VILNIUS UNIVERSITY

Gintarė Valeikaitė-Tauginienė

Study of factors determining the long-term quality of life after surgical treatment in patients with colorectal tumors

SUMMARY OF DOCTORAL DISSERTATION

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Academic supervisor – Prof. Dr. Tomas Poškus (Vilnius University, Medicine and Health Sciences, Medicine – M 001).

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Chairman – **Prof. Dr. Virgilijus Beiša** ((Vilnius University, Medicine and Health Sciences, Medicine – M 001).

Members:
Prof. Dr. Igors Iesalnieks (Munich University, Germany, Medicine and Health Sciences, Medicine – M 001);
Prof. Dr. Vytautas Kasiulevičius ((Vilnius University, Medicine and Health Sciences, Medicine – M 001);
Prof. Dr. Donatas Venskutonis (Lithuanian University of Health Sciences, Medicine and Health Sciences, Medicine M 001);
Prof. Dr. Gilvydas Verkauskas ((Vilnius University, Medicine and Health Sciences, Medicine – M 001).

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Vilnius University Hospital Santaros Klinikos.
Address: Santariškių str. 2, LT-08661, Vilnius, Lithuania

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VILNIAUS UNIVERSITETAS

Gintarė Valeikaitė-Tauginienė

Pacientų, sergančių storosios žarnos navikais, ilgalaikę gyvenimo kokybę po chirurginio gydymo lemiančių veiksnių tyrimas

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Mokslinis vadovas – **prof. dr. Tomas Poškus** (Vilniaus Universitetas, medicinos ir sveikatos mokslai, medicina – M 001).

Gynimo taryba:
Pirmininkas – **prof. dr. Virgilijus Beiša** (Vilniaus universitetas, medicinos ir sveikatos mokslai, medicina M – 001).

Nariai:
Prof. dr. Igors Iesalnieks (Miuncheno universitetas, Vokietija, medicinos ir sveikatos mokslai, medicina - M 001);
Prof. dr. Vytautas Kasiulevičius (Vilniaus universitetas, medicinos ir sveikatos mokslai, medicina M – 001);
Prof. dr. Donatas Venskutonis (Lietuvos sveikatos mokslų universitetas, medicinos ir sveikatos mokslai, medicina – M 001);
Prof. dr. Gilvydas Verkauskas (Vilniaus universitetas, medicinos ir sveikatos mokslai, medicina – M 001).

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ABBREVIATIONS

ASA – American Society of Anesthesiologists
BMI – body mass index
CRC – colorectal cancer
EMR – endoscopic mucosal resection
EORTC – European Organisation for Research and Treatment of Cancer
ESD – endoscopic submucosal dissection
HRQoL – health-related quality of life
LAC – laparoscopic assisted colectomy
OS – overall survival
QoL – quality of life
TEM – transanal endoscopic microsurgery
TaTME – transanal total mesorectal excision
VAS – Visual Analog Scale

CONTENT

1. INTRODUCTION

Colorectal cancer (CRC) is one of the most burdensome cancers in the Western world due to its high incidence, significant mortality, and increasing survivorship [1–3]. About 1.4 million people are diagnosed with new cases of colorectal cancer worldwide every year. Colon cancer is more common in developed countries and is associated with lifestyle [4]. Improving early diagnosis and advances in treatment leads to longer survival of these patients [5–7]. The emergence of new treatment options for CRC, such as laparoscopic and robotic surgery, transanal techniques, and neoadjuvant and total neoadjuvant chemo- and radiotherapy, result in better outcomes, as well as increasing the quality of life of the patients. Quality of life (QoL) is a multidimensional, dynamic, subjective, and patient-centered construct comprising physical, functional, emotional, and social or family well-being [8]. Not only does it provide patient-centered outcomes of cancer treatment, but it is also related to overall survival [9–11] and a good indicator of treatment quality [12,13]. In addition, QoL measurements have become particularly important in assessing the outcome of long-term treatment in chronic diseases or where improvement is only short-term and temporary, and where disease progression is unstoppable and only palliative treatment is possible. Health-related quality of life (HRQoL) research is of great significance and importance, as it helps to evaluate the effectiveness of treatment methods, health improvement, and disease prevention programs, and is useful in monitoring the state of public health and developing public health policy.

Transanal endoscopic microsurgery (TEM) is the technique of choice for low and middle T1 rectal cancer and advanced adenomas, with low morbidity, mortality, and good functional results [14–16]. However, some authors argue that the use of a 4- cm diameter rectoscope during the TEM procedure could impair anorectal function and cause fecal incontinence [17–19]. There is limited data on the long-term outcomes with regard to fecal incontinence after TEM,

which should be evaluated, as other transanal techniques such as transanal total mesorectal excision (TaTME) for conventional rectal cancer treatment are increasingly widely used.

Aim of the study

The aim of this study is to assess the long-term results of the quality of life after surgical treatment of CRC and to determine the factors associated with decreased quality of life in the long-term postoperative period.

Tasks of the study

1. Evaluate the results of QoL after six years after the operation:
   - survival results;
   - identification of factors determining QoL in the long postoperative period.
2. QoL results after transanal endoscopic microsurgery (TEM):

   - to find out the occurrence of fecal incontinence and its influence on GC results;
   - identify possible factors influencing the occurrence of fecal incontinence**.**

The novelty of the research

This is a long-term prospective study of patients operated on for colon and rectal tumors. Most surgical tests stop reporting results after 5 years and most are for surgical results. This study focused on quality of life outcomes. The second part of the study has a particularly long follow-up period after TEM surgery, with a median of 96 months, while most studies in the world report 60 months of monitoring results.

Practical significance

This study clearly shows that most patients will live a normal life if their cancer is cured. However, patients who have received adjuvant therapy and who have developed a stoma report poorer long-term quality of life. This would encourage doctors to choose treatments that would prevent such treatment. The long-term poorer functional outcomes after TEM than previously thought will encourage physicians to select patients more carefully for this operation.

2. MATERIALS AND METHODS

A separate study is carried out for the implementation of each study task:

1. A prospective study - to evaluate the results of survival and to determine the factors influencing QoL in the long postoperative period;
2. A retrospective study - to evaluate QoL outcomes after TEM.

