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The Utility and Efficacy of Laparoscopic Radical Cystectomy in Patients with Muscle-Invasive Bladder Cancer at a Single Institution

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Keywords
Muscle-invasive bladder cancer · Laparoscopic radical cystectomy · Open radical cystectomy

Abstract
Background: The aim of this study was to compare the surgical and oncological outcomes and complications of laparoscopic radical cystectomy (LRC) to those of open radical cystectomy (ORC) in patients with muscle-invasive bladder cancer (MIBC). ***Methods:*** Our study focused on patients with histologically confirmed stage T2–T4a urothelial carcinoma of the bladder without distant metastases, who underwent LRC (LRC group) or ORC (ORC group). The primary endpoints in this study were the overall survival (OS) and recurrence-free survival (RFS) rates. ***Results:*** In this study, 59 patients, 17 underwent LRC and 42 underwent ORC, were enrolled. The 2-year OS rate was 100% in the LRC group and 88.0% in the ORC group ($p = 0.85$). The 2-year RFS rate was 63.5% in the LRC group and 69.5% in the ORC group ($p = 0.321$). On multivariate analysis, the histological type, positive lymph node, and positive resection margin were significantly associated with the OS rates. ***Conclusions:*** This study suggested that LRC may achieve similar oncological outcomes and fewer perioperative complications and less blood loss compared to ORC. Therefore, LRC should be considered as one of the treatment options for patients with MIBC.

Introduction

Radical cystectomy (RC) remains the gold standard treatment for muscle-invasive bladder cancer (MIBC). Although the RC surgical technique and perioperative care have improved in recent years, the 5-year overall survival (OS) rate of patients with MIBC is approximately 60% [1, 2]. Open radical cystectomy (ORC) remains the most commonly adopted surgical approach; however, it is associated with high morbidity and significant mortality rates [3]. Minimally invasive endoscopic surgery (MIES) approaches, including laparoscopic radical cystectomy (LRC) and robot-assisted radical cystectomy (RARC), have been adopted for the treatment of MIBC to improve the perioperative morbidity and mortality [4–7].

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In Japan, RARC has been covered by the National Health Insurance from April 2018; however, not all hospitals have introduced the robot-assisted surgical system. Conversely, LRC has been widely accepted as a MIES that could reduce the perioperative morbidity and mortality [8]. Several clinical studies have reported the advantages of LRC, including a less incisional pain, decreased bowel exposure and desiccation, and decreased potential for fluid imbalances [9, 10]. Although numerous studies have demonstrated the feasibility and safety of LRC, it remains a challenging operative method for urologists, because of the longer operative time that not all patients can tolerate, the risk of pneumoperitoneum, and the peculiar surgical position [11]. In addition, it is a prolonged procedure that includes several technical steps and requires highly developed laparoscopic skills [12]. The aim of this study was to compare the surgical and oncological outcomes and complications of LRC to those of ORC in patients with MIBC.

Materials and Methods

Study Population

This retrospective study was conducted at the Gifu University Graduate School of Medicine in Japan. We reviewed the clinical and pathological records of 92 consecutive patients with MIBC who underwent RC and bilateral pelvic lymph node dissection (PLND), with or without neoadjuvant chemotherapy (NAC), between December 2004 and August 2018. Our study focused on patients with MIBC who had histologically confirmed stage T2–T4a urothelial carcinoma of the bladder without distant metastases. The patients who had distant metastases preoperatively, serious comorbidity, and lack of sufficient variables were excluded from this study. The patients were divided into 2 groups according to the type of surgery: LRC group and ORC group. The study protocol and informed consent documents were reviewed and approved by the Gifu University Institutional Review Board (No. 2018-013).

Treatment Schedule of NAC

All treatments were performed at our institution. The NAC regimen consisted of 1,000 mg/m^2 of gemcitabine on days 1, 8, and 15 and 70 mg/m^2 of cisplatin or carboplatin at an area under the curve of 5 according to Calvert's formula [13] on day 2. Each cycle lasted for 21 days. The patients who had been using anticancer agents before the surgery received at least 2 cycles of NAC. The patients were identified as cisplatin-ineligible if they met at least one of the following criteria: European Cooperative Oncology Group Performance Status of 2, creatinine clearance <60 mL/min, hearing loss grade ≥2, neuropathy grade ≥2, and/or New York Heart Association Class III heart failure [14].

