



Structured training curriculums for transanal total mesorectal excision in China: refinement is needed

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Background: Transanal total mesorectal excision (TaTME) is an alternative for mid-low rectal cancer. In China, this procedure has been performed in high-volume centers with structured training curriculums. The efficacy of the TaTME structured training curriculums in China is still unclear. This multicenter study aimed to explore the effectiveness of the structured training curriculums in China.

Methods: Seven high-volume centers in China participated in this study. The first 25 patients who underwent TaTME in each center were enrolled. In the cohort, patients were divided into 3 groups. The first 5 procedures (group 1) were performed under proctoring according to the requirement of structured training curriculums. The latter 20 cases without proctoring were split into 2 groups (10 cases in each group, groups 2 and 3) according to the order of operation date. The baseline characteristics, perioperative complications, and pathological outcomes were compared between groups 1 and 2, as well as between groups 2 and 3.

Results: Symptomatic anastomotic leakage (AL) occurred in 18.6% of the patients in group 2 compared with 5.7% in group 1 ($P_1=0.08$) and 5.0% in group 3 ($P_2=0.04$). Seven (11.3%) patients in group 2 developed defecation disorders whereas no patients had this complication in group 3 ($P_2=0.02$). Compared with group 2, the operative time was shorter (235 vs. 223 min, $P_2=0.40$), while the rates of intraoperative complications (15.7% vs. 5.7%, $P_2=0.10$), postoperative complications (31.3% vs. 25.7%, $P_2=0.06$), AL (20.0% vs. 8.6%, $P_2=0.04$), and positive distal resection margin (DRM) (7.5% vs. 2.9%, $P_2=0.27$) were lower in group 3.

Conclusions: The effect of the structured training curriculums was acceptable but needed further improvement. The prevalence of anastomosis-related complications and the quality control of specimens are still not optimal, and measures for refinement (for example, more cases under proctoring) are needed in the

curriculums.

Keywords: Rectal neoplasms; transanal total mesorectal excision (TaTME); structured training curriculums; short-term outcomes

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Introduction

Transanal total mesorectal excision (TaTME), consisting of rectal excision based on the concept of natural orifice transluminal surgery (NOTES), has roused extensive attention since its introduction in 2010 (1) and has been identified as a potential alternative for patients with mid and low rectal cancer (2,3). This so-called bottom-up approach could theoretically overcome some of the limitations of traditional TME, particularly by enhancing the visual surgical field exposure as well as distal mesorectal excision. While comparative studies have reported similar perioperative, pathological, and oncology results compared to open and laparoscopic surgery (4), obese patients, patients with low and ultra-low rectal carcinoma, and patients with a narrow pelvis are more likely to benefit from the TaTME technique (5,6). According to a worldwide registry, TaTME has been adopted by several colorectal surgeons and has been implemented in more than 30 countries (7). However, the lack of proficiency with the bottom-up approach and the long learning curve of the TaTME technique have been held responsible for some adverse events (8,9), which have led to severe criticism (10), the moratorium in Norway (11), as well as a “pause” recommended by the Association of Coloproctology of Great Britain and Ireland (12). Specialized curriculums have grown throughout the world in countries such as the Netherlands, the UK, Australia, and North America as early as 2014 (13-16), designed to facilitate the safe and widespread implementation of the TaTME technique. In view of the current questions, structured training and rigorous training programs are more necessary than ever.

The TaTME procedure was introduced and performed in China almost simultaneously with Western countries. However, the structured training curriculums were not set up in China until 2017. Since then, several high-volume centers were officially approved to implement the TaTME procedure. There is no objective assessment for the effectiveness of the structured training curriculums.

The overall assessment form is the predominant training outcome evaluation approach at present. In the structured training curriculums in North America and China (16,17), the recorders noted the events such as abdominal and transanal operative time, intraoperative difficulties as well as complications. The quality of rectal mesorectal specimen was evaluated by trainers. After completing the TaTME structured training curriculums, all the documents such as the cadaver surgical training self-assessments were openly shared so that other training centers could follow and learn from them. According to some poor results of the TaTME structured training curriculums, Tsai *et al.* (18) suggested that we should increase the cases that are performed under proctoring. Whereas the effectiveness of the structured training in China remains currently unclear, which raises our further concerns.