2.1 Prospective study

A prospective snapshot cohort study was performed. The study included patients operated with curative intent for CRC in three major cancer centers in Lithuania: Vilnius University hospital Santaros Clinics, Lithuanian University of Health Sciences Kaunas Clinics Hospital, and the National Cancer Institute. The patients were included in the study for three months: from September to December 2012. All patients older than 18 years admitted for elective curative surgery for colorectal cancer, with the diagnosis confirmed endoscopically and histologically were included. Patients who underwent emergency surgery were excluded. Informed consent was obtained, and baseline demographic information was collected by means of patient interviews preoperatively. Clinical and operative details, American Society of Anesthesiologists (ASA) grade, preoperative radiological evaluation, neoadjuvant treatment, operation type (right, left, or rectal procedure), presence of a stoma (or not), the final pathological diagnosis, and postoperative complications were also recorded.

Patients' quality of life was assessed before surgery, and at one, 24, and 72 months after the surgery. Validated Lithuanian translations of the EORTC QLQ-C30 (version 3.0) and QLQ-CR29 questionnaires were used in the current study. For both instruments, individual scores were converted to a score ranging from zero to 100, according to the EORTC manuals. A high score for the symptom/item scales

represented a high level of symptoms/problems related to specific colorectal surgery, whereas a high score for the functional scales and the global health/general quality-of-life index represented a high level of functioning, overall health, and quality of life. For items without a response, at least 75% of items completed by patients were considered assessable in the current study, and the mean was imputed for missing items in assessable cases according to EORTC scoring guidelines. The higher estimates in assessing the overall state of health and functional scales indicated better results. Higher estimates indicated more pronounced symptoms and worse postoperative outcomes. The factors that resulted in a statistically significantly worse quality of life outcome in the long-term period were identified.

Statistical analysis was performed using SPSS® software version 23 (SPSS, Chicago, IL, USA). Non-parametric statistical tests and multivariate logistic regression models were used. Overall survival (OS) was calculated as the difference between the date of operation and the date of death (from any cause) or 72 months after the operation. Survival curves were estimated using the Kaplan–Meier estimator. Survival curves were compared with the log-rank test.

2.2 Retrospective study

Patients, enrolled in a prospectively collected and maintained database of TEM operations in the Center of Abdominal Surgery, Vilnius University Hospital "Santaros Klinikos", between June 2003 and May 2016, were interviewed using a postal questionnaire.

Preoperative investigation and preparation

Standard preoperative evaluation of rectal tumors consisted of the digital rectal examination, rigid proctoscopy, colonoscopy, endorectal ultrasound, or magnetic resonance imaging. A computed tomography scan of the chest, abdomen, and pelvis was performed to rule out metastatic disease in cases of rectal cancer. Bowel preparation was performed using a Macrogol solution the day before the operation. 1.5-

g cefuroxime and 500-mg metronidazole combination was the antibiotic prophylaxis of choice at the time of induction of anesthesia. None of the patients had a prior history of chemoradiotherapy.

Surgical technique

All surgical procedures were performed by a single surgeon using TEM equipment (Wolf Company, Knittlingen, Germany) under general anesthesia. A 12- or 20-cm length rectoscope was used depending on the distance of the lesion from the anal verge. Patients were positioned in lithotomy, prone, or lateral decubitus position depending on the location of the lesion. The operation was started by marking resection margins 1 cm around the lesion using the monopolar dissector. The rectal wall defect was closed with PDS 3/0 running suture. Removed lesions were pinned on a board, measured, photographed, and sent for pathology examination. All patients were mobilized on the day of the procedure. The urinary catheter was removed the next day.

Postoperative follow-up

Every patient underwent digital rectal examination and rigid proctoscopy 1 to 3 months after the operation. Patients that were operated on for non-malignant lesions were controlled by rigid proctoscopy at 6 and 12 months and then annually. Patients with malignant lesions underwent more frequent surveillance: rigid proctoscopy with biopsies from the lesion site was taken every 3 months for 2 years after the operation and semi-annually after 2 years.

Questionnaire

Our questionnaire consisted of a EuroQol (EQ)-5D-5L quality of life questionnaire, a Wexner fecal incontinence grading scale, and additional questions. EQ-5D-5L questionnaire consists of a Visual Analog Scale (VAS) that ranges from 0 to 100 for the evaluation of current health perception and five questions about mobility, self-care, daily tasks, pain, and anxiety with five levels of answers for each

question [20]. The Wexner grading scale was used to evaluate the severity of fecal incontinence. It consists of five questions and the sum of scores ranging from 0 (perfect continence) to 20 (total incontinence) [21]. Additional questions were about the recurrence of the rectal lesion and the treatment that was used in cases of recurrence. History of other perianal operations was collected, as well as obstetric history in women [22]. Lithuanian Bioethics committee approved the study. Statistical analysis The EQ-5D-5L questionnaire was evaluated dichotomously. Wexner score was analyzed as a categorical variable, dividing patients into two groups: no or minor fecal incontinence (Wexner score of 2 or less) and non-minor incontinence (Wexner score of 3 or more). Kruskal-Wallis test was used when the Wexner score was analyzed as a continuous variable. Mann-Whitney U test was used for all other continuous variables, and the Fisher test was used for dichotomous variables. Multivariate stepwise logistic regression analysis was performed on factors, which had a significant association with incontinence in univariate analysis. Factors were considered significant if $p < 0.05$. Statistical analysis was performed using SPSS® software version 21.

3. RESULTS

3.1 Prospective study

Eighty-eight patients were included in the study. The demographic and clinical data are shown in Table 1. All patients were treated with surgery—58 (65.9%) patients with open surgery, 26 (29.6%) with laparoscopic surgery, and 4 (4.5%) with transanal endoscopic microsurgery. There were no conversions in the laparoscopic group. A stoma was formed in 31 patients, with 19 (21.6%) preventive ileostomies and 12 (13.6%) end colostomies. Adjuvant chemotherapy was commenced 1-month postoperatively for 23 (26.1%) patients and radiation therapy for 5 (5.7%); in the third month, chemotherapy was used in 27 (30.68%) patients and radiotherapy in 2 (2.27%) patients.

Table 1. Demographic and clinical data.

Characteristics	
Age (years) [mean± SD]:	64.2 ± 11.5
Gender [n (%)]:	
Men	46 (52.27%)
Women	42 (47.73 %)
ASA grade [n (%)]:	
I	8 (9.09 %)
II	38 (43.18 %)
III	40 (45.46 %)
IV	2 (2.27 %)
Tumor location [n (%)]:	
Colon	42(47.73%)
Rectum	46(52.27%)
Neoadjuvant treatment [n (%)]:	
Radiotherapy:	14 (15.90 %):
Short course radiotherapy	2 (2.27 %)
Long course radiotherapy	12(13.64 %)
Chemotherapy (in addition)	11 (12.50 %)

Table 1. Demographic and clinical data (continuation).

