

Risk Factors for Complications Following Lateral Pelvic Lymph Node Dissection for Rectal Cancer

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Abstract. *Background: Lateral pelvic lymph node metastasis impairs the oncological outcomes of patients with rectal cancer. Although lateral pelvic lymph node dissection (LLND) might be an effective procedure for such patients, the associated risk factors for postoperative complications are unknown. Patients and Methods: The operative outcomes of 21 patients undergoing unilateral LLND and 26 patients undergoing bilateral LLND for rectal cancer were compared. The risk factors for complications were evaluated using a logistic regression model. Results: Univariate and multivariate analyses revealed that a longer operative time (≥ 480 min) was the most important risk factor for grade II or more postoperative complications according to the Clavien–Dindo classification (odds ratio=6.58; 95% confidence interval=1.35–32.1; $p=0.020$). A bilateral procedure was not a significant risk factor for postoperative complications. Conclusion: Surgeons should make efforts to shorten the operative time to reduce the risk of postoperative complications.*

Although total mesorectal excision (TME) after neoadjuvant chemoradiotherapy (NACRT) is the standard surgical procedure for lower rectal cancer in most Western countries (1–5). Lateral pelvic lymph node (LLN) metastasis occurs in 10–25% of patients with rectal cancer, affecting their oncological outcomes (6–8). LLN dissection (LLND) has been routinely performed for locally advanced rectal cancer at many tertiary hospitals or cancer centers in Japan. A

retrospective multicenter study in Japan reported that the incidence of LLN metastasis in patients with T3 or T4 lower rectal cancer was 18.1% (9). Therefore, the Japanese Society for Cancer of the Colon and Rectum guidelines recommend performing bilateral LLND following TME in cases of cancer stages II–III (10–12). However, the treatment strategy for patients with rectal cancer with clinical LLN metastasis has not yet been established worldwide. LLND might be an effective treatment option for such patients.

LLND is technically demanding and can cause intraoperative or postoperative adverse effects. To establish the clinical significance of LLND in patients with rectal cancer, identifying the risk factors for postoperative complications of LLND is essential. However, to the best of our knowledge, no previous studies have reported such risk factors. In this study, the risk factors for postoperative complications of TME and LLND in patients with rectal cancer were elucidated.

Patients and Methods

Patients. Between November 2005 and September 2019, 55 patients with rectal cancer underwent TME with LLND at Kobe University Hospital. Among them, eight patients were excluded because of three cases were recurrent, two were emergency cases, and three cases had missing data. Finally, 47 patients were included in this study. Twenty-one of them underwent unilateral LLND, whereas 26 underwent bilateral LLND. The data of the patients were retrospectively collected and analyzed.

The clinical stage of rectal cancer was determined based on imaging studies, including colonoscopy, computed tomography, magnetic resonance imaging, and positron-emission tomography. LLNs were regarded as regional lymph nodes although tumors were classified according to the American Joint Committee on Cancer TNM system (13). Pathological staging was decided by professional pathologists following the American Joint Committee on Cancer staging guidelines (14). Proximal D2 or D3 dissection was generally performed according to the Japanese Society for Cancer of the Colon and Rectum guidelines

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Key Words: LLND, rectal cancer, TME, complication.

Table I. Patient demographics.