Thus, we aimed to evaluate the intraoperative complications and postoperative outcomes of the TaTME procedure at the beginning phase of implementation so as to explore the effectiveness of the structured training curriculums in China. We present the following article in accordance with the STROBE reporting checklist (available at <https://atm.amegroups.com/article/view/10.21037/atm-22-1693/rc>).

Methods

Centers and patients

Seven high-volume centers, having undergone the structured training curriculum set up by the Structured Training and Workshop Chinese TaTME (STWCT) group, participated in our study. We retrospectively collected the data of the first 25 consecutive TaTME cases in each center following STWCT training.

The inclusion criteria are as follows: (I) aged 18 to 75 years old; (II) rectal adenocarcinoma conformed by histopathological examination; (III) the lower margin of the tumor was ≤ 7 cm; (IV) the preoperative stage was $T_{0-3}N_{0-2}M_0$.

Patients were excluded based on the following exclusion

criteria: (I) prior history of other malignancy; (II) distant metastases at initial diagnosis; (III) emergency surgery for intestinal obstruction, bleeding, or perforation; (IV) patients with poor anal function and incontinence before operation (Wexner >10).

In the cohort, patients were divided into 3 groups. The first 5 procedures (group 1) were performed under proctoring according to the requirement of structured training curriculums. The latter 20 cases without proctoring were split into 2 groups (10 cases in groups 2 and 3, respectively) according to the order of operation date. The seven high-volume centers were informed and agreed with this study. The study was approved by ethics committee of Ruijin Hospital (approval number: 2019-82) and the need for informed consent was waived because of the retrospective nature of this study. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013).

Structured training curriculum

The STWCT is organized by the Chinese Society of Colorectal Surgery, Chinese Surgical Society, Chinese Medical Association. Requirements for trainees were as follows: (I) sufficient experience and proficiency in the laparoscopic TME technique, with more than 30 laparoscopic TME procedures performed as the first operator; (II) at least 5 cases of transanal endoscopic microsurgery (TEM) or transanal minimally invasive surgery (TAMIS) procedures. The prerequisites for proctors included: (I) more than 5 years of experience in laparoscopic surgery specialized in rectal cancer; (II) completion of at least 30 TaTME procedures; (III) experience with fresh frozen cadaver surgical training; (IV) publication of at least two academic research papers on TaTME per year.

The curriculum consists of three different elements: lecture sessions, watching live TaTME surgery, and TaTME cadaver surgical training. Following the completion of the cadaver surgical training, the first five real TaTME procedures needed to be performed under proctoring.

Surgical details

The surgical procedures followed the instructions of the Chinese consensus on transanal endoscopic surgery (19). The abdominal procedure and the transanal procedure were performed either sequentially by one team or simultaneously by two teams.

Outcomes

We recorded perioperative outcomes, pathological results, and short-term follow-up. Postoperative complications within 30 days were assessed according to the Clavien-Dindo classification (CD). Major postoperative complications were defined as CD \geq III. Grade B to C anastomotic leakage (AL) was considered as symptomatic AL according to the International Rectal Cancer Study Group guidelines modified by Tzu-Liang Chen and Fingerhut (20,21). The quality of the mesorectum was defined as complete, nearly complete, and incomplete according to Quirke *et al.* (22). A positive distal resection margin (DRM) was diagnosed by the presence of tumor cells within 1 mm from the DRM. A positive circumferential resection margin (CRM) was defined as the presence of tumor cells within 1 mm from the CRM. Defecation function was evaluated at 6 months after TaTME surgery (or the closure of the stoma if one had been performed). A Wexner score >10 indicated the existence of defecation dysfunction (23). Missing variables were marked as missing data.