Characteristics	
Type of operation [n (%)]:	
Open	58 (65.91%)
Laparoscopic	30 (34.09%)
Stage [n (%)]:	
In situ	3 (3.41 %)
I	25 (28.41 %)
II	19 (21.59 %)
III	37 (42.05 %)
IV	4 (4.54 %)
Hospital stay (days) [mean± SD]:	9.9 ± 4.0

Regarding survival, 29 patients died 72 months after surgery (33.0%), with a 6-year survival rate of 67% that was equal between men and women (p = 0.448) (Figures 1 and 2).

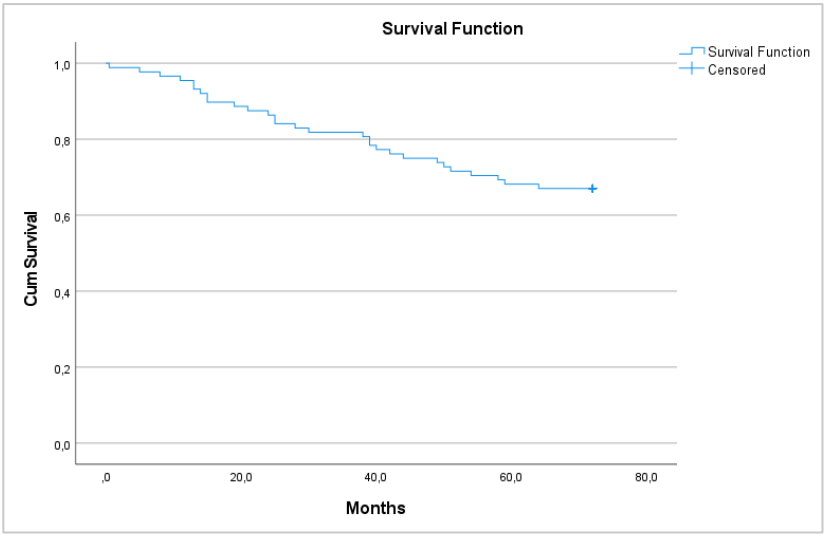

Figure 1. 6-year overall survival

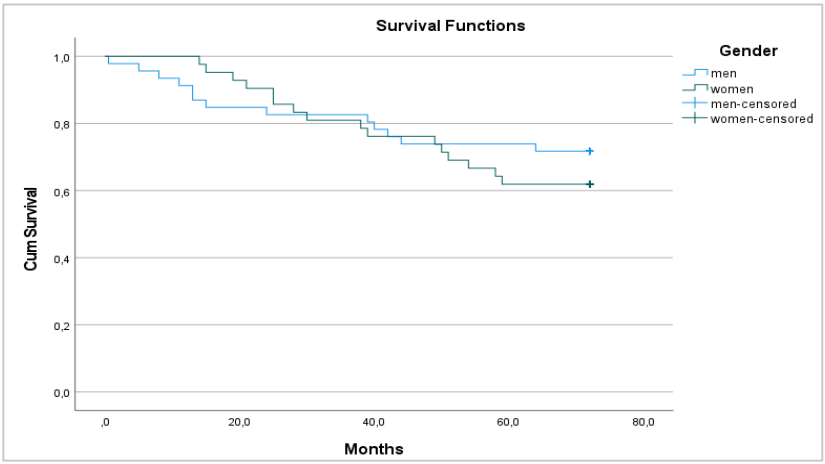

Figure 2. 6-year overall survival between men and women

Most patients had stage III cancer — 37 (42%). Patients with stage IV cancer did not survive after 6 years, although all patients with a tumor in situ survived ($p < 0.001$) (Figure 3).

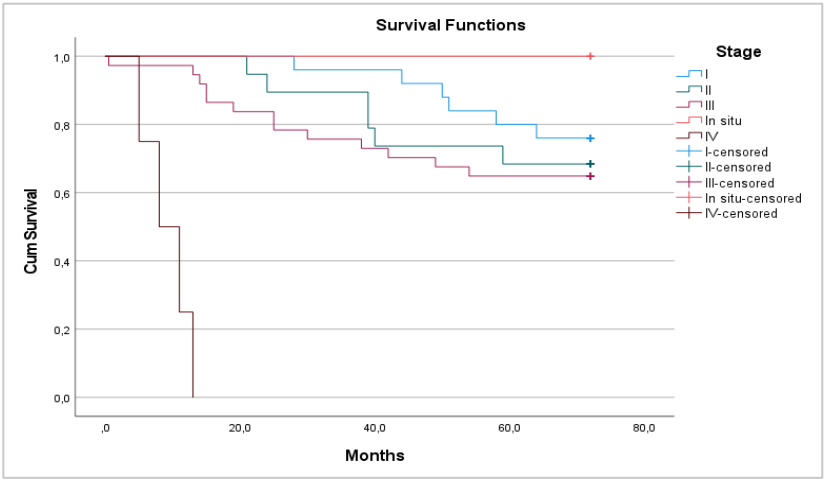

Figure 3. 6-year overall survival between pathological stages.

Fifty of the remaining 59 living patients (84.8%) responded to the questionnaire 72 months after surgery. Evaluating changes in QoL 72

months after surgery with assessments before surgery both QLQ—C30 and QLQ—CR29 questionnaire responses revealed good long-term CRC surgical treatment results, showing improved general (60; 69.5; 65.33; p = 0.06) and functional (70.3; 79.8; 85.3; p = 0.041/72.9; 78.93; p = 0.049) scale estimates and decreased symptom scale ratings (24.3; 19; 17; p = 0.034)/22; 12.7; p = 0.025) (Figures 4 and 5)

