

The Pattern of Colorectal Cancer Surgery in Lithuania in 2005: Do Results Meet Expectations?

Eligijus Poškus¹, Saulius Mikalauskas¹, Valdemaras Jotautas¹, Paulius Žeromskas¹, Tomas Poškus¹, Kęstutis Strupas¹, Narimantas Evaldas Samalavičius², Marius Lasinskas², Andrius Sklepavičius², Algimantas Tamelis³, Žilvinas Saladžinskas³, Dainius Pavalkis³, Audronė Jakaitienė⁴, Giedrė Smailytė²

¹Centre of Abdominal Surgery, Clinic of Gastroenterology, Nephrourology and Surgery, Faculty of Medicine, Vilnius University, ²Institute of Oncology, Vilnius University, ³Department of Surgery, Medical Academy, Lithuanian University of Health Sciences, ⁴Centre of Bioinformatics and Biostatistics, Department of Human and Medical Genetics, Faculty of Medicine, Vilnius University, Lithuania

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Summary. The aim of this study was to expose the pattern of the surgical treatment of colorectal cancer in Lithuania in 2005.

Material and Methods. A retrospective analysis of 590 patients treated for colorectal cancer in the surgical departments of the Hospital of Lithuanian University of Health Sciences, the Institute of Oncology of Vilnius University, and Vilnius University Hospital Santariškių Klinikos in 2005 was performed. Demographic data, preoperative evaluation, postoperative complications assessed according to the Clavien–Dindo classification, the quality of pathological examination, and survival rates were analyzed.

Results. A total of 590 patients, 269 women (45.6%) and 321 men (54.4%), were included in this study; the mean age was 68.3 years (SD, 11.2). Tumors were found in the colon of 274 patients (46.4%) and in the rectum of 316 patients (53.6%). An abdominal ultrasound scan was preoperatively performed in 516 patients (87.5%) and a chest x-ray in 316 patients (53.6%); 35 patients (5.9%) underwent abdominal computed tomography. Endorectal ultrasound was done in 99 (31.7%) cases. Neoadjuvant radiotherapy for T3 and T4 rectal tumors was applied in 42 cases (18.1%). Besides, 211 patients (35.8%) developed postoperative complications with an anastomotic leak emerging in 20 cases (3.4%). Death occurred in 7 patients (1.18%). On the average, 11.15 lymph nodes (SD, 6.02) were found in pathological specimens. Circumferential resection margins were assessed in 58 cases (18.4%). The overall 5-year survival rate was 52.06%.

Conclusions. The preoperative evaluation and the treatment of patients with colorectal cancer were not sufficiently consistent in Lithuania in 2005. In order to improve the treatment of colorectal cancer, standardization or the national database of colorectal cancer is necessary.

Introduction

The prevalence of colorectal cancer is increasing in Lithuania as well as at the global scale. The number of colorectal cancer cases in Lithuania has doubled during the last 20 years. In 2009, 868 new colon and 740 rectal cancer cases were registered in Lithuania (1).

The quality and the results of diagnosis and treatment have improved significantly during the last decade in many countries: the disease is diagnosed at its earlier stages, and surgery and chemotherapy are applied proactively with an overall effect on improved survival rates (2–6). Sadly, the results of colorectal cancer management in Lithuania are not so optimistic. Diagnosis in the late stage is frequent: up to 45% of patients have stage III and IV cancer and only 35% are diagnosed with stage I and

II colorectal cancer. The stage is not reported in approximately 20% of new cases, and the data imply that more advanced stages of colorectal cancer have also been possible (1). Undoubtedly, late diagnosis worsens the results of treatment and increases healthcare costs.

On the contrary, many developed countries are reporting improved results related to advancements in diagnostics, disease staging and treatment modalities, and implementation of screening programs. More accurate data collection and precise monitoring of treatment quality play a substantial role here, too (7). Therefore, following the models implemented in other European countries (8, 9), more attention has recently been given to the diagnostics and the treatment of this disease in Lithuania, too: a colorectal cancer screening program was initiated in 2009, and colorectal cancer management guidelines were approved by the Ministry of Health in 2012.

