



Peri-operative efficacy and long-term survival benefit of robotic-assisted radical cystectomy in septuagenarian patients compared with younger patients: a nationwide multi-institutional study in Japan

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Received: 30 August 2018 / Accepted: 8 May 2019 / Published online: 23 May 2019
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Abstract

Background To determine the peri-operative safety and oncological value of robotic-assisted radical cystectomy (RARC) for older and younger patients in an initial Japanese RARC series.

Methods We retrospectively analyzed the demographics, complications, peri-operative and oncological outcomes of 253 consecutive patients with bladder cancer who underwent RARC at 34 institutions in Japan between April 2009 and March 2017. The patients were assigned to groups according to ages at surgery of < 70 (younger; $n = 125$) and ≥ 70 (older; $n = 128$) years.

Results Mean Charlson comorbidity index ($p = 0.045$) and the incidence of a history of previous abdominal surgery ($p = 0.002$) were significantly higher, whereas a history of neoadjuvant chemotherapy ($p = 0.028$) and neobladder ($p < 0.001$) were significantly lower in the older group. Mean total operative time was significantly shorter ($p = 0.019$) and mean estimated blood loss ($p = 0.013$) was significantly lower in the older group. Post-operative Grade \geq II complications were comparable at 0–30, 31–90 and 91 days after surgery despite urinary tract associations. Rates of positive surgical margins and mean numbers of removed lymph nodes were comparable between the two groups. Although 5-year overall survival rates were significantly lower ($p = 0.03$) for older patients, 5-year cancer-specific ($p = 0.10$) and recurrence-free survival rates were comparable ($p = 0.20$) between the groups.

Conclusion Using RARC potentially allows the application of less invasive procedures and cancer control for septuagenarian patients that are equivalent to those for younger patients.

Keywords Muscle invasive bladder cancer · Peri-operative outcome · Long-term survival · Robotic-assisted radical cystectomy · Multi-institutional study

Introduction

The incidence of bladder cancer (BCa) distinctly increases with age. The risk of muscle-invasive bladder cancer increases approximately three- to sixfold for men and women aged ≥ 70 years [1]. Although radical cystectomy (RC) with

pelvic lymph node dissection (PLND) is the gold standard therapy for muscle-invasive and high-risk superficial bladder cancer [2], the peri-operative morbidity of open radical cystectomy (ORC) is quite high. Therefore, older patients, and those with poor performance status, or multiple comorbidities cannot in principle tolerate ORC [3].

Rapid population aging is presently a global problem. Estimates indicate that the ratio of persons aged > 65 years in the world population will increase from 8.3% in 2015 to 18.1% in 2060. The aging rate in Japan has remained the highest in the world since 2005, and it increased to 26.7% in 2015. This pace is more than two times faster than that in Western countries [4]. Thus, the management of invasive

Electronic supplementary material The online version of this article (<https://doi.org/10.1007/s10147-019-01470-6>) contains supplementary material, which is available to authorized users.

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bladder cancer in older patients will become more important. However, consensus regarding this has not been reached.

The oncological and survival outcomes of minimally invasive robotic-assisted radical cystectomy (RARC) and ORC have recently been compared. The advantages of RARC have been emphasized in terms of blood loss, blood transfusion, length of hospital stay and peri-operative complications [5–9]. Furthermore, since robotic-assisted surgery has the advantage of a shorter learning curve than conventional laparoscopic surgery according to a systematic review of radical prostatectomy [10], indications for RC among patients with difficulties regarding surgery and elderly patients have expanded with the advent of RARC. However, the survival benefit of RARC among has been investigated only in small groups of elderly patients.

Because health insurance has covered robotic-assisted radical prostatectomy (RARP) since 2012, robotic-assisted surgery has spread quickly throughout Japan. In addition, robotic-assisted partial nephrectomy (RAPN) has been covered by health insurance since 2016, and this has increased the importance of robotic-assisted surgery to treat urological pathologies. The number of RARC has increased annually, and RARC has been covered by insurance only since April 2018.

The present study aimed to determine the peri-operative safety, oncologic effects and survival benefits of RARC among Japanese elderly, compared with younger patients in an initial series before health insurance cover became available. This nationwide study was an initiative of the Japanese Society of Endourology and included 34 institutions focused around a university hospital. As far as we can ascertain, the present study includes the largest comparison of RARC between consecutive older and younger patients.