	Unilateral LLND (n=21)	Bilateral LLND (n=26)	p-Value
Median age (range), years	66 (52-88)	64 (39-82)	0.284
Gender, n (%)			0.768
Male	14 (66.7)	16 (61.5)	
Female	7 (33.3)	10 (38.5)	
Median BMI (range), kg/m ²	23.1 (17.2-29.3)	22.6 (16.6-34.2)	>0.999
ASA score, n (%)			>0.999
1	5 (23.8)	5 (19.2)	
2	14 (66.7)	18 (69.2)	
3	2 (9.5)	3 (11.5)	
Median distance from AV (range), cm	2 (0-30)	3 (0-10)	0.273
NACRT, n (%)			0.102
Yes	18 (85.7)	16 (61.5)	
No	3 (14.3)	10 (38.5)	
CEA	5.1 (1.0-151.3)	3.3 (0.9-33.0)	0.069
CA19-9	27.0 (1.8-1,189.2)	13.0 (3.0-1,148.0)	0.128
(y)cT*, n (%)			0.383
0/is/1	1 (4.8)	0 (0.0)	
2	0 (0.0)	1 (3.8)	
3	3 (14.3)	4 (15.4)	
4	11 (52.4)	18 (69.2)	
(y)cN*, n (%)			0.706
0	9 (42.9)	10 (38.5)	
1	8 (38.1)	8 (30.8)	
2	4 (19.0)	8 (30.8)	
(y)cStage*, n (%)			0.72
0	3 (14.3)	6 (23.1)	
I	0 (0.0)	3 (11.5)	
II	6 (28.6)	5 (19.2)	
III	8 (38.1)	7 (26.9)	
IV	4 (19.0)	5 (19.2)	
Adjuvant therapy, n (%)			0.055
Yes	18 (85.7)	15 (57.7)	
No	3 (14.3)	11 (42.3)	

ASA: American Society of Anesthesiologists; AV: anal verge; BMI: body mass index; CA19-9: carbohydrate antigen 19-9; CEA: carcinoembryonic antigen; LLND: lateral pelvic lymph node dissection; NACRT: neoadjuvant chemoradiotherapy. *According to the American Joint Committee on Cancer TNM system (13).

(15). This study was approved by the Ethics Committee of the Institutional Review Board (approval number: B200266).

Indication for LLND. LLND was performed as a therapeutic or prophylactic procedure for patients with rectal cancer. As a therapeutic procedure, LLND was indicated for patients with clinical LLN metastasis who received NACRT. NACRT consisted of a total radiation dose of 45-50.4 Gy and oral 5-fluorouracil-based chemotherapy. LLN metastasis was clinically diagnosed based on pretreatment images, showing LLNs with a diameter of >7 mm based on computed tomography or magnetic resonance imaging.

Table II. Operative outcomes after lateral pelvic lymph node dissection (LLND).

	Unilateral LLND (n=21)	Bilateral LLND (n=26)	p-Value
Operative procedure, n (%)			0.01
Low anterior resection	1 (4.8)	11 (42.3)	
Intersphincteric resection	1 (4.8)	1 (3.8)	
Abdominoperineal resection	18 (85.7)	13 (50.0)	
Total pelvic exenteration	1 (4.8)	1 (3.8)	
Lymph node dissection*, n (%)			0.194
prxD2	2 (9.5)	0 (0.0)	
prxD3	19 (90.5)	26 (100.0)	
Approach			0.52
Laparoscopic	14 (66.7)	20 (76.9)	
Open	7 (33.3)	6 (23.1)	
Median operative time (range)**, min	531 (317-1,513)	555 (350-1,138)	0.341
Median estimated blood loss (range)**, g	480 (0-5,220)	107 (0-4,749)	0.299
Transfusion, n (%)			0.758
Yes	13 (61.9)	18 (69.2)	
No	8 (38.1)	8 (30.8)	
Median no. of harvested LNs (range)	19 (6-56)	36 (11-77)	<0.001
Median no. of harvested LLNs (range)	8 (3-22)	20 (6-51)	0.001
Pathological LLN metastasis, n (%)			0.715
Yes	3 (14.3)	5 (19.2)	
No	18 (85.7)	21 (80.8)	
R0 resection, n (%)			0.447
Yes	20 (95.2)	26 (100.0)	
No	1 (4.8)	0 (0.0)	

LLN: Lateral pelvic lymph node; LN lymph node. *According to the Japanese Classification of Colorectal, Appendiceal, and Anal carcinoma (15). **The data are expressed as the median (range).

