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

Philipp Baumeister[1]; Davide Galioto[1]; Marco Moschini[1]; Chiara Lonati[1]; Stefania Zamboni[1]; Luca Afferi[1]; Patrick Stucki[1]; Hansjörg Danuser[1]; Dirk Lehnick[2]; Livio Mordasini[1]; Agostino Mattei[1]

[1]Department of Urology, Luzerner Kantonsspital, Lucerne, Switzerland; [2]Department of Biostatistics, Luzerner Kantonsspital, Lucerne,Switzerland

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Correspondence: Dr. Philipp Baumeister, Department of Urology, Luzerner Kantonsspital, Lucerne, Switzerland; philipp.baumeister@luks.ch

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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 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 ≥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)[1–3]. RC is a complex surgical procedure that involves genitourinary and gastrointestinal tract, 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 rates (0.8-8.2%) [4].

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

However, 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 centralisation of complex surgical procedures, by analysing RC perioperative and oncological outcomes and complications over a 10-year experience 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 and clinical, surgical and pathological data were retrospectively collected. The surgical procedures were performed by 3 experienced senior staff members (Danuser H., Mattei A. and Stucki P.), each having an experience of more than 50 RC before January 2009. Informed signed consent has been obtained from all patients involved. Patient medical records, including inpatient notes, hospital discharge letters, outpatient letters and hospital readmission 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 Anaesthesiologists 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≥30. The Charlson Comorbidity Index (CCI) was used to assess comorbidities. All complications were graded according to the 2004 Modified Clavien–Dindo Grading System [10].

Pathological data included histology, tumor grade according to 1973 and 2004/2016 World Health Organization (WHO) classification[11] and stage according to the American Joint Committee on Cancer (AJCC) Tumour, Node, Metastasis (TNM) classification (8th 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 survival (PFS) were assessed using the Kaplan-Meier method. Statistical analyses were performed using Stata (Version 15.1, StataCorp, College Station, Texas, USA).

Results

Clinicopathologic 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 years (range: 29-93). Median BMI was 26.3 kg/m^2 and 16.5% of patients were obese. Eighty patients (57.1%) had ASA 2 and 55 (39.3%) had ASA≥3. Overall, 113 patients were diagnosed with urothelial carcinoma, 20 squamous, 5 sarcomatoid, 2 glandular and 1 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 min (IQR: 346-461 min) (Table 2). Most of the surgical procedure (94.3%) consists of ORC, the remaining part of RARC. An incontinent UD was performed in 110 patients (69.6%): 104 patients (65.8%) received an ileal conduit and 6 (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, 5 (3.2%) and 13 (8.2%) patients underwent a reintervention within 30 and 90 days after RC. Most of reoperations consisted of wound or uretero-ileal anastomosis revision after dehiscence.

Postoperative adverse events

Complications are depicted in Table 3. A total of 143 complications were reported in 89 patients (56.3%): among patients experienced complications, 105 (73.4%) had minor complications

(Clavien class 1 or 2) and 38 (26.6%) had major complications (Clavien class ≥ 3) with no intraoperative deaths.

Among major complications, the most frequent events were wound infection and wound dehiscence requiring VAC-therapy or a secondary wound closure, occurring in 5 (3.2%) and 7 (4,4%) patients, respectively; complications of uretero-ileal anastomosis (dehiscence or stenosis) were observed in 7 patients (4.4%). Gastrointestinal major complications (including bowel obstruction and perforation) were reported in 4 patients (2.5%), whereas heart major complications in 3 (1.9%). Three patients died within the hospitalisation period because of postoperative complications (Clavien 5): acute respiratory distress syndrome (ARDS), septicaemia 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. Gastrointestinal minor complications (including paralytic ileus, dysphagia, diarrhoea, vomiting) occurred in 9 patients (5.7%). Respiratory and heart minor complications occurred in 8 (5.1%) and 3 (1.9%) patients, respectively. Lower limb hypoesthesia was reported in 2.5% of cases (4 patients).