Patients and methods

Patients

The Ethics Committees at the participating Japanese institutions approved the present study. Clinical and laboratory data regarding 253 consecutive patients with BCa who underwent RARC between April 2009 and March 2017 were retrospectively collected from each institution. Bladder cancer was pathologically confirmed by transurethral resection of bladder tumors (TURBT) in all patients before undergoing RARC. All RARC operations proceeded using the robot-assisted da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA, USA). However, surgical details of RARC, intracorporeal urinary diversion (ICUD), extracorporeal urinary diversion (ECUD) and lymph node dissection were not strictly standardized and were left to the discretion of the surgeons at each institution.

The patients were grouped according to whether they were aged < 70 (younger) or ≥ 70 (older) years at the time of surgery. Patient demographics, peri-operative outcomes, complications, and oncologic outcomes were assessed. Complications were compared using the Clavien–Dindo classification system. Survival analysis included overall survival (OS), cancer-specific survival (CSS) and recurrence-free survival (RFS). The definition of RFS in the present study was the duration from surgery to metastasis or local recurrence determined by follow-up imaging. Patients with suspected pre-operative lymph node or distant metastasis were excluded from survival analysis.

Statistical analysis

All data were statistically analyzed using SAS 9.4 software (SAS Institute, Cary, NC, USA). Continuous and categorical variables were compared using Student *t* tests and Fisher exact tests, respectively. Survival rates estimated from Kaplan–Meier curves were compared between the younger and older groups using log-rank tests. Values with $p < 0.05$ were considered significant.

Results

Patient demographics

Table 1 shows the demographics of the 125 younger and 128 older patients. Significant factors comprised the mean Charlson comorbidity index (CCI), a history of previous abdominal surgery, pre-operative albumin (Alb) value, a history of neoadjuvant chemotherapy, clinical T3, ileal conduit and neobladder. Mean BMI, pre-operative hemoglobin (Hb) value, and rates of adjuvant chemotherapy tended to be lower, but pre-operative creatinine (Cr) C-reactive protein (CRP) values, and rates of ureterocutaneostomy tended to be higher among the older patients. However, the differences did not reach significance.

Peri-operative surgical outcomes

Table 2 shows the peri-operative surgical outcomes. Mean total operative time was significantly shorter in the older patients, whereas the mean amount of console time was similar between the two groups. The EBL during the construction of a urinary diversion was significantly lower among the older patients. Although the older patients tended to require blood transfusions relatively more often, the amounts of intra-operative and post-operative blood transfusions did not significantly differ.

Table 1 Patient demographics

	Younger (age < 70 years) <i>n</i> = 125	Older (age ≥ 70 years) <i>n</i> = 128	<i>P</i> value
Mean age, years (IQR)	62.4 (39–69)	76.3 (70–92)	
Male/female	105/20	102/26	0.374
Mean BMI, kg/m ² (IQR)	23.3 (16.7–30.1)	22.8 (14.4–32.2)	0.133
Mean CCI (IQR)	1.30 (0–6)	1.53 (0–8)	0.045
History of previous abdominal surgery (%)	23 (18.4)	46 (35.9)	0.002
Mean pre-operative Hb level, g/dL (IQR)	12.3 (8.4–17.6)	11.8 (7.6–15.3)	0.085
Mean pre-operative Alb level, g/dL (IQR)	4.1 (2.8–5.1)	3.8 (1.8–4.8)	<0.001
Mean pre-operative Cr level, mg/dL (IQR)	0.93 (0.45–2.22)	1.10 (0.37–9.15)	0.114
Mean pre-operative CRP level, mg/dL (IQR)	0.41 (0.0–7.6)	0.64 (0.0–15.8)	0.538
Neoadjuvant chemotherapy (%)	65 (52.0)	49 (38.3)	0.028
Adjuvant chemotherapy (%)	25 (20.0)	15 (11.7)	0.071
<i>Clinical stage</i>			
cTis (%)	5 (4.0)	11 (8.6)	0.133
cT1 or less (%)	19 (15.2)	21 (16.4)	0.793
cT2 (%)	57 (45.6)	68 (53.1)	0.231
cT3 (%)	36 (28.8)	22 (17.2)	0.028
cT4 (%)	8 (6.4)	6 (4.7)	0.551
cNOM0 (%)	114 (91.2)	113 (88.2)	0.301
<i>Urinary diversion</i>			
ICUD/ECUD	46/79	42/86	0.506
Ureterocutaneostomy (%)	13 (10.4)	22 (17.2)	0.118
Ileal conduit (%)	62 (49.6)	80 (62.5)	0.039
Neobladder (%)	50 (40.0)	23 (18.0)	<0.001
Others (%)	0 (0.0)	3 (2.3)	0.247