LLND was performed only on the side of swollen LLNs. For patients with swollen LLNs on both sides, bilateral LLND was performed. For patients with rectal cancer stage cT3-4/Nany/M0 who did not undergo NACRT, prophylactic LLND was performed.

LLND procedure. In this study, TME with LLND was performed on all patients *via* either open or laparoscopic approach. The internal iliac and obturator areas were dissected in standard LLND, as described previously (16). The internal iliac area was surrounded by the ureterohypogastric nerve fascia and vesicohypogastric fascia. The obturator area was surrounded by the lateral pelvic wall and vesicohypogastric fascia. First, the obturator area was dissected while preserving the obturator nerve. The obturator vessels were resected. Then the internal iliac nodes were dissected by skeletonizing the internal iliac artery and its branches. The internal pudendal artery or inferior vesical artery was resected only when metastatic lymph nodes were suspected of invading the artery. During the procedure, special caution was paid not to injure the ureterohypogastric nerve fascia, including the ureter and pelvic plexus.

Table III. Postoperative outcomes after lateral pelvic lymph node dissection (LLND).

	Unilateral LLND (n=21)	Bilateral LLND (n=26)	<i>p</i> -Value
Postoperative complications (CD≥II), n (%)	17 (81.0)	15 (57.7)	0.121
Urinary disturbance	2 (9.5)	3 (11.5)	
Ureteral injury	1 (4.8)	0 (0)	
Neuropathy in lower limb	0 (0)	4 (15.4)	
Lymphorrhea	1 (4.8)	3 (11.5)	
Anastomotic leakage	2 (9.5)	2 (7.7)	
Wound infection	5 (23.8)	3 (11.5)	
Wound dehiscence	5 (23.8)	3 (11.5)	
Pelvic abscess	3 (14.3)	1 (3.8)	
Bleeding	0 (0)	2 (7.7)	
DVT	2 (9.5)	0 (0)	
Other	2 (9.5)	2 (7.7)	
Postoperative complications (CD≥III), n (%)	9 (42.9)	7 (26.9)	0.403
LLND-related complications* (CD≥II), n (%)	4 (19.0)	7 (26.9)	0.774
Median postoperative hospital stay (range), days	37 (22-130)	27 (15-80)	0.069
Re-operation within 30 days, n (%)	2 (9.5)	1 (3.8)	0.841
Mortality within 30 days, n (%)	0 (0)	0 (0)	>0.999

CD: Clavien–Dindo classification; DVT deep vein thrombosis.
*Including urinary disturbance, ureteral injury, neuropathy in lower limb, and lymphorrhea.

Complications. Postoperative complications were defined and recorded as complications which developed within 30 days after surgery and were categorized according to the Clavien–Dindo classification (17). Grade I was any deviation from the normal postoperative course; grade II included pharmacologic treatment; grade III covered complications requiring surgical, endoscopic, or radiologic intervention; grade IV included life-threatening complications requiring Intensive Care Unit management; and grade V complications caused postoperative death.

Statistical analysis. Statistical analysis was performed using the JMP software (SAS Institute Inc., Cary, NC, USA). Continuous variables were expressed as median values (with range). Student's *t*-test or Mann–Whitney *U*-test was used to compare the continuous variables according to their data distribution. The analysis of categorical variables was performed using the chi-square test. A *p*-value of less than 0.05 was considered statistically significant. Variables with a *p*-value of less than 0.1 in a univariate analysis were further evaluated in a multivariate analysis using a logistic regression model.

Results

Patient and tumor characteristics are summarized in Table I. Although no significant differences were identified between the unilateral and bilateral LLND groups, the carcinoembryonic

Table IV. Pathological outcomes.

