

# Single staff cystectomy in a low-volume center: Oncological outcomes and complications

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## Abstract

**Introduction:** Radical cystectomy (RC) with bilateral pelvic lymph node dissection (PLND) is a complex surgical procedure, associated with substantial perioperative complications. Previous studies suggested reserving it to high-volume centers in order to improve oncological and perioperative outcomes. However, only limited data exist regarding low-volume centers with highly experienced surgeons. We aimed to assess oncological and perioperative outcomes after RC performed by experienced surgeons in the low-volume center of Luzerner Kantonsspital, Lucerne, CH.

**Methods:** We retrospectively analyzed the data of 158 patients who underwent RC and PLND performed between 2009 and 2019 at a single low-volume center by three experienced surgeons, each having performed at least 50 RCs. Complications were graded according to the 2004 modified Clavien-Dindo grading system.

**Results:** A total of 110 patients (70%) received an incontinent urinary diversion (ileal conduit or ureterocutaneostomy) and 48 patients (30%) received a continent urinary diversion (ileal orthotopic neobladder, ureterosigmoidostomy, or Mitrofanoff pouch). Median operating time was 419 minutes (interquartile range [IQR] 346–461). Overall, at RC specimen, 71.5% of patients had urothelial carcinoma, 12.6% squamous, 3.1% sarcomatoid, 1.2% glandular, and 0.6% small cell carcinoma. Median number of lymph nodes removed was 23 (IQR 16–29.5). Positive margins were found in eight patients (5.1%). Overall five-year survival rate was 52.4%. The complication rate was 56.3%: 143 complications were found in 89 patients, 36 (22.8%) with Clavien  $\geq$ 3. The 30-day mortality rate was 2.5%.

**Conclusions:** RC could be safely performed in a low-volume center by experienced surgeons with comparable outcomes to high-volume centers.

## Introduction

Radical cystectomy (RC) with bilateral pelvic lymph node dissection (PLND) followed by urinary diversion (UD) represents the gold standard treatment for non-metastatic muscle-invasive and recurrent non-muscle-invasive bladder cancer (BCa).<sup>1-3</sup> RC is a complex surgical procedure that involves the genitourinary and gastrointestinal tracts, pelvic organs, and lymph nodes. Although RC and UD represent well-established surgical procedures, they are still associated with substantial perioperative morbidity (27–72%) and considerable perioperative mortality (0.8–8.2%) rates.<sup>4</sup>

Currently, an important concern is represented by the management of high-risk procedures (such as RC) and cancer care and whether they should be centralized in specialized high-volume hospitals.<sup>5</sup> To date, several studies have arbitrarily provided definitions for hospital and surgeon volumes.<sup>6-9</sup> In recent literature, the definition of a high-volume hospital has been set to an amount of 50–55 RCs per year,<sup>6</sup> and the threshold value for the surgeon volume has been set to an amount of eight RCs per surgeon per year.<sup>8,9</sup>

At present, only limited evidence evaluates RC outcomes in small-volume medical facilities, and the existing literature on this topic is lacking in accuracy and quality of peri- and postoperative complications analyses. We aimed to contribute to the present debate about centralization of complex surgical procedures by analyzing RC perioperative and oncological outcomes and complications over a 10-year period in the low-volume center of Luzerner Kantonsspital, Lucerne, CH.

## Methods

### Study design and population

The present study involves 158 patients who underwent open radical cystectomy (ORC) or robot-assisted radical cystectomy (RARC) from January 2009 to March 2019 at our institute (Luzerner Kantonsspital, Lucerne, Switzerland). All patients who underwent RC during the last 10 years were identified using our clinic operating system; clinical, surgical, and pathological data were retrospectively collected. The surgical procedures were performed by three experienced senior staff members (HD, AM, PS), each having an experience of more than 50 RCs before January 2009. Informed signed consent was obtained from all patients involved.

