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ORIGINAL ARTICLE

Complications within 90 days after radical cystectomy for bladder cancer: results of a multicenter prospective study in Japan

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Abstract

Purpose We prospectively evaluated the 90-day postoperative mortality and morbidity of open radical cystectomy by using a standardized reporting methodology. Additionally, we assessed the preoperative characteristics to determine risk factors for major complications.

Methods This multicenter prospective study included 185 consecutive patients undergoing open radical cystectomy from October 2010 through March 2014. Postoperative complications within 90 days were recorded and graded according to the modified Clavien–Dindo classification.

Results Totally, 328 postoperative complications were observed in 149 patients (80.5%). Of these events, 73 (22.2%) were high grade (≥ Grade III), and developed in 46 patients (24.9%). Three patients (1.6%) died postoperatively. Urinary tract infection, wound complications, and paralytic ileus were common complications that occurred in 55 (29.7%), 42 (22.7%) and 41 (22.2%) patients, respectively. Ureteroenteric stricture was diagnosed in 13 of the 151 patients (8.6%) undergoing intestinal urinary diversion. Emergency room visits were required for 13 patients (7.0%) and readmission after discharge was needed for 36 (19.5%). A body mass index ≥ 25 kg/m^2, smoking history and Charlson Comorbidity Index ≥ 2 were independent risk factors for high-grade complications, and their odds ratios (95% confidence intervals) were 2.357 (1.123–4.948), 2.843 (1.225–6.596) and 3.025 (1.390–6.596), respectively.

Conclusions Open radical cystectomy is associated with a high incidence of postoperative complications. Most, however, are of low grade. Our results suggest that obesity, a smoking history, and increasing comorbidity are risk factors for major complications.

Keywords Cystectomy · Comorbidity · Postoperative complication · Urinary bladder cancer

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Introduction

Radical cystectomy (RC) with lymph node dissection and urinary diversion (UD) is the gold standard treatment for patients with muscle-invasive bladder cancer or high-risk non-muscle invasive bladder cancer. With recent improvements of surgical procedures and perioperative care, the treatment-related morbidity and mortality rates have decreased during the last two decades [1]. However, RC remains one of the most invasive urological procedures in spite of these improvements.

Many studies have reported the postoperative morbidity and mortality rates of patients who undergo RC with UD [2–10]. The mortality and morbidity rates ranged from 0 to 9.0% and 30 to 70%, respectively, and varied widely among these reports. In a retrospective study using a care pathway in a cohort of 304 patients, the mortality rate was 0.3%, and overall major and minor complication rates were 4.9 and 30.9%, respectively [2]. Another large study including 1142 patients reported that the mortality and overall early complication rates were 2.7 and 67%, respectively [3]. This discrepancy may be explained by lack of standardized definitions of perioperative mortality and postoperative complications. In fact, there were differences in the definition of perioperative death among the reports, whether death due to cancer was included or not, and various follow-up periods such as 30 and 90 days were employed. Furthermore, most of these studies were done in a retrospective manner and might have underreported preoperative comorbidity and minor postoperative complications.

The demand for studies using standard definitions of complications, standard follow-up, and prospectively collected data is growing [11]. These are necessary for accumulation of evidence to create guidelines for postoperative management, better comparisons of different surgical techniques and counseling patients. Among various classifications of complications, the Clavien–Dindo classification (CDC) is applicable to most procedures for comprehensive surgical outcome assessment. To improve the quality of reporting on surgical complications, Martin et al. [12] proposed 10 criteria of ideal standard methods for reporting surgical complications, including methods of accruing data, the duration of follow-up, and outpatient information, as well as definitions of complications, mortality and morbidity, procedure-specific complications, severity grade, hospital stay and risk factors.

In this study, we prospectively evaluated the 90-day postoperative mortality and morbidity of open RC by using a standardized reporting methodology. Additionally, we assessed the preoperative characteristics to determine risk factors for major complications.