Operative Procedure

In the ORC group, the patients underwent a standard surgical procedure using a transperitoneal approach [15]. All LRCs were performed by 2 expert surgeons (K.N. and S.Y.) via a laparoscopic approach without robotic assistance, as follows: in all cases, 4 trocars were used; the camera port (12 mm) was placed 2 cm above the umbilicus, a 12-mm trocar was placed 4 cm below the umbilicus, and 2 trocars (5 mm) were placed 2 cm below the umbilicus on the midclavicular line on both sides. The patients were placed in the Trendelenburg position (15°). The whole procedure was carried out using a flexible scope. The bilateral ureters were mobilized near the urinary bladder. The peritoneum was incised in the midline between the rectum and the bladder. The ampulla of the vas deferens was transected bilaterally, and the seminal vesicles were dissected. The posterior layer of Denonvilliers' fascia was then incised and dissected as far as the apex of the prostate. The anterior cavity of the bladder was sufficiently exposed, until the pubic bone and endopelvic fascia. The lateral vascular bundles were incised close to the bladder, using a vessel-sealing system. The endopelvic fascia was incised, and the dorsal vein complex was ligated using a 2-0 braided polyglactin suture. Both ureters were clipped and divided close to the bladder. If ileal neobladder reconstruction was not performed as a urinary diversion, urethra was removed with bladder. In female patients, anterior pelvic exenteration, including the bladder, uterus, and anterior vaginal wall, was usually performed. The vagina was usually resected using a vessel-sealing system to achieve good hemostasis. The specimens were removed vaginally, and the dome of the vagina was then sutured. The choice of urinary diversion was determined according to the surgeon's discretion and/or the patient's preference.

Pelvic Lymph Node Dissection

An extended PLND was carried out with boundaries at the aortic bifurcation proximally, genitofemoral nerve laterally, circumflex iliac vein distally, hypogastric vessels and the obturator fossa posteriorly, and presacral nodes. The standard PLND template included removal of the obturator, external iliac, and hypogastric lymph node chains.

Urinary Diversion

The enrolled patients underwent extracorporeal urinary diversion, including ileal conduit (IC) or ureterocutaneostomy. With regard to IC, an approximately 5-cm midline incision is made below the umbilicus. The left ureter was delivered under the sigmoid colon to the right side. A 20-cm ileal segment is selected for an IC approximately 20 cm away from the ileocecal valve. Oral side of the IC segment was closed using a 3-0 polyglactin suture. Six-F single-J ureteric stents were inserted into both ureters. The Bricker surgical technique was adopted for ureteroileal anastomosis [16]. The stoma was made in a standard fashion. A ureterocutaneostomy was made by the V-Flap technique or Square Flap technique [17]. The distal end of mobilized ureter was exteriorized through preselected stoma site.

Patient Evaluation

The following baseline information was obtained for each patient: complete history and physical examination findings, Eastern Cooperative Oncology Group Performance Status, abdominal and pelvic computed tomography (CT) or magnetic resonance imaging (MRI), and chest radiography or CT.

The diagnosis of MIBC was confirmed by pathologists at our institution by reviewing the results of transurethral resection and the baseline magnetic resonance imaging findings.

Table 1. Patient characteristics

	LRC group (n = 17)	ORC group (n = 42)	p value
Age, year, median, IQR	65 (62–71)	74 (65–77)	0.056
Gender, n (%)			
Male	13 (76.5)	31 (73.8)	0.835
Female	4 (23.5)	11 (26.2)	
Clinical T, n (%)			
T2	7 (41.2)	17 (40.5)	0.935
T3	8 (47.1)	21 (50)	
T4a	2 (11.7)	4 (9.5)	
Clinical N, n (%)			
Negative	14 (82.4)	39 (92.9)	0.234
Positive	3 (17.6)	3 (7.1)	
BMI, kg/m^2, median, IQR	23.2 (20.1–24.3)	22.3 (20.1–23.8)	0.576
NAC, n (%)	10 (58.8)	27 (64.2)	0.535
Follow-up period, months, median, IQR	6.7 (1.9–14.6)	46.4 (12.2–72.4)	<0.001

LRC, laparoscopic radial cystectomy; ORC, open radical cystectomy; IQR, interquartile range; NAC, neoadjuvant chemotherapy.