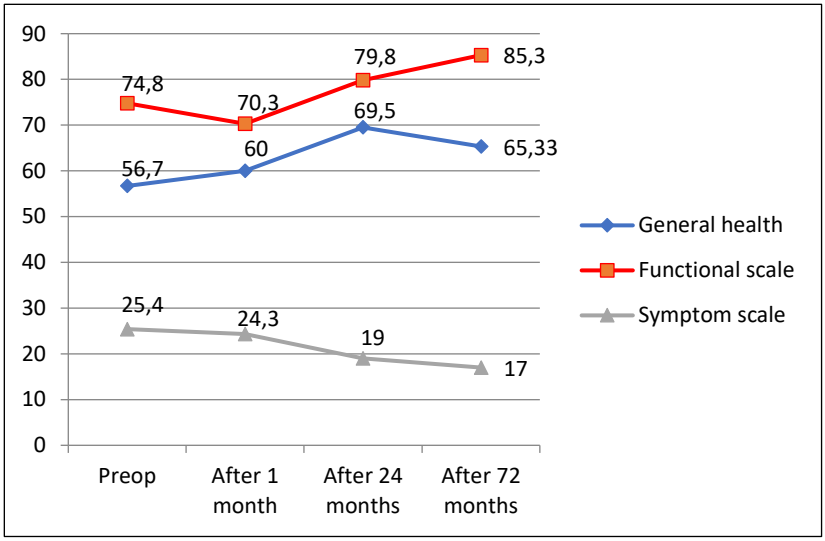

Figure 4. QLQ-C30 questionnaire outcomes for 72 months after surgery

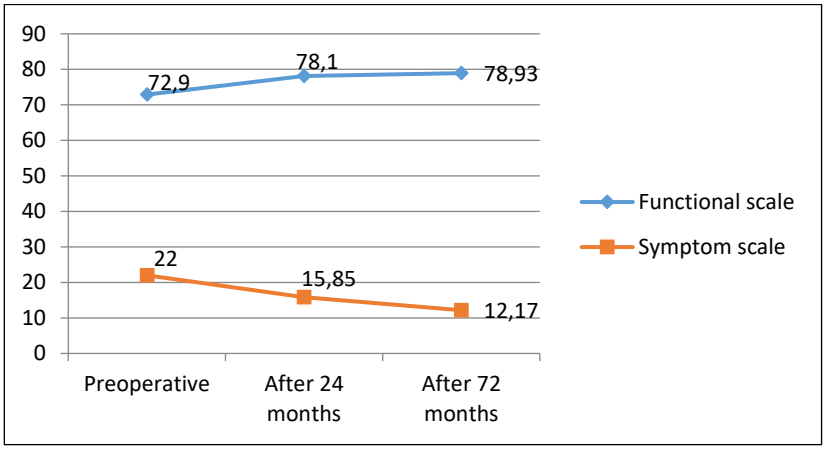

Figure 5. QLQ – CR29 questionnaire outcomes for 72 months after surgery

Evaluating the QoL 72 months after surgery between stages of both overall health status and overall QoL scores, we did not find any significant differences (p = 0.687; p = 0.457) (Figures 6 and 7).

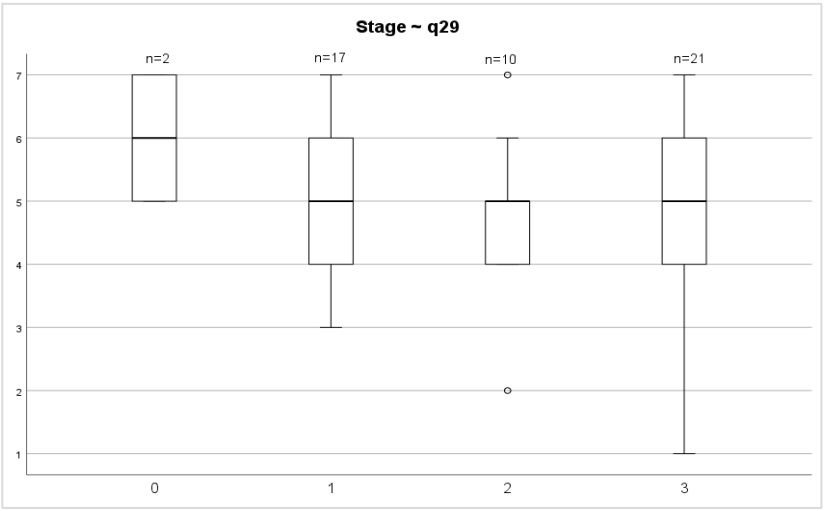

Figure 6. Stage and general health status

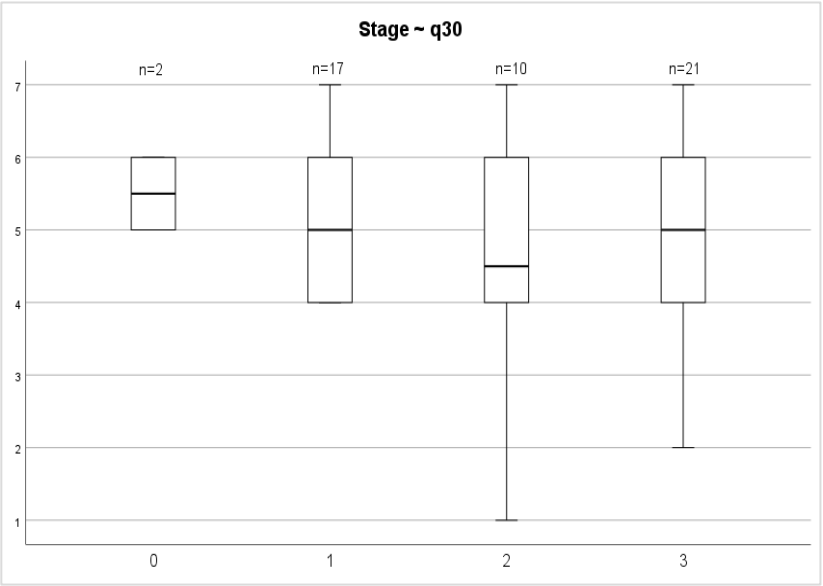

Figure 7. Stage and overall QoL

Forty-six (52.3%) patients had rectal cancer. This localization of tumors is associated with worse overall health status and overall QoL scores (Figures 8 and 9). However, no significant differences between these groups were found ($p = 0.2035$; $p = 0.1002$).