Materials and methods

Patient selection and assessment of data

From October 2010 through March 2014, 185 consecutive patients underwent open RC at Sapporo Medical University Hospital and 9 affiliate institutions participating in the Sapporo Medical University Urologic Oncology Consortium project. Patients who had received prior external beam radiotherapy were excluded from this study. Preoperative characteristics of the patients such as age, sex, BMI, ECOG-PS, the ASA score, Charlson Comorbidity Index (CCI) [13], smoking history, presence of hydronephrosis, serum creatinine and neoadjuvant chemotherapy were recorded prior to RC. BMI was calculated preoperatively according to the WHO guidelines, and divided into the following subgroups. The clinical stage and surgical parameters such as the operating time, intraoperative blood loss and transfusion requirement were recorded immediately after surgery. Pathological examination was performed by experienced pathologists at each institution according to the 2009 TNM classification. The postoperative complications were updated appropriately in a timely manner during the hospital stay. After discharge, the patients were told to come to the hospital where they had undergone surgery if they felt any change of their health status. Thus, complete information about complications was collected within a period of 90 days after surgery. This study was approved by the institutional review board of Sapporo Medical University (#20-84).

Preoperative and postoperative procedures

The standard procedure of RC including standard lymphadenectomy was performed for all patients. Lymphadenectomy included bilateral pelvic and at least bilateral common iliac lymph nodes. Urinary diversion types included ileal conduit, orthotopic neobladder and ureterocutaneostomy and percutaneous nephrostomy. Orthotopic neobladder substitution was performed by modified Studer methods with Nesbit anastomosis or the Le Duc-Camey anti-reflux method. Urethrectomy was indicated for male patients with high risk for urethral involvement or recurrence. In female patients, the uterus and ovaries were removed depending on age.

We adopted shared guidelines for preoperative and postoperative care including intravenous administration of antibiotic agents and parenteral nutrition. Briefly, only mechanical bowel preparation was performed the day before surgery. As prophylaxis for infection, antibiotics were intravenously administrated every 3 h and continued postoperatively for up to 2 days at the physicians' discretion. A nasogastric tube was placed intraoperatively and removed immediately after surgery. Continuous lower thoracic epidural analgesia with

local anesthetics was used for postoperative pain control if possible. Early postoperative feeding of semiliquid food was started on postoperative day 2, and then solid food was gradually introduced until resumption of a regular diet.

Definitions of complications

Postoperative mortality was defined as death from any cause occurring within 90 days after surgery. Postoperative complications within the same period were recorded and graded according to the modified CDC. We further grouped all complications into 11 categories as reported by the Memorial-Sloan Kettering Cancer Center [3]. Some common complications were defined in detail, including paralytic ileus, wound complications and urinary tract infection. Prolonged oral intake, the need for total parenteral nutrition and insertion of an ileus tube or a nasogastric tube again were considered to be paralytic ileus of Grade I, II and IIIa, respectively. Wound complications (surgical site infection and wound dehiscence) for which intravenous administration of antibiotics or an increase in the length of the hospital stay was needed were defined as Grade II. Wound dehiscence that needed resuture under local or general anesthesia and emergency operations for prolapse of visceral organs were defined as Grade III and IV, respectively. Most urinary tract infections requiring antibiotic chemotherapy were usually classified into Grade II, whereas complicated UTI associated with hydronephrosis needing nephrostomy or stenting, and sepsis were defined as Grade III and IV.

Statistical analysis

Univariate and multivariate logistic regression analyses were done to identify predictive factors of patients developing high-grade complications within 90 days after surgery. The following perioperative variables were categorized as risk factors: age, sex, BMI, a history of smoking, prior abdominal surgery, ECOG-PS, the ASA score, CCI, clinical T stage and neoadjuvant chemotherapy. A P value < 0.05 was considered statistically significant, and statistical analyses were performed using commercial software (SPSS version 16; IBM, Chicago, IL, USA).