IQR interquartile range, *BMI* body mass index, *CCI* Charlson comorbidity index, *Hb* hemoglobin, *Alb* albumin, *Cr* creatinine, *CRP* C-reactive protein, *ICUD* intracorporeal urinary diversion; *ECUD* extracorporeal urinary diversion

Table 2 Peri-operative outcomes

	Younger (age < 70 years) <i>n</i> = 125	Older (age ≥ 70 years) <i>n</i> = 128	<i>P</i> value
Mean total operative time, min (IQR)	523 (231–913)	485 (183–890)	0.019
Mean console time, min (IQR)	291 (80–725)	288 (70–673)	0.884
Mean EBL, ml (IQR)	523 (0–3500)	388 (0–1560)	0.013
Intra-operative blood transfusion (%)	11 (8.8)	19 (14.8)	0.173
Post-operative blood transfusion (%)	9 (7.2)	14 (10.9)	0.383
Interval to walk, day (IQR)	2.1 (1–7)	2.1 (1–14)	0.845
Interval to flatus, day (IQR)	3.07 (1–10)	3.02 (1–14)	0.817
Interval to resumption of a regular diet, days (IQR)	11.22 (2–33)	11.58 (2–37)	0.671
Length of hospital stay, day (IQR)	25.26 (11–76)	24.79 (10–90)	0.727

IQR interquartile range, *EBL* estimated blood loss

Complications

Table 3 shows post-operative complications at POD 0–30, 31–90 and 91. Rates of ≥ grade II complications were the highest at POD 0–30 regardless of an association with the

urinary tract. The incidence of complications associated with the urinary tract or arising outside any of the three post-operative periods did not significantly differ between the two groups. The most common grade II complications associated with the urinary tract at POD 0–30 were pyelonephritis

Table 3 Complications

	Younger (age < 70 years) n = 125	Older (age ≥ 70 years) n = 128	P value
<i>Grade II or greater associated with urinary tract</i>			
0–30 days (%)	24 (19.2)	22 (17.2)	0.745
31–90 days (%)	14 (11.2)	9 (7.0)	0.279
91 days—(%)	12 (9.6)	11 (8.6)	0.829
<i>Grade II or greater non-associated with urinary tract</i>			
0–30 days (%)	21 (16.8)	29 (22.6)	0.271
31–90 days (%)	3 (2.4)	5 (3.9)	0.722
91 days—(%)	8 (6.4)	12 (9.4)	0.486
<i>Grade III or greater associated with urinary tract</i>			
0–30 days (%)	3 (2.4)	4 (3.1)	1.000
31–90 days (%)	6 (4.8)	0 (0.0)	0.013
91 days—(%)	4 (3.2)	4 (3.1)	1.000
<i>Grade III or greater non-associated with urinary tract</i>			
0–30 days (%)	6 (4.8)	6 (4.7)	1.000
31–90 days (%)	1 (0.8)	1 (0.8)	1.000
91 days—(%)	6 (4.8)	9 (7.0)	0.596

($n = 15$), followed by urinary leak ($n = 4$) in the younger group, and pyelonephritis ($n = 16$), followed by anastomotic ureteral stricture ($n = 2$ cases) in the older group. At POD 31–90, pyelonephritis ($n = 4$) and anastomotic urethral stricture ($n = 2$) were more prevalent in the younger group, and pyelonephritis ($n = 6$) and urinary retention ($n = 1$) were prevalent in the older group. After POD 91, pyelonephritis ($n = 6$), anastomotic and anastomotic urethral stricture ($n = 1$ each) developed in the younger group, whereas pyelonephritis ($n = 4$) and anastomotic urethral stricture ($n = 2$) developed in the older group. The most prevalent grade II complications that were not associated with the urinary tract

at POD 0–30 were prolonged ileus, which resolved with conservative management ($n = 7$) and wound infection ($n = 2$) in the younger group and prolonged ileus ($n = 12$), wound infection and pelvic dead-space infection ($n = 2$ each) in the older group. At POD 31–90, prolonged ileus and wound pain ($n = 1$ each) developed in the younger group and prolonged ileus, deep-vein thrombosis and peritonitis ($n = 1$ each) developed in the older group. Prolonged ileus developed in four patients in each group after POD 91.