However, there are still major problems with an

Correspondence to E. Poškus, Centre of Abdominal Surgery, Vilnius University Hospital Santariškių Klinikos, Santariškių 2, 08661 Vilnius, Lithuania. E-mail: eligijus.poskus@santa.lt

extensive monitoring of treatment results as well as the quality control system in Lithuania. In order to overcome these problems, bowel cancer registries have been developed in the neighboring Scandinavian and many other developed countries. Unfortunately, Lithuania is still lacking such an institution. The Lithuanian Cancer Registry is not very helpful in this situation as it contains only very basic data. Therefore, an initiative group of researchers from the Faculty of Medicine of Vilnius University, Vilnius University Hospital Santariškių Klinikos (VUHSK), the Institute of Oncology of Vilnius University (IOVU), and the Lithuanian University of Health Sciences (LUHS) was established with support from the Research Council of Lithuania with the intention to improve the management quality of colorectal cancer patients. One of the tasks of this group was to initiate the development of the national colorectal cancer registry or database. In the proceedings of this group, an essential step in order to assess the effect of future changes was to evaluate the baseline routine practice of diagnostics, staging, and surgical treatment and to assess comprehensively immediate and long-term results of the treatment of colorectal cancer patients. Therefore, this study was designed in line with the abovementioned specified goals and its aim was to expose the pattern of the surgical treatment of colorectal cancer in Lithuania in 2005. This analysis will serve as a stepping stone for future studies about colorectal cancer in the country.

Material and Methods

A retrospective analysis of the data of the patients treated for colorectal cancer in the surgical departments of the LUHS, the IOVU, and VUHSK in 2005 was performed. Demographic characteris-

tics (age and gender), preoperative diagnostics and staging, preoperative and surgical treatment options, histopathological tumor examination, morbidity, mortality, and 1-year and 5-year survival data were analyzed.

Intra- and postoperative morbidity was measured according to the Clavien-Dindo classification (Table 1). The quality of the histopathological specimen evaluation was assessed according to the TNM staging system, lymphovascular invasion, differentiation grade, completeness of resection (R), and specifically for rectal tumors, involvement of circumferential resection margins and integrity of the mesorectal fascia. Actual survival data were obtained from the Lithuanian Cancer Registry.

The statistical software IBM SPSS (v.21) was used for the statistical analysis. Continuous variables are expressed as mean (SD). Continuous variables were checked for the normality of distribution by the Kolmogorov-Smirnov and Shapiro-Wilk tests and compared using the Student *t* test when the data were normally distributed or the Mann-Whitney test when the data were nonnormally distributed. The association between categorical variables was verified using the Pearson chi-square test. The vital status of the study group was assessed on September 30, 2012, by passive follow-up using the data from the Lithuanian Cancer Registry. Survival was estimated by the Kaplan-Meier method. The difference between the survival curves was determined using the log-rank test. The level of significance was set at 0.05.

Results

A total of 590 patients with a mean age of 68.3 years (SD, 11.2) were included in this study. There were 269 women (45.6%) and 321 men (54.4%).

Table 1. Clavien-Dindo Classification

Grade	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions
	Allowed therapeutic regimens are drugs such as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications
	Blood transfusions and total parenteral nutrition are also included
Grade III	Requiring surgical, endoscopic, or radiological intervention
Grade IIIa	Intervention not under general anesthesia
Grade IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications)* requiring IC/ICU management
Grade IVa	Single organ dysfunction (including dialysis)
Grade IVb	Multiorgan dysfunction
Grade V	Death of a patient
Suffix "d"	If a patient suffers from a complication at the time of discharge, the suffix "d" (for "disability") is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication

CNS, central nervous system; IC, intermediate care; ICU, intensive care unit.

*Brain hemorrhage, ischemic stroke, subarachnoid bleeding, but excluding transient ischemic attacks.

