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ORIGINAL ARTICLE

Postoperative complications and short-term oncological outcomes of patients aged ≥80 years undergoing robot-assisted radical cystectomy

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Abstract
Purpose To assess complication rates and early oncological outcomes of patients aged ≥80 years who underwent robot-assisted radical cystectomy (RARC).
Methods A total of 368 consecutive patients underwent radical cystectomy from April 2001 to September 2013 in a tertiary referral center. Sixty-one patients aged ≥80 years underwent RARC and constitute the cohort of interest. Complications arising within 30 and 90 days of surgery were graded using the modified Clavien classification and were additionally categorized by organ system using a standardized complication reporting system. Recurrence-free survival, disease-specific survival and overall survival were calculated using Kaplan–Meier curves.
Results Median age was 83 years (range 80–94). Twenty-nine (48 %) of all tumor specimens were stage ≥pT3. The median number of nodes removed was 19 (range 6–67). The soft tissue positive margin rate was 10 %. A total of 27 (44 %) patients had complications within 90 days, of which 9 had major complications. Two patients (3 %) died from surgical complications within 90 days. At a median follow-up of 13 months, 12 (20 %) patients had developed recurrent cancer and subsequently died from disease. An additional 13 (21 %) patients died from non-cancer-related causes. The median overall survival time was 36.0 months. At 2 years, recurrence-free, cancer-specific and overall survival rates were 73, 74 and 61 %, respectively.
Conclusions In patients aged ≥80 years, RARC is feasible with acceptable perioperative morbidity and favorable short-term oncological outcomes. Therefore, RARC should be considered a valid option for carefully selected patients aged ≥80 years with bladder cancer.

Keywords Bladder cancer · Complications · Octogenarians · Robot-assisted radical cystectomy · Survival

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Introduction

With the growth of an aging population in the years ahead, there is still a lack of consensus regarding the management of older patients with BCa [1]. Despite its indisputable value in selected patients [2–6], open radical cystectomy (RC) is associated with a significant risk for major complications and perioperative mortality in patients aged ≥80 years [2, 5, 7–10].

In an effort to improve perioperative outcomes without compromising oncologic efficacy, robot-assisted radical cystectomy (RARC) has gained increasing interest in recent years. Potential advantages of RARC include decreased intraoperative blood loss, reduced analgesic requirements and early ambulation [11], which may be particularly valuable in older patients. The early evidence indicates that comparable results can be achieved with open RC and RARC in terms of surgical efficacy, as assessed by positive surgical margin (PSM) rates and lymph node yield [11–13].

To date, the potential benefits of RARC in patients aged ≥80 years have not been well described [14]. To redress

this deficiency, we identified a cohort of patients aged ≥80 years who underwent RARC and assessed perioperative complications using a standardized method of reporting [15–17]. In addition, short-term (2 years) oncological outcomes were evaluated.

Materials and methods

Patient population

Upon study approval by the Institutional Review Board, data on 368 consecutive patients who underwent RC from April 2001 and September 2013 were reviewed. The authors complied with the Declaration of Helsinki regarding ethical conduct in research involving human subjects. Of all, 79 (19 %) patients were aged ≥80 years at the time of surgery. A total of 61 (77 %) of these 79 patients underwent RARC and constitute the cohort of interest. All RARCs were performed by one single surgeon (D.S.S.), using previously described technique [18]. Limits of the bilateral pelvic lymph node dissection were the upper common iliac artery superiorly, Cooper's ligament (including the node of Cloquet) inferiorly, the genitofemoral nerve laterally and the sacral promontory medially. Urinary diversion was performed extracorporeally [11]. An orogastric tube is inserted for surgery, then removed before the patient awakens. Placement of a naso-gastric tube is not routinely performed perioperatively.