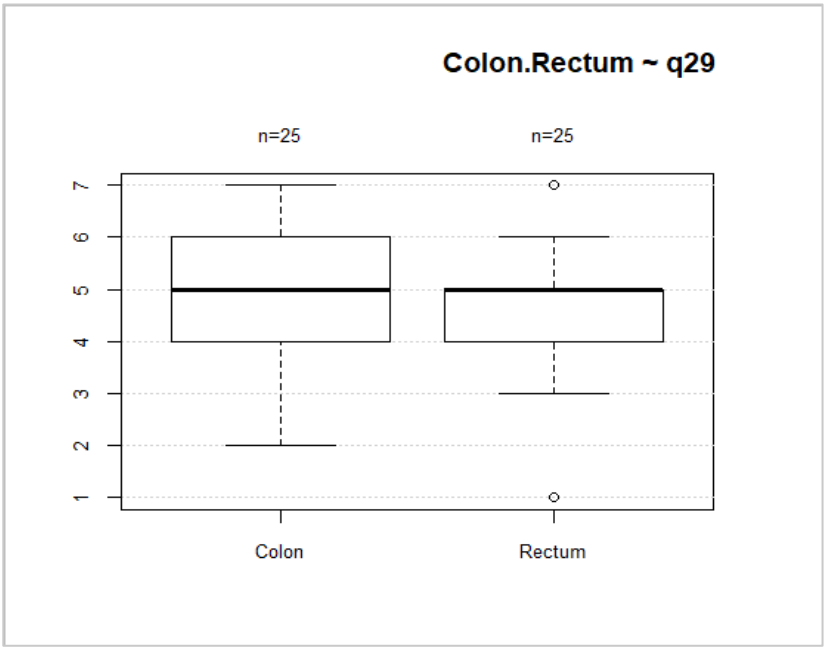

Figure 9. Tumor location and general health status

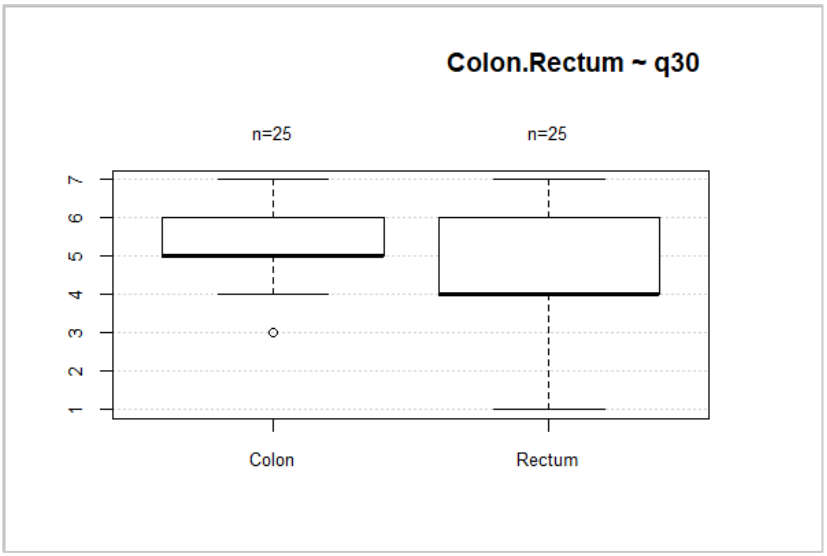

Figure 10. Tumor localization and overall QoL

We performed multivariate logistic regression models, which revealed that age (≥ 65 years), stoma formation, and rectal cancer are significant predictors of worse QoL (Table 2)

Table 2. Multivariate analysis of factors predicting poorer QoL

	Factor	Value	Std. Error	T value	p value	OR
Global health status/ QoL	Gender (men)	-0.738	0.886	-0.834	0.405	0.478
	Age (≥65years)	**-0.122**	**0.043**	**-2.834**	**0.005**	**1.130**
	Tumor location (rectum)	4.109	2.131	1.928	0.054	60.887
	Neoadjuvant treatment	-3.276	2.017	-1.624	0.104	0.038
	Stage (III)	-2.123	1.906	-1.114	0.265	0.120
	Stoma	2.831	1.637	1.729	0.084	16.955
	Adjuvant treatment	0.136	0.972	0.140	0.889	1.146
	ASA (III-IV)	2.249	1.343	1.674	0.094	9.478
	Operation type (open)	-1.456	1.022	-1.424	0.155	0.233
Functional scale	Gender (men)	-0.3194	0.3895	-0.82	0.412	0.727
	Age (≥65years)	**-0.0301**	**0.0158**	**-1.90**	**0.050**	**1.031**
	Tumor location (rectum)	0.4095	0.9399	0.44	0.663	1.506
	Neoadjuvant treatment	1.5647	1.6295	0.96	0.337	4.781

Table 2. Multivariate analysis of factors predicting poorer QoL (continuation)

	Stage (III)	-0.5621	0.8546	-0.66	0.511	0.570
	Stoma	**-4.044**	**2.082**	**-1.943**	**0.050**	**57.043**
	Adjuvant treatment	**-3.987**	**1.676**	**-2.379**	**0.017**	**0.019**
	ASA (III-IV)	-0.1952	0.5530	-0.35	0.724	0.823
	Operation type (open)	-0.0825	0.4866	-0.17	0.865	0.921
Symptom scale	Gender (men)	-1.412	1.014	-1.393	0.164	0.244
	Age (≥65years)	**-0.170**	**0.055**	**-3.108**	**0.002**	**1.185**
	Tumor location (rectum)	**-3.512**	**1.802**	**-1.949**	**0.050**	**2.049**
	Neoadjuvant treatment	0.800	1.656	0.483	0.63	2.226
	Stage (III)	0.035	1.112	0.031	0.98	1.035
	Stoma	**-5.877**	**2.592**	**-2.267**	**0.023**	**36.806**
	Adjuvant treatment	-0.093	1.242	-0.075	0.940	0.911
	ASA (III-IV)	-0.243	1.400	-0.174	0.862	0.784
	Operation type (open)	-1.707	1.194	-1.429	0.153	0.181

3.2 Retrospective study

One hundred thirty-two patients that reported back a median of 96 months from their operation (range 12–168 months) were included in the final analysis out of 271 patients who underwent TEM operation in our center; 139 (51.3%) patients did not respond (Fig.11). Table 3

presents general demographic and clinical data from the responders and non-responders of the TEM cohort. There were no significant differences in perioperative characteristics between the responder and nonresponder groups in the statistical analysis.