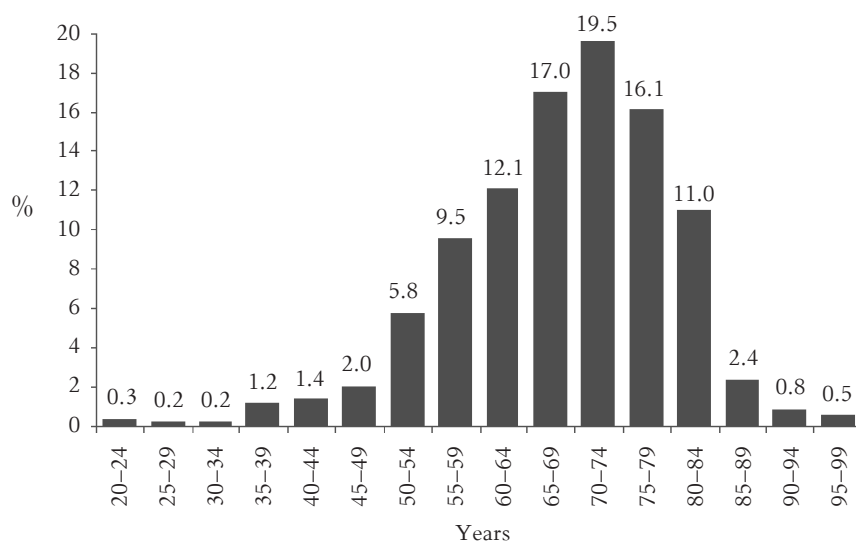


Fig. 1. Distribution of the patients by age groups

They accounted for 39% of all the patients treated for colorectal cancer in Lithuania in 2005 (1). The majority (84.6%) of the patients were admitted on an elective and 15.4% on an emergency basis. The highest prevalence rate of colorectal cancer was observed in the age group from 50 to 80 years (80% of all patients). The distribution of the patients by age groups is shown in Fig. 1.

Colon tumors were found in 274 (46.4%) and rectum tumors in 316 patients (53.6%). The pattern of tumor location was different in men and women: in men, 43.3% of tumors were found in the colon and 56.7% in the rectum in comparison with 50.2% and 49.8%, respectively, in women ($P=0.098$). The sigmoid colon was the most common location of colon cancer (110 cases, 40.1%). The distance of tumors from the anal verge was indicated in 201 cases (63.6%) of rectal cancer, and the most frequent tumor localization was the lower third of the rectum (110 cases, 54.7%). Synchronous tumors at the time of diagnosis were found in 27 patients (4.6%); there were 15 cases of double primary malignancies in the colon, 8 cases in the rectum, and 5 cases in both the colon and the rectum. The details on the location of tumors are shown in Tables 2 and 3.

Colonoscopy was the main diagnostic tool for the majority of the elective patients (90%). Barium enema was a definitive diagnostic measure in 8% and virtual colonoscopy in 2% of the patients. Therefore, it can be concluded that 10% of all the patients were operated on without a definite histological diagnosis.

The staging of the disease was mostly based on abdominal ultrasound ($n=516$, 87.5%) and a chest x-ray ($n=316$, 53.6%), whereas only 1 patient underwent computed tomography (CT) of the chest and only 35 patients (5.9%) had an abdominal CT

Table 2. Tumor Distribution According to Location and Gender

Location	Gender		Total
	Men	Women	
Colon	139 (43.3)	135 (50.2)	274 (46.4)
Rectum	182 (56.7)	134 (49.8)	316 (53.6)
Total	321	269	590

Values are number (percentage).

Table 3. Location of Colon Cancer

Location	Gender		Total
	Men	Women	
Cecum	11 (7.9)	14 (10.4)	25 (9.1)
Ascending colon	20 (14.4)	23 (17.0)	43 (15.5)
Hepatic flexure	10 (7.2)	8 (5.9)	18 (6.5)
Transverse colon	9 (6.5)	6 (4.4)	15 (5.4)
Splenic flexure	4 (2.9)	8 (5.9)	12 (4.3)
Descending colon	11 (7.9)	10 (7.7)	21 (7.6)
Sigmoid colon	58 (41.8)	52 (38.5)	110 (39.6)
Rectosigmoid junction	16 (11.5)	14 (10.4)	30 (11.2)
Total	139	135	274 (100)

Values are number (percentage).

scan documented.

The local staging of a rectal tumor was performed only in the minority of the cases. Only 2 patients underwent magnetic resonance imaging (MRI) for the determination of local tumor advancement, and an endorectal ultrasound (ERUS) scan was done in 99 patients (31.7%). T3 and T4 tumors were found in 61 patients (61.6%) of those diagnosed. Unfortunately, irregular documentation of the patients' data in different institutions and a retrospective nature of the study cannot provide the complete picture of the diagnostic and staging process, and some data are missing.