Patient medical records, including inpatient notes, hospital discharge letters, outpatient letters, and hospital re-admission records, were extracted from our clinical operating system and all the medical data were reviewed for demographics (age, gender, body mass index [BMI], and American Society of Anesthesiologists [ASA] score), preoperative variables (neoadjuvant chemotherapy, staging, and pathology), information about intraoperative parameters (type and technique of UD, operative time, transfusions), and perioperative outcomes (complications, hospital stay). Obesity was defined as BMI $\geq$ 30. The Charlson comorbidity index (CCI) was used to assess comorbidities. All complications were graded according to the 2004 Modified Clavien-Dindo grading system.<sup>10</sup>

Pathological data included histology, tumor grade according to 1973 and 2004/2016 World Health Organization (WHO) classification,<sup>11</sup> and stage according to the American Joint Committee on Cancer (AJCC) Tumor, Node, Metastasis (TNM) classification (8<sup>th</sup> edition). Histology included urothelial carcinoma and variant histologies, such as squamous, micropapillary, sarcomatoid, small cell carcinoma, and glandular variants. We assigned the diagnosis of variant histology if the pathological report revealed any morphological features that differed from pure urothelial carcinoma, regardless the actual percentage found; therefore, each variant histology could be expressed in a pure or mixed form (when it was associated to urothelial carcinoma).

Each patient was assigned a specific patient ID and all personal data were anonymously stored in a SecuTrial database. The Swiss ethics committee approved this retrospective study.

### Statistical analysis

Categorical variables were expressed as frequencies and percentages; continuous variables were reported as medians, interquartile ranges (IQR), means, and standard deviation (SD). Overall survival (OS) and progression-free sur-

vival (PFS) were assessed using the Kaplan-Meier method. Statistical analyses were performed using Stata (Version 15.1, StataCorp, College Station, TX, U.S.).

## Results

### Clinicopathological characteristics

Demographics and clinical characteristics are summarized in Table 1. Between 2009 and 2019, 158 patients underwent RC: 72% were men, with an overall median age of 71

**Table 1. Demographic characteristics of 158 patients treated with radical cystectomy and bilateral pelvic lymph node dissection between 2009 and 2019 at a single institution**

Variable	Value
Age (years)	
Mean (SD)	70 (10.2)
Median (range)	71 (29–93)
Gender	
Male, n (%)	114 (72)
Female, n (%)	44 (28)
Body mass index (kg/m <sup>2</sup> )	
Mean (SD)	26.7 (4.3)
Median (range)	26.3 (16.26–37.28)
Charlson comorbidity index, n (%)	
$\leq$ 1	110 (69.6)
2	25 (15.8)
3	13 (8.2)
$\geq$ 4	10 (6.3)
ASA score, n (%)	
1	5 (3.57)
2	80 (57.14)
3	54 (38.57)
4	1 (0.71)
Clinical T stage, n (%)	
$\leq$ cT2	128 (81)
cT3	6 (3.79)
cT4	4 (2.54)
Clinical N stage, n (%)	
cN0	130 (82.28)
cN1	2 (1.27)
cN2	5 (3.16)
cN3	1 (0.63)
Neoadjuvant chemotherapy, n (%)	
Yes	16 (10.1)
No	142 (89.9)
Adjuvant chemotherapy, n (%)	
Yes	30 (18.99)
No	128 (81.01)

ASA: American Society of Anesthesiologists; SD: standard deviation.

years (range 29–93). Median BMI was 26.3 kg/m<sup>2</sup> and 16.5% of patients were obese. Eighty patients (57.1%) had ASA 2 and 55 (39.3%) had ASA $\geq$ 3. Overall, 113 patients were diagnosed with urothelial carcinoma, 20 squamous, five sarcomatoid, two glandular, and one small cell carcinoma. Neoadjuvant chemotherapy was given to 16 patients (10.1%) and preoperative intravesical instillation was performed in 25 for non-muscle-invasive BCa (15.8%).

### Perioperative outcomes

Median operating time was 419 minutes (IQR 346–461) (Table 2). Most of the surgical procedures (94.3%) were of ORC, the remaining were done via RARC. An incontinent UD was performed in 110 patients (69.6%): 104 patients (65.8%) received an ileal conduit and six (3.8%) an ureterocutaneostomy. A continent UD (orthotopic neobladder, ureterosigmoidostomy, or Mitrofanoff pouch) was performed in 48 patients (30.4%); among continent UD, Studer orthotopic neobladder was performed in 32% of patients. Median hospital stay was 17 days (IQR 13–21). Respectively, five (3.2%) and 13 (8.2%) patients underwent a re-intervention within 30 and 90 days after RC. Most of re-operations consisted of wound or uretero-ileal anastomosis revision after dehiscence.

