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Log odds of positive nodes as a prognostic factor for rectal cancer: a retrospective study

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SUMMARY

OBJECTIVE: Rectal cancer is an important cause of mortality and morbidity globally. The aim of this study was to investigate whether the log odds of positive nodes system is a better indicator than tumor node metastasis and lymph node ratio systems to determine rectum cancer prognosis, which is an important cause of mortality and morbidity globally.

METHODS: This was a single-center retrospective cross-sectional study. Data were obtained from the medical records of patients with rectum adenocarcinoma followed at Gazi University Hospital. The clinicopathological data of 128 patients with rectum adenocarcinoma who underwent low anterior resection or abdominoperineal resection between January 2010 and December 2018 was retrospectively reviewed. Patients with rectum adenocarcinoma as the first and only primary diagnosis, which was confirmed by histopathological examination, than those who had undergone complete curative resection via low anterior resection or abdominoperineal resection were included. Those with familial adenomatous polyposis or Lynch syndrome, those under 18 years of age, with a synchronous tumor, peritoneal spread, or metastatic disease at the time of diagnosis, and those with <12 lymph nodes dissected from the resection material were excluded from the study.

RESULTS: In multivariate analysis, age, perineural invasion, tumor node metastasis stage, lymph node ratio stage, and log odds of positive nodes stage were found to be independent prognostic factors ($p<0.05$). LODDS2 patients' mortality rates were 9.495 times higher than LODDS0 patients [hazard ratio=9.495, (95%CI 4.155–21.694), $p<0.001$] while LNR2 stage patients' mortality rates were 7.016 times higher than LNR0 stage patients [hazard ratio=7.016, (95%CI 3.123–15.765), $p<0.001$] and N2 stage patients had a 5.135 times higher risk of mortality than those who were in N0 stage [hazard ratio=5.135 (95%CI 2.451–10.756), $p<0.001$].

CONCLUSION: Log odds of positive nodes is a more valuable prognostic factor for rectal cancer patients than tumor node metastasis and lymph node ratio systems to determine rectum cancer prognosis.

KEYWORDS: Rectal cancer. Adenocarcinoma. TNM staging. Lymph nodes.

INTRODUCTION

Rectal cancer is the eighth most frequently diagnosed cancer worldwide, as 732 new cases and 339 deaths are reported anually[1]. The histopathological analysis of the resected specimen is the most powerful tool to evaluate the prognosis after curative surgery. Surgical treatment should include the resection of the affected bowel segment as well as the en-bloc resection of the draining lymph nodes and blood vessels that supply the segment. Alongside its prognostic value, the status of the lymph nodes guides the physician on the adjuvant chemotherapy treatment[2].

Currently, the American Joint Committee on Cancer/International Union Against Cancer Classification (AJCC/UICC) tumor node metastasis (TNM) system is the most commonly used system for pathological N (pN) staging. The National Comprehensive Cancer Network (NCCN) guidelines recommend the analysis of 12 or more lymph nodes for optimal staging of colorectal cancer (CRC); however, the number of dissected lymph nodes (NDLN) is mostly affected by the skill of the surgeon, the width of the lymph node dissection, or the thoroughness of the pathologist to detect the pNs, as well as the personal patient variation[3]. For this reason, in the past decade, new parameters such as the number of positive lymph nodes, the number of negative lymph nodes, and the lymph node ratio (LNR) were proposed. LNR is evaluated which is the ratio of the number of positive lymph nodes to the number of total lymph nodes. Several studies have proven that LNR might be a better predictor for the survival of patients with CRC as it is less affected by the number of total lymph

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nodes[4]. Therefore, LNR has been proposed for AJCC staging as an alternative or a complementary method. Nonetheless, LNR does not provide a more significant prognostic evaluation, as LNR0 is the same as the pN0 classification; thus, the LNR classification system is not beneficial for N0 patients[2].