Specimens obtained during the cystoprostatectomy were extensively examined to determine the presence of MIBC. We performed a pathological examination of complete transmural sections of the bladder wall to accurately determine the pathological stage of the tumor. In addition, histological examination of several sections from various sites within the bladder, including the dome, anterior wall, lateral wall, posterior wall, trigone, and both ureters, was performed to identify superficial disease or a second primary tumor. Tumor staging was performed according to the staging system defined in the *AJCC Cancer Staging Manual* [18].

Follow-Up Schedule

Each patient was evaluated every 3 months using ultrasonography (to check for hydronephrosis), urine cytology, and renal and liver function tests. CT of the chest to pelvis was performed every 6 months for 5 years and annually thereafter.

Statistical Analysis

Primary endpoints in this study were the oncological outcomes, including OS, cancer-specific survival (CSS), and recurrence-free survival (RFS). Secondary endpoints were the surgical outcomes, including operative time, estimated blood loss (EBL), perioperative complications, pathological T stage, lymph node involvement (pN), and the rate of positive surgical margin. RFS was defined as the time from RC to appearance of local or regional disease/metastasis or death. Data were analyzed using IBM SPSS Statistics 24 software (IBM Corp., Armonk, NY, USA). Differences between the LRC and ORC groups were compared using Student's t test or Mann-Whitney U test for categorical variables. The OS, CSS, and RFS after RC were examined using the Kaplan-Meier method. The relationship between the survival rates and subgroup classification was analyzed using the log-rank test. Multivariate analysis was performed using a Cox proportional hazard model. All p values were 2-sided, and the significance level was set at $p < 0.05$.

Results

Patient Characteristics

The pretreatment characteristics of the patients are listed in Table 1. Seventeen patients underwent LRC and 42 underwent ORC. All patients were diagnosed with muscle-invasive urothelial carcinoma on the basis of histological examination of the specimens obtained via transurethral resection.

The median age of the enrolled patients was 71 years (interquartile range [IQR], 63.5–77 years), and the median follow-up period was 24.7 months (IQR, 7.8–59.5 months). The number of the patients who were ineligible for cisplatin was 3 (17.6%) in the LRC group and 11 (26.2%) in the ORC group. Among the patients who received NAC, the median number of NAC cycles was 3 (IQR, 3–4 cycles).

Surgical Outcomes

Surgical outcomes and perioperative data are shown in Table 2. LRC had a significantly longer operative time than ORC. Conversely, the EBL in LRC was significantly lower than that in ORC. Likewise, the time to liquid and liquid diet in the LRC group was significantly shorter than that in the ORC group.

No intraoperative complications were associated with this procedure in either of the groups. Table 3 lists the perioperative complications in both groups. In the ORC group, 11.9% of the patients had grade ≥3 surgical site

Table 2. Surgical outcomes and perioperative data

	LRC cohort (n = 17)	ORC cohort (n = 42)	p value
Surgical time (median, IQR), min	638 (584–715)	481 (447–554)	<0.001
Surgical time for RC and PLND (median, IQR), min	303 (256–331)	360 (315–419)	0.045
Surgical time for urinary diversion (median, IQR), min	105 (69–132)	96 (55–110)	0.353
EBL (median, IQR), mL	330 (260–400)	1,368 (811–1,793)	<0.001
Lymph node dissection, n (%)			
Standard	17 (100)	7 (16.7)	<0.001
Extend	0	35 (73.3)	
Urinary diversion, n (%)			
Ureterocutaneostomy	4 (23.5)	3 (7.1)	0.407
IC	13 (76.5)	38 (90.5)	
Ileal neobladder	0	1 (2.4)	
Blood transfusion, n (%)	1 (5.9)	25 (59.5)	<0.001
Time to liquid (median, IQR), day	1 (1–1)	2 (1–4)	<0.001
Time to liquid diet (median, IQR), day	2 (2–3)	4 (2–5)	0.002
Length of hospital stay (median, IQR), day	20 (19–22)	29 (23–39)	0.008

LRC, laparoscopic radial cystectomy; ORC, open radical cystectomy; IC, ileal conduit; IQR, interquartile range; RC, radical cystectomy; PLND, pelvic lymph node dissection; EBL, estimated blood loss.