**Table 2. Perioperative outcomes of 158 patients treated with radical cystectomy and bilateral pelvic lymph node dissection between 2009 and 2019 at a single institution**

Variable	Value
Type of procedure, n (%)	
Open radical cystectomy	149 (94.3)
Robot-assisted radical cystectomy	9 (5.7)
Type of urinary diversion, n (%)	
Ileal conduit	104 (65.8)
Neobladder	48 (30.4)
Ureterocutaneostomy	6 (3.8)
Operating time (minutes)	
Mean (SD)	406.2 (88.9)
Median (range)	419 (151–628)
Pelvic lymph node dissection, n (%)	
Yes	136 (86%)
Number of lymph node removed	
Median (IQR)	23 (16–29.5)
Length of hospital stay (days)	
Mean (SD)	18 (10)
Median (IQR)	17 (13–21)
Re-operation	
30 days, n (%)	5 (3.2)
90 days, n (%)	13 (8.2)

IQR: interquartile range; SD: standard deviation.

**Table 3. Complications of 158 patients treated with radical cystectomy and bilateral pelvic lymph node dissection between 2009 and 2019 at a single institution**

Highest Clavien-Dindo class	n (%)
Minor complications	53 (33%)
1	7 (4.4%)
2	46 (29%)
Major complications	36 (23%)
3a	17 (10%)
3b	14 (8.9%)
4a	2 (1.3%)
5	3 (1.9%)
Overall complication rate	89 (56%)

### Postoperative adverse events

A total of 143 complications were reported in 89 patients (56.3%) (Table 3). Among those who experienced complications, 105 (73.4%) had minor complications (Clavien class 1 or 2) and 38 (26.6%) had major complications (Clavien class  $\geq$ 3) with no intraoperative deaths.

Among major complications, the most frequent events were wound infection and wound dehiscence requiring vacuum-assisted closure therapy or a secondary wound closure, which occurred in five (3.2%) and seven (4.4%) patients, respectively. Complications of uretero-ileal anastomosis (dehiscence or stenosis) were observed in seven patients (4.4%). Major gastrointestinal complications (including bowel obstruction and perforation) were reported in four patients (2.5%) and major heart complications in three (1.9%). Three patients died within the hospitalization period because of postoperative complications (Clavien 5), including acute respiratory distress syndrome (ARDS), septicemia, and aspiration pneumonia. Among minor complications, blood transfusions and urinary tract infections (including low urinary tract infections, pyelonephritis, and urosepsis) represented the most common events, occurring in 29 (18.4%) and 17 (10.8%) patients, respectively. Minor gastrointestinal complications (including paralytic ileus, dysphagia, diarrhoea, vomiting) occurred in nine patients (5.7%). Minor respiratory and heart complications occurred in eight (5.1%) and three (1.9%) patients, respectively. Lower limb hypoesthesia was reported in 2.5% of cases (four patients).

### Postoperative oncological outcomes

Pathological outcomes for RC are shown in Table 4. Organ-confined disease (pT $\leq$ 2 and pN0) was detected in 75 patients (45%), including 30 patients (19%) with pT $\leq$ 1 and 45 (28.5%) with pT2, while extravesical disease (pT  $\geq$  3) was detected in 66 patients (41.8%), including 51 patients with pT3 and 15 with pT4. Among extravesical disease

**Table 4. Pathological outcomes of 158 patients treated with radical cystectomy and bilateral pelvic lymph node dissection between 2009 and 2019 at a single institution**

