ORIGINAL ARTICLE
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Risk factors affecting oncological outcomes of surgical resections for middle and lower rectal cancer

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ABSTRACT

Objective: In our study, it was aimed to evaluate the factors affecting oncological outcomes in resections for rectal cancer.

Material and Methods: Between January 2010 and December 2014, patients with rectal tumors were analyzed retrospectively. Demographic and pathological data and oncological outcomes were analyzed as disease-free survival, overall survival, and local recurrence.

Results: A total of 158 patients' data were obtained. Median age was 60 (22-83). Fifty-three patients were older than 65 years of age (138). Ninety-five (60%) patients were males, and 63 (40%) were females. Eighty patients (50.4%) had middle rectal, and 78 (49.6) patients had lower rectal cancer. There was no effect of tumor localization on oncological outcomes. Univariate analyses revealed the effects of age (p= 0.003), operation type (p< 0.001), nodal status (p< 0.001), malignant lymph node ratio (p< 0.001), stage of the disease (p< 0.001), distal resection margin (p= 0.047), perineural invasion (p< 0.001), lymphatic invasion (p< 0.001), venous-vascular invasion (p= 0.025), local recurrence (p< 0.001) and distant metastasis (p< 0.001) on overall survival rates. Univariate analyses revealed the effects of nodal status (p= 0.007), malignant lymph node ratio (p= 0.005), stage of the disease (p= 0.008), perineural invasion (p= 0.004) and venous-vascular invasion (p< 0.001) on disease-free survival rates. Univariate analyses revealed the effects of anastomotic leak (p= 0.015) and venous-vascular invasion (p= 0.001) on local recurrence rates.

Conclusion: Older age, advanced nodal status, and distant metastasis were detected as independent risk factors for overall survival. Perineural and venous-vascular invasion were detected as independent risk factors for disease-free survival. Lastly, anastomotic leak and venous-vascular invasion were detected as independent risk factors for local recurrence.

Keywords: Rectal cancer, rectal surgery, survival, local recurrence

INTRODUCTION

Heald published the definition of total mesorectal excision (TME) in 1982 that started the modern rectal cancer surgery era (1). Five-year disease-free survival of 80% and 4% local recurrence rates published by Heald were spectacular (2). Heald proposed that the principle of TME is to preserve the "Holy Plan" in harmony with embryological principles and to perform resection with sharp dissection in this space (3). Additionally, evidence was presented that TME not only improved oncological outcomes but also significantly ameliorated quality of life. Significant decreases were shown in urinary and sexual autonomic dysfunctions in the postoperative period with the preservation of hypogastric nerves (4).

In the following years, the importance of reaching tumor-negative margins during rectal surgery was appreciated since adjuvant treatment, applied in cases with positive surgical margins, had not shown the effectiveness of resection with negative surgical margins (5). Furthermore, Swedish and Dutch studies revealed the importance of neoadjuvant therapy in the treatment of rectal cancer (6-8). Current guidelines emphasize the crucial role of neoadjuvant chemoradiotherapy in obtaining negative surgical margins in patients with T3 and T4 tumors detected by preoperative imaging techniques (9). Although there have been plenty of ongoing developments in rectal surgery for over a century; the main goals should be summarized as reaching tumor-free surgical margins, reducing loco-regional recurrences, increasing survival and disease-free survival times, and maintaining the quality of life are still the constant intentions (1).

In our study, it was aimed to evaluate the factors affecting oncological outcomes in resections for middle and lower rectal cancer.

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MATERIAL and METHODS

Following the receival of ethics committee's approval (2016-14/18), patients who underwent surgery had been followed with the diagnosis of rectal cancer in our center between January 1, 2010, and December 31, 2014 were included in the study. To make the patient groups homogeneous, patients who were operated under emergency conditions with bleeding or intestinal obstruction and/or whose resection material was not suitable for pathological examination were excluded. Likewise, cases with distant metastases and considered unresectable at the time of diagnosis or during surgery were also excluded from the study. Patients with any pathological diagnosis without adenocarcinoma were also excluded (Figure 1).