Log odds of positive nodes (LODDS) is an empirical logistic formula that uses pathological lymph node data to classify the survival differences between patients who are in the same stage of the disease[2]. LODDS was first proposed by Vinh-Hung et al., for predicting the prognosis of breast cancer. In their study, it was shown that LODDS performed equally well in node-negative (pN-) and node-positive (pN+) patients as a prognostic indicator[5]. Without considering nodal positivity, this formula aids clinicians in deciding whether patients with aggressive tumors belong to higher risk categories, and it may also help decide the best adjuvant treatment options. Recently, LODDS has been suggested as a new prognostic index for colorectal cancers and non-colorectal cancers[6]. Prior research has demonstrated that lymph node classification by LODDS is a prognostic indicator that is highly effective at identifying individuals with a homogeneous prognosis, regardless of the status or quantity of lymph nodes. The LODDS classification is an excellent independent prognostic factor for CRC patients who have NLND <12 and no lymph node metastasis[6,7].

The aim of this study is to investigate whether LODDS system is a better indicator than TNM and LNR systems to determine rectum cancer prognosis, which is an important cause of mortality and morbidity globally.

METHODS

Patients and eligibility criteria

This was a single-center retrospective cross-sectional study that was approved by our local Ethics Committee (Decision No. 26.10.2021-13), and all patients provided a written informed consent form.

The data for the present study were collected from a chart review using medical records of patients with rectum adenocarcinoma who underwent low anterior resection (LAR) or abdominoperineal resection (APR) at the Department of General Surgery at Gazi University Hospital between January 2010 and December 2018. Gazi University Hospital is located in Ankara, the capital city of Turkey, where approximately 7 million people live. Moreover, it is a reference hospital that accepts patients from all regions of the country, especially from the Central Anatolian region. In particular, patients with gastrointestinal tract cancer requiring complex surgical procedures are referred. The patient eligibility criteria were as follows: [1] patients with rectal cancer who underwent LAR or APR between January 2010 and December 2018; [2] rectal cancer as the first and only primary diagnosis; [3] rectum adenocarcinoma confirmed by histopathological examination; and [4] complete curative resection (R0 resection). The exclusion criteria were as follows: [1] patients under the age of 18 years; [2] synchronous tumor; [3] peritoneal dissemination or metastatic disease at the time of diagnosis; [4] patients who have familial adenomatous polyposis (FAP) or Lynch syndrome; and [5] NDLN<12.

Demographic data such as age and gender, as well as operative and clinicopathological data (neoadjuvant radiotherapy and chemotherapy, adjuvant chemotherapy, tumor size, histopathological type and grade of the tumor, lymph node metastasis, NDLN, perineural invasion, and staging) were analyzed from the database of our department, and their effect on overall survival (OS) was evaluated.

The 8th edition of the TNM classification system of the American Joint Committee on Cancer (AJCC) was used to determine the tumor stage and pathological features of the tumor. Examination of at least 12 lymph nodes was considered adequate lymph node dissection, and these patients were included in the study.

Lymph node metastasis status was examined under three categories: the AJCC TNM classification system, LNR, and LODDS. The LNR was calculated as the number of positive LNs divided by the NDLN. Based on the review of previous literature, patients were divided into three groups for analysis of the LNR: LNR0 (≤0.05), LNR1 (>0.05≤0.20), and LNR2 (>0.20)[6].

An empirical logistic formula was used to calculate the LODDS value: log (pnod+0.5)/(tnod+0.5), where *tnod* is the NDLN and *pnod* is the number of positive lymph nodes. According to LODDS values, patients were divided into three categories: LODDS0 (≤-1.36), LODDS1 (>-1.36≤-0.53), and LODDS2 (>-0.53). For the standardization of the evaluation, the same cutoff points that were previously found to be significant to survival in a large study were employed[6,7].

Statistical analysis

The statistical analyses were carried out on IBM SPSS Statistics 23 (Statistical Package for Social Sciences). For categorical variables, frequency distribution (number, percentage) was used; for numerical variables, descriptive statistics (mean, standard deviation) were used. Kaplan-Meier and Cox regression analyses were performed to evaluate the factors that affect OS. For analyses, a $p \leq 0.05$ was considered statistically significant.

RESULTS

Between January 2010 and December 2018, 154 patients with rectum adenocarcinoma were operated in our clinic. A total of 26 patients who had FAP, or Lynch syndrome, were under 18 years of age, had synchronous tumors, peritoneal spread, or metastatic disease at the time of diagnosis, and had <12 lymph nodes dissected from the resection material were excluded from the study. Thus, 128 patients with rectal adenocarcinoma who underwent LAR or APR were included in this study. The mean age of patients was 59.95±13.03 years. Among the patients who were eligible for the study, 78 (60.9%) were males and 50 (39.1%) were females. When classified by LODDS stage, 88 patients were LODDS0 (68.8%), 27 patients were LODDS1 (21.1%), and 13 patients were LODDS2 (10.2%) (Table 1).