Preoperative treatment was instituted in 51 patients. Only 1 colon and 8 rectal cancer patients

received preoperative chemotherapy. Neoadjuvant radiotherapy for T3 and T4 rectal tumors was applied in 42 patients (18.1%), of these, 8 were treated with combined neoadjuvant chemoradiotherapy. The details of preoperative radiotherapy are shown in Table 4.

Almost all the operations were performed through the laparotomy approach. Laparoscopic resection was performed only in 9 patients (1.5%), and transanal endoscopic microsurgery (TEM) was elaborated in 8 patients (1.3%). There were 236 colon resections, 174 anterior resections of the rectum, and 135 abdominoperineal resections performed. The latter 135 cases accounted for 42.7% of the operations of rectal cancer. The remaining 45 operations were performed mainly for palliative reasons.

After colorectal surgery, some patients were treated with adjuvant chemo-, radio-, or chemoradiotherapy. However, due to the retrospective nature of this study, a complete data collection was not possible as the patients were managed in different institutions. The data from only 1 center (LUHS) were available: after rectal surgery, 29 patients (27.1%) of 107 received postoperative chemoradiation. The postoperative TNM classification is presented in Table 5.

In large part, the histopathological examination indicated T, N, G, L, V, and R status. The quality of rectal resection (integrity of the mesorectal fascia) was not assessed at all, and circumferential resection margins were evaluated in only 58 patients (18.4%) with rectal cancer. Positive resection margins were found in 9 (15.5%) of them. The number of the examined lymph nodes was reported in 329 cases (55.8%), and the mean number was 11.15 (SD, 6.02); however, 223 specimens (67.8%) contained fewer than 12 lymph nodes and 67 (20.4%) fewer than 6 lymph nodes. The distribution of the patients according to the number of lymph nodes is shown in Table 6.

Postoperative recovery was uneventful in 379 patients (64.2%); meanwhile, 211 patients (35.8%) developed complications: 103 (37.6%) after the colon and 108 (34.2%) after the rectal procedure. Postoperative complications occurred in 52 emergency patients (57.1%) (35 [53.0%] colon and 17 [68.0%] rectal cancer cases) and in 159 elective patients (31.9%) (68 [33.0%] colon and 91 [31.0%] rectal cancer cases) ($P<0.001$). The distribution of postoperative complications by cancer type is shown in Table 7. The most common surgical complication was a wound infection, which developed in 55 patients (9.3%). An anastomotic leak occurred in 20 patients (3.4%); in 8 (2.9%) and 12 (6.9%) after colon and rectal resections, respectively.

The complications were also evaluated according to the Clavien-Dindo classification (Table 8). Simpler grade 1 and 2 complications were most com-

Table 4. Preoperative Radiotherapy for Rectal Cancer

Preoperative Radiotherapy	n (%)
Short-course	11 (3.5)
Long-course	31 (9.8)
Not applied	274 (86.7)
Total	316 (100)

Table 5. Postoperative TNM Status

Category	Colon Cancer	Rectal Cancer	Total
T			
Tis	3 (1.1)	15 (4.8)	18 (3.1)
T1	5 (1.8)	11 (3.5)	16 (2.7)
T2	19 (7.0)	54 (17.3)	73 (12.5)
T3	158 (57.9)	176 (56.4)	334 (57.1)
T4	88 (32.2)	56 (17.9)	144 (24.6)
No data	1 (0.4)	4 (1.3)	5 (0.8)
N			
0	152 (55.9)	147 (47.1)	299 (51.2)
1	62 (22.8)	95 (30.4)	157 (26.9)
2	58 (21.3)	69 (22.1)	127 (21.7)
No data	2 (0.7)	5 (1.6)	7 (1.2)
M			
0	204 (74.5)	278 (88.0)	482 (81.7)
1	62 (22.6)	36 (11.4)	98 (16.6)
No data	8 (2.9)	2 (0.6)	10 (1.7)

Values are number (percentage).

Table 6. Number of Examined Lymph Nodes

Number of Lymph Nodes	n (%)
<6	67 (20.4)
6–11	156 (47.4)
≥12	106 (32.2)
Total	329

mon. They occurred in 22.5% of all the patients. Surgical reintervention under general anesthesia for degree 3 surgical complications was performed in 11.0% of the patients.