Table 3. Perioperative complications (in n (%)) according to the Clavien-Dindo classification

Type of complication	LRC group (n = 17)		ORC group (n = 42)	
	any grade	≥grade 3	any grade	≥grade 3
SSI	2 (11.8)	0	9 (21.4)	5 (11.9)
Pyelonephritis	3 (17.6)	0	6 (14.2)	0
Ileus	2 (11.8)	1 (5.9)	8 (19.0)	4 (9.5)
Cerebral infarction	0	0	1 (2.4)	1 (2.4)
Lymphorrhea	1 (5.9)	0	0	0

LRC, laparoscopic radial cystectomy; ORC, open radical cystectomy; SSI, surgical site infection.

Table 4. Pathological outcomes

	LRC group (n = 17)	ORC group (n = 42)	p value
Pathological T stage, n (%)			
T0	2 (11.7)	4 (9.6)	0.294
Tis	0	3 (7.1)	
Ta/1	0	9 (21.4)	
T2	4 (23.5)	12 (28.6)	
T3	8 (47.1)	10 (23.8)	
T4a	3 (17.6)	4 (9.6)	
Type of histology, n (%)			
Urothelial carcinoma	17 (100)	38 (90.4)	0.194
Other histological cancer	0	4 (9.6)	
Removal lymph nodes (median, IQR), n	22 (13–24)	11 (7–14)	<0.001
Lymph node involvement, n (%)	5 (29.4)	3 (7.1)	0.034
Positive RM, n (%)	0	2 (4.8)	0.843

LRC, laparoscopic radial cystectomy; ORC, open radical cystectomy; IQR, interquartile range; RM, resection margin.

infections (SSIs) and 9.5% had ileus according to the Clavien-Dindo classification [19]. Conversely, only 1 patient in the LRC group had grade 3 ileus. None of the patients had died within 90 days of surgery.

Pathological Outcomes

All patients were evaluable for pathological outcomes. Table 4 lists the histopathological details. Overall, the surgical specimens of 6 (10.2%) patients showed stage pT0 disease. Eight patients (13.6%) had lymph node involvement. Two patients had a positive resection margin (RM) in the ORC group.

Oncological Outcomes

By the end of the follow-up period, 11 patients, including 1 patient in the LRC group and 10 in the ORC group, had died. The patient from the LRC group died of MIBC. In the ORC group, 7 patients died of MIBC and 3 died of other causes, including other cancers in 2 patients and an unknown cause in 1 patient.

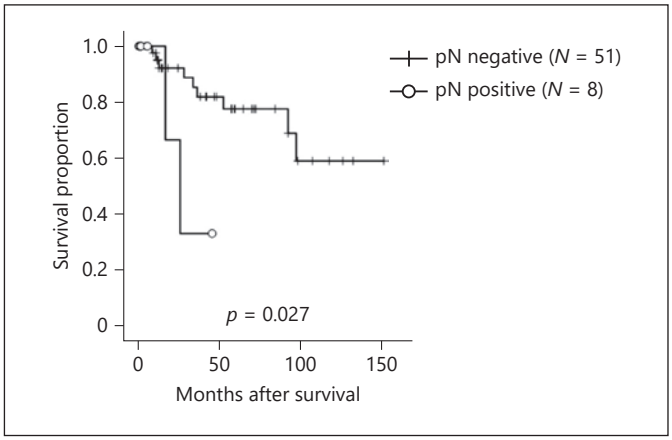

Fig. 1. According to the lymph node involvement (pN), the 2-year OS rate was 92.2% in the pN-negative group and 66.7% in the pN-positive group ($p = 0.027$). OS, overall survival.