Results

The patients' clinical characteristics and perioperative outcomes are shown in Table 1. The median age was 72 years and the male-to-female ratio was approximately 4:1. The series included a few patients with impaired physical status such as a CCI ≥ 3 or ASA score ≥ 3. More than half of the patients had organ-confined disease. For three patients who had distant metastases at the time of operation, cystectomy was performed for the purpose of relieving severe symptoms such as continuing bleeding and bladder irritability. The regimen most often employed for neoadjuvant chemotherapy was gemcitabine plus cisplatin, which was carried out for approximately 20% of the patients. Ileal conduit was adopted for a large number of patients, whereas only a small number of patients underwent neobladder substitution as urinary diversion. The decision on the type of urinary diversion was affected by physicians' and patients' preferences in addition to medical contraindications for neobladder substitution such as positive cancer in the prostatic urethra.

Tables 2 and 3 show all of the postoperative complications observed within 90 days after surgery in this study

Table 1 Preoperative characteristics and perioperative outcomes of 185 patients

Median age (range), years	72 (39–89)
Sex, *n* (%)	
Male	147 (79.4)
Female	38 (20.6)
Median BMI (range), kg/m^2	23.4 (15.2–34.2)
Charlson CI, *n* (%)	
0, 1	145 (78.4)
2	25 (13.5)
≧ 3	15 (8.1)
PS, *n* (%)	
0	143 (77.3)
≧ 1	42 (22.7)
ASA, *n* (%)	
1, 2	169 (91.4%)
3	16 (8.6)
Clinical T stage, *n* (%)	
≦ T2	118 (63.8)
T3	49 (26.5)
T4	18 (9.7)
Clinical N stage, *n* (%)	
N+	15 (8.1)
Clinical M stage, *n* (%)	
M+	3 (1.6)
Neoadjuvant chemotherapy, *n* (%)	44 (23.8%)
Median operating time (range), min	450 (171–764)
Median estimated blood loss (range), ml	1495 (200–10650)
Need for allogenic transfusion	99 (53.5%)
No. of removed lymph nodes	23 (0–75)
Urinary diversion, *n* (%)	
Ileal conduit	136 (73.5)
Cutaneous ureterostomy	32 (17.3)
Neobladder	15 (8.1)
Nephrostomy	1 (0.5)
None	1 (0.5)
Median postoperative hospital stay (range), days	24 (7–171)

Table 2 Overall events of postoperative complications (surgical, gastrointestinal, infectious, wound and genitourinary)

Grade	I	II	IIIa	IIIb	IVa	IVb	V	All
Surgical								6
Intraoperative vascular injury	2	1	0	2	0	0	0	
Intraoperative ureteral injury	0	0	0	1	0	0	0	
Gastrointestinal								79
Ileus	15	10	14	1	1	0	0	
Anastomotic bowel leak	0	1	0	0	0	0	0	
Gastrointestinal bleeding	0	0	1	0	0	0	0	
Diarrhea	4	3	0	0	0	0	0	
Constipation	9	12	0	0	0	0	0	
Gastroenteritis	2	4	0	0	0	0	0	
Others (duodenal ulcer 1, anorexia 1)	0	2	0	0	0	0	0	
Infectious								80
Pyelonephritis (UTI)	1	50	3	0	1	0	0	
Sepsis/bacteremia	0	6	0	0	5	0	0	
Abscess	0	5	1	1	0	0	0	
Fever of unknown origin	0	2	0	0	0	0	0	
Others (Catheter-related infection 1, infected aortic aneurysm 1, epididymitis 2, virus infection 1)	0	4	0	0	0	1	0	
Wound								50
Wound infection/wound dehiscence	19	11	4	6	2	0	0	
Incisional hernia	3	0	0	1	0	0	0	
Others (wound pain 2, urostomy stenosis 2, fixated drain tube 1, stoma site infection 1,)	2	0	1	1	0	0	0	
Genitourinary								41
Ureteric anastomotic stenosis	3	0	6	3	1	0	0	
Creatinine increased	14	5	1	0	0	0	0	
Ureteric anastomotic leakage	1	2	1	1	0	0	0	
Renal failure	0	0	0	0	2	0	0	
Fulminant tumor progression	0	0	0	0	0	0	1	