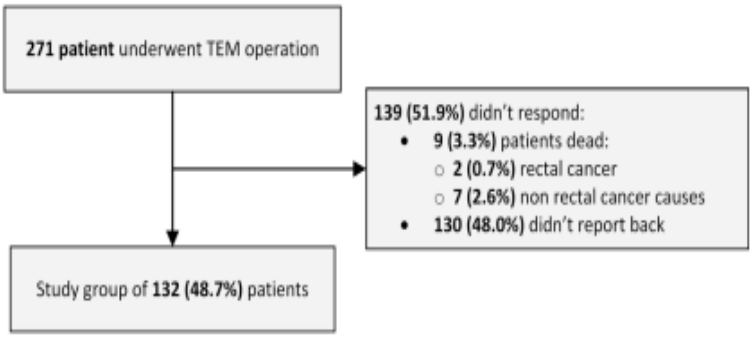

Fig. 11. Flow chart of the study population

Table 3. General demographic and clinical data

	Study group (n=132)	Non-responders (n=139)
Patients' age at the time of the operation (years) [median (range)]	64,5 (18-89)	69 (35-92)
Gender [n(%)]		
Male	58 (43,9)	65 (46,8)
Female	74 (56,1)	74 (53,2)
Tumor size (cm) [median (range)]	3 (0,3-10)	3 (0,4-12)
Tumor distance from anal verge (cm) [median (range)]	8 (1-20)	9 (1-25)
Operating time (min) [median (range)]	55 (10-210)	55 (10-260)
Hospital stay (days) [median (range)]	5 (2-16)	6 (2-25)
Intraoperative complications		
Perforation to the peritoneal cavity	0	2 (1,4)
Perforation to the vagina	0	1 (0,7)

Table 3. General demographic and clinical data (continuation)

Morbidity (within 30 days) [n (%)]		
No	127 (96,2)	137 (98,6)
Yes	5 (3,8)	2 (1,4)
Follow-up period (months) [median (range)]	96 (12-168)	n.a
Wexner scale sum [mean ± SD]	2,1 ± 4,0	n.a
Histology results		
Adenomas		
Tubulovillous adenoma [n (%)]	83 (62,9)	73(52,5)
Tubular adenoma [n(%)]	7 (5,3)	5 (3,6)
Vilous adenoma [n(%)]	2 (1,5)	3 (2,2)
Hyperplastic polyp [n(%)]	2 (1,5)	-
Carcinomas		
Ca in situ [n(%)]	17 (12,9)	30 (21,6)
T1 [n(%)]	8 (6,1)	10 (7,2)
T2 [n(%)]	4 (3,0)	7 (5,0)
T3 [n(%)]	-	1 (0,7)
Carcinoid [n(%)]	2 (1,5)	3 (2,2)
Other		
Stricture (postoperative) [n (%)]	1 (0,8)	5 (3,6)
Lipoma [n(%)]	-	1 (0,7)
Inflammation [n(%)]	3 (2,3)	-
Basophilic granuloma [n (%)]	-	1 (0,7)
Hyperplastic gastric mucosa [n (%)]	1 (0,8)	-
Scar [n(%)]	1 (0,)8)	-
Biopsy for suspected Hirschsprung disease	1 (0,	

n.a. not available

Wexner score distribution is presented in Table 4. Ninety-four (71.2%) patients had minor fecal incontinence—they reported a Wexner score of 2 or less after the TEM operation. Thirty-eight patients (28.8%) reported a Wexner score of 3 or more. They suffered from non-minor fecal incontinence. They also reported significantly worse quality of life in all tested life spheres (Table 5.) than those that were completely continent or had minor incontinence.

Table 4. Wexner score distribution

Wexner score	0	1	2	3	4-5	6-7	≥8
Number of patients [n(%)]	80 (60,6)	10 (7,6)	4 (3,0)	9 (6,8)	15 (11,4)	2 (1,5)	12 (9,1)

Table 5. Quality of life and EQ-5D-5L VAS scorer

Quality of life evaluation	Wexner score < 3 (n=94)	Wexner score ≥ 3 (n=38)	*P-value*
VAS score (n) [median (range)]	85 (40-100)	65 (20-100)	<0,001
Mobility problems [n (%)]	22 (23,4)	19 (50,0)	0,004
Self-care problems [n (%)]	12 (12,8)	15 (39,5)	0,001
Daily-task problems [n (%)]	22 (23,4)	21 (55,3)	0,001
Pain or discomfort [n (%)]	35 (37,2)	27 (71,1)	0,001
Anxiety [n (%)]	34 (36,2)	25 (65,8)	0,003

Variables that were analyzed in relation to fecal incontinence after the TEM procedure are presented in Table 6. Fifty-eight (78.4%) of 74 women in the study had vaginal delivery; this variable was not statistically significant (40 (76.9%) vs. 18 (81.8%); p = 0.764). Other obstetric history variables were counted from the 58 women, who had a vaginal delivery. We did not find any statistically significant obstetric variables that could be attributed as a cause of fecal incontinence. We did notice a higher percentage of episiotomy in women, having better continence after TEM (15 (37.5%) vs. 2 (11.1%), but the difference was not statistically significant (p = 0.061). Three of the 11 studied variables were statistically significant. Patients that report non-minor fecal incontinence were older at the time of the operation (63 (18–82) vs. 68 (50– 89) years; p = 0.004), underwent longer operations (50 (10– 140) vs. 60 (15–210) min; p = 0.017), and

were operated for malignant lesions more often (17 (18.3%) vs. 14 (36.8%); p = 0.040).

Table 6. Variables of fecal incontinence

Variables	Wexner score < 3 (n=94)	Wexner score ≥ 3 (n=38)	*P*-value
Patients' age (years) [median (range)	63 (18-82)	68 (50-89)	0,004
Gender [n(%)]			0,848
Male	42 (44,7)	16 (42,1)	
Female	52 (55,3)	22 (57,9)	
Tumor size (cm) [median (range)	3 (0,3-10)	4 (0-8)	0,097
Tumor distance from anal verge (cm) [median (range)]	9 (1-20)	7 (1-20)	0,146
Operating time (min) [median (range)]	50 (10-140)	60 (15-210)	0,017
Hospital stay (days) [median (range)]	5 (2-16)	6 (2-14)	0,385
More than one TEM operation [n (%)]	3 (3,2)	4 (10,5)	0,105
More than one rectal lesion [n (%)]	4 (4,3)	3 (7,9)	0,178
Malignant lesion histology [n (%)]	17 (18,3)	14 (36,8)	0,040
Use of radiotherapy after TEM [n (%)]	3 (3,2)	0 (0)	0,557
Other rectal operations [n (%)]	2 (2,1)	2 (5,3)	0,578
Obstetric history variables	Wexner score < 3 (n=52)	Wexner score ≥ 3 (n=22)	
Vaginal delivery [n (%)]	40 (76,9)	18 (81,8)	0,764
	Wexner score < 3 (n=40)	Wexner score ≥ 3 (n=18)	
More than 2 childbirths [n (%)]	6 (15,0)	3 (16,7)	1,000

Table 6. Variables of fecal incontinence (continuation)

Episiotomy during delivery [n (%)]	15 (37,5)	2 (11,1)	0,061
Perineal rupture during delivery [n (%)]	10 (25,0)	5 (27,8)	1,000
Use of forceps during delivery [n (%)]	0 (0)	2 (11,1)	0,093

We studied the impact of the pathology of the lesion on the Wexner score and found out that patients that were operated on for invasive cancer later had significantly worse Wexner scores compared to patients that had benign lesions (1.4 ± 2.6 vs. 4.9 ± 6.5; $p = 0.012$). Table 7 presents the results of the multivariate analysis. Older age at the time of operation was independently associated with the risk of developing non-minor fecal incontinence (OR 1.057, 95% CI 1.010–1.106; $p = 0.016$).