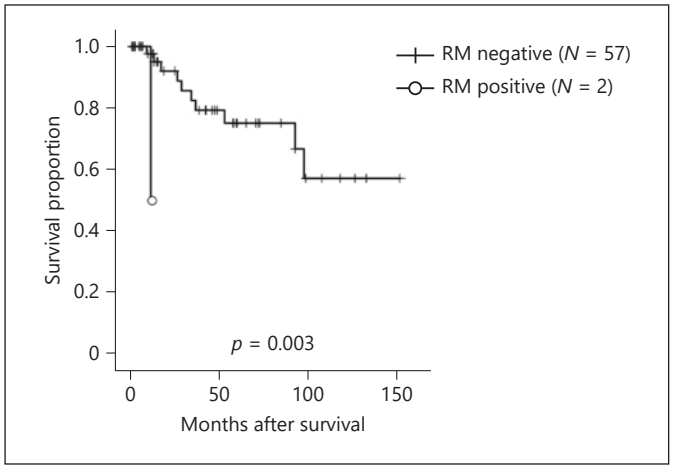

Fig. 2. With regard to the RM, the 2-year OS rate was 92.0% in the RM-negative group and 75.1% in the RM-positive group ($p = 0.003$). RM, resection margin; OS, overall survival.

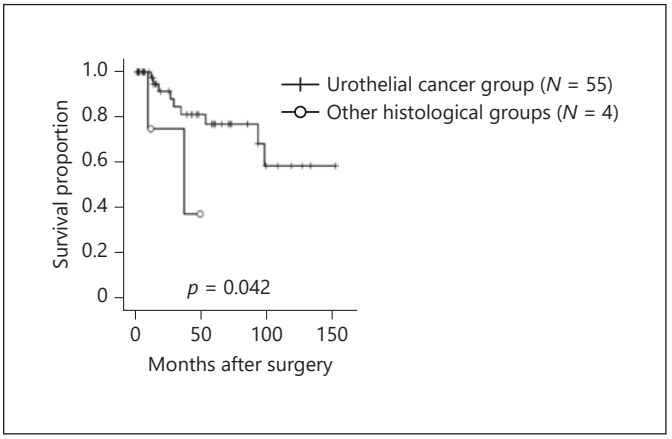

Fig. 3. According to the histological type of the tumor, the 2-year OS rate was 91.5% in the urothelial cancer group and 77.1% in the other histological groups ($p = 0.042$). OS, overall survival.

Table 5. Multivariate analysis for OS

Covariates	*p* value	Hazard ratio	95% CI
Positive RM	0.009	0.016	0.001–0.36
Lymph node involvement	0.017	0.102	0.016–0.659
Type of histology	0.046	0.154	0.025–0.967
Removal lymph nodes (*n*)	0.385	0.948	0.839–1.07

OS, overall survival; RM, resection margin.

The 2-year OS, CSS, and RFS rates among the enrolled patients were 89.9, 89.9, and 65.3%, respectively. The 2-year OS rate was 100% in the LRC group and 88.0% in the ORC group ($p = 0.85$). The 2-year RFS rate was 63.5% in the LRC group and 69.5% in the ORC group ($p = 0.321$).

According to the pN, the 2-year OS rate was 92.2% in the pN-negative group and 66.7% in the pN-positive group ($p = 0.027$, log-rank test; shown in Fig. 1). The 2-year OS rate was 92.0% in the RM-negative group and 75.1% in the RM-positive group ($p = 0.003$, log-rank test; shown in Fig. 2). According to the histological type of the tumor, the 2-year OS rate was 91.5% in the urothelial cancer group and 77.1% in the other histological groups ($p = 0.042$, log-rank test; shown in Fig. 3). On multivariate analysis, the histological type of the tumor and the number of positive lymph nodes and positive RMs were significantly associated with the OS rate (Table 5).