The mean length of stay was 17.5 days (SD, 9.2): 16.4 days (SD, 7.4) after the colon procedure and 18.5 (SD, 10.5) days after the rectal procedure. The patients with colon cancer following emergency admission stayed significantly longer ($P=0.052$); this cannot be applied to those with rectal cancer due to a very wide data distribution. As expected, the patients with postoperative complications stayed longer, and the highest increase in hospital stay was observed for patients with anastomotic dehiscence compared with those with other complications ($P<0.001$).

Surprisingly, the postoperative mortality was rather low, and only 7 patients (1.2%) died: 6 (2.2%) after the colon resection and only 1 (0.3%) after the rectal resection.

The overall 1- and 5- year survival rates were 79.4% (95% CI, 75.9%–82.4%) and 52.1% (95% CI, 47.9%–56.1%), respectively. The 5-year survival rates for men and women were 49% (95% CI, 43.3%–54.5%) and 55.6% (95% CI, 49.9%–61.3%), respectively, but the observed difference was not

Table 7. Postoperative Morbidity

Complication	Colon Cancer	Rectal Cancer	Total
No complications	171 (62.4)	208 (65.8)	379 (64.2)
Wound infection	30 (10.9)	24 (7.6)	54 (9.2)
Eventration	3 (1.1)	5 (1.6)	8 (1.4)
Bowel obstruction, relaparotomy	2 (0.7)	7 (2.2)	9 (1.5)
Ileus, treated conservatively	7 (2.5)	2 (0.6)	9 (1.5)
Intra-abdominal abscess	8 (2.9)	8 (2.5)	16 (2.7)
Intra-abdominal mass	1 (0.4)	1 (0.3)	2 (0.3)
Bowel perforation	0 (0)	1 (0.3)	1 (0.17)
Anastomotic leak	8 (2.9)	12 (6.9)	20 (3.4)
Sepsis	6 (2.2)	2 (0.6)	8 (1.4)
Urological complications	8 (2.9)	16 (5.1)	24 (4.1)
Renal failure	2 (0.7)	0 (0)	2 (0.3)
Cardiovascular complications	5 (1.8)	7 (2.2)	12 (2.0)
Pulmonary complications	2 (0.7)	0 (0)	2 (0.3)
Psychiatric disorders	2 (0.7)	2 (0.6)	4 (0.7)
Other	19 (6.9)	21 (3.8)	40 (6.8)
Total	274 (100)	316 (100)	590 (100)

Values are number (percentage).

Table 8. Complications According to Clavien-Dindo Classification

Type	Degree of Complication According to Clavien-Dindo						Total
	0	1	2	3	4	5	
Rectum	208 (65.8)	19 (6.0)	44 (13.9)	42 (13.3)	2 (0.6)	1 (0.3)	316
Colon	171 (62.4)	24 (8.8)	46 (16.8)	23 (8.4)	4 (1.5)	6 (2.2)	274
Total	379 (64.2)	43 (7.2)	90 (15.3)	65 (11.0)	6 (1.0)	7 (1.2)	590

Values are number (percentage).

significant (Fig. 2). Better survival was associated with less advanced cancer ($P < 0.00001$) (Fig. 3). The 5-year survival rate for the patients with colorectal cancer of different stages was as follows: stage 0, 87.8% (95% CI, 59.5%–96.8%); stage I, 80.5% (95% CI, 66.8%–89.0%); stage II, 74.8% (95% CI, 67.9%–80.3%); stage III, 49% (95% CI, 41.8%–55.7%); and stage IV, 4.2% (95% CI, 1.6%–9.0%) (Fig. 3). No significant differences in the survival rates were observed comparing different age groups (Fig. 4). The patients younger than 50 years (who would be not eligible for the colorectal cancer screening program) had 47.6%, 50- to 74-year-old patients (probable participants of the colorectal cancer screening program) had 53.8%, and the patients older than 75 years had 48.9% 5-year survival rates (Fig. 4).

Discussion

In 2005, 39.0% of all the patients with a newly diagnosed colorectal cancer in Lithuania were operated on in the surgical departments of the HLUHS, the IOVU, and VUHSK (1). It would be reasonable to conclude that the rest of the patients could have received less qualified help, and a more extensive referral of these patients to the large clinical centers is necessary.