Table 7. Multivariate analysis of risk factors for developing nonminor fecal incontinence after TEM operation

Risk factor	95% CI (confidence interval)	Odds ratio	*P*-value
Age at the time of operation	1,010-1,106	1,057	0,016
Operating time	0,998-1,023	1,010	0,100
Malignant lesion histology	0,685-4,551	1,766	0,239

4. DISCUSSION

4.1 Prospective study

We found that the QoL of patients increased two years after surgery and was maintained for up to six years. In a German study, QoL was assessed one and three years after diagnosis. Most patients with CRC reported high overall QoL and only small deficits in physical functioning, but deficits in emotional and social functioning persisted over years in patients with CRC. Improvements in QoL from the first to the third year after diagnosis in patients who remained free of disease were very modest and limited to fewer financial difficulties, a better future perspective, and fewer stoma-related problems [23].

We found that decreased long-term QoL was associated with age, stoma formation, and the use of radiotherapy. The study that investigated HRQoL in terms of symptoms and functional outcomes in disease-free survivors of rectal cancer showed that age, female sex, stoma, and late complications predicted worse physical functioning; stoma and chemoradiotherapy—worse body image and age, female sex, and late major complications worse sexual functioning [24]. Another study revealed that patients with ostomies who had any late complications had lower overall HRQoL (OR 1.5; 95% CI 0.9–2.6). This was not the case for patients with anastomoses (OR 0.9; 95% CI 0.5–1.5) [25].

Comparing laparoscopic vs. open surgery 18 months after surgery, any differences in QoL between patients randomized to laparoscopic-assisted colectomy (LAC) or open colectomy favored LAC. However, the magnitude of the benefits was small; only age and activity were predictive of poor QoL [26]. We also didn't find any influence of the type of surgery on QoL. The COLORII trial revealed that HRQoL after rectal cancer surgery was not affected by the surgical approach [27]. Other studies have shown the opposite. Elderly patients undergoing laparoscopic colectomy for cancer experience fewer postoperative local complications than elderly patients

undergoing an open colectomy [28]. Nevertheless, in the first postoperative month, these patients experienced worse global QoL than younger patients undergoing the same operation with impairment of all functions and the presence of fatigue, sleep disturbances, appetite loss, and dyspnea [29]. HRQoL generally improved over the first year after laparoscopic colectomy, reaching even better levels than before surgery. There was an early postoperative improvement in the patients' emotional status [30].

A prospective survey of a population-based sample of 763 colorectal cancer patients assessed sociodemographic variables, health behaviors, optimism, threat appraisal, and perceived social support at 5 months post-diagnosis as predictors of QoL and psychological distress 5 years post-diagnosis. Risk factors for worse QoL and/or greater psychological distress included later-stage disease, having a permanent stoma, rectal cancer, fatigue, smoking, being single, low social support, low optimism, and a more negative cancer threat appraisal [31].

The association between a post-diagnosis lifestyle score and HRQoL in the long-term CRC survivals indicated that lifestyle behaviors, such as a body mass index (BMI) < 30 kg/m2, dietary intake, physical activity, and smoking status, were associated with HRQol among CRC long-term survivors in a cross-sectional study [32].

The six-year OS of patients in our cohort (67%) was similar to those found in hospital-based studies in Brazil (63.5%) [33], Italy (66.45%) [34], and Taiwan (68.7%) [35]. We did not identify differences based on gender or tumor location but found differences between clinical stages in OS. Similar findings were obtained in a Brazilian study [33].

The main disadvantage of this study is its small cohort. We tried to capture a snapshot of short-term surgical practice in the country, providing data on the long-term survival and QoL of CRC patients. We also included only patients undergoing elective surgery with curative intent. Emergency surgery for colorectal cancer does not

influence overall and disease-free survival [36]; the data on the QoL of this small sub-group of patients should be studied further.

4.2 Retrospective study

Our study found that 28.8% of patients complain of fecal incontinence 8 years after TEM. Patients' quality of life and their perception of their own health after TEM procedure depend on their ability to maintain normal continence. Contrary to other studies, we found that long-term fecal incontinence after TEM operation is not negligible [18, 37]; it is almost twice higher than that in the population-based studies of the cohorts of similar age: according to the systematic review by Ng et al., the prevalence of fecal incontinence ranges from 2.3 to 12.0% [38]. Two other population-based studies [39, 40] identified that the prevalence of fecal incontinence may occur in up to 15% of over 70-year-olds. Longer operating time, older age, and malignant lesion pathology correlate with long-term fecal incontinence; however, older age at the time of the TEM operation was the single independent risk factor in a multivariate model. Allaix et al. [41] report Wexner score mean of 0.05 ± 0.37 60 months after TEM, although they only included patients that were completely continent before the operation. Our patients reported a mean Wexner score of 2.1 ± 4.0, which is significantly higher. Most of the studies do not report any negative [18, 19, 41–43] and sometimes even positive [37, 44] effects of TEM on continence. On the other hand, Restivo et al. [14] argue that fecal incontinence after TEM is not negligible and that should be explained to the patient before the operation. Only a few other studies analyze possible risk factors for fecal incontinence. Two studies provide data that TEM operation prolonged for more than 2 h is a risk factor for lowering anal resting pressure, without relevant clinical consequences [19, 45]. Postoperative complications and neoadjuvant chemotherapy could be also associated with the impairment of post-operative anorectal function [14] in cancer patients.

The main advantage of our study is the unrivaled follow-up period of a median of 96 (12–168) months while other similar studies report follow-up times ranging from 6 to 60 months [41, 44]. Another strength of our study is the application of standardized questionnaires such as the EQ-5D-5L quality of life questionnaire and Wexner fecal incontinence grading scale. We also analyzed whether the reported fecal incontinence after TEM in women could be attributed to obstetric history variables; this kind of information is not presented in any other similar studies. We did not find any correlation between previous vaginal deliveries and perianal operations and fecal incontinence in our study cohort.