according to category. A total of 328 postoperative complications of any CDC grade were observed in 149 patients (80.5%). The mean number of complications per patient was 1.8 and high-grade (Grade III or more) complications developed in 46 patients (24.9%). Urinary tract infection was the most common complication, and affected 55 patients (29.7%), followed by wound complications in 42 (22.7%) and paralytic ileus in 41 (22.2%). Ureteroenteric stricture was diagnosed in 13 of the 151 patients (8.6%) who underwent intestinal urinary diversion. Constipation, increased serum creatinine and delirium were observed in 21 (11.4%), 20 (10.8%) and 15 (8.1%) patients, respectively, almost all of which were Grade II or less. Emergency room visits were required for 13 patients (7.0%) and readmission after discharge was needed for 36 patients (19.5%).

The results of univariate and multivariate logistic regression analyses to determine the preoperative risk factors for high-grade intra- and postoperative complications are shown in Table 4. In univariate analysis, BMI $\geq$ 25 kg/m^2, a smoking history and CCI $\geq$ 2 were significant risk factors. All of them were independent risk factors for high-grade complications associated with RC. The remaining variables, age, sex, the ASA score, tumor stage and neoadjuvant chemotherapy, had no significant association with the incidence of high-grade complications. There is no significant difference in morbidity and mortality rate between continent and incontinent UD groups. The overall mortality rate within 90 days after surgery was 1.6%. The details of the patients who died within 90 days after RC are shown in Table 5. One patient died of tumor progression and liver insufficiency within 30 days of surgery. Palliative radical cystectomy was originally planned for her with the purpose of controlling bladder bleeding and severe anemia. Another patient died of pulmonary embolism on postoperative day 7. Before that, he developed wound dehiscence (Grade IIIb) and underwent an emergency operation for wound closure on postoperative

Table 3 Overall events of postoperative complications (cardiac, pulmonary, bleeding, thromboembolic, neurological and miscellaneous)

Grade	I	II	IIIa	IIIb	IVa	IVb	V	all
Cardiac								9
Cardiac insufficiency	1	0	0	0	0	0	1	
Arrhythmia	0	4	1	0	0	0	0	
Angina pectoris	0	2	0	0	0	0	0	
Pulmonary								7
Pneumonia	2	3	0	0	0	0	0	
Acute respiratory distress syndrome	0	0	0	0	1	0	0	
Hypoxia	1	0	0	0	0	0	0	
Bleeding								11
Postoperative anemia requiring transfusion	1	9	0	0	0	0	0	
Intracranial hemorrhage	0	0	0	0	1	0	0	
Thromboembolic								3
Deep venous thrombosis	0	2	0	0	0	0	0	
Pulmonary embolism	0	0	0	0	0	0	1	
Neurological								19
Peripheral neuropathy	1	2	0	0	0	0	0	
Delirium	6	8	0	0	1	0	0	
Suicide attempt	0	1	0	0	0	0	0	
Miscellaneous								23
Acidosis	1	7	1	0	0	0	0	
Lymph leakage	2	0	0	0	0	0	0	
Lymphocele	1	0	1	0	0	0	0	
Lymphedema	3	0	0	0	0	0	0	
Liver dysfunction	1	1	0	0	0	0	0	
Enthesopathy	1	1	0	0	0	0	0	
Arterial hypertension	0	1	0	0	0	0	0	
Arytenoid dislocation	0	0	0	1	0	0	0	
Allergic reaction	0	0	1	0	0	0	0	

Table 4 Univariate and multivariate logistic regression analyses to assess the association between preoperative parameters and incidence of high grade complications