In contrast, the rates of grade \geq III urinary tract and other complications were higher at POD 0–30 and 91. Although the incidence of post-operative complications did not significantly differ between the two groups at essentially any time, significantly more complications were associated with the urinary tract only at POD 31–90 in the younger group. However, the rates of events were very low in each group. Supplementary Table 1 shows details of grade \geq III complications. Supplementary Table 2 shows the complications associated with ICUD versus ECUD in each group. Both rates of grade \geq II and \geq III complications did not significantly differ throughout the entire post-operative period.

Oncological outcomes

Table 4 and Fig. 1a–c, respectively, show peri-operative oncological outcomes and survival outcomes including OS, CSS and RFS. Extravesical disease (pT3/pT4) was identified 25.6% and 30.4% of the younger and older groups, respectively. The rates of positive LN, lymphovascular invasion, histologic variants and PMS did not significantly differ between the groups. Pelvic lymph node dissection was required for 123 younger and 119 older patients. The mean number of LN removed was notably similar between the two groups.

Table 4 Oncologic outcomes

	Younger (age < 70 y) n = 125	Older (age ≥ 70 y) n = 128	P value
<i>Pathological stage</i>			
pT0 (%)	25 (20.0)	22 (17.2)	0.565
pTis (%)	13 (10.4)	15 (11.7)	0.738
pT1 or less (%)	29 (23.2)	24 (18.8)	0.385
pT2 (%)	26 (20.8)	28 (21.9)	0.835
pT3 (%)	25 (20.0)	30 (23.4)	0.507
pT4 (%)	7 (5.6)	9 (7.0)	0.640
pN+ (%)	20 (16.0)	17 (13.3)	0.541
Lymphovascular invasion (%)	33 (26.4)	34 (26.6)	0.977
Histologic variant (%)	13 (10.4)	15 (11.7)	0.738
PSM (%)	8 (6.4)	4 (3.1)	0.250
Mean number of LN removed (IQR)	19.0 (0–80)	18.7 (0–55)	0.846

