case-matched by BMI and tumor location. We did not match patients by age, because it would require reduction in sample size and age does not significantly affect the course of surgery.

Table 3 Pathological characteristics

	taTME, <i>n</i> =26	lapTME, <i>n</i> =26	<i>p</i>
TME quality			
Grade 1, <i>n</i> (%)	4 (15.4)	4 (15.4)	1.0
Grade 2–3, <i>n</i> (%)	22 (84.6)	22 (84.6)	
Resection margins			
CRM+ (<1 mm), <i>n</i> (%)	2 (7.7)	3 (11.5)	0.499
Distal resection margin			
mm, median (min.–max.)	30 (7.0–60.0)	25 (9.0–70.0)	0.695
pTNM			
pT0, <i>n</i> (%)	6 (23.1)	5 (19.2)	0.759
pT1–2, <i>n</i> (%)	7 (26.9)	6 (23.)	
pT3, <i>n</i> (%)	12 (46.2)	14 (53.9)	
pT4a, <i>n</i> (%)	1 (3.8)	1 (3.8)	
pN+, <i>n</i> (%)	13 (50.0)	10 (38.5)	0.288
Number of resected lymph nodes			
Median (min.–max.)	12 (5–60)	16 (2–54)	0.147

taTME transanal mesorectal excision, lapTME laparoscopic mesorectal excision

Similar inclusion criteria were used in a study by Rouanet P. et al., although BMI was not restricted [5]. Good TME quality was achieved in all patients, although the CRM positivity rate was higher than in our study (13% vs. 7.7%). The morbidity rate was similar to our group (30% vs. 34.6%).

Wu et al. used slightly different criteria for difficult pelvis. All patients in their study group had tumors located <5 cm from the anal verge and sex was not restricted. Neoadjuvant chemoradiotherapy was also mandatory. We used the type of surgical procedure rather than tumor location as an inclusion criterion. TME can be equally difficult regardless of tumor location if complete mobilization up to the pelvic floor is performed. Serious postoperative complications after taTME were observed more frequently than in our study (3 [11.5%] vs. 5 [25%], respectively). Specimen quality and CRM positivity rate were not reported in English [17].

The quality of TME was equal in our study groups, and thus we failed to achieve our predefined endpoint. However, we reached another important endpoint—there was a tendency toward a higher rate of stapling anastomoses. Although it did not reach a statistical significance, it may justify further evaluation in a larger patient group. Placing a linear stapler was technically impossible in some patients with a narrow pelvis, and thus we had to switch to hand-sewn coloanal anastomosis in order to pursue sphincter preservation, thus sacrificing some extra length of the rectal stump. Transanal TME allows one to place a double purse-string suture and avoid using a linear stapler, which significantly decreases the impact of pelvic size on the anastomotic technique. The level of anastomosis is an important predictor of anorectal dysfunction and avoiding an unnecessary switch to coloanal anastomosis may improve the functional

outcomes for patients with difficult pelvis undergoing taTME [18, 19].

An important finding in our study was that the morbidity rate was comparable after taTME in difficult cases and taTME and laparoscopic TME in the general population, based on the data presented by our team previously (34.6% vs. 27% and 26%, respectively; [11]). These results are also similar to those reported in the CLASSIC, COLOR II, and COREAN trials (37%, 40%, and 21.2%, respectively; [7, 20, 21]). Thus, taTME can be considered a safe alternative to the laparoscopic approach. We observed no technique-specific complications in the taTME group.

Although both high BMI and male sex are established risk factors for conversion to open surgery [22–24], the conversion rate in our study was similar to the results achieved in the general population [20]. In two cases, taTME was converted to the laparoscopic approach. In both cases the conversion was due to difficulty in identifying the surgical plane from below; both patients had previously undergone preoperative chemoradiation, which significantly altered the surgical layers. We conclude that taTME may not be suitable for all rectal cancer patients. Preoperative treatment may cause individual alterations in pelvic tissues, the optimal choice of surgical approach in some cases may be selected only intraoperatively, and the surgical plane must be pursued where it is more evident. The more techniques an individual surgeon has mastered and is ready to apply, the higher the chances to achieve good TME quality in a difficult patient.

Limitations

The main limitation of this study is the small sample size, which forced us to use arbitrarily chosen endpoints. We failed to observe any benefits of taTME in

terms of specimen quality or CRM positivity. We observed a tendency toward more stapling anastomoses in the taTME group, but it did not reach statistical significance. The sample size was sacrificed in favor of a very detailed patient selection and, while a randomized trial with such inclusion criteria seems unlikely, our study may serve as a model for future retrospective analyses of clinical registries. Our surgical team had a relatively low experience in minimally invasive colorectal surgery prior to the initiation of this study. This may explain the high conversion rate. The low initial experience may limit the generalizability of our results. However, our findings may be more important to surgical teams who have only started to perform laparoscopic colorectal surgery and consider the role of taTME in their practice.

Conclusion

In conclusion, in our study laparoscopic excision and taTME were equal in terms of specimen quality and morbidity in rectal cancer patients with a difficult pelvis. Both procedures seem to provide comparable outcomes. A tendency toward a higher rate of stapling anastomoses in the taTME group needs to be proven in a larger patient group and supported by objective measurements of the anorectal function of patients.

Compliance with ethical guidelines

Conflict of interest S.S. Gordeyev, K.E. Dzhumabaev, Z.Z. Mamedli, N.A. Kozlov, Y.E. Surayeva, M.Y. Fedyanin, and A.O. Rasulov declare that they have no competing interests.

Ethical standards All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1975 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

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