

Quality of Life after Transanal Total Mesorectal Excision - A Single-Center Study

Martin Karamanliev*

University Hospital Georgi Stranski, Department of surgical oncology, Faculty of Medicine, Medical University Pleven, Bulgaria

***Corresponding author:**

Martin Petrov Karamanliev, M.D.
59 Panayot Volov street, B ap. 16
5800, Pleven, Bulgaria
Phone: +359894242247
E-mail: martinkaramanliev@gmail.com
<https://orcid.org/0000-0001-5166-0752>

ABSTRACT

Introduction: Transanal total mesorectal excision (TaTME) has been used as a surgical technique for rectal cancer treatment for over a decade now. The bottom-up dissection provides a better view of the pelvic sensory nerve fibers, which theoretically could lead to better nerve preservation, hence better functional outcomes. Nevertheless, concerns about worsening of the functional results due to low anastomosis and sphincter damage caused by the platform have been raised. There is no clear data showing advantage or disadvantage of TaTME compared to robotic total mesorectal excision (rTME) or laparoscopic TME in terms of functional results. This study aims to present single-center data on quality of life (QoL) after TaTME.

Material and Methods: A single-center prospective study on the quality of life after the first 16 consecutive cases of TaTME from July 2019 to June 2021 was conducted. Quality of life (QoL) was assessed with a questionnaire. A total of 13 patients were analyzed by EuroQoL-5D (EQ-5D), EORTC QLQ-C30, EORTC QLQ-CR29, IPSS, LARS and Vaizey scores 1–9. Quality of Life data collection was done according to the following algorithm: (a) In patients without a stoma – preoperatively, at 3, 6, and 12 months, and annually thereafter; (b) in patients with a stoma – preoperatively, at 3 months postoperatively (if there was no stoma reversal), and after stoma reversal at 3, 6, and 12 months, and annually thereafter. All procedures were performed by the same team.

Results: A total of 13 patients completed the questionnaires preoperatively and at least once postoperatively. Statistically significant improvement was found in the following parameters postoperatively compared with preoperative levels: EuroQoL-5D pain/discomfort ($p=0.014$); physical functioning ($p=0.046$), financial problems ($p=0.025$); global health in QLQ-C30 ($p=0.001$), degree of anxiety/depression in QLQ-CR29 ($p=0.020$), specific quality of life in the IPSS questionnaire ($p=0.011$). No statistical differences were found in: the visual analogue self-reported health scale in EuroQoL-5D ($p=0.114$); social functioning in the QLQ-C30 ($p=0.705$); fecal incontinence for patients without a stoma in QLQ-CR29 ($p=0.317$); degree of LARS ($p=0.763$); Vaziey score ($p=0.782$).

Conclusion: quality of life after TaTME seems promising, large, well-structured trials in the scientific area are needed.

Key words: TaTME, quality of life, rectal cancer

Abbreviations:

TaTME: transanal total mesorectal excision;
TME: total mesorectal excision;
QoL: quality of life;
LARS: Low anterior resection syndrome;
IPSS: International prostate symptom score;
CT: computer tomography;
MRI: magnetic resonance imaging;
SPSS: statistical product and service solutions.

INTRODUCTION

Transanal total mesorectal excision (TaTME) has been used as a surgical

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technique for rectal cancer treatment for over a decade now. It was developed to overcome technical difficulties in pelvic dissection for low- and mid-rectal cancer, thus leading to a better quality specimens and oncologic results. The bottom-up dissection provides a better view of the pelvic sensory nerve fibers which theoretically could lead to better nerve preservation and better functional outcomes. Nevertheless, concerns about worsening of the functional results due to low anastomosis and sphincter damage caused by the platform have been raised.

TaTME shows promising results after the learning curve is passed (1,2). The learning curve of TaTME seems to be steeper than other techniques with around 60 cases for major complications reduction, 70 cases for operative time reduction, and 25-30 cases for anastomotic leak reduction (3,4). Data show no major difference between TaTME and robotic total mesorectal excision (rTME) (5).