IQR interquartile range, PSM positive surgical margin, LN lymph node

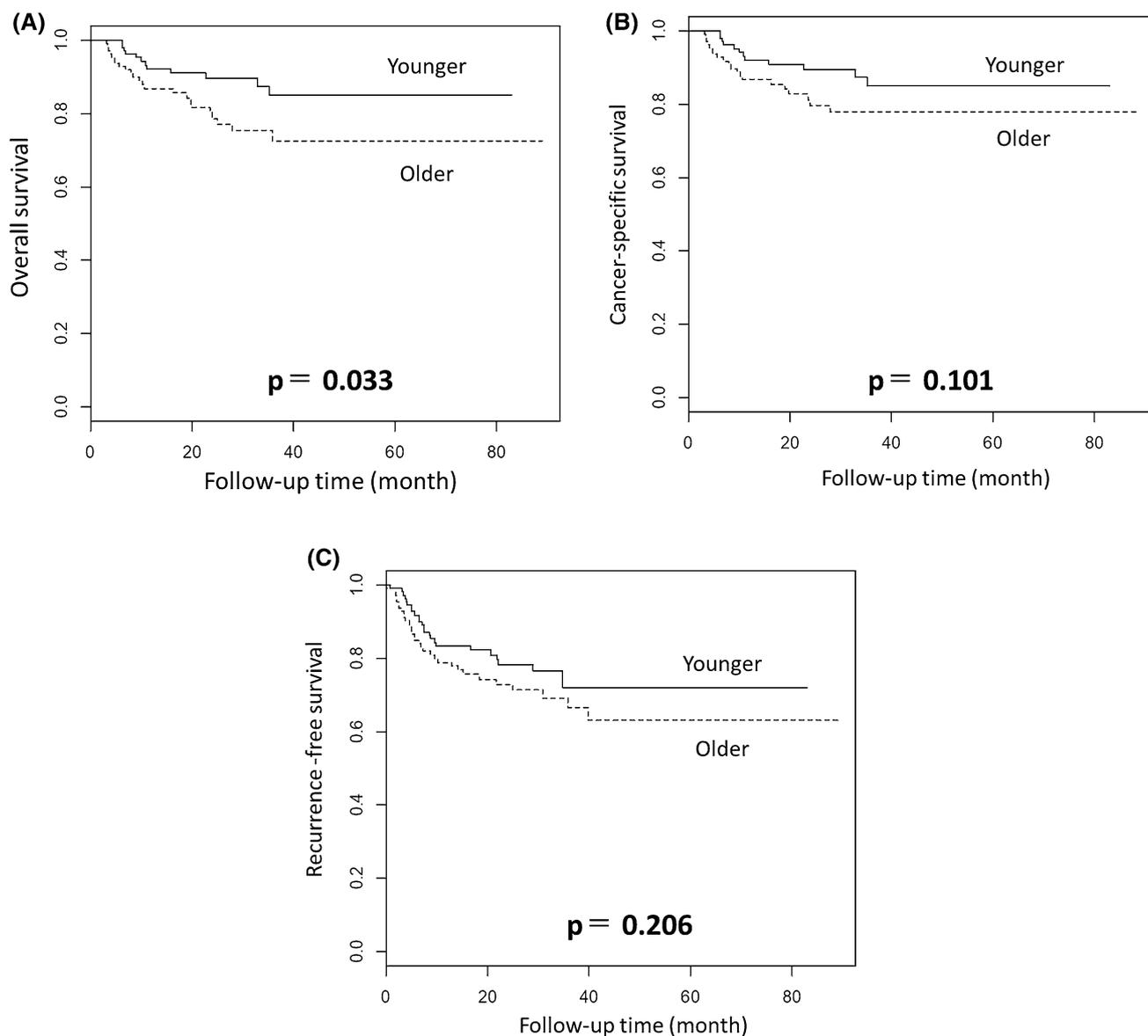


Fig. 1 Kaplan–Meier survival curves. Comparison of overall (a), cancer-specific (b) and recurrence-free (c) survival rates of patients aged ≥ 70 and < 70 years

The patients were followed up for a mean of 25.4 months. The predicted 5-year OS, CSS and RFS rates in the younger and older groups were 85.3% and 72.6%, 85.0% and 78.0%, and 72.1% and 63.0%, respectively.

Discussion

The gold standard of therapy for muscle-invasive and high-risk superficial bladder cancer is ORC. Although many reports have described ORC, consensus regarding its suitability for older patients has not been reached due the disadvantages such as high morbidity and mortality rates, and

the physical vulnerability of older patients. A systematic review by Fonteyne et al. examined survival and morbidity data after ORC extracted from reports of 42 studies that included at least 100 older and younger patients. They concluded that OS significantly decreased in older patients, and that increasing age was significantly associated with a worse OS for patients aged > 70 compared with < 70 years (hazard ratios, 1.34–1.46). In addition, CSS also worsened with age, and multivariate analysis selected age > 80 years as a significant predictor (hazard ratios, 1.56–2.54). Moreover, perioperative morbidity significantly increased with age, with patients aged > 80 years having a 4.61–6.25-fold increase in risk compared with those aged < 80 years. Overall,

peri-operative mortality and early mortality are increased in older patients; mortality rates in those aged > 70 years were significantly higher at POD 30 and 90 (odds ratios, 1.6 and 5.8, respectively) [11]. In contrast, Donat et al. reported different findings of a comparison between patients aged < 80 and \geq 80 years. They found that octogenarians had higher rates of minor (55% vs. 50%) and major (17% vs. 13%) complications than younger patients, although the difference did not reach significance. Moreover, although octogenarians were more likely to die of causes unrelated to bladder cancer than younger patients (5-year cumulative incidence of death from other causes, 42.3% and 17.8%, respectively), disease-specific survival was similar for octogenarians and younger patients (5-year cumulative incidence of death from disease 25.7% and 24.6%, respectively) [12].

