

Learning Curve of Robotic Total Mesorectal Excision versus Transanal Total Mesorectal Excision - A Single-Center Study

Martin Karamanliev^{1*}, Tsanko Yotsov^{1,2}, Dobromir Dimitrov¹

¹University Hospital Georgi Stranski, Department of Surgical Oncology, Faculty of Medicine Medical University – Pleven, Pleven, Bulgaria

²University of Ruse, Department of Health care, UMHAT Medica Ruse, Bulgaria

*Corresponding author:

Martin Petrov Karamanliev, MD
59 Panayot Volov str. B ap. 16,
5800, Pleven, Bulgaria
Phone: +359894242247
E-mail: martinkaramanliev@gmail.com
Martin Karamanliev - <https://orcid.org/0000-0001-5166-0752>
Tsanko Yotsov - <https://orcid.org/0000-0003-3313-1093>
Dobromir Dimitrov - <https://orcid.org/0000-0003-3308-5736>

ABSTRACT

Introduction: Rectal cancer treatment has changed over the last several decades. Total mesorectal excision (TME) has proven to be the gold standard in rectal cancer surgery. Transanal total mesorectal excision (TaTME) and robotic total mesorectal excision (RoTME) for low and mid rectal cancer are implemented to overcome some of the difficulties of the laparoscopic approach. The aim of this study is to show a single-center experience in the learning curves of both RoTME and TaTME.

Material and methods: A single-center prospective study comparing the first 17 consecutive RoTME cases from January 2016 to May 2019 to the first 16 consecutive cases of TaTME from July 2019 to June 2021 was conducted. The difference in the time periods is due to the later implementation of TaTME in the center. All procedures were performed by a single team.

Results: A total of 33 patients were included in the study – 17 RoTME patients and 16 TaTME patients. The groups were homogeneously distributed in terms of patients' characteristics and stage. Comparing the two groups, no statistically significant differences between them were found in terms of complication rates ($p=0.692$), positive circumferential resection margins rates ($p=0.000$), frequency of anastomotic leak rates ($p=0.596$), time from completion of radiotherapy to surgery ($p=0.229$) and time from surgery to ileostomy closure ($p=0.880$). A statistically significant shorter operative time was found in the TaTME group ($p=0.008$).

Conclusion: The learning curve should be considered in all procedures. A structured training pathway for TaTME and RoTME is essential. No differences between RoTME and TaTME in the learning curve were observed in our center.

Key words: TaTME, RoTME, rectal cancer, learning curve

Abbreviations:

TaTME – transanal total mesorectal excision;
RoTME – robotic total mesorectal excision
LaTME – laparoscopic total mesorectal excision;
TME – total mesorectal excision;
CT – computer tomography;
MRI – magnetic resonance imaging.

INTRODUCTION

Rectal cancer treatment has changed over the last several decades. Total mesorectal excision (TME) has proven to be the gold standard in rectal cancer surgery (1,2). The first study to show that laparoscopic total mesorectal excision (LaTME) was oncologically equivalent to open TME was the COLOR II study. The design was a noninferiority, phase 3 randomized prospective clinical trial conducted in 30 centers in 8 countries (Belgium, Canada, Denmark, Germany,