Outcomes measures

Complications

All complications within 30 and 90 days were collected prospectively, using a standardized complication reporting system [15–17]. Regular correspondence with patients and their physician ensured that treatment received outside of our institution was accounted for in our database. All complications were graded using the modified Clavien classification system [15]. Grade 1 and Grade 2 complications were defined as minor, and Grade 3–5 complications were defined as major. Additionally, all complications were categorized by organ system [11, 17]. Of note, ileus was defined as the inability to pass flatus ≥5 days or to otherwise tolerate an oral diet (e.g., nausea/emesis, abdominal distension) and requiring naso-gastric tube.

Oncologic outcomes

Patient follow-up was offered every 3–4 months the first year, semi-annually for the second year, and annually thereafter. Diagnostic imaging was performed at least annually or when clinically indicated. For patients who died during the duration of the study, the cause of death was determined by the investigators through review of medical records or death certificates.

Statistical analysis

Adjusted odds ratios (OR) and 95 % confidence intervals (CI) were calculated to assess predictors of both overall and major complications. Potential confounders included in multivariable analyses were patient's age at RARC (continuous), gender, body mass index (BMI; continuous), American Society of Anesthesiologists (ASA) score (2 vs >2), Charlson Comorbidity Index (CCI; 2 vs >2), prior surgery/radiation, total operative time (continuous) and estimated blood loss (EBL) (continuous). Because ASA score and CCI were not collinear in our model (variance inflation factor <2), both comorbidity scores were considered. Recurrence-free survival, cancer-specific survival and overall survival were generated using the Kaplan–Meier method for the whole cohort and within subgroups stratified by tumor stage. Statistical significance was computed with the log-rank test. All calculations were performed using IBM SPSS 21 (IBM, Armonk, NY, USA). A two-sided p value <0.05 was considered significant.

Results

Baseline and pathologic data

Median age was 83 years (range 80–94) (Table 1). Twenty-nine (48 %) of all tumor specimens were stage ≥pT3. Lymph node dissection was omitted in two patients with bulky T4 disease who underwent palliative cystectomies because of intractable symptoms and in one patient who had scarred tissue after radiation. Nodal stage could not be determined after review of the pathology report in one patient. In the remaining 57 patients, the median number of nodes removed was 19 (range 6–67). Soft tissue PSM was found in 6 (10 %) patients. Specifically, five (19 %) of 27 patients with ≥pT3 disease had PSM, of whom four (80 %) had N2 stage, while one patient with T2 N0 disease had a PSM.

Complications

A total of 47 complications occurred in 27 patients within 90 days of surgery (Table 2). Within 30 days of surgery, 24 (75 %) of 32 complications were minor and eight (25 %) were major. Within 90 days of surgery, 35 (74 %) of 47 complications were minor and 12 (26 %) were major. Infectious complications were by far the most common

Table 1 Baseline characteristics of patients aged ≥80 years undergoing robot-assisted radical cystectomy

	Patients ($n = 61$)
Age [median (range)]	83 (80–94)
Gender [*n* (%)]	
Male	54 (89)
Female	7 (11)
Ethnic origin	
White (%)	51 (84)
Black (%)	2 (3)
Asian (%)	5 (8)
Other (%)	3 (5)
BMI in kg/m^2 [median (IQR)]	25 (17–47)
History of smoking	
Yes	32 (52)
No	29 (48)
ASA score	
2	18 (30)
3	39 (64)
4	4 (7)
CACI	
2	14 (23)
3	19 (31)
4	9 (15)
5	11 (18)
6	3 (5)
7	4 (7)
8	1 (2)
Previous abdominal surgery	
Yes	20 (33)
No	41 (67)
Previous radiotherapy	
Yes	13 (21)
No	48 (79)
Type of urinary diversion	
Ileal conduit	58 (95)
Indiana pouch	2 (3)
Continent reservoir with appendix	1 (2)
Neoadjuvant chemotherapy	
No	56 (92)
Yes, complete responder	1 (2)
Yes, partial responder	3 (5)
Yes, non-responder	1 (2)
Histologic type	
TCC	59 (97)
Small cell carcinoma	2 (3)
Pathologic stage [*n* (%)]	
pT0	2 (3)
pTa	4 (7)
pTcis	7 (11)
pT1	6 (10)
pT2	13 (21)
pT3	20 (33)
pT4	9 (15)
Lymphovascular invasion	
Yes	18 (30)
No	43 (70)
Concomitant CIS[a]	
Yes	30 (49)
No	24 (39)
Soft tissue positive margin	
Yes	6 (10)[b]
No	53 (90)
LND performed	
Yes	58 (95)
No	3 (5)
Number of lymph nodes removed in case of LND [median (range)]	19 (6–67)
Nodal stage [*n* (%)]	
pNx	4 (7)
pN0	47 (77)
pN1	2 (3)
pN2	8 (13)
Adjuvant chemotherapy	
Yes	2 (3)
No	59 (97)