Statistical analysis

Comparisons were performed either between groups 1 and 2 (P_1) or between groups 2 and 3 (P_2). A two-sided P value <0.05 was regarded as statistically significant. Continuous data were recorded as median [range], while categorical data were summarized as percentages. Pearson's χ^2 test or Fisher's exact test were used to analyze categorical values. Student's *t*-test was adopted for continuous variables. The Wilcoxon rank-sum test was used for continuous variables that were not normally distributed. Statistical analyses were carried out using SAS version 6.2.9200.

Results

Baseline characteristics and operative details of the study population

Patient baseline characteristics are listed in *Table 1*. The median follow-up duration was 21.5 (range, 0.3–38.2) months. No statistically significant difference was noted between groups 1 and 2 or between groups 2 and 3. Without proctoring, intraoperative problems occurred in 34/140 (24.3%) patients. The most common problem was smoke interference (24/140, 17.1%), followed by incorrect dissection plane (13/140, 9.3%), unstable air pressure (6/140, 4.3%), and purse-string failure (2/140, 1.4%). The

Table 1 Patient baseline characteristics

Baseline characteristics	Group 1 (n=35)	Group 2 (n=70)	Group 3 (n=70)	P ₁ value	P ₂ value
Age (years) ^a	61.0 [24.0–77.0]	58.5 [28.0–79.0]	60 [33.0–85.0]	0.23	0.16
Sex (M:F)	29:6	46:24	45:25	0.07	0.86
BMI (kg/m ²) ^a	23.7 [18.5–34.5]	23.3 [16.0–31.0]	24.1 [14.0–31.8]	0.47	0.15
ASA grade, n (%)				0.43	1.00
I–II	33 (94.3)	61 (87.1)	60 (85.7)		
III–IV	2 (5.7)	9 (12.9)	10 (14.3)		
Tumor distance from anal verge (cm) ^a	5 [3.0–6.8]	5 [3.0–8.0]	5 [2.0–9.0]	0.99	0.85
Neoadjuvant therapy, n (%)				0.54	0.85
No	24 (68.6)	52 (74.3)	51 (72.9)		
Yes	11 (31.4)	18 (25.7)	19 (27.1)		
History of lower abdominal or pelvic surgery, n (%)				0.87	1.00
No	34 (97.1)	66 (94.3)	66 (94.3)		
Yes	1 (2.9)	4 (5.7)	4 (5.7)		

^a, values are median [range]. P₁, comparison between groups 1 and 2; P₂, comparison between groups 2 and 3. BMI, body mass index; ASA, American Society of Anesthesiologists.

median operative time was 224 (range, 106–490) min. No statistically significant difference in the operative time was found between groups 1 and 2 or between groups 2 and 3 (215 *vs.* 235 min, P₁=0.13; 235 *vs.* 223 min, P₂=0.40). However, further analysis showed that the operative time in group 2 was 53 min longer than that in group 1 (290 *vs.* 237 min, P₁=0.21), and was 50 min longer than that in group 3 (290 *vs.* 240 min, P₂=0.23) when the abdominal and transanal procedures were performed sequentially. Intraoperative complications occurred in 16/175 (9.1%) patients, including severe bleeding (≥300 mL), perforation of the rectum, and urethral or vaginal injury. The intraoperative complication rate increased from 2.9% (1/35) in group 1 to 15.7% (11/70) in group 2 (P₁=0.10) and then declined to 5.7% (4/70) in group 3 (P₂=0.10) (Table 2).

Postoperative outcomes

The median postoperative hospital stay was 10 (range, 5–50) days. A prolonged postoperative hospital stay was observed in group 2 compared with group 1 (10 *vs.* 11, P₁=0.05). The mortality within 30 days after surgery was 0.6% for the whole cohort (1 patient in group 2 died from a heart attack). The rate of major postoperative complications increased from 2.9% (1/35) in group 1 to

10.0% (7/70) in group 2 (P₁=0.36) and then decreased to 1.4% (1/70) in group 3 (P₂=0.06). An ascending trend was found in the rate of symptomatic AL between groups 1 and 2 (5.7% *vs.* 18.6%, P₁=0.08). However, a statistically significant decrease in the symptomatic AL rate occurred in group 3 (18.6% *vs.* 7.1%, P₂=0.04). Seven (11.3%) patients in group 2 had defecation disorders while no patients in group 3 developed this complication (P₂=0.02). The prevalence of anastomotic stenosis did not differ between groups 2 and 3 (Table 3). Three (10.3%) patients in group 1, 6 (10.9%) patients in group 2, and 8 (15.1%) patients in group 3 did not undergo stoma closure until the censoring date due to anastomotic complications (leakage, stenosis).