Age, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) score, tumor location (distal rectum or middle rectum), and the existence of upfront neoadjuvant therapy history were evaluated in the preoperative period. According to the type of resections performed during the operation, the patients were divided into two groups those who underwent abdominoperineal resection (APR) or anterior resection (AR). Low anterior resection (LAR), very low anterior resection (VLAR), and Hartmann's procedures were evaluated within the AR group. In the postoperative period, the following parameters were analyzed; anastomotic leakage, dimensions of tumor (T stage), nodal status (N stage), malignant lymph node ratio (MLNR), pathological TNM staging, tumor grade, circumferential resection margin (CRM) involvement, distal resection margin (DRM) involvement, TME integrity in the pathology specimens, presence of a mucinous component in the tumor, presence of perineural invasion, presence of lymphatic invasion, presence of venous-vascular invasion, survival time, disease-free survival, local recurrence and existence of distant metastasis. For the evaluation of TME, pathology specimens were divided into three groups.

1- Complete TME: The mesorectal fascial plane has a smooth surface, and minor irregularities and defects are less than 5 mm in depth.

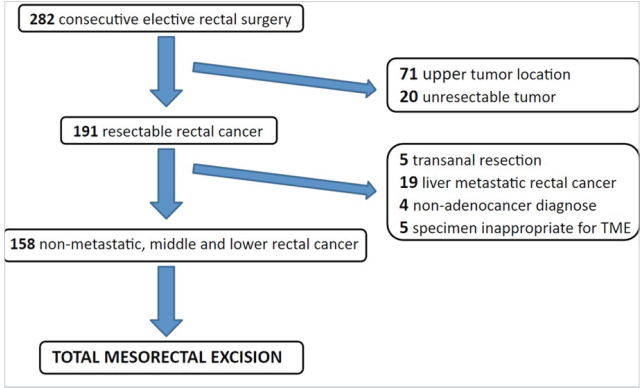

Figure 1. Flow-chart diagram.

2- Near Complete TME: There are one or more defects greater than 5-mm deep in the mesorectum, but a macroscopic muscular layer is not observed in the defect area. Mesorectal defects are moderate.

3- Incomplete TME: Defects in the mesorectum reach the muscularis propria, and the removed mesorectal tissue is inadequate.

All procedures were performed by two experienced surgeons working in the colorectal surgery unit. All specimens were freshly evaluated by the same pathologist. In addition to TME integrity, CRM and DRM were also evaluated in the specimens. TNM classification, which was determined by the American Joint Committee on Cancer (AJCC) and the Union for International Cancer Control (UICC) in 1954 and was last revised in 2010, was used for oncological evaluation and postoperative treatment planning (10).

Patients' survival time was calculated as the period between the date of surgery and the day of death. The time to the recurrence of local and/or distant metastasis after the operation was identified as disease-free survival. Minimum and maximum follow-up periods were 23 and 81 months, respectively. Date of death data were obtained from the Turkish Ministry of Health death notification database.

Data conformity to normal distribution was evaluated with the Shapiro-Wilk test. The Kaplan-Meier test was used to evaluate survival times. Variables found to be significant in the Kaplan-Meier analysis were evaluated in terms of independent risk factors with stepwise forward Cox regression analysis. Cox regression analysis was used for the analysis of local recurrence.

RESULTS

A total of 158 patients, 63 (40%) females, with a median age of 60 (22-83) years, were included in the study. In terms of body mass index (BMI), 47 (30%) patients were found to have a BMI of 30 and above. In terms of ASA scores, there were 44 (27.8%) patients for ASA-I, 109 (69%) patients for ASA-II, and only five (3.2%) patients for ASA-III (Table 1). Tumors of 80 patients were located in the middle rectum. Seventy-eight patients had a distal located rectal tumor. Considering the number of surgeries performed, anterior resection (AR) was performed in 119 (75.5%) patients and APR was performed in 39 (24.5%) of the patients.

Mean number of harvested lymph nodes per patient was 14.6 ± 9. Malignant lymph nodes were not detected in 94 (59.5 %) patients (N0). Thirty-four (21.5 %) patients had 1-3 malignant lymph nodes (N1). Four or more malignant lymph nodes were detected in 30 (18.9 %) patients (N2).