Discussion

RC remains one of the most effective treatments for MIBC and for high-grade, recurrent non-muscle-invasive tumors [1, 2]. However, ORC is associated with high morbidity and significant mortality [3]. MIES is a precise operative procedure expected to provide excellent visualization, decreased blood loss, fewer overall complications, shorter length of hospital stay, and shorter time to regular diet [20]. Although LRC has been covered by the public health-care system since 2012 and has gradually gained popularity in Japan, the Japanese public health-

care system included coverage for RARC as well in 2018. Thus, the use of MIES may shift from LRC to RARC in Japan [21]. Indeed, there is a decreased learning curve in RARC for surgeons without experience in laparoscopic surgery [12]. In addition, the robotic surgical system has a potential benefit in overcoming the technical difficulties of the LRC, including fatigue, tremor, and intracorporeal suturing [12]. Actually, we introduce RARC with intracorporeal urinary diversion in patients who underwent RC from 2018 at our institution. However, not all hospitals have introduced the robot-assisted surgical system worldwide. Furthermore, patients who undergo RARC need to endure a pneumoperitoneum with a significant degree of Trendelenburg angulation. For this reason, patients with severe cardiorespiratory complications may be relatively contraindicated for RARC. Therefore, the authors considered that it is important to analyze the safety and efficacy of LRC in patients with MIBC.

MIES may provide lower blood loss, less pain, and rapid bowel recovery compared with ORC. In addition, MIES for MIBC was previously expected to reduce the rates of intra- or perioperative complications, including gastrointestinal complications or SSI. In this study, although LRC had a significantly longer operative time than ORC, the EBL and the rate of blood transfusion in LRC were significantly lower than those in ORC. Likewise, the bowel recovery period in the LRC group was significantly shorter than that in the ORC group. With regard to perioperative complications, only 1 patient in the LRC group developed grade 3 ileus. Albisinni et al. [21] reported that 47% of the patients who underwent LRC experienced complications within 90 days after surgery [22]. Of these, SSI was the most frequent, followed by gastrointestinal and genitourinary events [20]. Kanno et al. [5] reported that the rate of gastrointestinal complications within 90 days was 25%, which is almost comparable to those reported in the ORC series (11–29%) [21] In contrast, the rate of abdominal wall-related complications within 90 days was lower than that reported in the ORC series [22]. Thus, even in LRC, we should pay attention to perioperative complications after surgery.

The OS and RFS rates are recognized to evaluate the efficacy of a therapy for malignant neoplasms. In this study, LRC achieved comparable OS ($p = 0.85$) and RFS ($p = 0.321$) rates to those of the ORC at a median follow-up period of 24.7 months (IQR, 7.8–59.5 months). In this study, the number of removal lymph node in the LRC group was significantly higher than that in the ORC group. Indeed, the surgical techniques between ORC and LRC may reflect this outcome. However, LRC followed by PLND achieves a clean and magnified view because of less bleeding compared with open surgery. Therefore, LRC may remove more perivascular tissue, including lymph nodes. The number of positive RMs and pN was significantly associated with the OS rates. A positive RM is an independent predictor of metastatic progression and leads to an increased probability of cancer-specific death [23]. Dotan et al. [22] reported that the overall positive RM rate was 4.2% for ORC and 7% for extravesical disease [23]. In addition, positive RMs almost doubled the risk of metastatic progression and BC death [23]. In the International Laparoscopic Cystectomy Registry, the positive RM rate was only 2% [24]. In our previous study, the oncological outcomes, including OS and RFS rates, were significantly improved in patients with MIBC who received NAC compared with those who underwent RC alone [7, 24, 25]. In this study, NAC followed by LRC did not significantly improve the OS rates. Therefore, the timing of RC may play an important role in obtaining a maximum effect of NAC.

The present study has several limitations. First, because this was a retrospective study, there is an inherent potential for bias. Second, a relatively small number of patients were enrolled in the present study and the follow-up period was relatively short.

In conclusions, this study suggested that LRC may achieve similar oncological outcomes and fewer perioperative complications and less blood loss compared to ORC. Therefore, LRC should be considered as one of the treatment options for patients with MIBC. Further prospective randomized trials are required to confirm the clinical usefulness of LRC.

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Statement of Ethics

This study was approved by the Gifu University Institutional Review Board (No. 2018-013).

Disclosure Statement

The authors declare that they have no conflict of interest to disclose.

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The authors did not receive any funding.

Authors Contribution

K.N., S.Y., and T.K.: conception or design of the work; acquisition, analysis, or interpretation of data; and drafting the work or revising. T.E., S.H., M.T., T.T., D.K., M.T., K.I., Y.M.M., and K.H.: data collection. K.M. and T.T: supervision.

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