Variable	Value
Pathological T stage, n (%)	
pT0	8 (5.1)
pTa	1 (0.6)
pTis	3 (1.9)
pT1	18 (11.4)
pT2	45 (28.5)
pT3	51 (32.3)
pT4	15 (9.5)
Pathological N stage, n (%)	
0	101 (63.9)
1	16 (10.1)
2	22 (13.9)
3	1 (0.6)
Histological variants, n (%)	
Transitional cell carcinoma	113 (71.5)
Squamous differentiation	20 (12.6)
Sarcomatoid carcinoma	5 (3.1)
Glandular differentiation	2 (1.2)
Small cell carcinoma	1 (0.62)
Presence of carcinoma in situ, n (%)	43 (27)
Lymphovascular invasion, n (%)	21 (13)
Perineural invasion, n (%)	16 (10)
Positive margins, n (%)	8 (5.1)

patients, positive margins were detected in eight patients (5.1%). PLND was performed in 136 patients (86%) and the median number of lymph nodes removed was 23 (IQR 16–29.5). N1 and N2 diseases were found in 16 (10.1%) and 22 (13.9%) patients, respectively. At a mean followup time of 26.5 months (SD 29.8), the 30- and 90-day mortality rates were 2.5% and 4.4%, respectively. Respectively, OS and PFS were 61.9% and 54.9% at three years, and 52.4% and 48.6% at five years.

## Discussion

RC and UD represent complex, high-risk surgical procedures, characterized by perioperative morbidities and significant mortality. Previous studies have shown a significant discrepancy in mortality rates for complex surgical procedures performed in high- and low-volume centers, suggesting that the former have better infrastructures and more experienced surgeons, resulting in better outcomes.<sup>4,5</sup> To date, several studies have provided large RC series that analyzed multiple factors potentially associated with improved postoperative outcomes and decreased complications.<sup>4,12-14</sup> Hospital volume,<sup>12,14</sup> surgeon volume,<sup>13</sup> and patient's distance from the hospital<sup>12</sup> have been taken into account by analyzing their relationship to survival rates after RC. A stronger cor-

relation has been found between improved postoperative outcomes and hospital volume, rather than other factors. Moreover, the topic of centralizing RC procedures in high-volume, selected institutions has been addressed by several studies.<sup>5,15,16</sup> In their systematic review, Goossens-Laan et al<sup>5</sup> found an inverse association between postoperative mortality and hospital volume but claimed that additional quality criteria, such as infrastructure and experience level, should be taken into account in speculating potential centralization projects. Notably, to date, different criteria have been proposed to define hospital and surgeon volumes.<sup>6,8,17</sup> Previous studies set rather low threshold values, defining a high-volume hospital as performing 16–32 RCs per year.<sup>8,17</sup> More recently, Arora et al,<sup>6</sup> analyzing the relationship between hospital volume and RC morbidity, suggested to increase said threshold to 50–55 RCs per year. Similarly, surgeon volume definition has not been clearly defined but recent studies have set the threshold value to an amount of eight RCs per surgeon per year.<sup>8,9</sup> Considering these criteria, our hospital meets the definition of low-volume hospital, counting an average of 16 RCs per year.

However, although results of large RC series are currently available, data about the safety and efficacy of RC in centers with limited caseloads are lacking. Most of the available studies have analyzed data from large-population datasets or referral centers with high patient and surgeon volumes,<sup>5,12-16</sup> whereas a small number of reports deals with perioperative oncological outcomes and complications in low-volume centers, where many RCs are performed. Most single-center studies have focused their attention on specific surgical techniques or compared operative outcomes of different surgical approaches.<sup>18,19</sup> To our knowledge, the current series represents the first report of outcomes of RC performed in a low-volume center by experienced surgeons that provides a comprehensive overview of results for different surgical techniques, reflecting the reality of most institutions.

We made several findings. First, we considered complications as a useful way of evaluating surgical techniques and operating outcomes. Previous studies compared RC outcomes in different centers using the Clavien-Dindo system, showing remarkable discrepancies in quantity and severity of complications, especially between low- and high-volume hospitals.

In their systematic review, Moschini et al<sup>4</sup> examined 49 contemporary series of RC, reporting a postoperative complication rate of 48.7% (range 27.0–72.5%) for ORC and 38.4% (range 27–42%) for RARC. In our 10-year cohort, complications were reported in 89 patients with an overall complication rate of 56.3%. Although only nine patients of this cohort underwent RARC, previous studies have shown that complication rates of ORC are comparable to those of RARC.<sup>4,18,20,21</sup> RARC has been proven equivalent to the open approach in terms of oncological and functional outcomes,

with less blood loss, fewer transfusion, shorter hospital stays, and quicker recovery.<sup>21</sup> Mani et al<sup>16</sup> stratified patients who underwent RC at the same institution in two different time periods (group A treated between 1989 and 2010, and group B treated between 2010 and 2013). In their groups, complication rate varied from 58–86.1% and major complications were reported in 30% and 35.2% of cases among group A and group B, respectively.