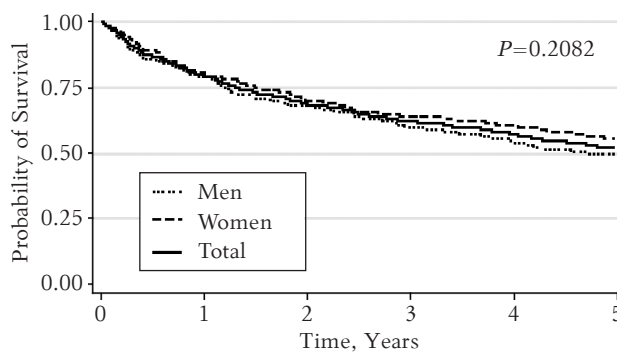


Fig. 2. Overall survival estimates and survival estimates by gender

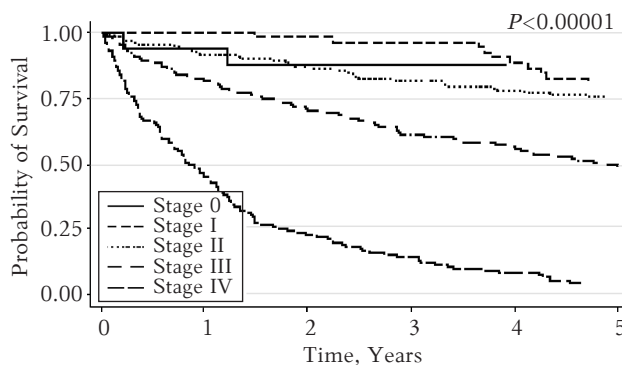


Fig. 3. Survival estimates by cancer stage

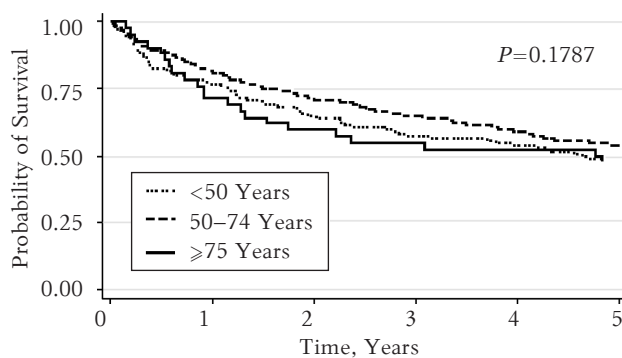


Fig. 4. Survival estimates by age groups

In our study, the gender proportion, the tumor location, and the number of synchronous tumors were similar to these in other countries (10). The mean age of operated patients was more than 68 years, and the percentage of emergency cases (15.6%) was lower than that described in the literature (11). Patients who required emergency operations were more frequently admitted to regional hospitals.

Although it is crucial to determine the cancer stage before an operation, in 2005, only 5.9% of all the patients had an abdominal CT scan done before surgery. Meanwhile, it is well recognized that a CT scan enables accurate diagnostics of both extra- and intrahepatic metastases and helps assess treatment efficiency (12). As for rectal cancer, ERUS competes with MRI in this setting (13–17). Of these 2 modalities, the former is more valuable for T1 and T2 tumors, whereas the latter examination is useful in the assessment of T3 and T4 tumors and in the determination of affected pelvic lymph nodes. In this study, it was shown that only 31.7% of the patients underwent ERUS and 2 patients had an MRI scan. It is well known that the proper assessment by ERUS can be affected by the extent of T3 and T4 rectal tumors and is considered to be not so accurate in this setting. Meanwhile, T3 and T4 tumors were diagnosed by ERUS in 61.6% of the patients in this study.

Nowadays, colorectal cancer management is complex, and accurate staging enables prioritization of treatment options (18). There are many different radiotherapy modalities with a different timing of the operation afterwards; however, it is commonly agreed that in case of T3 and T4 rectal cancers or lymph node involvement $>N0$, patients are treated with radiotherapy or radiochemotherapy preoperatively. The aims of this treatment are a reduction in tumor size, disappearance of metastatic lymph nodes (downstaging and downsizing), diminished risk of local recurrence, and higher chances of successful primary anastomosis, allowing to avoid abdominoperineal resection (APR) (18). As seen in the present study, neoadjuvant radiotherapy was used only in 42 patients (18.1%) with T3 and T4 tumors. Most probably this is the reason why APR was done in 42.7% of the patients, whereas the desirable proportion is approximately 20%–30% (19).