Mean follow-up time was 63 (± 11.2) months. Mean overall survival time was 63 (± 5.4) months and mean disease-free survival time was 54.3 (± 2.5) months. There were 21 (13.2%)

Table 1. Demographics and perioperative data of the patients

	n	%
Age		
<65	105	66.5
≥65	53	33.5
Sex		
Female	63	39.9
Male	95	60.1
ASA Score		
1	44	27.8
2	109	69.0
3	5	3.2
Obesity		
BMI< 30	111	70.3
BMI≥ 30	47	29.7
Tumor Status		
0	23	14.6
1	10	6.3
2	26	16.5
3	94	59.5
4	5	3.2
Nodal Status		
0	94	59.5
1	34	21.5
2	30	19.0
Stage		
0	22	13.9
1	29	18.4
2A	43	27.2
2B	1	.6
2C	1	.6
3A	5	3.2
3B	41	25.9
3C	16	10.1

ASA: American Society of Anesthesiologists, BMI: Body mass index.

patients with local recurrence. Mean duration to local recurrence was 18.4 (± 11.2) months. There were 27 (17.1%) patients with distant metastasis. When the distribution of metastases was examined, 17 lung, 10 liver, six bone, one brain and one breast metastases were documented.

Factors Affecting Overall Survival

Sex, ASA score, obesity, tumor level, neoadjuvant therapy, anastomotic leak, T stage of the tumor, adjuvant therapy, CRM involvement, TME integrity, tumor grade, and mucinous omponent of the tumor did not have a statistically significant effect on overall survival. However, older age, APR, advanced N stage, high malignant lymph node ratio (MLNR), advanced TNM stage, 10 mm or less DRM, perineural invasion, lymphatic invasion, venous-vascular invasion, local recurrence development, and distant metastases had a statistically significant effect on overall survival time. In Kaplan-Meier analysis, when the factors affecting survival time were examined by Cox regression analysis, it was determined that older age, advanced N stage and development of distant metastases were independent risk factors (Table 2, Figures 2-4).

Factors Affecting Disease-Free Survival

Age, sex, ASA score, obesity, tumor level, neoadjuvant therapy, anastomosis leak, surgery type, tumor T stage, adjuvant therapy, CRM involvement, DRM distance, TME integrity, tumor grade, a mucinous component of the tumor and lymphatic invasion did not have a statistically significant effect on disease-free survival. However, advanced N stage, MLNR, advanced TNM stage, presence of perineural invasion and venous-vascular invasion were statistically significant for disease-free survival. In the Kaplan-Meier analysis, when the factors affecting disease-free survival were examined by Cox regression analysis, it was determined that perineural invasion and venous-vascular invasion were independent risk factors (Table 3, Figures 5,6).

Factors Affecting Local Recurrence

Age, sex, ASA score, tumor level, neoadjuvant therapy, type of surgery, tumor N stage, MLNR, TNM stage, adjuvant treatment, CRM involvement, DRM distance, TME integrity, tumor grade, mucinous component of the tumor, the perineural and lymphatic invasion did not show a statistically significant effect on the development of local recurrence. In the Kaplan-Meier analysis, it was found that anastomotic leak and venous-vascular invasion were factors affecting local recurrence. Moreover, Cox regression analysis revealed that both anastomotic leak and venous-vascular invasion were independent risk factors (Table 4).

DISCUSSION

Colorectal cancer is the third most common type of cancer among men and the second most common among women worldwide (11). As a result of all the developments in rectal cancer surgery, the combination of total mesorectal excision with neoadjuvant and adjuvant approaches has become the main treatment strategy for rectal cancer today. In our study, factors affecting the oncological outcomes of resections for rectal cancer were evaluated.

The effect of age on survival is still controversial in the literature (12,13). In our study, we observed that the survival of patients over 65 years of age decreased significantly compared to younger counterparts. Furthermore, in accordance with Tilly et al., we showed that sex had no effect on oncological outcomes (13). Yet, according to Shin et al., while the male sex was found to have a significant positive effect on survival, no effect on disease-free survival was demonstrated (14). Anatomical differences between male and female pelvises and differences in intraabdominal fat tissue distribution may have led to different results in different studies (15).