	Unilateral LLND (n=21)	Bilateral LLND (n=26)	<i>p</i> -Value
Histological type, n (%)			0.434
Well/moderately	16 (76.2)	19 (73.1)	
Mucinous/poorly	1 (4.8)	4 (15.4)	
Other	4 (19.0)	3 (11.5)	
(y)pT*, n (%)			0.693
0/is	2 (9.5)	2 (7.7)	
1	1 (4.8)	1 (3.8)	
2	5 (23.8)	10 (38.5)	
3	10 (47.6)	12 (46.2)	
4	3 (14.3)	1 (3.8)	
(y)pN*, n (%)			0.741
0	12 (57.1)	12 (46.2)	
1	5 (23.8)	9 (34.6)	
2	4 (19.0)	5 (19.2)	
(y)pStage*, n (%)			0.414
0	2 (9.5)	2 (7.7)	
I	2 (9.5)	5 (19.2)	
II	8 (38.1)	4 (15.4)	
III	6 (28.6)	8 (30.8)	
IV	3 (14.3)	7 (26.9)	
Lymphatic invasion, n (%)			>0.999
Absent	17 (85.0)	22 (88.0)	
Present	3 (15.0)	3 (12.0)	
Vascular invasion, n (%)			0.617
Absent	19 (95.0)	22 (88.0)	
Present	1 (5.0)	3 (12.0)	
Pathological LLN metastasis, n (%)	3 (14.3)	5 (19.2)	0.715

LLN: Lateral pelvic lymph node; LLND: lateral pelvic lymph node dissection. *Tumors were classified according to the American Joint Committee on Cancer TNM system (13).

antigen level and the rate of adjuvant chemotherapy were higher in the unilateral group; there were also more cases administered NACRT in the unilateral LLND group.

Table II shows the operative outcomes. Abdominoperineal resection was performed significantly more frequently in the unilateral LLND group. Although the operative time and blood loss in the two groups did not differ significantly, the numbers of harvested lymph nodes and LLNs were significantly larger in the bilateral group ($p<0.001$ and $p=0.001$, respectively).

Postoperative data are presented in Table III. The rate of overall postoperative complications in grade II or more according to the Clavien–Dindo classification in the two groups was similar. Lower limb neuropathy developed more frequently in the bilateral LLND group. The rate of LLND-related complications, including urinary disturbance, ureteral injury, neuropathy in lower limbs, and lymphorrhea, in the two groups was also similar. The postoperative hospital stay was longer in the unilateral LLND group, possibly due to the

Table V. Univariate and multivariate analyses of risk factors for postoperative complication (Clavien–Dindo classification \geq II) after lateral pelvic lymph node dissection (LLND).

	Patients (n=47)	Univariate analysis		Multivariate analysis	
		<i>p</i> -Value		OR (95% CI)	<i>p</i> -Value
Age: <70 vs. \geq 70 Years	31 vs. 16	0.467			
Sex: Male vs. female	30 vs. 17	0.112			
BMI: \geq 25 vs. <25 kg/m ²	9 vs. 38	0.375			
ASA score: III vs. I, II	5 vs. 42	0.552			
Distance from AV: <3 vs. \geq 3 cm	27 vs. 20	0.384			
Tumor size: \geq 5 vs. <5 cm	15 vs. 32	0.418			
NACRT: Yes vs. no	34 vs. 13	0.201			
CEA: \geq 5 vs. <5 ng/ml	22 vs. 25	0.065		2.55 (0.47-13.80)	0.278
CA19-9: \geq 37 vs. <37 ng/ml	12 vs. 35	0.553			
ycT*: 3, 4 vs. 0-2	38 vs. 9	0.020		2.53 (0.38-16.6)	0.333
ycN*: 1, 2 vs. 0	21 vs. 26	0.880			
ycStage*: III, IV vs. 0-II	24 vs. 23	0.680			
Approach: Open vs. laparoscopic	13 vs. 34	0.917			
LLND: Bilateral vs. unilateral	26 vs. 21	0.120			
Lymph node dissection**: D3 vs. D2	45 vs. 2	0.993			
Operation time: \geq 480 vs. <480 min	31 vs. 16	0.013		6.58 (1.35-32.1)	0.020
Blood loss: \geq 400 vs. <400 g	21 vs. 26	0.288			
Transfusion: Yes vs. no	12 vs. 35	0.070		4.87 (0.45-52.6)	0.192

ASA: American Society of Anesthesiologists; AV: anal verge; BMI: body mass index; CA19-9: carbohydrate antigen 19-9; CEA: carcinoembryonic antigen; CI: confidence interval; NACRT neoadjuvant chemoradiotherapy; OR: odds ratio. *According to the American Joint Committee on Cancer TNM system (13). **According to the Japanese Classification of Colorectal, Appendiceal, and Anal carcinoma (15).

overall grade III or more complications that developed more frequently in that group.