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the Netherlands, Spain, South Korea and Sweden). From January 20, 2004 to May 4, 2010, 1044 patients meeting the inclusion criteria were included with a 2:1 randomization to the laparoscopic arm, with comprehensive preoperative evaluation centralized, including patient imaging referrals. Patients in the laparoscopic arm had significantly lower blood loss, shorter time to recovery of bowel function, shorter hospital stay, and longer operative time. Specimen quality of completeness and positive CRMs did not differ significantly between the two groups, as did morbidity and mortality up to 1 month after the intervention. The conversion rate in the laparoscopic group was 17% (3). Due to the high rates of conversion to open surgery in LaTME, robotic surgery was investigated to show a possible reduction due to the advantages of better visualization, manipulation and maneuverability of the instruments. The ROLARR randomized trial was designed to demonstrate a 50% reduction in conversion rates comparing RoTME and LaTME. 471 patients from 29 centers in 10 countries were enrolled. Randomization was 1:1. The rates of oncological safety, complications and mortality did not differ significantly between the two groups. However, the conversion rate in the RoTME arm was 8.1%, and in the LaTME arm – 12.2%, the study failed to demonstrate the desired 50% reduction (4). A systematic review of randomized clinical trials by Jones et al. comparing RoTME and LaTME (including the ROLARR study) showed a statistically significant reduction in the rate of conversions ($P = 0.00001$), as well as a reduction in time to recovery of the GIT passage and hospital stay (5). Although the robotic learning curve may be shorter than laparoscopy for some skills and easier procedures (i.e. right hemicolectomy) (6,7), learning curves for laparoscopic and robotic rectal resections are similar, with a mastery phase around 32-40th case (8).

Transanal total mesorectal excision (TaTME) was developed with the idea to overcome some technical difficulties in pelvic dissection for low and mid rectal cancer. The first large prospective single-center study was published by Lacy et al. and included 140 consecutive patients. Ninety-three patients (66.4%) received neoadjuvant therapy. The rate of complete pathological response was 15 patients (10.7%). Authors report 0% intraoperative complications and 0% conversions. The macroscopic quality assessment of the specimen is "complete" in 97.1%, "near-complete" in 2.1% and "incomplete" in 0.7%. Thirty-day morbidity showed mild complications (Clavien-Dindo I and II) in 24.2% and severe (Clavien-Dindo III and IV) in 10%. No 30-day postoperative mortality was reported. Patient

follow-up was 15 months, with a 2.3% local recurrence rate and a 7.6% systemic recurrence rate (9). The first 80 cases from Amsterdam, Netherlands also showed good preliminary results. The cohort included patients with T1-T3 tumors without distant metastases. The macroscopic quality assessment of the specimen was "complete" in 88%, "near-complete" in 9% and "incomplete" in 3%. Average operative time – 204 min. Intraoperative complications were reported in 5 patients. Postoperative morbidity was reported in 39% of patients, of which 12% were severe complications (Clavien-Dindo III-V). A positive CRM was reported in 2 patients (10). Safe implementation of TaTME is essential as it is a difficult procedure to master that comes with new complications (urethral injury) (11–14). A national moratorium for TaTME has been declared in Norway after early high local recurrence rates (15). TaTME shows promising results after the learning curve is passed (13,16). The learning curve of TaTME seems to be longer than other techniques with around 70 cases for operative time reduction, 60 cases for major complications reduction and 25-30 cases for anastomotic leak reduction (17,18). The aim of this study is to show a single-center experience in the learning curves of both RoTME and TaTME.

MATERIAL AND METHOD

A single-center prospective study comparing the first 17 consecutive RoTME cases from January 2016 to May 2019 to the first 16 consecutive cases of TaTME from July 2019 to June 2021 was conducted. The difference in the time periods is due to the later implementation of TaTME in the center. All procedures were performed by a single team. The inclusion criteria were: histologically proven invasive carcinoma of the rectum, ASA Class I – III, signed informed consent for inclusion in the study, staging with endorectal ultrasound or MRI and whole-body contrast-enhanced CT. The exclusion criteria were: contraindications for general anesthesia, recurrent rectal cancer and emergency surgery. The ERAS protocols were followed for all patients. Mechanical bowel preparation was done on the day before surgery and preoperative antibiotic prophylaxis with II-generation Cephalosporin and Metronidazole was done i.v. 60 minutes prior to skin incision. TaTME was done by a two-team (Cecil) approach and single-stapled colorectal anastomosis with a 32 mm EEA circular stapler was performed. RoTME was done in a standard manner and double-stapled colorectal anastomosis with 32 mm EEA circular stapler was performed. In ultralow rectal tumors, a

hand-sewn coloanal anastomosis was done in both groups. The decision to perform a protective loop ileostomy was taken individually based on age, sex, neoadjuvant therapy, smoking, total serum protein and albumin levels, the distance of the anastomosis from the anal verge, and after risk assessment with an anastomotic leak calculator (19). Data analysis was performed with IBM SPSS statistics 26.0 statistical software. $p < 0.05$ (95% confidence interval) was accepted as a level of significance at which the null hypothesis is rejected.