A wide range of data is available on the quality of life (QoL) after TaTME. Initial studies showed worse short- and mid-term functional results, but most of the subsequent studies showed comparable results between the different minimally invasive TME procedures (6-9). There is no clear data that prove advantage or disadvantage of TaTME over rTME or laparoscopic TME in terms of functional results (6,10-12). This study aims to present single-center data on QoL after TaTME.

MATERIAL AND METHOD

A single-center prospective study on the quality of life after the first 16 consecutive cases of TaTME from July 2019 to June 2021 was conducted. QoL was assessed with a questionnaire. A total of 13 patients were analysed by EuroQol-5D (EQ-5D), EORTC QLQ-C30, EORTC QLQ-CR29, IPSS, LARS and Vaizey scores (13-21). Quality of Life data collection was done according to the following algorithm: (a) In patients without a stoma – preoperatively, at 3, 6, and 12 months and annually thereafter; (b) in patients with a stoma – preoperatively, at 3 months postoperatively (if there was no stoma reversal), and after stoma reversal at 3, 6, and 12 months, and annually thereafter.

All procedures were performed by the same team. The inclusion criteria were: signed informed consent for inclusion in the study, histologically proven invasive carcinoma of the middle or lower rectum, staging with endorectal ultrasound or MRI and whole-body contrast-enhanced CT, and ASA Class I – III. 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. The preoperative work-up included a complete blood count, biochemical assessment, carcino-embryonic antigen (CEA), colonoscopy, pelvic MRI and whole-body contrast-enhanced CT. TaTME was done by a two-team (Cecil) approach and single-stapled colo-rectal anastomosis with a 32 mm EEA circular stapler was performed. Patients in stage IIB or higher, received neoadjuvant treatment. The assessment for stoma formation was based on age, sex, neoadjuvant therapy, smoking habits, total serum protein and albumin levels, the distance of the anastomosis from the anal verge. Risk assessment was also performed using an anastomotic leak calculator (22). 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. For the analysis of the change of QoL in every patient, data were compared preoperatively with the last completed questionnaire postoperatively.

RESULTS

A total of 16 patients underwent surgery in the study period, with a mean age of 69,9 years and a mean BMI of 26.98. Most of the patients (81.25%) had undergone neoadjuvant treatment (*table 1*). A total of 13 patients completed the questionnaires preoperatively and at least once postoperatively (two patients filled the preoperative questionnaire and were lost to follow-up after). The median follow-up was 14 months (range 3 to 36 months). It should be noted that these patients had their surgery at the beginning of the learning curve of the team, which could also affect the functional results.

Data from the VAS on patient self-reported health and pain levels in the EuroQol-5D, physical and social functioning, financial problems and global health in the QLQ-C30, fecal incontinence and depression levels in the QLQ-CR29, IPSS score, LARS levels and Vaizey score were tested for normal distribution of the data with the Kolmogorov-Smirnov and Shapiro-Wilk tests. All data were not normally distributed (*table 2*). Thus, non-parametric tests for comparing the scores before and after the procedure were used - Friedman test and Kendall's W test.

When analyzing VAS data from the EuroQol-5D questionnaire the preoperative score was 64.85 ± 10.86

Table 1 - Patients' characteristics and outcomes

	TaTME
Mean age (years)	69,94
Men/women, n (%)	11 (68,75%) / 5 (31,25%)
Mean BMI	26,98
pT stage	
T0	2 (12,5%)
T1	1 (6,25%)
T2	9 (56,25%)
T3	3 (18,75%)
T4	0
pN stage	
N0	16 (100%)
N1	0
N2	0
N3	0
pM stage	
M0	16 (100%)
M1	0
Neoadjuvant treatment, n (%)	13 (81,25%)
Complete pathologic response, n (%)	2 (15,38%)
Distant from anal verge	
< 5 cm, n (%)	5 (31,25%)
5-10 cm, n (%)	10 (62,5%)
> 10 cm, n (%)	1 (6,25%)
Positive CRM	0
Positive distal margin, n (%)	1 (6,25%)
Loop ileostomy, n (%)	12 (75%)
Blood loss 0-50 ml, n (%)	16 (100%)
Blood loss 50-100 ml n (%)	0
Blood loss > 100 ml, n (%)	0
Quality assessment of the specimen	
complete, n (%)	14 (87,5%)
near-complete, n (%)	2 (12,5%)
incomplete, n (%)	0

(mean±SD) and the postoperative was 86.23±5.49 (mean±SD).