Pathological outcomes are shown in Table IV. No significant differences were observed between the two groups in terms of each factor. Pathological LLN metastasis was observed in eight out of the 47 patients (17.0%).

Univariate and multivariate logistic regression analyses revealed that a longer operative time (\geq 480 min) was the most important risk factor for postoperative complications of grade II or more according to the Clavien–Dindo classification (odds ratio=6.58; 95% confidence interval=1.35-32.1; p =0.020; Table V). Neither NACRT nor a bilateral procedure were significant risk factors for postoperative complications following LLND.

Discussion

Although the introduction of TME has improved the oncological outcomes of patients with rectal cancer, postoperative recurrence in LLNs affects their long-term survival (2, 10-12). Although LLND might be an essential procedure for patients at high risk for LLN recurrence, it is technically demanding and can cause high morbidity. In this study, it was demonstrated that a longer operative time was the most significant risk factor for postoperative complications of TME with LLND.

A longer operative time was also reported to be associated with increased adverse events after colorectal surgery (18). According to a cohort study from the American College of Surgeons National Surgical Quality Improvement Program, longer operative procedures were found to cause more superficial surgical site infections, organ space infections, wound dehiscence, urinary tract infections, and prolonged hospital stay (18). The study proposed that the operative time might serve as a proxy for surgical complexity. Wang *et al.* also reported that a prolonged operative time increased the risk of perineal wound complications after abdominoperineal resection of rectal cancer, resulting in a lower long-term survival rate (19). Therefore, surgeons should make efforts to reduce the operative time to minimize the risk of complications after LLND and improve the oncological outcomes.

Interestingly, whether the LLND was unilateral or bilateral was not associated with postoperative complications. Moreover, other factors that are generally considered to be associated with high morbidity rates, such as high body mass index, cT3-4 stages, and performance of NACRT, were irrelevant to postoperative complications. Importantly, all LLND procedures in this study were performed by Board-certified surgeons of the Japanese Society of Gastroenterological Surgery. A recent study showed that Board-certified surgeons contribute to the favorable outcomes of gastroenterological surgery (20). Furthermore, all

laparoscopic LLND procedures were performed by surgeons certified by the Endoscopic Surgical Skill Qualification System of the Japan Society for Endoscopic Surgery. Nonaka *et al.* reported that even laparoscopic extended TME for locally advanced rectal cancer can be performed safely by such Board-certified surgeons (21). Surgical quality assurance under such conditions might contribute to the lack of significant associations of high body mass index, cT3-4, large tumor size, and NACRT.

This study had several limitations. Firstly, potential selection biases could not be avoided because it was a retrospective, small-scale, single-institutional study. Secondly, male sexual functions were not evaluated, which have been pointed out as an LLND-related complication (22). The inclusion of male sexual function would be ideal in evaluating LLND-related complications correctly.

In conclusion, a long operative time was significantly associated with postoperative complications faced by patients with rectal cancer who had undergone LLND. The results suggest that surgeons should make efforts to shorten the operative time to reduce the risk of postoperative complications after LLND.

Conflicts of Interest

The Authors have no conflicts of interest to declare.

Authors' Contributions

Conception and design: DO and TM. Surgery: TM, KY, HH, and RS. Acquisition of data: DO, NU, and HG. Analysis and interpretation of data: TM, SK, HH, and TO. Writing: DO and TM. Review and revision of the article: YK.

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