BMI body mass index, *ASA* American Society of Anesthesiologists, *CCI* Charlson Comorbidity Index, *CIS* carcinoma in situ, *LND* lymph node dissection, percentages may not sum to 100 % due to rounding

[a] Not including patients with Tcis only in bladder specimen

[b] Not including two patients with bulky T4 disease who received palliative cystectomies without pelvic lymph node dissection

complication (38 %), followed by gastrointestinal and cardiac complications. No patient died from complications within 30 days of surgery. Two patients (3 %) died from surgical complications within 90 days, one patient from infectious complications (abdominal abscess) and another one from complications following a small bowel leak.

In a logistic regression model, patient's age at RARC, gender, BMI, prior surgery/radiation, ASA score (2 vs >2), CCI (2 vs >2), operative time and EBL were not found to be independent predictors for any complication or major complications (all p values > 0.05).

Oncologic outcomes

Mean and median follow-up for surviving patients were 23 and 16 months, respectively (SD ± 21; range 1–81). At last follow-up, 36 (59 %) patients were alive without evidence of disease. Specifically, 22 (36 %) patients with follow-up

greater than 12 months and 13 (21 %) patients with follow-up greater than 24 months were alive without evidence of disease at last follow-up. Twelve (20 %) patients, all with pathological stage ≥pT3, developed recurrent disease and subsequently died from disease. Median time to recurrence was 5 months (range 1–17). No port-site recurrence was documented. None of the patients with stage ≤pT2 developed disease recurrence after mean and median follow-up intervals of 25 and 18 months, respectively (SD ± 21.7; range 1–81). In addition, 13 (21 %) patients died from non-cancer-related causes, for an overall mortality rate of 41 %.

Kaplan–Meier survival curves are depicted in Fig. 1. Median overall survival time was 36.0 months (95 % CI 29.6–42.4). At 1 and 2 years, the actuarial recurrence-free survival rates were 82 and 73 %, respectively, the actuarial cancer-specific-survival rates were 85 and 74 %, respectively, and the actuarial overall survival rates were 73 and 61 %, respectively. Stratification of survival outcomes by tumor stage showed significantly lower survival rates with increasing pathologic stage (all $p < 0.0001$). Median overall survival times were 47.0 months (95 % CI 17.0–48.7) for stage T2, 15 months (95 % CI 13.2–27.0) for stage T3 and 6.0 months (95 % CI 3.8–16.5) for stage T4.

Discussion

The current study demonstrates that less than half (44 %) of all patients aged ≥80 years undergoing RARC for BCa suffer complications within 90 days. After a median follow-up of 16 months, 59 % of patients are alive without evidence of disease. As the average life span increases and BCa management in older patients is expected to become a major challenge, we take the view that RARC may be an attractive option for selected patients aged ≥80 years diagnosed with muscle-invasive or high-risk non-muscle-invasive BCa.