	Univariate			Multivariate		
	OR	95% CI	*P* value	OR	95% CI	*P* value
Age ≥ 70 years (ref, < 70 years)	1.788	0.877–3.642	0.110	–	–	–
Female sex (ref, male)	1.307	0.522–3.098	0.543	–	–	–
BMI ≥ 25 kg/m^2 (ref, < 25 kg/m^2)	2.173	1.076–4.389	0.030	2.357	1.123–4.948	0.023
Smoking history, yes (ref, no)	2.534	1.133–5.666	0.024	2.843	1.225–6.596	0.015
Prior surgery, yes (ref, no)	0.984	0.502–1.927	0.962	–	–	–
ECOG-PS ≥ 1 (ref, 0)	1.085	0.494–2.382	0.839	–	–	–
ASA score ≥ 2 (ref, 1)	1.312	0.621–2.775	0.477	–	–	–
CCI ≥ 2 (ref, < 2)	2.957	1.400–6.243	0.004	3.025	1.390–6.596	0.005
Clinical T stage ≥ T3 (ref, < T3)	1.108	0.335–3.666	0.866	–	–	–
NAC, yes (ref, no)	0.392	0.143–1.073	0.068	–	–	–

NAC neoadjuvant chemotherapy

day 3. The other patient developed paralytic ileus, sepsis, renal insufficiency, delirium and wound complications, and died of heart failure at 2 months after surgery. He was only 61 years old and preoperatively had no sign of heart disease.

Discussion

RC is a representative general surgical procedure in urology associated with high invasiveness that may contribute to relatively high mortality and morbidity. A European

Table 5 Details of patients who died within 90 days after radical cystectomy

Case	A	B	C
Age	61	74	67
Sex	Male	Male	Female
BMI	23.1	30.8	23.7
Charlson CI	1	3	0
PS	1	0	1
ASA score	2	2	1
Clinical stage	T1N0M0	T2N0M0	T4aN3M1
NAC	–	–	GC 2
Ope time	516	437	453
EBL	1399	1941	2505
POD death	58	7	19
Cause of death	Cardiac insufficiency	Pulmonary embolism	Tumor progression
Complication (Grade)	Ileus (IIIa), sepsis (IVa), renal failure (IVa), delirium (II), SSI (II)	SSI (IIIb), ileus (II)	

group conducted a multicenter prospective observational study of 679 patients who underwent RC. In their study, the mortality rate within 90 days was 9.0% [8]. They found that clinically node-positive disease and distant metastatic disease were independent risk factors for perioperative mortality, which suggests that they included a significant number of cancer-related deaths. This may account for their higher mortality rate. On the other hand, although the rate of major complications was similar, our series had a much higher overall complication rate than their study [14]. Not only a difference in races, but also differences in hospital volume (median 49 cystectomies per year) and perioperative management might have affected the different incidences of minor complications.

Several studies have reported the impact of comorbidities on postoperative complications after RC. A population-based study by Abdollah et al. showed that the CCI was a statistically significant predictor of postoperative mortality [7]. Furthermore, Mayr et al. assessed the impacts of four comorbidity indices, the ASA score, ACE-27, CCI and ECOG PS, on perioperative mortality within 90 days after RC, all of which were shown to be independent predictors [5]. In a retrospective study using the ACE-27 as a comorbidity instrument, Fairey et al. [15] concluded that increasing comorbidity was independently associated with an increased risk of 90-day mortality and postoperative complications after RC. Furthermore, in a study by Roghmann et al. using a standardized methodology, both the CCI and BMI were significant risk factors for high-grade complications [9].

The BMI and a history of smoking were also independent risk factors for postoperative complications in the current study. Several investigators have reported the negative impacts of the BMI on operative and postoperative courses. Lee et al. [16] observed that the BMI was correlated with the perioperative complication rate, estimated blood loss and operative time. In our series, particularly, ileus and wound trouble accounted for a large number of postoperative complications. Several reports showed that the rate of postoperative ileus was associated with the BMI [17, 18]. Associations between the BMI and wound trouble such as surgical site infection and wound dehiscence in abdominal surgery are well reported [19, 20]. Furthermore, smoking is also a well-known risk factor for surgical site infection. On the other hand, ureteric anastomotic stenosis has not been reported to be directly associated with the BMI or smoking. It may be associated with other factors such as the type of anastomosis and urinary tract infection [21]. Interestingly, however, Richards et al. reported that the incidence of grade III or higher postoperative complications within 30 days after RC was an independent risk factor for ureteric anastomotic stenosis [22]. As discussed in other reports, patients with high BMIs tend to have more postoperative complications, suggesting a potential association between a high BMI and the incidence of ureteric anastomotic stenosis. Moreover, ureteral anastomotic leakage was the other reported risk factor for ureteric anastomotic stenosis [22]. It is well known that smoking induces tissue ischemia, leading to anastomotic leakage in gastrointestinal tract surgery, suggesting that smoking also potentially induces ureteral anastomotic leakage, which can lead to anastomotic stenosis [23, 24].