Postoperative oncologic outcomes

Pathological outcomes for RC are shown in Table 4. Organ-confined disease (pT ≤ 2 and pN0) was detected in 75 patients (45%), including 30 patients (19%) with pT≤1 and 45 (28.5%) with pT2, while extravesical disease (pT ≥ 3) was detected in 66 patients (41.8%), including 51 patients with pT3 and 15 with pT4. Among extravesical disease patients, positive margins were detected in 8 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 follow up 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 3 years, and 52.4% and 48.6% at 5 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 [4, 5]. To date, several studies have provided large RC series which analysed multiple factors potentially associated with improved postoperative outcomes and decreased complications [4, 12–14]. Hospital volume [12, 14], surgeon volume [13] and patient's distance from the hospital [12] have been taken into account by analysing their relationship to survival rates after RC. A stronger correlation 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, that suggested to perform RC in centers with high surgical caseload [5, 15, 16]. In their systematic review Goossens et al. [5] 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 centralisation projects.

Notably, to date different criteria have been proposed to define hospital- and surgeon-volumes [6, 8, 17]. Previous studies set rather low threshold values defining high volume hospital, varying between 16-32 RC per year [8, 17]. More recently, Arora et al. [6], analysing the relationship between hospital volume and RC morbidity, suggested to increase said threshold to 50-55 RC per year. Similarly, surgeon-volume definition has not been clearly defined but recent studies have set the threshold value to an amount of 8 RC per surgeon per year [8, 9]. Considering these criteria, our hospital meets the definition of low-volume hospital, counting an average of 16 RC per year.

However, although results of large RC series are currently available, data about the safety and efficacy of RC in centers with limited caseload are lacking. Most of the available studies have analysed data from large population datasets or referral centers with high patient- and surgeon-volumes [5, 12–16], whereas a small number of reports deals with perioperative, oncological outcomes and complications in a low volume centers, where many RC are performed. Most of monocentric studies have focused their attention on specific surgical techniques or compared operative outcomes of different surgical approaches [18, 19]. 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. This study aims to implement the currently lacking literature with new data about RC performed at a low-volume center.

We made several findings. First, we considered complications as a useful mean 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. [4] 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 9 patients of this cohort underwent RARC, previous studies have shown that complication rates of ORC are comparable to those of RARC [4, 18, 20, 21]. 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 [21]. Mani et al.[16] stratified patients who underwent RC at the same institution in 2 different time periods. In their groups, complication rate varied from 58% to 86.1% and major complications were reported in 30% and 35.2% patients, respectively. Notably, in our cohort only 22.8% of patients had major complications with Clavien class ≥ 3, while 33.5% had minor complications (Clavien class ≤ 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) pathway, which is aimed at reducing length of stay, perioperative complications and costs. In particular, Williams et al.[22] in their systematic review reported minor and major complications of 64% and 14% at 30-day and 53% and 24% at 90-day, 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 margins (PSM) rate less than 10-5% have been stated as surgical quality index [23–25]. In their systematic review Perera et al. [23] 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% to 16%[26–31]. In a multicentre international cohort, Novara et al.[28] found PSM in 278 (6.3%) of 4,410 patients, while Dotan et al. [31] reported rates of 4.2% in a single-center series of 1,591 patients. In line with previous literature, we found PSM in 8 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 recent series of high-volume center RC. Nielsen et al. [14] made an evaluation of 30- and 90-day mortality rate for 35,055 patients who underwent RC for bladder cancer in 1,118 hospitals using the National Cancer Data Base (Maryland – USA). Mortality rates at low- and high-volume centres were compared. Overall, 30- and 90-day mortality rates were 2.7% and 7.2%: 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. [4] found an average 30-day mortality rate of 3.8% for patients who underwent ORC, ranging from 0.8% to 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.[14], these rates appear to be more similar to those from high-volume hospital. The reason underlying this is probably the surgical team experience. In particular, each surgeon involved in the present study had performed more than 50 RC before this series starting period. In addition, these 3 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 of these results could be sought in preexisting 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 patient's comorbidities or surgeon's choice. In addition, though 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) which have not been separately compared.

In conclusion, we found that an experienced staff operating in a low-volume centre 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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Figures and Tables

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^2)	
Mean (SD)	26.7 (4.3)
Median (range)	26.3 (16.26–37.28)
Charlson comorbidity index, n (%)	
≤1	110 (69.6)
2	25 (15.8)
3	13 (8.2)
≥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 (%)	
≤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.

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 (ORC)	149 (94.3)
Robot-assisted radical cystectomy (RARC)	9 (5.7)
Type of urinary diversion, n (%)	
Ileal conduit	104 (65.8)
Neobladder	48 (30.4)
Ureterocutaneostomy	6 (3.8)
Operating time (min.)	
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)
Reoperation	
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%)

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)