Earlier reports on outcomes of RARC have included younger and healthier patients with lower disease burden and the absence of prior pelvic treatment (radiation, surgery) [18, 19], which reflects the expected selection bias when a new surgical technique is introduced. In recent years, as experience with RARC increased, a few authors have attempted to address the role of RARC in older patients. In a small series of 23 patients aged ≥80 years undergoing cystectomy, a 34.8 % complication rate within 90 days, with no mortality, was reported [14]. Less encouraging was the high PSM rate of 26 %, although it has to be noted that 70 % of all patients were staged ≥pT3. Using lower cutoffs of 70 and 75 years, respectively, two other studies aimed to compare operative and complication outcomes of younger and older patients undergoing RARC and found no differences [20, 21]. However, such comparative analyses are likely accompanied by bias in patient selection. Moreover, the first study was characterized by a particularly low number of patients with advanced

Table 2 Distribution and detailed description of 30- and 90-day complications

	Patients ($n = 61$)	
	30 days	90 days
Patients with complications [*n* (%)]	19 (31)	27 (44)
Patients with major complications [n (%)]	5 (8)	9 (15)
Highest grade of complications		
Grade 0 [*n* (%)]	42 (69)	34 (56)
Grade 1 [*n* (%)]	2 (3)	3 (5)
Grade 2 [*n* (%)]	12 (20)	15 (25)
Grade 3 [*n* (%)]	4 (7)	5 (8)
Grade 4 [*n* (%)]	1 (2)	2 (3)
Grade 5 [*n* (%)]	0	2 (3)
Complications (*n*)	32	47
1. Surgical	1 (3)	1 (2)
Common bile duct injury	1	1
2. Wound	2 (6)	2 (4)
Wound infection	2	2
3. Pulmonary	0	0
4. Neurologic	0	0
5. Genitourinary	2 (6)	3 (6)
Acute renal failure	1	1
Urinary retention	1	1
Ureteral stricture	0	1
6. Infectious	12 (38)	18 (38)
Fever of unknown origin	2	2
Urinary tract infection	3	4
Pyelonephritis	1	1
Bacteremia/septicemia	1	7
Abdominal abscess	5	5
7. Gastrointestinal	4 (13)	9 (19)
Ileus	3	3
Clostridium difficile	1	3
Gastrointestinal bleeding	0	1
Bowel leak	0	2
8. Cardiac	5 (16)	6 (13)
Atrial fibrillation	2	2
Supraventricular tachycardia	2	2
Ventricular tachycardia	1	2
9. Bleeding	3 (9)	3 (6)
Significant transfusion (>2 units)	1	1
Hematoma	1	1
Symptomatic anemia	1	1
10. Miscellaneous	1 (3)	1 (2)
Oral candidiasis	1	1
11. Thromboembolic	2 (6)	4 (9)
Deep venous thrombosis	2	4