Some reports have described the peri-operative and oncological outcomes of robotic-assisted surgery in small groups of older patients. Coward et al. compared the outcomes of RARC and extracorporeal urinary diversion between patients aged \geq 70 ($n=38$) and < 70 ($n=61$) years at a single institution. The older patients had a significantly lower BMI, higher ASA scores, less orthotopic neobladders and a shorter surgical duration than younger patients. Peri-operative complications and pathologic outcomes were equivalent between the younger and older patients in that study [13]. Guillotreau et al. investigated outcomes between two cohorts that were similar to those in the study by Coward et al., including 131 and 15 patients treated by laparoscopic radical cystectomy and RARC, respectively. Ileal conduit was significantly more prevalent among the older patients. Estimated blood loss, total operative time, the rates of transfusion, peri-operative complication, PSM and the mean number of removed LN did not significantly differ. The 5-year OS and CSS rates for older and younger patients were 75% and 87% ($p=0.03$), and 51% and 54% ($p=0.73$), respectively [14]. Nguyen et al. assessed the feasibility of RARC in 61 octogenarian patients. The rates of all complications within POD 30 and 90 days were 31% and 44%, and the ratios of major complications were 8% and 15%, respectively. Infection was the most prevalent (38%), followed by gastrointestinal (19%) and cardiac (13%) complications. The PSM rate was 10% and a median of 19 LN were removed. Two-year OS, CSS and RFS rates were 61%, 74% and 73%, respectively [15].

Patient demographics were not homogeneous between the older and younger patients in the present study; Mean CCI, rate of a history of previous abdominal surgery and ileal conduit were significantly higher, but pre-operative Alb values, the rate of neoadjuvant chemotherapy and orthotopic neobladder were significantly lower among the older patients. These findings reflect the vulnerability of older patients. Although mean pre-operative hemoglobin values did not significantly differ, the higher rates of neoadjuvant chemotherapy among the younger patients potentially affected

these findings. Some previous comparisons between older and younger patients have found similar trends in patient demographics [13–15].

In terms of peri-operative outcomes, the mean total operative time was significantly shorter in the older patients. This was presumably due to differences in types of urinary diversion, since rates of neobladder were significantly higher among the younger patients, and the mean amount of console time was equivalent between the two groups. Although the reason for the significantly lower mean EBL in older patients remains unclear, differences in the type of urinary diversion, surgical duration, and surgeon experience might have been involved. Peri-operative transfusion rates, interval to recovery of bowel function and length of hospital stay were similar between the two groups. These findings support the value of RARC as a minimally invasive procedure for patients of all ages. Although the present total operative time was relatively longer and EBL was relatively higher in younger patients compared with the results of previous studies and a systemic review, we considered that our findings might have been associated with differences in experience among the surgeons at the participating institutions. The hospital stay in the present study was also considerably longer than in previous studies, which is due to the nature of the hospitalization system in Japan.

The rates of all complications were highest at 0–30 days after surgery. The rates of all events reached a plateau of \sim 10% at 30 days after surgery. Although the rates of all types of major grade \geq III post-operative complications were very low, they occurred more frequently between POD 0–30 and 91. The rate of events associated with the urinary tract at 31–90 was significantly higher in younger patients. The reasons for this remain unclear. However, major complications occurred at an essentially consistent frequency throughout the entire post-operative period regardless of association with the urinary tract. Moreover, the rates of grade \geq II complications in the present study were 36% within 30 days and 49% within 90 days after surgery in the younger patients, and 39% and 51% in the older patients, respectively. The rate of grade \geq III complications within 30 and 90 days after surgery were, respectively, 7% and 13% in the younger patients, and 8% and 9% in the older patients. These outcomes were comparable to those of previous studies [7, 16].

Pyelonephritis was the most common among grades and types of complications, followed by prolonged ileus during all post-operative periods, and these findings were similar to those of previous studies. However, most studies found relatively large numbers of cardiac complications, whereas we found none [16–19]. Moreover, leg compartment syndrome was a characteristic complication of older patients that requires careful consideration, because older patients are more susceptible to leg hypoperfusion caused by remaining in the Trendelenburg position for long periods [20, 21].

We also compared the rates of complications between ICUD and ECUD in each group, although this was not the main purpose of this study. We were unable to identify a significant difference between the two procedures throughout the entire post-operative period. However, various limitations might have influenced the results.