One of the drawbacks of our study is a high number of nonresponders. One hundred thirty-nine (51.9%) patients that underwent TEM operation did not report back. This may lead to reporting bias, but as shown in Table 1, the responder and non-responder groups were identical, implying that the bias could be minimal. The large number of non-responders could be explained by the long duration of follow-up (14 years since the first operation for some patients) and the increasing age of the patients (median 66 years at the time of operation). Similar problems occur in most trials, reporting very distant outcomes after surgical operations [46–48]. The other disadvantage of our study is the use of only Wexner fecal incontinence grading score without any additional objective measurements, such as anorectal manometry.

However, anorectal manometry and patient-reported outcomes on the quality of life may differ, and the latter seems to be more important and practically feasible. Another limitation of the present study is the lack of preoperative quality of life and fecal incontinence evaluation, and this could not be alleviated by asking patients how they felt before the operation, while the long time period would have caused a significant recall bias. This could be important as the patients who are more likely to be incontinent are also older. Thus, incontinence may be the result of increasing age, rather than TEM operation [49]. However, we found other significant associations of incontinence with

malignant histology and the operating time on univariate analysis. Both factors should be studied further, as the number of prolonged transanal procedures for rectal cancer (transanal total mesorectal excision (TaTME)) is increasing rapidly. Although few initial studies report 1-year functional outcomes similar to laparoscopic operations [50], results after 1 year may be very different to those of several years for symptoms of fecal incontinence, as they could manifest later in life [51].

Several non-randomized studies [52, 53] report that endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) are as effective as TEM for removing large rectal lesions. Although quality of life has not been assessed yet, Barendse et al. [54] suggest that functional results after EMR and ESD are equal to the results after TEM. Given this information, EMR and ESD may be a more cost-effective solution for removing rectal lesions than TEM as they do not require expensive and specific equipment

CONCLUSIONS

1. The overall survival of patients depends directly on the stage of the disease.
2. Most patients return to a stable quality of life within 24 months after the operation, and it remains stable by 72 months. Age, stoma, adjuvant treatment, and colorectal cancer were independent risk factors for deteriorating quality of life.
3. Fecal incontinence after TEM is higher than
previously thought, and it significantly impairs quality of life.
4. Older age at the time of surgery was an independent risk factor for significant fecal incontinence. Meanwhile, we found no correlation between previous natural births and perianal surgery and fecal incontinence.

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The presentation and approbation of the results

Publications:

1. Jakubauskas M, Jotautas V, Poskus E, Mikalauskas S, Valeikaite-Tauginiene G, Strupas K, Poskus T. Fecal incontinence after transanal endoscopic microsurgery.Int J Colorectal Dis. 2018 Apr;33(4):467-472. DOI: 10.1007/s00384-018-2983-0. Epub 2018 Feb22. PMID: 29470728.
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Presentations:

1. Gintarė Valeikaitė-Tauginienė, Agnė Kraujelytė, Tomas Poškus, Eligijus Poškus, Žilvinas Saladžinskas, Narimantas Samalavičius, Kęstutis Strupas. "Ilgalaikė gyvenimo kokybė po storosios ir tiesiosios žarnos vėžio gydymo: prospektyvinė studija" 2019 10 11-12 Lietuvos chirurgų asociacijos suvažiavimas, Klaipėda, Lietuva
2. Gintare Valeikaite-Tauginiene ,Agne Kraujelyte, Tomas Poskus, Eligijus Poskus, Zilvinas Saladzinskas, Algimantas Tamelis, Narimantas Samalavicius, Kestutis Strupas. "Long-term quality of life after elective colorectal cancer surgery: a prospective cohort study". 2019 12 14-18 "7th DILEMMAS & DEBATES IN COLORECTAL SURGERY " London, United Kingdom
3. Gintare Valeikaite-Tauginiene ,Agne Kraujelyte, Eligijus Poskus, Zilvinas Saladzinskas, Algimantas Tamelis, Narimantas Samalavicius, Kestutis Strupas, Tomas Poskus. "Long-term quality of life after elective colorectal cancer surgery: a prospective cohort study". 2021 09 22-24 "16th Scientific and Annual Meeting of the European Society of Coloproctology "
4. Gintare Valeikaite-Tauginiene, Agne Kraujelyte, Eligijus Poskus, Zilvinas Saladzinskas, Algimantas Tamelis, Narimantas Samalavicius, Kestutis Strupas, Tomas Poskus. "Long-term quality of life after elective colorectal cancer surgery: a prospective cohort study". 2021 11 08-10 "40th Congress of the European Society of Surgical Oncology " Lisbon, Portugal

BRIEF INFORMATION ABOUT THE DISSERTANT

Gintarė Valeikaitė – Tauginienė was born on the 13 July, 1980 in Ukmergė. In 1998 she graduated from Ukmergės Jono Basanavičiaus secondary school. Between 1998 and 2004 studied at the Medical Faculty of Kaunas University of Medicine. A diploma of Medical Doctor was obtained in 2004. From 2004 to 2005 worked as a primary resident at the second Kaunas clinical hospital. In 2005 entered residency of abdominal surgery at Kaunas University Hospital "Kauno Klinik‘s" and completed the program in 2010. Qualification of the abdominal surgeon was obtained in 2010. As an abdominal surgeon worked at Trakų hospital (2010 – 2015), and the Baltic and American Clinic (2010- 2021). Since 2010 works as an abdominal surgeon and coloproctologist at "Z clinic". In 2015 started working at the Center of Abdominal and Oncosurgery center of Vilnius University Hospital "Santaros Klinikos".

Started research work during her studies at the Medical Faculty of Kaunas University of Medicine. Has written and co-authored several scientific articles published in Lithuanian scientific journals. During her studies, she did an internship at Kalundborg Hospital in Denmark. Research work continued during the residency. Presented several scientific papers at Lithuanian and international scientific conferences in Austria and Estonia. During her residency, she did an internship at the University Hospital Erlangen in Germany. Between 2016 and 2020 she was a doctoral student at Vilnius University. Research work "Study of factors determining the long-term quality of life after surgical treatment in patients with colorectal tumors" was performed at the Center of Abdominal and Oncosurgery of Vilnius University hospital "Santaros Klinik‘s" in collaboration with the Department of Surgery of Kaunas University Hospital "Kauno Klinikos" and Department of Surgery of National Cancer Institute. Three scientific articles in reviewed international journals and four abstracts in Lithuanian and international editions were published on the subject of this dissertation.

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