In the pain/discomfort section of the EuroQoL-5D questionnaire, three items are possible: 1-No pain/

discomfort, 2-Moderate pain/discomfort, and 3-High pain/discomfort. For the analysis, data were compared between the preoperatively completed questionnaire and the last postoperatively completed one. The mean preoperative score was 1.73 and the postoperative was 1.27.

The Physical functioning scores range from 0 (worst possible) to 100 (best possible). There are five items (questions) with three degrees of freedom. The mean preoperatively was 89.77±15.82 (mean±SD) and post-operatively 97.46±5.03 (mean±SD).

The Scores for social functioning range from 0 (worst possible) to 100 (best possible). There are two items (questions) with three degrees of freedom. The mean preoperatively was 69.38±9.05 (mean±SD) and postoperatively was 73.15±12.62 (mean±SD).

The scores for financial problems related to the treatment and the disease range from 0 (worst possible) to 100 (best possible). The item (question) is one and has three degrees of freedom. The mean pre-operatively was 25.38±14.47 (mean±SD) and post-operatively was 12.69±16.71 (mean±SD).

The Global health status scores range from 0 (worst possible) to 100 (best possible). There are two items (questions) with six degrees of freedom. The mean pre-operatively was 64.15±8.7 (mean±SD) and post-operatively was 82.08±8.29 (mean±SD).

The Fecal incontinence scores for patients without a stoma range from 0 (complete incontinence) to 100 (best possible continence). There are six items (questions) with four degrees of freedom. The mean preoperatively was 15.38±13.87 (mean±SD) and post-operatively was 14.08±15.73 (mean±SD).

The anxiety/depression scores range from 0 (worst possible state) to 100 (best possible state). There are two items (questions) with four degrees of freedom.

Table 2 - Tests of Normality

	Kolmogorov-Smirnova			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
VAS	0,326	26	0	0,643	26	0
PAIN	0,436	26	0	0,583	26	0
PhysFunc	0,354	26	0	0,585	26	0
SocialFunc	0,344	26	0	0,799	26	0
FinancialProb	0,376	26	0	0,63	26	0
GlobalHealthC30	0,338	26	0	0,632	26	0
FIC2R9	0,229	26	0,001	0,863	26	0,003
AnxC2R9	0,222	26	0,002	0,856	26	0,002
IPSS	0,209	26	0,005	0,872	26	0,004
LARS	0,159	26	0,089	0,902	26	0,017
Vaizey	0,227	26	0,001	0,777	26	0

a. Lilliefors Significance Correction

The mean preoperatively was 35.85 ± 24.33 (mean $\pm$ SD) and postoperatively was 19.15 ± 24.24 (mean $\pm$ SD).

The LARS questionnaire consists of five questions with three or four degrees of freedom and gives a total score between 0 (no LARS) and 42 (major/high LARS). The division into subgroups is: 0-20 points - no LARS, 21-29 points - low LARS, 30-42 points - high LARS. The mean preoperatively was 15.46 ± 14.08 (mean $\pm$ SD) and postoperatively was 16.31 ± 16.04 (mean $\pm$ SD). Preoperatively, 7 patients were no LARS, 4 patients with minor LARS, and 2 patients with major LARS. Postoperatively, 8 patients were no LARS, 2 patients with minor LARS, and 3 patients with major LARS.

The Vaizey questionnaire contains seven questions (4 questions with five degrees of freedom and 3 questions with two degrees of freedom) and gives a total of between 0 (perfect continence) and 24 points (complete incontinence). The mean preoperatively was 2.62 ± 3.33 (mean $\pm$ SD) and postoperatively was 1.85 ± 1.82 (mean $\pm$ SD).