Percentages may not sum to 100 % due to rounding

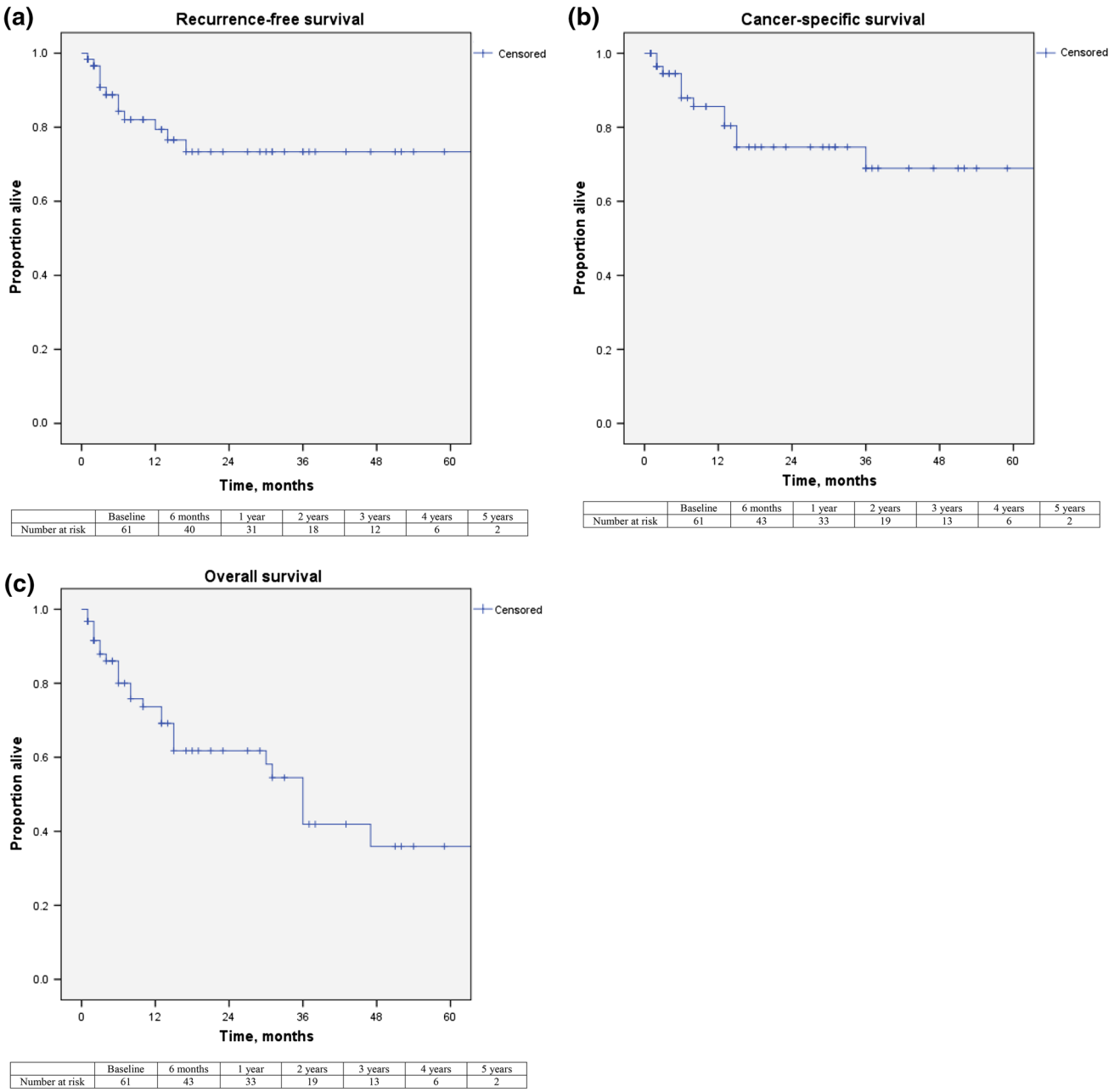

Fig. 1 Kaplan–Meier estimates of (**a**) recurrence-free, (**b**) cancer-specific and (**c**) overall survival probabilities in patients aged ≥80 years who underwent robot-assisted radical cystectomy and pelvic lymph node dissection for bladder cancer

disease in both groups [20]. The three aforementioned studies reported complication rates of 34 % within 30 days [20] and 34.8–45 % within 90 days [14, 21]. A major strength of the current study is the use of a standardized complication reporting system. Martin et al. [16] first established ten criteria that should be included when reporting complications. Subsequently, Shabsigh et al. [17] incorporated these recommendations into a complication reporting system for RC, which provided a model for the current and other recent studies evaluating RARC [11, 12, 22].

While the long-term oncologic outcomes of open RC in the general population have been well described [23], controversy exists regarding the benefit of surgery in patients aged ≥80 years [1]. Three multicenter studies have shown that patients aged ≥80 years are more likely to experience cancer recurrence and cancer-specific death than younger patients [3–5]. However, advanced age in these studies was also associated with higher pathological stage, lymphovascular invasion and positive PSMs [3–5], as well as pathological upstaging [3]. Survival analyses may thus have been