Current guidelines recommend that a continent UD should be offered to all patients without specific contraindications. There are controversies whether the type of UD influences postoperative morbidity and mortality after RC. In general, continent diversion (such as ileal neobladder) might include higher morbidity rates due to its complicated procedure. However, in the present study, no significant difference in morbidity and mortality rate between continent and incontinent UD groups was observed. This result

is supported by other studies. In a prospective large study from a European tertiary center, the risk of postoperative complications did not vary according to UD type. Abe et al. [25] reported that there was no significant difference in the overall morbidity rate, although the patients with ileal neobladder had more infectious complications. A matched pair analysis in Korean series also showed no difference in 30- and 90-day morbidity and mortality [26].

The median postoperative hospital stay in our series was longer than in a cohort in the USA, but similar to that of large series in Japan [6] and that of one in Italy [27]. However, the length of hospital stay is strongly influenced by the healthcare system of each country and the individual hospital policy.

There has been a growing acceptance of minimally invasive surgery such as laparoscopic (LRC) and robot-assisted laparoscopic radical cystectomy (RARC). However, a recent systematic review concluded that RARC had a lower 90-day rate of complications of any grade, whereas the high-grade complication and mortality rates were similar to those of open RC, although RARC can be performed safely [28]. Some prospective studies showed that there were no significant differences in 90-day postoperative complication rates between open RC and RARC, although RARC provided possible benefits such as reducing intraoperative blood loss, inpatient narcotic requirements and time to regular diet [29, 30]. Furthermore, a recent randomized controlled trial from an experienced high-volume cancer center failed to identify a definite advantage of RARC over open RC and reported similar complication rates, lengths of hospital stay and short-term QOL outcomes in the two groups, although RARC had a significantly lower intraoperative blood loss [31]. To clarify the possible advantages of LRC/RARC with regard to postoperative complications, further studies with larger sample sizes and standardized assessment of complications are needed. LRC/RARC is already widespread due to its potential lesser invasiveness and many surgeons are trying to improve the technique. Therefore another randomized controlled study to compare the outcomes of open RC and LRC/RAPC might be infeasible in the present circumstances and the outcomes of LRC/RAPC should be verified by comparison with reported results of open RC as a control. However, most studies about open RC do not meet the criteria for reports of surgical complications [32] because they do not report the definitions of complications, the grade/severity, outpatient data, comorbidities and the duration of the reporting period, which are essential to improve the quality of surgical complication reporting. In addition, Lawrentschuk et al. [11] found that standard definitions of complications, standard follow-up, and prospectively collected data were needed to create evidence-based guidelines and improve postoperative outcomes of RC. The present study may have significant value because of its use of a standardized reporting methodology advocated by Martin et al. [12] and prospective assessment.

Our study has some limitations. First, although data were collected prospectively, the number of patients was small. This may have resulted in the failure to identify some potential risk factors predicting complications. Second, despite the application of the CDC, the complication grading had potential interobserver biases. Nevertheless, our study has the special strength of prospective collection of data, where the categories and severities of postoperative complications were defined in advance of surgery and complications were reported immediately after their incidence.

In conclusion, although open RC is associated with significant morbidity, most of the complications are minor. Because obesity, increasing comorbidity and a history of smoking might be associated with high-grade complications, we should be aware of these risk factors and inform patients of them before surgery.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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