RESULTS

A total of 33 patients were included in the study – 17 RoTME patients and 16 TaTME patients. Patients' characteristics and outcomes are shown in *table 1*. Homogeneity between the two groups was assessed by Levene's test. TaTME and RoTME groups were homogeneously distributed by gender ($p=0.131$), age ($p=0.975$), ASA score ($p=0.877$), BMI ($p=0.052$), T stage ($p=0.877$), N stage ($p=0.000$), M stage ($p=0.000$), neoadjuvant therapy ($p=0.166$) and tumor distance from anal verge ($p=0.638$). The groups were inhomogeneously distributed in terms of protective loop ileostomy creation ($p=0.004$).

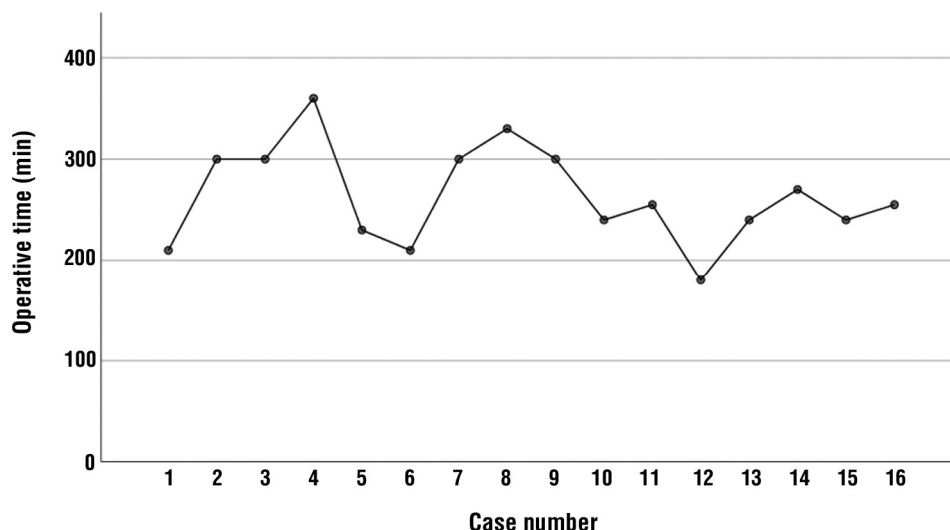
The mean operative time in the TaTME group was 263.75 min (range 180 to 360 min). The mean operative time for the first 5 cases was 280 min, and for the last 5 cases – 237 min. A tendency to decrease the operative time is observed. However, the ANOVA variation analysis, does not show statistical significance ($df=3$, $p=0.438$). *Fig. 1* shows the change in operative time in the group. Strategic conversions were reported in two patients. An intraoperative complication, proximal purse-string failure, occurred in one patient (6.25%). A second continuous suture was placed transanally over the first with 2/0 propylene, a thorough wash-out with antiseptic solutions was performed, and the operation proceeded in a standard manner without further intra- or postoperative complications. No other intraoperative complications were observed in the TaTME group. In one patient (6.25%) anastomotic leak was reported. A small pelvic abscess was seen on CT. The patient had a protective ileostomy and the abscess was drained under general anesthesia transanally (Clavien-Dindo III). No other postoperative complications were observed until the 30th postoperative day. Late complications included a ventral hernia in the area of ileostomy repair in one patient who underwent open mesh hernioplasty.