The IPSS questionnaire contains seven questions with six degrees of freedom to answer about specific symptoms and overall quality of life related to urination. The IPSS score ranges from 0 (asymptomatic) to 35 (severely symptomatic). 1-7: mild grade, 8-19: moderate grade and 20-35: severe grade. The mean preoperatively was 2.00 ± 1.22 (mean $\pm$ SD) and post-operatively 0.69 ± 0.85 (mean $\pm$ SD).

Statistically significant improvement in the following parameters postoperatively compared with preoperative levels was found: EuroQol-5D pain/discomfort ($p=0.014$); physical functioning ($p=0.046$), financial problems ($p=0.025$); global health in QLQ-C30 ($p=0.001$), degree of anxiety/depression in QLQ-CR29 ($p=0.020$), specific quality of life in the IPSS questionnaire ($p=0.011$).

No statistical differences were found in: visual analogue self-reported health scale in EuroQol-5D ($p=0.114$); social functioning in the QLQ-C30 ($p=0.705$); fecal incontinence for patients without a stoma in QLQ-CR29 ($p=0.317$); degree of LARS ($p=0.763$); Vaziey score ($p=0.782$)(*table 3*).

DISCUSSION

Quality of life after TaTME is a widely discussed and important topic as the procedure is a tool to help with difficult and low rectal tumors. These patients usually have worse QoL and higher fecal and urinary incontinence rates. Low anastomosis and sphincter trauma from the platform could lead to worse QoL. However, better nerve endings visualization and preservation could lead to better QoL and incontinence rates.

Table 3 - Friedman and Kendall's tests

VAS in EuroQol-5D		Pain/discomfort in EuroQol-5D		Physical functioning in QLQ-C30		Social functioning in QLQ-C30		Financial problems in QLQ-C30		Global health in QLQ-C30		Fecal incontinence in QLQ-C29		Anxiety / depression in QLQ-CR29		LARS score		Vaizey score		IPSS score	
N	13	N	13	N	13	N	13	N	13	N	13	N	13	N	13	N	13	N	13	N	13
df	1	Chi-Square	6	Chi-Square	4	Chi-Square	0.143	Chi-Square	5	Chi-Square	12	Chi-Square	1	Chi-Square	5.444	Chi-Square	0.091	Chi-Square	0.077	Chi-Square	6.4
Asymp. Sig	0.114	df	1	df	1	df	1	df	1	df	1	df	1	df	1	df	1	df	1	df	1
		Asymp. Sig	0.014	Asymp. Sig	0.046	Asymp.	0.705	Asymp.	0.025	Asymp.	0.001	Asymp.	0.317	Asymp.	0.02	Asymp.	0.763	Asymp.	0.782	Asymp.	0.011
Kendall's test		Correlation	0.46	Kendall's W	0.308	Kendall's W	0.011	Kendall's W	0.385	Kendall's W	0.923	Kendall's W	0.077	Kendall's W	0.419	Kendall's W	0.007	Kendall's W	0.006	Kendall's W	0.492
		Sig.	0.114	Chi-Square	4	Chi-Square	0.143	Chi-Square	5	Chi-Square	12	Chi-Square	1	Chi-Square	5.444	Chi-Square	0.091	Chi-Square	0.077	Chi-Square	6.4
				Asymp. Sig	0.046	Asymp. Sig	0.705	Asymp. Sig	0.025	Asymp. Sig	0.001	Asymp. Sig	0.317	Asymp. Sig	0.02	Asymp. Sig	0.763	Asymp. Sig	0.782	Asymp. Sig	0.011