influenced by longer delay between diagnosis and surgery and/or reluctance to offer RC, leading to a large group of older patients with more desperate cases referred to tertiary centers [3, 4]. Conversely, another multicenter study found no difference in recurrence-free, cancer-specific and overall survival rates between age groups [6]. Although it is usually admitted that higher age is associated with higher rates of complications and perioperative mortality [7, 24], several open RC series have demonstrated that surgery nevertheless provides survival benefit in selected patients aged ≥80 years [2–6]. Collectively, these conflicting data have led to the perception that elderly patients will not tolerate surgery because of age and/or comorbidity. In fact, a SEER study showed that only 16 % of patients aged 80–84 years and 4 % of those aged ≥85 years with muscle-invasive cancer undergo RC [25].

Evidence on long-term oncologic efficacy of RARC is still lacking. Surrogate markers for acceptable oncological outcome have been proposed by Herr et al. [26] and include a soft tissue PSM rate less than 10 % and a lymph node yield greater than 10–14. Our median lymph node yield was 19 (range 6–67), and our soft tissue PSM rate was 10 %. PSM was more likely to occur in the setting of extravesical disease, as was the case in open RC series [27]. Therefore, our surgical technique is in line with these benchmark recommendations for quality of surgery. Although patient selection needs to be accounted for, our 74 % cancer-specific and 61 % overall survival rates at 2 years are in line or higher than numbers reported in open RC series evaluating patients aged ≥80 years, with numbers ranging from 55 to 75 % [3–6] and 50 to 60 % [4–6], respectively. Although the follow-up interval is relatively short, our results were achieved despite the fact that 48 % of all patients had extravesical disease, a proportion that is consistent with open RC series evaluating patients aged ≥80 years [2, 3, 5, 6], and despite the fact that only 8 % of patients received neoadjuvant chemotherapy.

In all, our findings argue that RARC is feasible and beneficial in patients aged ≥80 years. However, as emphasized throughout this manuscript, the role of patient selection when evaluating a new surgical technique cannot be underappreciated. Our patients may have represented a selected group that despite high comorbidity profile had favorable factors that warranted the indication for the robotic approach. These factors include patient characteristics such as biological age, physical activity, oral anticoagulation, or tumor variables such as tumor size and local status. Nevertheless, the 61 patients in the current study represent 77 % of all patients aged ≥80 years that underwent RC at our institution, as our 10-year experience with RARC makes us comfortable offering this approach to the majority of older patients.

We acknowledge some limitations of our study. First, our study lacks a comparison cohort. We did not compare ≥80 years RARC patients with ≥80 years open RC patients because selection bias in favor of RARC would have been encountered. By the same token, comparison to a group of younger patients who underwent RARC would not have provided objective results. Outcomes of patients aged ≥80 years should be evaluated in the context of age-matched counterparts who did not undergo RC, ideally in a prospective, randomized trial. Due to our position as a tertiary referral center, it is also possible that we did not capture all complications that occurred after hospital discharge. Another limitation of our study is that it only reflects the experience of a single surgeon in a high-volume tertiary referral center.

These limitations notwithstanding, our study is the first to provide an accurate assessment of perioperative complications as well as short-term oncological outcomes in a large cohort of patients aged ≥80 years. The 2-year survival data are clinically useful when counseling patients aged ≥80 years with BCa, who have a life expectancy of 9.1 years in the USA (9.7 years for women, 8.2 years for men) [28].

Conclusions

RARC in patients aged ≥80 years is associated with acceptable morbidity and favorable short-term oncological outcomes, suggesting that RARC duplicates the oncological principles of open RC in this group of patients. Therefore, RARC is a valid option for selected patients aged ≥80 who are diagnosed with muscle-invasive, high-risk and recurrent non-muscle-invasive BC.

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

Ethical standard The creation and retrospective review of the Weill Cornell Medical College Bladder Cancer Database was approved by the Institutional Review Board of Weill Cornell Medical College and therefore conforms to the ethical standards laid down in the 1964 Helsinki Declaration and its later amendments. No information with the potential to disclose patient identities was included.

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