Pathological outcomes

The quality of the mesorectum was deemed complete in 87.3% of patients, and positive CRM and DRM were found in 3.4% and 4.1% of the whole cohort, respectively. Better pathological results were observed in groups 1 and 3, with more complete mesorectum (96.7% *vs.* 80.0%, P₁=0.07; 80.0% *vs.* 90.0%, P₂=0.13) and less positive DRM (0.0% *vs.* 7.5%, P₁=0.24; 7.5% *vs.* 2.9%, P₂=0.27) than in group 2 (Table 4).

Table 2 Surgical details

Surgical details	Group 1 (n=35)	Group 2 (n=70)	Group 3 (n=70)	P ₁ value	P ₂ value
Intraoperative problems, n (%)	NA			NA	0.43
No		55 (78.6)	51 (72.9)		
Yes		15 (21.4)	19 (27.1)		
Incorrect dissection plane		6 (8.6)	7 (10.0)		
Smoke interference		11 (15.7)	13 (18.6)		
Unstable air pressure		0 (0.0)	6 (8.6)		
Purse-string failure		2 (2.6)	0 (0.0)		
Technique anastomosis, n (%)				0.76	0.70
Hand sewn	9 (25.7)	20 (28.6)	18 (25.7)		
Stapler	26 (74.3)	50 (71.4)	52 (74.3)		
Specimen removal, n (%)				0.58	1.00
Transanal	30 (85.7)	57 (81.4)	57 (81.4)		
Laparotomy	5 (14.3)	13 (18.6)	13 (18.6)		
Protective stoma, n (%)				0.61	0.69
No	6 (17.1)	15 (21.4)	17 (24.3)		
Yes	29 (83.9)	55 (78.6)	53 (75.7)		
Operative time (min) ^a					
Sequentially	215 [110–330]	235 [106–490]	223 [120–385]	0.13	0.40
Simultaneously	237 [180–330]	290 [150–490]	240 [150–365]	0.21	0.23
Simultaneously	195 [110–245]	210 [106–360]	201 [120–385]	0.09	0.71
Intraoperative complications, n (%)				0.10	0.10
No	34 (97.1)	59 (84.3)	66 (94.3)		
Yes	1 (2.9)	11 (15.7)	4 (5.7)		
Severe bleeding (≥300 mL)	0 (0.0)	5 (7.1)	2 (2.9)		
Perforation of rectum	0 (0.0)	2 (2.9)	0 (0.0)		
Urethral or vaginal injury	1 (2.9)	4 (5.7)	2 (2.9)		

^a, values are median [range]. P₁, comparison between groups 1 and 2; P₂, comparison between groups 2 and 3. NA, not available.

Discussion

This study showed that the effect of structured training curriculums for TaTME in China was acceptable but needed further improvement. The relatively worse pathological results and greater number of perioperative complications (especially anastomosis-related complications) in the first 10 cases without proctoring (group 2) suggested that some specific issues need to be refined in the Chinese structured training curriculums.

The prevalence of intraoperative problems in our study

cohort was consistent with the international TaTME registry (23.7%) (7). It is worth noting that due to the poor results in group 2, a relatively high overall prevalence of intraoperative complications was observed in our study (9.1%) compared to the registry (6.0%) (7). However, the intraoperative complication rate in group 3 sharply dropped, lower than other TaTME cohorts without structured training courses (8.0% by Perdawood *et al.*, 13.0% by Persiani *et al.*) (24,25). Veltcamp Helbach *et al.* (13) recently published their initial 10 TaTME procedure results after undergoing a structured training pathway and showed a low rate of intraoperative