The result of Kaplan-Meier analysis showed that the mean survival was not significantly different in sex, neoadjuvant chemotherapy, differentiation of the tumor, or tumor diameter ($p>0.05$); however, age, T stage, perineural invasion, N stage, LODDS stage, TNM stage, and LNR groups had a statistically significant difference ($p<0.05$) (Table 2).

The OS of patients who were over 65 years of age, patients with T4 tumor stage, and patients with N1 or N2 nodal stage (compared to T2 or T3 stage and N0 stage, respectively), patients who had perineural invasion, and patients who were in LODDS2 stage and LNR2 stage (compared to LODDS0 or LODDS1 and LNR0 or LNR1, respectively) was significantly decreased (Table 2).

According to the Cox regression analysis, sex, neoadjuvant chemotherapy, differentiation, tumor diameter, and T stage status did not have a significant effect on mortality ($p>0.05$); however, age, perineural invasion, N stage, LODDS stage, TNM stage, and LNR stage had a significant effect on mortality ($p<0.05$) (Table 3).

The mortality risk of patients >65 years was 2.440 times higher than that of those <65 years, and it was also 2.043 times higher for patients with perineural invasion than those without. When TNM nodal stages were compared, TNM N2 stage patients had a 5.135 times higher risk of mortality than those who were in the TNM N0 stage. Comparison of LODDS0 stage patients with others showed that LODDS1 stage patients' mortality rates were 3.124 times higher, while LODDS2 stage patients' mortality rates were 9.495 times higher than LODDS0 patients. Similarly, the mortality risk of LNR L1 stage patients was 7.016 times higher than that of LNR L0 stage patients. When compared, TNM Stage 3 patients had a 5.213 times higher mortality risk than Stage 1 patients (Table 3).

The multivariate analysis revealed that age, perineural invasion, LNR1 vs. LNR0 (LNR2 vs. LNR0), LODDS1 vs. LODDS0, and LODDS2 vs. LODDS0 were the independent prognostic factors for rectal adenocarcinoma prognosis, as shown in Table 3.

Table 1. Demographic and tumor characteristics, and tumor staging system properties of all patients.

		n	%
Age (years)	<65	82	64.1
	Above 65	46	35.9
Sex	Female	50	39.1
	Male	78	60.9
Neoadjuvant CRT	-	61	47.7
	+	67	52.3
Neoadjuvant RT	-	52	40.6
	+	76	59.4
Differentiation	Low	16	12.5
	Middle	95	74.2
	High	17	13.3
Tumor diameter (mean±SD)		33.82±18.07	
	<2 cm	34	26.6
	2–5 cm	74	57.8
	>5 cm	20	15.6
T stage	T1	8	6.3
	T2	29	22.7
	T3	73	57.0
	T4	18	14.1
Perineural invasion	-	100	78.1
	+	28	21.9
Positive LN (mean±SD)		1.56±3.36	
Total LN (mean±SD)		24.77±11.45	
N stage	N0	86	67.2
	N1	22	17.2
	N2	20	15.6
LODDS stage	LODDS 0	88	68.8
	LODDS 1	27	21.1
	LODDS 2	13	10.2
TNM stage	Stage 1	28	21.9
	Stage 2	58	45.3
	Stage 3	42	32.8
LNR stage	LNR 0	89	69.5
	LNR 1	25	19.5
	LNR 2	14	10.9

LNR: lymph node ratio.

Table 2. Univariate analysis of clinicopathological factors associated with overall survival.