The mean operative time in the RoTME group was 332.35 min (range 180 to 480 min). In terms of the

Table 1 - Patients' characteristics and outcomes in TaTME and RoTME groups

	TaTME	RoTME
Mean age (years)	69.94	66.53
Men/women. n (%)	11 (68.75%) / 5 (31.25%)	9 (52.94%) / 8 (47.06%)
Mean BMI	26.98	28.35
pT stage		
T0	2 (12.5%)	1 (5.88%)
T1	1 (6.25%)	0
T2	9 (56.25%)	8 (47.06%)
T3	3 (18.75%)	7 (41.18%)
T4	0	0
pN stage		
N0	16 (100%)	14 (82.35%)
N1	0	2 (11.77%)
N2	0	1 (5.88%)
N3	0	0
pM stage		
M0	16 (100%)	17 (100%)
M1	0	0
Neoadjuvant treatment. n (%)	13 (81.25%)	12 (70.59%)
Complete pathologic response. n (%)	2 (15.38%)	1 (8.33%)
Distant from anal verge		
< 5 cm. n (%)	5 (31.25%)	3 (17.65%)
5-10 cm. n (%)	10 (62.5%)	12 (70.59%)
> 10 cm. n (%)	1 (6.25%)	2 (11.76%)
Mean operative time (min)	263.75	332.35
Conversion	2 (12.5%)	3 (17.65%)
Possitive CRM	0	0
Possitive distal margin. n (%)	1 (6.25%)	1 (5.88%)
Loop ileostomy. n (%)	12 (75%)	8 (47.06%)
Blood loss 0-50 ml. n (%)	16 (100%)	16 (94.12%)
Blood loss 50-100 ml n (%)	0	0
Blood loss > 100 ml. n (%)	0	1 (5.88%)
Quality assessment of the specimen		
complete. n (%)	14 (87.5%)	15 (88.24%)
near-complete. n (%)	2 (12.5%)	2 (11.76%)
incomplete. n (%)	0	0
Anastomosis		
Hand-sewn (coloanal). n (%)	6 (37.5%)	1 (5.88%)
Stapled (colorectal). n (%)	8 (50%)	14 (82.35%)
No anastomosis. n (%)	2 (12.5%)	2 (11.76%)
Anastomotic leak. n (%)	1 (6.25%)	2 (11.76%)
Time to ileostomy closure (days)	92.44	129.5
Time from neoadjuvant therapy end to surgery (days)	64.1	56.3

improvement of operative time with progress in the learning curve, the average operative time for the first 5 cases was 350 min, and for the last 5 cases - 276 min. A tendency to decrease the operative time is observed. However, the ANOVA variation analysis, does not show statistical significance ($df=1$, $p=0.458$). *Fig. 2* shows the change in operative time in the group. Strategic conversions were reported in three patients. An intraoperative complication, bleeding from presacral vessels, occurred in one patient (5.88%). Meticulous hemostasis was performed and an absorbable hemostat was placed. No

Figure 1 - Change in operative time in TaTME group

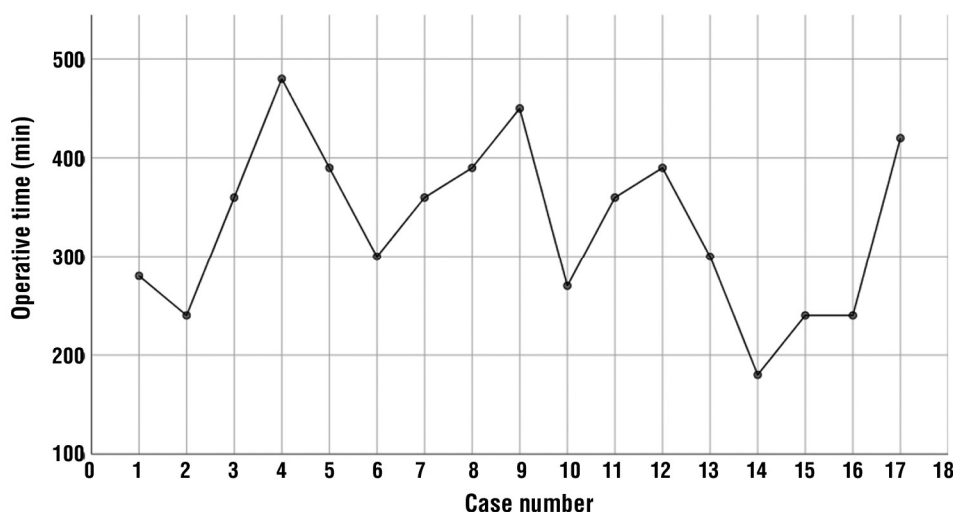
blood transfusion was required in the postoperative period. No other intraoperative complications were observed. Anastomotic leak was reported in two patients (men). A small pelvis abscess a rupture of the colorectal anastomosis of more than 50% was seen on CT. Reanastomosis was performed under general anesthesia (Clavien-Dindo III). In the second patient, a complete rupture of the coloanal anastomosis with retraction of the proximal colon was found, without CT evidence of an abscess. Reanastomosis was performed under general anesthesia (Clavien-Dindo III). Both patients had a protective ileostomy. Both patients had undergone neoadjuvant chemoradiotherapy. No other postoperative complications were observed until the 30th postoperative day.