Table 3 Short-term clinical outcomes

Short-term clinical outcomes	Group 1 (n=35)	Group 2 (n=70)	Group 3 (n=70)	P ₁ value	P ₂ value
Postoperative hospital stay (days) ^a	10 [5–25]	11 [6–40]	10 [5–50]	0.05	0.57
Postoperative complications, n (%)				0.36	0.06
None or minor (CD I–II)	34 (97.1)	63 (90.0)	69 (98.6)		
Major (CD ≥ III)	1 (2.9)	7 (10.0)	1 (1.4)		
Symptomatic AL, n (%)				0.08	0.04
No	33 (94.3)	57 (81.4)	65 (92.9)		
Yes	2 (5.7)	13 (18.6)	5 (7.1)		
Abdominal infection, n (%)		Missing =10	Missing =10	1.00	1.00
No	34 (97.1)	58 (96.7)	57 (95.0)		
Yes	1 (2.9)	2 (3.3)	3 (5.0)		
Defecation disorders, n (%)	Missing =6	Missing =8	Missing =12	0.40	0.02
No	28 (96.5)	55 (88.7)	58 (100.0)		
Yes	1 (3.5)	7 (11.3)	0 (0.0)		
Anastomotic stenosis, n (%)	Missing =7	Missing =11	Missing =16	0.29	0.64
No	27 (96.4)	51 (86.4)	45 (83.3)		
Yes	1 (3.6)	8 (13.6)	9 (16.7)		

^a, values are median [range]. P₁, comparison between groups 1 and 2; P₂, comparison between groups 2 and 3. CD, Clavien-Dindo classification.

complications (5.0%) with no urethral injury and 3 cases of visceral injury. Thus, structured training curriculums seem to allow surgeons to quickly overcome the technical challenges of the TaTME procedure. However, the relatively high incidence of intraoperative complications during the earliest phase of implementation should be recognized in the curriculums. The median operative time was comparable to other TaTME publications with the help of training curriculums (26,27). According to our study, operative time increased in group 2 and then decreased in group 3, especially when the abdominal and transanal procedures were sequentially performed by one surgical team.

Postoperative complication rates ranging from 21.8% to 46.3% and AL rates ranging from 10.5% to 17.9% have been reported (28–31). Our 5.1% rate of major postoperative complications was lower than that in other studies (8.6–10.9%) (31–33). This might indicate that structured training curriculums in China contribute to the acceptable prevalence and severity of postoperative complications, as well as AL. Compared to the 30–42% prevalence of defecation disorders reported by previous

studies (34–36), patients in our study obtained a better preservation of defecation function. However, the assessment time of this event was heterogeneous among these studies (3 months, half a year, or 1 year after surgery).

The rate of complete mesorectum was relatively low (especially in group 2) compared with recent reports (100.0% by Veltcamp Helbach *et al.*, 94.5% by Zeng *et al.*) (37,38). Moreover, the rate of positive DRM was higher than the 0.5–2.0% rates reported in other studies (39–41). All positive DRMs occurred in cases without proctoring (5 cases in group 2 and 2 cases in group 3). Several reasons might account for the poor pathological results in our study. On one hand, all 7 patients with a positive DRM had an ultra-low tumor (mean distance from the anal verge =3.3 cm; range, 2.5–5.0 cm). In our opinion, this might have increased the technical difficulty in obtaining a clear DRM and performing the purse-string procedure because the transanal platform provides limited manipulation space in these ultra-low cases. On the other hand, more than half of the patients were diagnosed with pT_{≥3} stage in our cohort. This might indicate that more aggressive tumor