Laparoscopic colorectal surgery is gaining worldwide acceptance because of its confirmed reliability (20–22). Our study demonstrated that only 9 laparoscopic colorectal resections (1.5%) were performed in 2005.

According to the data in literature, postoperative complications after colon and rectal operations are frequent; they can reach up to 30%–40% and are more common after rectal resections (23). The re-

sults of this study indicated that complications were observed more frequently after colon surgery, comprising 37.6% of the cases (34.2% after rectal surgery). It has been reported that an anastomotic leak after colon surgery is observed in 1%–4%, while after rectal surgery, it occurs in between 3% and 16%–19% of patients. Thus, the incidence of this complication in Lithuania does not exceed global standards (24–26): in our study, it occurred in 2.9% of the patients after colon surgery and 6.9% after rectal surgery. Only 7 patients (1.18%) died after operations, of which only 1 patient after rectal surgery (0.3%). It is an excellent rate, considering the overall mortality to be 2%–6% according to the literature (27).

A unified evaluation of postoperative complications is essential for the adequate comparison of treatment results. This evaluation allows improvements in the quality of treatment. The Clavien-Dindo classification of postoperative complications is constantly gaining acceptance worldwide (28, 29). We were the first in Lithuania to use this classification.

Only an accurate pathological examination enables a proper evaluation of surgical work quality, planning of postoperative treatment strategy, and giving accurate survival and recurrence prognosis rates (30, 31). Therefore, rigorous requirements for the pathological specimen evaluation were created. Although the mean number of examined lymph nodes was 11 and close to the required 12, in up to 67.8% of the patients, the number of lymph nodes did not reach 12. In addition, in the cases of rectal cancer, it is crucial to assess circumferential resection margins as it is one of the most significant prognostic factors for local recurrence (32). However, it was evaluated only in 18.4% of the patients. On the other hand, surgical work quality is indicated not only by a negative or a positive circumferential resection margin, but by the integrity of the mesorectal fascia as well (17). A circumferential resection margin is considered positive if a tumor or a mesorectal metastatic lymph node is closer than 2 mm to the radial resection margin. In the current study, it was positive in 9 patients (15.5%), whereas integrity of the mesorectal fascia was not assessed at all. The evaluation of this parameter would allow the determination of the ability of surgeons to perform a total mesorectal excision, a crucial step in rectal resection.

While analyzing the survival data, we can observe that the overall 5-year survival rate was not high (52.1%) as compared with the 5-year survival rate in the United States and Germany reaching up to 63.0% (4) and 65.9% (33), respectively. It is worth noting that a lot of attention is paid nowadays to the patients suffering from stage IV cancer, especially

those with isolated hepatic metastases (34). The current study found that only 4.2% of those patients survived 5 years. However, it is well known that with the implementation of modern treatment strategies, it is possible to prolong the survival of those patients up to 18%–19% (35). The survival of patients younger than 50 years also raises concerns as it is 47.62% ($P=0.1787$), i.e., lower than the overall survival rate. This is a group of fairly young patients, in which survival rates could be increased up to 60%–63% with early diagnostics, further analysis of colorectal cancer prevalence, and adequate treatment (36).

In order to improve colorectal cancer treatment results, the screening program was initiated in 2009 by the Ministry of Health of the Republic of Lithuania. Moreover, the Research Council of Lithuania organized a team of scientists in 2010. This team developed a scientific project to analyze and improve the results of colorectal cancer treatment. One of the aims of this project was to evaluate the efficiency of the screening program and its results (37). The data in this article are the first attempt to analyze some of the characteristics of colorectal cancer treatment in Lithuania in 2005. Hopefully, in the following prospective publications of this pro-

ject, we will see an improvement in the preoperative evaluation of these patients, increase in laparoscopic operation rates, reduced numbers of abdominoperineal resections, and an overall complex approach to colorectal cancer treatment.

Conclusions

The system of colorectal cancer diagnosis, staging, reporting of histopathological examination, and treatment was not fully standardized and suboptimal in Lithuania in 2005. The implementation of the standards, approved by the Ministry of Health in 2012, raises the necessity of more precise regulation and quality control. The establishment of the national colorectal cancer registry or national database would be highly helpful in adjusting treatment and surveillance of patients as well as in improving the survival rates.

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Statement of Conflict of Interest

The authors state no conflict of interest.

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