Assessment using the visual analogue scale for self-rated health within the EuroQol-5D questionnaire, showed no statistically significant differences between pre- and postoperative scores, although there was a trend towards improvement. These results are encouraging in view of the fact that no deterioration in health was observed after the surgical intervention. When analyzing the data in the pain/discomfort section of the EuroQol-5D questionnaire, a statistically significant lower level of pain/discomfort was observed in patients postoperatively ($p=0.014$). Pain and discomfort were associated with the quality of surgical intervention, the presence of complications in the perioperative period and recurrence-free survival. In K-related sample analysis (Friedman test and Kendall's W test) of non-parametric data of physical functioning data in QLQ-C30, there was a statistically significant improvement in patients' physical functioning postoperatively ($p=0.046$). In view of improving the global quality of life after surgical interventions, physical functioning is an important indicator providing clarity on patients' return to their normal lifestyle. In the same questionnaire analysis of social functioning data, they did not show statistical significance, which also means that there was no deterioration in patients' social functioning after the surgical intervention ($p=0.705$). In the analysis of financial problems in the QLQ-C30, the data showed a statistically significant improvement in patients' financial problems during the follow-up period. Despite a good and functioning healthcare system and free treatment for cancer patients, financial difficulties appear in a large proportion of patients during the period of active treatment. These are probably related to transportation costs, outpatient care, consumables for surgical treatment not covered by the health system, etc. Postoperative improvement in global health within the QLQ-C30 questionnaire was observed with very strong statistical significance ($p=0.001$). This is very promising and indicates good compliance, good awareness, patient expectations achieved, good surgical and therapeutic outcomes with low complication rates, etc. Fecal incontinence is one of the most commonly studied and important indicators related to the quality of surgery and the quality of life of patients. The analysis of fecal incontinence data for patients without a stoma within the QLQ-CR29 questionnaire showed a lack of statistical significance of pre- and postoperative outcomes. This is a positive result in this case due to the clear association between the surgical intervention and the worsening of fecal continence in patients. In TaTME, there is the advantage of visualizing and preserving the terminal

nerve endings of the plexus hypogastricus inferior and plexus prostaticus. Anxiety/depression within the QLQ-CR29 questionnaire after analysis of non-parametric data (Friedman test and Kendall's W tests) showed statistically significant improvement postoperatively ($p=0.020$). LARS as a specific, internationally validated and widely used questionnaire for the level of fecal incontinence plays an important role in the follow-up and assessment of the quality of the surgical intervention. Pre- and postoperative data analysis showed no statistically significant difference in scoring ($p=0.763$), which is a positive result as no worsening of incontinence rates was observed. Vaizey questionnaire is also common for the assessment of fecal incontinence and the results also showed no statistical significance with a close p-value ($p=0.782$), which also indicates the stability and reliability of the data.

A lot of research has been dedicated to comparing the functional outcomes after laparoscopic TME and TaTME, with several meta-analyses showing that both procedures result in similar functional outcomes and QoL (23,24). Although TaTME was introduced to get a better view in the pelvis, initial concerns about worsening of the functional outcomes were raised (6,25). TaTME allows sphincter preservation in some patients who otherwise will undergo an abdominoperineal excision, leading to a lower anastomosis and potential worsening of anal continence. The most commonly used tools to compare QoL were questionnaires (EORTC QoL questionnaires, International Index of Erectile Function, Female Sexual Function Index, LARS, Wexner, IPSS, and Vaizey scores), endoscopic transanal ultrasound and anorectal manometry (14,16,17,19,26,27).

An important conclusion about TaTME and any other TME techniques is that TaTME may lead to significant functional impairments so patients should receive preoperative counseling on this topic and be fully aware of the potential consequences of their treatment (28). The reported major LARS scores in these patients are 25%-33% and higher. Nevertheless, the majority of these patients had major LARS even before the procedure (26,27). Major LARS is considered one of the most important functional outcome measurements due to its great impact on the quality of life. However, stoma formation and anastomotic leak affect the QoL negatively and are connected with higher rates of major LARS. The currently available data on QoL after TaTME come mostly from small studies, with some bias, different variables, missing information and other limitations (6,11,19,25,26,29,30). More well-structured research is needed.

CONCLUSION

Quality of life after TaTME seems promising. Large, well-structured trials in the scientific area are needed.

Conflicts of interest

The author declare that they have no conflict of interest.

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Ethics of approval

This study was approved by the ethical committee in Medical University Pleven.

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