Table 2. Factors on overall survival

	n= 158	Univariate Analysis		Multivariate Analysis	
		Median (SEM)	Sig.	Hazard Ratio (%95 CI)	Sig.
Age					
<65	105	71.88 (3.09)		1	
≥65	53	53.22 (3.75)	p= 0.003	2.511 (1.455-4.333)	p= 0.001
Nodal Status					
0	94	76,.67 (2.97)		1	p= 0.002
1	34	54.45 (529)		2.248 (1.110-4.550)	p= 0.024
2	30	47.60 (5.26)	p< 0.001	3.347 (1.684-6.652)	p= 0.001
Distant Metastasis					
No	122	74.89 (2.84)		1	
Yes	36	43.26 (4.0)	p< 0.001	3.630 (2.035-6.473)	p< 0.001

SEM: Standard estimated mean.

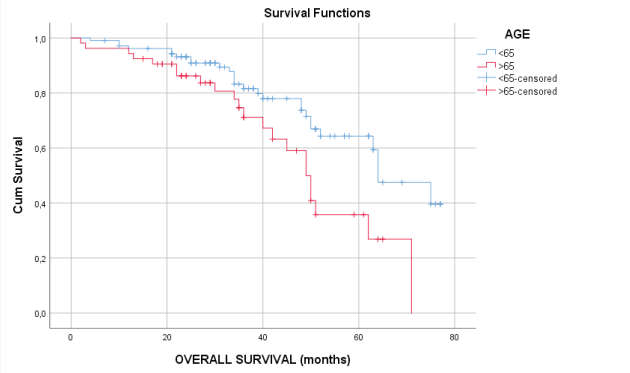

Figure 2. Kaplan-Meier graphics; age on overall survival (months).

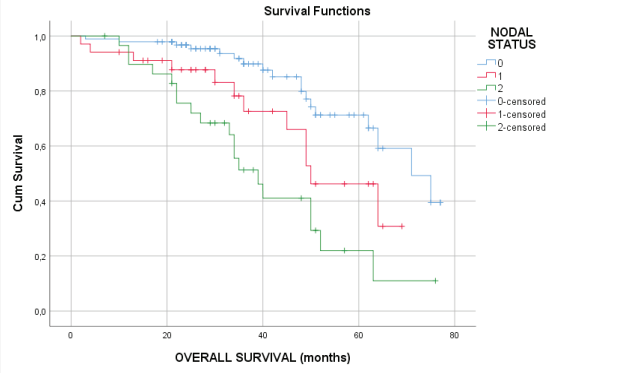

Figure 3. Kaplan-Meier graphics; nodal status on overall survival (months).

Removal of at least 12 lymph nodes in rectal surgery is recommended for adequate oncological evaluation and proper management of adjuvant therapies (16). Our pathology results met this target recommended in the AJCC guidelines for lymph node dissection (10). In our study, advanced N stage was found to be a poor prognostic factor as expected.

After neoadjuvant chemoradiotherapy had become the standard in the treatment of locally advanced rectal cancer, the

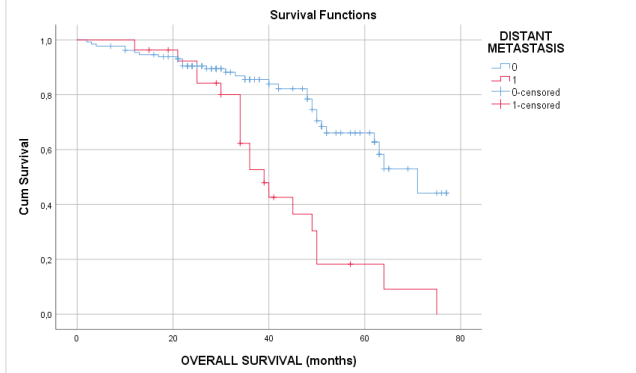

Figure 4. Kaplan-Meier graphics; distant metastasis on overall survival.

number of lymph nodes that could be removed decreased (17). For this reason, MLNR, calculated by dividing the number of malignant lymph nodes removed by the number of all lymph nodes removed, plays a key role in determining the prognosis in these patients (18,19). In the study of Rosenberg et al., including 3026 patients, it has been shown that the MLNR may be a better tool in effectively directing decision-making compared to the current TNM evaluation (20). Since our series included patients receiving neoadjuvant therapy, MLNR was also examined in addition to the number of malignant lymph nodes. When the patients were analyzed in three different groups as 0.0-0.20 and 0.20-1.0 according to their lymph node ratio, it was shown that MLNR had a significant effect on overall survival (p< 0.001) and disease-free survival (p= 0.005). Higher MLNR was found to be associated with worse survival times.