Notably, in our cohort, only 22.8% of patients had major complications (Clavien grade  $\geq 3$ ), while 33.5% had minor complications (Clavien grade  $\leq 2$ ). Besides, 89 patients of the present series showed no sign of complications. Our complications rates are in line with previous literature on this topic in the context of enhanced recovery after surgery (ERAS) protocols, which is aimed at reducing length of stay, perioperative complications, and costs. In particular, Williams et al,<sup>22</sup> in their systematic review reported minor and major complications of 64% and 14% at 30 days and 53% and 24% at 90 days, respectively.

Secondly, we focused on oncological outcomes of RC. In this regard, a minimum lymph nodes yield consisting in the removal of at least 10 lymph nodes and positive surgical margin (PSM) rate less than 10–15% have been specified as surgical quality indices.<sup>23–25</sup> In their systematic review, Perera et al<sup>23</sup> reported an association between increasing nodal counts and improved OS: nodal count  $>21$  has been shown to improve 10-year OS from 32% to 59% compared to nodal count  $<10$  ( $p=0.005$ ). In previous RC series, the reported PSM rates varied from 2–16%.<sup>26–31</sup> In a multicenter, international cohort, Novara et al<sup>28</sup> found PSM in 278 (6.3%) of 4410 patients, while Dotan et al<sup>31</sup> reported rates of 4.2% in a single-center series of 1591 patients. In line with previous literature, we found PSM in eight patients (5.1%), with a median number of 23 lymph nodes removed (IQR 16–29.5).

Lastly, we compared the mortality rate in our cohort to those reported in a recent series of high-volume RC centers. Nielsen et al<sup>14</sup> made an evaluation of 30- and 90-day mortality rate for 35 055 patients who underwent RC for BCa in 1118 hospitals using the National Cancer Data Base (Maryland, U.S.). Mortality rates at low- and high-volume centers were compared. Overall, 30- and 90-day mortality rates were 2.7% and 7.2%, respectively — 1.9% and 5.7% among high-volume hospitals and 3.2% and 8.0% among low-volume hospitals, respectively. In their systematic review, Moschini et al<sup>4</sup> found an average 30-day mortality rate of 3.8% for patients who underwent ORC, ranging from 0.8–8.2%. The 30- and 90-day mortality rates observed at our low-volume center were 2.5% and 4.4%, respectively. When compared with outcomes observed by Nielsen et al,<sup>14</sup> these rates appear to be similar to those from high-volume hospital. The underlying reason for this is likely the surgical team experience; each surgeon involved in the present study had performed more than 50 RCs before the starting period.

In addition, these three surgeons had previously experienced a training period in Bern led by Dr. Studer, known for the orthotopic neobladder technique that bears his name.

Our study is not devoid of limitations. First, data were collected in a retrospective design and therefore subject to bias, which do not allow definitive conclusions to be drawn. Secondly, our center showed low rates of both neoadjuvant and adjuvant chemotherapy compared to standard of care; a possible explanation for these results could be sought in pre-existing comorbidities of patients, which did not make patients eligible to cisplatin chemotherapy. Although this limitation could frequently occur in retrospective studies, it may have affected our results, especially survival outcomes. Moreover, approximately 10% of patients have not undergone LND, possibly due to the patient's comorbidities or surgeon choice. In addition, although our study covers a wide time range, the number of patients is quite small. Finally, our cohort includes two different surgical techniques (ORC vs. RARC) that have not been separately compared.

## Conclusions

We found that an experienced staff operating in a low-volume center can produce results comparable to those obtained in high-volume centers in terms of perioperative complications and survival. Therefore, the present study suggests that patients could safely undergo RC in a low-volume center provided it is performed by adequately experienced surgeons.

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This paper has been peer-reviewed.

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