		Estimates	95%CI		p-value
			Lower bound	Upper bound	
Age (years)	<65	102.908	91.552	114.263	**0.003***
	Above 65	75.463	61.288	89.637	
Sex	Female	92.698	80.648	104.748	0.562
	Male	91.004	79.224	102.785	
Neoadjuvant CT	-	91.576	78.500	104.652	0.276
	+	97.121	84.618	109.624	
Differentiation	1. Low	77.779	63.692	91.866	1–2 (0.898)
	2. Middle	94.279	83.280	105.278	1–3 (0.416)
	3. High	87.838	63.662	112.014	2–3 (0.519)
Tumor diameter	<2 cm	92.227	78.736	105.719	1–2 (0.431)
	2–5 cm	93.832	81.844	105.820	1–3 (0.186)
	>5 cm	69.650	53.073	86.227	2–3 (0.610)
T stage	T1	72.792	56.695	88.888	1–2 (0.806) 1–3 (0.772) 1–4 (0.407) 2–3 (0.850) **2–4 (0.040)* 3–4 (0.026)***
	T2	100.530	83.662	117.398	
	T3	97.129	84.515	109.744	
	T4	67.589	47.373	87.805	
Perineural invasion	-	98.244	88.029	108.459	**0.035***
	+	65.815	52.193	79.437	
N stage	N0	108.873	99.105	118.641	**1–2 (0.001)***
	N1	71.375	52.277	90.474	**1–3 (0.001)****
	N2	50.460	35.643	65.277	2–3 (0.191)
LODDS stage	LODDS 0	109.122	99.421	118.823	**1–2 (0.001)***
	LODDS 1	71.835	55.500	88.170	**1–3 (0.001)****
	LODDS 2	36.250	23.241	49.259	**2–3 (0.008)***
TNM stage	Stage 1	114.180	100.051	128.309	1–2 0.453
	Stage 2	105.604	92.895	118.313	**1–3 (0.001)****
	Stage 3	63.720	50.268	77.171	**2–3 (0.001)****
LNR group	LNR 0	108.249	98.530	117.968	**1–2 (0.001)***
	LNR 1	71.120	53.757	88.483	**1–3 (0.001)****
	LNR 2	39.798	26.871	52.725	2–3 (0.056)
Overall		93.509	83.998	103.019	

*p<0.05; **p<0.001.

DISCUSSION

In our study, we compared the prognostic effect of LODDS with TNM and LNR classifications in patients with rectal cancer who had undergone surgery with curative intent. Our data indicate that LODDS is a strong prognostic factor for rectal cancer patients. When compared with LODDS0 patients, LODDS1 [hazard ratio (HR)=3.123, (95%CI 1.550–6.719), p=0.001] and LODDS2 [HR=9.495, (95%CI 4.155–21.694), p<0.001] had a worse OS.

The most common metastatic route for colorectal cancer is lymph node metastasis, and lymph node status is the key to predicting the prognosis of these patients. Postoperative adjuvant therapy depends on accurate lymph node staging. Currently, the 8th edition of the AJCC TNM Classification is widely used to assess the prognosis of CRC patients; however, only three pathological indicators (T, N, and M status) are considered for this classification, thus limiting its ability for an accurate evaluation. The assessment of ≥12 nodes is recommended by

Table 3. Multivariate analysis of clinicopathological factors associated with overall survival.

	p-value	HR	95%CI	
			Lower	Upper
Age (years)	**0.005***	2.440	1.315	4.527
Sex	0.564	1.209	0.634	2.307
Neoadjuvant CT	0.279	0.711	0.383	1.319
Differentiation	0.788			
Differentiation (1)	0.851	1.096	0.421	2.855
Differentiation (2)	0.547	1.425	0.449	4.525
Tumor diameter	0.530			
Tumor diameter (1)	0.434	1.358	0.632	2.919
Tumor diameter (2)	0.267	1.755	0.651	4.732
T Stage	0.114			
T1	0.916	1.086	0.233	5.061
T2	0.802	1.205	0.282	5.155
T3	0.175	2.897	0.622	13.482
Perineural invasion	**0.040***	2.043	1.034	4.037
N stage	**0.001****			
N1	**0.003***	3.151	1.478	6.719
N2	**0.000***	5.135	2.451	10.756
LODDS stage	**0.001****			
LODDS stage (1)	**0.001***	3.124	1.550	6.298
LODDS stage (2)	**0.001****	9.495	4.155	21.694
TNM stage	**0.001****			
TNM 1	0.439	1.503	0.535	4.221
TNM 2	**0.001***	5.213	1.972	13.775
LNR	**0.001****			
LNR (1)	**0.002***	3.040	1.496	6.175
LNR (2)	**0.001****	7.016	3.123	15.765