Our results revealed the negative effects of the perineural invasion on overall survival and disease-free survival. Moreover, multivariate analysis showed that perineural invasion is an independent risk factor for disease-free survival. On the other hand, Kanso et al. have found no effect of perineural invasion on survivals (21). In the study of Allaix et al., the overall survival and disease-free survival times of patients with lymphatic invasion have

Table 3. Factors on disease-free survival

	n= 158	Univariate Analysis		Multivariate Analysis	
		Median (SEM)	Sig.	Hazard Ratio (%95 CI)	Sig.
Perineural Invasion					
No	131	58.68 (2.58)		1	
Yes	27	35.11 (4.84)	p= 0.004	2.263 (1.211-4.231)	p= 0.010
Venous-Vascular Invasion					
No	152	57.08 (2.46)		1	
Yes	6	14.00 (3.88)	p< 0.001	5.289 (2.061-13.570)	p= 0.001

SEM: Standard estimated mean.

Table 4. Factors on local recurrence

	n= 158	Univariate Analysis		Multivariate Analysis	
		Median (SEM)	Sig.	Hazard Ratio (%95 CI)	Sig.
Anastomotic Leak					
No	154	68.38 (1.85)		1	
Yes	4	41.33 (11.98)	p= 0.015	5.83 (1.34-25.40)	p= 0.019
Venous-Vascular Invasion					
No	152	68.88 (1.79)		1	
Yes	6	30.67 (8.73)	p= 0.001	6.59 (1.91-22.73)	p= 0.003

SEM: Standard estimated mean.

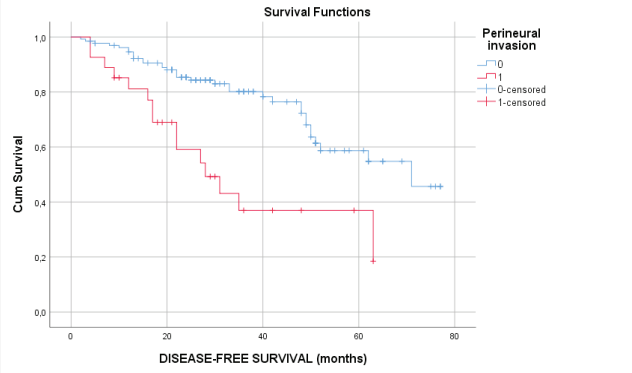

Figure 5. Kaplan-Meier graphics; perineural invasion on disease-free survival.

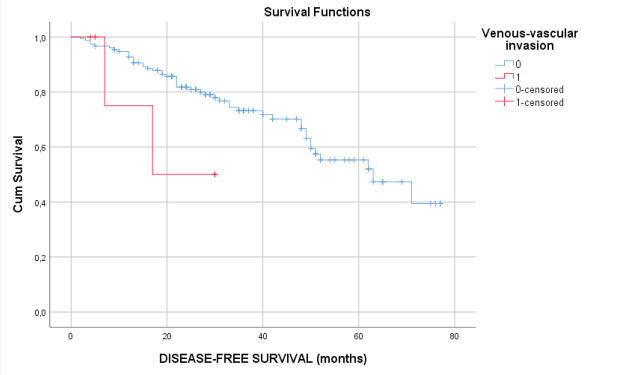

Figure 6. Kaplan-Meier graphics; venous-vascular invasion on disease-free survival.

been found to be significantly shorter (12). They observed that lymphatic invasion was a negative risk factor for overall survival, but not for disease-free survival. Our results are similar to these.

Venous-vascular invasion is considered a negative prognostic factor although its specific relation with overall survival and disease recurrence in patients with rectal cancer is still unknown (22). While venous-vascular invasion is useful in evaluating the risk of disease recurrence, it may also give an idea about whether the patient will benefit from neoadjuvant and/or adjuvant treatments (23,24). We determined that the presence of venous-vascular invasion was an unfavorable prognostic factor for overall survival. Moreover, venous-vascular invasion was found to be an independent risk factor for disease-free survival and local recurrence.