Table 4 Pathological outcomes

Pathological outcomes	Group 1 (n=35)	Group 2 (n=70)	Group 3 (n=70)	P ₁ value	P ₂ value
Tumor stage, n (%)		Missing =2	Missing =2	0.16	0.15
pT _{≤2}	20 (57.1)	29 (42.7)	39 (57.3)		
pT _{≥3}	15 (42.9)	39 (57.3)	29 (42.7)		
Node stage, n (%)		Missing =9	Missing =3	0.76	0.91
pN0	26 (74.3)	41 (67.2)	45 (67.2)		
pN1	6 (17.1)	14 (23.0)	14 (20.9)		
pN2	3 (8.6)	6 (9.8)	8 (11.9)		
Quality of specimen, n (%)	Missing =5	Missing =10	Missing =10	0.07	0.13
Complete	29 (96.7)	48 (80.0)	54 (90.0)		
Nearly complete and incomplete	1 (3.3)	12 (20.0)	6 (10.0)		
Harvested lymph nodes ^a	13 [4–34]	14 [1–34] (Missing =1)	13 [1–37] (Missing =1)	0.79	0.70
Positive CRM, n (%)	Missing =5	Missing =11	Missing =10	0.55	1.00
No	30 (100.0)	57 (96.6)	57 (95.0)		
Yes	0 (0.0)	2 (3.4)	3 (5.0)		
Positive DRM, n (%)		Missing =3	Missing =1	0.24	0.27
No	35 (100.0)	62 (92.5)	67 (97.1)		
Yes	0 (0.0)	5 (7.5)	2 (2.9)		

^a, values are median [range]. P₁, comparison between groups 1 and 2; P₂, comparison between groups 2 and 3. CRM, circumferential resection margin; DRM, distal resection margin.

infiltration was an obstacle to achieving adequate TME. Epidemiological studies of rectal cancer seem to show a high prevalence of low tumors (less than 6 cm from the anal verge, >75%) and locally advanced tumors (>90%) in China (42,43). Thus, even with the structured training curriculums, there is a need for surgeons in China to select the appropriate patients in their initial series of TaTME cases. These results warrant our attention and improvement is necessary.

The fact that patients in group 2 presented worse postoperative outcomes and lower pathological quality should not be neglected. A questionnaire study was conducted among trainees in one of the 7 participant centers (Shanghai Renji Hospital) after the structured training curriculums (44). During the curriculums, trainees' surgical skills (e.g., finding the correct anatomical plane, purse-string stitching) were adequately practiced and evaluated by proctors during cadaver surgical training. Other issues more difficult to assess, such as nerve preserving surgery, anastomosis quality, and adequate tumor margin, might be improved only by

practice with real cases instead of cadaver surgical training, as suggested by the worse outcomes in group 2 and better outcomes in group 3 patients in our study. Thus, we suggest that 5 real patient cases under proctoring after the training curriculums might be inadequate. Indeed, Tsai *et al.* (18) recommended at least 10 cases under proctoring to further reduce the postoperative complication rate in the beginning phase of TaTME implementation. There is also room for improvement in terms of the pathological quality of specimens during the curriculums. We suggest that, in cadaver surgical training, “the targeted tumor” needs to be “located” at different levels (mid, low, and ultra-low) of the rectum.

Our study had several strengths. Firstly, to the best of our knowledge, this is the first multicenter study focused on the initial implementation phase of the structured training curriculums in China. Secondly, the perioperative outcomes and pathological results were comparable to the results of the 2 latest TaTME studies in China (45,46), but we further evaluated the effectiveness and limitations of the Chinese

TaTME structured training curriculums with a comparative approach between the 5 cases under proctoring and the first 10 cases without proctoring, and then between the first 10 and the next 10 cases. Thirdly, the 7 institutions which participated in our study were all high-volume centers with more than 300 TME cases per year, representing the highest level of rectal cancer treatment in China.

The limitations of this study should not be neglected. Firstly, the level of evidence was limited by the retrospective nature of our study and the potential selection bias at the beginning of TaTME implementation. Secondly, the sample size of this study was small, with only 25 cases per center. Thirdly, the follow-up duration was short, and the long-term oncological outcomes need to be investigated.

Conclusions

In conclusion, the perioperative outcomes of the first 25 consecutive cases undergoing TaTME in each center indicated that the effect of the structured training curriculums was acceptable but needed further improvement. The relative high rate of postoperative complications as well as worse pathological results in the first 10 cases without proctoring suggest that some specific issues should be refined in the curriculums.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The seven high-volume centers were informed and agreed with this study. The study was approved by ethics committee of Ruijin Hospital (approval number: 2019-82) and the need for informed consent was waived because of the retrospective nature of this study.

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