HR: hazard ratio. *p<0.05; **p<0.001.

the present guidelines from the AJCC. A study by Tsai et al., showed that the accuracy of detecting pN depends on the number of NDLN, as the 5-year survival rate of CRC patients with NDLN<18 was significantly lower than that of patients with NDLN ≥18[8]. Nonetheless, NDLN is affected by multiple variables, such as surgical factors, pathological factors, and patient factors. Therefore, there is a constant risk of understaging when an inadequate lymphadenectomy is performed. A large population-based study with 131.935 patients by Gönen et al., revealed that the probability of missing a positive lymph node is 29.7%, 20%, and 13.6% if 5, 8, and 12 lymph nodes are examined, respectively. They also calculated the probability of a patient being correctly staged as node-negative and thus developed the nodal staging score (NSS). They found that 1, 4, 13, and 21 nodes need to be examined to maintain an NSS of 90% for T1, T2, T3, and T4 tumors, respectively[9]. Therefore, it is not surprising that understaging is inevitable after an inadequate lymph node harvest. The TNM staging system remains one of the most widely used classifications for oncological outcomes despite the risk of stage migration, which led researchers to investigate novel prognostic factors for an accurate treatment.

Another problem for staging is that the total number of dissected lymph nodes (TLN) decreases after neoadjuvant chemoradiation therapy (CRT); therefore, TLN may not be an adequate parameter for rectal cancer operation after CRT. Studies by Park et al.[10] and Wang et al.[11] also showed that the yPN category cannot be used to divide patients into prognostic groups. Only 20% of cases who received neoadjuvant CRT have

TLN≥12. On the contrary, a number of studies have shown that a decrease in TLN might suggest an improved response to neoadjuvant CRT[12]. However, a population-based study has found that only 37% of colon cancer patients received adequate lymph node evaluation[13], and this could lead to inadequate staging and inaccurate treatment.

Lymph node ratio has been proposed as a novel prognostic factor because it includes information on both positive lymph nodes and total lymph nodes. Nonetheless, LNR provides no additional prognostic information for node-negative CRC patients, which accounts for 75% of all CRC patients, as LNR is the same as the pN0 classification for these patients[14].

A study by Vinh-Hung et al., was the first one to propose a novel classification for lymph node staging in breast cancer[5]. In the past two decades, LODDS has become an important factor for staging. Wang et al., analyzed 24.477 patients with stage 3 colon cancer from the SEER registry and concluded that LODDS is a better prognostic factor than LNR[11]. Persiani et al., also found that NDLN influenced the prognostic power of LODDS less than other nodal staging systems, making it a highly reliable staging system[7]. Similarly, several authors found that LODDS was a prognostically superior factor to LNR in gastric cancer patients[15,16].

However, our study has several limitations that need to be considered. First, this study was retrospective, and a limited number of patients from one hospital were included. Therefore, our findings must be verified by multicenter studies with larger cohorts. Second, there are other factors that affect prognosis, including BRAF and KRAS mutations, microsatellite instability, and adjuvant treatments. By integrating these factors, it is possible to improve the LODDS classification further.

CONCLUSION

Our results showed that LODDS is a more reliable and valuable prognostic factor than TNM staging and LNR classification, especially in node-negative patients, since it is independent of NDLN in rectal cancers. However, the available literature analyzing the prognostic significance of LODDS is limited, and more studies are needed.

INFORMED CONSENT

Informed consent was obtained from all individual participants included in the study.

ETHICS COMMITEE APPROVAL

This study was approved by the Research Ethics Committee of Gazi University (approval No. 26.10.2021-13) and was conducted in accordance with the Declaration of Helsinki.

AUTHORS' CONTRIBUTIONS

AY: Conceptualization, Writing – original draft, Writing – review & editing. **CB:** Formal Analysis, Project administration, Writing – review & editing. **SA:** Methodology, Project administration, Writing – review & editing. **BK:** Investigation, Writing – original draft, Writing – review & editing. **CK:** Formal Analysis, Investigation, Resources. **HG:** Formal Analysis, Writing – review & editing. **KD:** Investigation, Writing – review & editing. **HB:** Project administration, Writing – review & editing, **OY:** Conceptualization, Supervision, Validation, Writing – review & editing.

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