Anastomotic leak was detected as a risk factor for local recurrence (LR) in our study. Four patients underwent low anterior resection, complicated with anastomotic leak and two (50%) of them experienced LR. Other 19 local recurrences occurred in 154 patients without anastomotic leak (12.4%). These findings correlated with a current, specific-designed study (25). Koedam et al. have proven that an anastomotic leak increases the 2.96-fold risk of local recurrence. On the other hand, there are three other current trials proposing no increased risk for LR for patients with anastomotic leaks (26-28).

Major limitation of this study is its retrospective nature. The fact that the minimum follow-up period of five years has not been completed for fully evaluating the oncological results is another

weakness of this research. However, homogenous data from a subspecialized center give this study its clinical values.

CONCLUSION

In conclusion; older age, advanced nodal status, and distant metastasis were detected as independent risk factors for overall survival. Perineural and venous-vascular invasion were detected as independent risk factors for disease-free survival. Lastly, anastomotic leak and venous-vascular invasion were detected as independent risk factors for local recurrence.

Ethics Committee Approval: This study was approved by Uludağ University Faculty of Medicine Clinical Research Ethics Committee (Decision no: 2016-15/18, Date: 09.08.2016).

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Author Contributions: Concept - ATY, İT; Design - ATY; Supervision - ÖI, ATY; Data Collection and/ or Processing - İT; Analysis and/or Interpretation - İT; Literature Search - İT, ÖI-; Writing Manuscript - All of auhtors; Critical Reviews - ÖI, ATY

Conflict of Interest: The authors have no conflicts of interest to declare.

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ORİJİNAL ÇALIŞMA-ÖZET
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Orta ve distal yerleşimli rektum kanserinin cerrahi rezeksiyonlarında onkolojik sonuçlara etkili faktörler

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ÖZET

Giriş ve Amaç: Çalışmamızda rektum kanseri rezeksiyonlarında onkolojik sonuçları etkileyen faktörleri değerlendirmeyi amaçladık.

Gereç ve Yöntem: Ocak 2010 ile Aralık 2014 tarihleri arasında rektum tümörü olan ve ameliyat edilen hastalar retrospektif olarak incelendi. Demografik ve patolojik verilerin yanında onkolojik sonuçlar, hastalıksız sağkalım, genel sağkalım ve lokal nüks olarak incelendi.

Bulgular: Toplam 158 hasta çalışmaya dahil edildi. Ortanca yaş 60 (22-83) idi. Elli üç hasta 65 yaşından büyüktü (138). Hastaların 95'i (%60) erkek, 63'ü (%40) kadın idi. Seksen (%50,4) hastada orta, 78 (49,6) hastada alt rektum kanseri vardı. Tümör lokalizasyonunun onkolojik sonuçlar üzerinde etkisi yoktu. Tek değişkenli analizlerde sağkalıma etkili faktörler yaş (p= 0,003), operasyon tipi (p< 0,001), nodal durum (p< 0,001), malign lenf nodu oranı (p< 0,001), hastalığın evresi (p< 0,001), distal rezeksiyon sınırı (p= 0,047), perinöral invazyon (p< 0,001), lenfatik invazyon (p< 0,001), venöz-vasküler invazyon (p= 0,025), lokal nüks (p< 0,001) ve uzak metastaz (p< 0,001) olması saptandı. Tek değişkenli analizlerde hastalıksız sağkalım için etkili faktörler; ileri nodal durum (p= 0,007), malign lenf nodu oranı (p= 0,005), hastalığın evresi (p= 0,008), perinöral invazyon (p= 0,004) ve venöz-vasküler invazyon (p< 0,001) olması saptandı. Tek değişkenli analizlerde lokal nükse etkili faktörler olarak anastomoz kaçağının olması (p= 0,015) ve venöz-vasküler invazyonun (p= 0,001) olması saptandı.

Sonuç: İleri yaş, ileri nodal durum ve uzak metastaz gelişmesi genel sağkalım için bağımsız risk faktörleri olarak saptandı. Perinöral ve venöz-vasküler invazyon hastalıksız sağkalım için bağımsız risk faktörleri olarak tespit edildi. Son olarak anastomoz kaçağı gelişmesi ve venöz-vasküler invazyon olması lokal nüks için bağımsız risk faktörleri olarak tespit edildi.

Anahtar Kelimeler: Rektum kanseri, rektum cerrahisi, sağkalım, lokal nüks

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