Comparing the two groups, no statistically significant

differences between them were found in terms of complication rates ($p=0.692$), positive circumferential resection margins rates ($p=0.000$), frequency of anastomotic leak rates ($p=0.596$), time from completion of radiotherapy to surgery ($p=0.229$) and time from surgery to ileostomy closure ($p=0.880$). A statistically significant shorter operative time was found in the TaTME group ($p=0.008$).

DISCUSSION

Minimally invasive surgery has already proven its equal oncological safety compared to open TME and advantages in the treatment of rectal carcinoma in terms of lower morbidity, shorter hospital stay, faster patient recovery, less trauma and less blood loss

Figure 2 - Change in operative time in RoTME group

(3,20–23). Disadvantages of LaTME in low and mid rectal tumors are associated with a high conversion rate and difficult mobilization of the horizontal part of the rectum. The advantages in this part of the robotic TME and transanal TME are already beginning to be outlined (5,12,24,25). Transanal TME aims for better visualization and manipulation of the horizontal part of the rectum with a bottom-up view and direct visualization of the terminal nerve endings of the plexus hypogastricus inferior and plexus prostaticus, thus their preservation. This should theoretically lead to lower rates of pelvic incontinence and impotence. Better visualization also aims to achieve better specimen quality leading to better oncological safety.

The strategic conversions are carried out in the initial stages of the intervention in the presence of factors that cause difficult dissection or the need for tactile feedback. These conversions have not been reported to have a higher complication rate than patients without conversion or those with open surgery. In late conversions usually occur after a complication (bleeding, bowel perforation, ureteral lesion, bladder, etc.) or dissection in an unclear surgical plane. Late conversions were associated with a significantly higher complication rate. Some studies divide conversions into < 30 minutes from the start of surgery and > 30 minutes, with the two groups having different levels of complications (26). All studies show a lower rate of conversions and complications in high-volume centers. The conversion rate drops dramatically with experience. Experienced teams show conversion rates below 8%, while some studies show conversion rates above 25% (27).

In this study, a statistically significant shorter operative time was found in the TaTME compared to the RoTME group ($p=0.008$). Two obvious reasons having a direct impact on operative time are present: 1) two teams are working simultaneously in TaTME vs one team and docking in RoTME; 2) the team was more experienced in rectal cancer treatment in TaTME period due to the later implementation of TaTME in the center.

The learning curves of TaTME and RoTME are of specific scientific interest nowadays. In general, they are close to similar or TaTME learning curve is longer (7,16,17,28). Studies suggest the rate of anastomotic leakage and urological lesions could be higher in TaTME, but the rate of conversion could be higher in RoTME (29). Structured training pathway, including specialization, long training periods, accumulation of experience and proctoring, is important in shortening the learning curve for difficult procedures (7,30).

CONCLUSION

The learning curve should be considered in all procedures. A structured training pathway for TaTME and RoTME is essential. No differences between robTME and TaTME in the learning curve were observed in our center.

Conflicts of interest and source of funding

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Ethical Approval

This study was approved by the Ethics Committee of Medical University – Pleven, No 552/04.07.2019.

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