Oncological outcomes of RARC have been evaluated as rates of PMS and numbers of removed LN. In the era of ORC, surrogate markers for acceptable oncological outcomes reported by Herr et al. comprised a PMS rate < 10% and an LN yield > 10–14 [22]. A systematic review of RARC found that the PMS rates ranged between 4 and 9% in series of > 100 patients and that the LN yield from all series was 19 [8]. All parameters of oncological outcomes were equivalent between older and younger patients in the present study. Furthermore, both the PMS rate and the mean number of removed LN met the acceptable outcomes indicated by previous studies. We excluded patients with suspected lymph node or distant metastasis before surgery to evaluate the long-term survival outcomes of RARC in natural candidates for radical cystectomy. The 5-year OS was significantly worse in the older patients, probably because of a shorter life expectancy and higher rate of death from other causes. The finding of statistically equivalent 5-year CSS and RFS between the two groups indicated that RARC potentially conferred the same significant survival benefit on older, as well as younger patients. Few reports have described the long-term survival outcomes of RARC. According to a systematic review of RARC, the 5-year OS, CSS and RFS were 39–66%, 66–80% and 53–74%, respectively [8]. Several studies at high-volume centers have found 5-year OS and CSS rates after RARC of about 70%, which was similar to those reported for the ORC series [23–25]. The present survival outcomes were in line with, or higher than those of previous studies.

The present nonrandomized, retrospective comparison of patients from several institutions has several limitations. The patients' demographics, surgical procedures, the extent of PLND and the experience of surgeons at each institution were not standardized, which might have caused some selection bias. In addition, the number of patients was insufficient. The results might change if a larger number of patients were added, particularly results regarding survival outcomes. Finally, all RARC in the present study proceeded before health insurance coverage became available in Japan, and neoadjuvant chemotherapy was insufficient for various reasons, such as financial hardship. However, Japanese health insurance started to cover RARC in April 2018, which should resolve these issues.

In conclusion, although septuagenarian patients with muscle invasive bladder cancer are at relatively higher risk for surgery, RARC offers a minimally invasive alternative and a potentially equivalent level of cancer control to that

among patients aged < 70 years. The significance of RARC will increase, as the number of indications for RARC will increase at an accelerated pace in rapidly aging societies.

Acknowledgements These clinicopathological statistics are based on the results from a number of institutions in Japan. We are grateful for the cooperation of many Japanese urologists. This document was created by the Japanese Society of Endourology. Cooperative institutions for the present study are: Department of Urology, the University of Tokyo Graduate School of Medicine; Department of Urology, Kobe University Graduate School of Medicine; Department of Urology, Hamamatsu University School of Medicine; Department of Urology, Iwate Medical University School of Medicine; Department of Urology, Kagawa University, Faculty of Medicine.; Department of Urology, Shiga University of Medical Science; Department of Urology, Takamatsu Red Cross Hospital; Department of Urology, Teine Keijinkai Medical Center; Department of Urology, Kobe City Medical Center General Hospital; Ibaraki Clinical Education and Training Center, Faculty of Medicine; Department of Urology, St. Luke's International Hospital; Department of Urology, Wakayama Medical University; Department of Urology, Kyoto City Hospital; Department of Urology, Nagoya University Graduate School of Medicine; Department of Urology, Kyoto University Hospital; Department of Urology, Ehime Prefectural Central Hospital; Department of Urology, Gifu Prefectural General Medical Center; Department of Urology, Hiroshima City Hiroshima Citizens Hospital; Department of Urology, Aichi Medical University School of Medicine; Department of Urology, Kitasato University School of Medicine; Department of Urology, Ehime University Graduate School of Medicine; Department of Urology, Shizuoka General Hospital; Department of Urology, Tohoku University Graduate School of Medicine; Department of Urology, Tokyo Medical University; Department of Urology, Tokushima University Graduate School; Department of Urology, Akita University School of Medicine; Department of Urology, Institute of Biomedical and Health Science, Hiroshima University; Department of Urology, Kochi Medical School, Kochi University; Department of Urology, Hirosaki University Graduate School of Medicine; Department of Urology, Fujita Health University; Department of Urology, Juntendo University; Department of Urology, Shimane University School of Medicine; Department of Urology, Jyoban Hospital of Tokiwa Foundation; Division of Urology, Department of Surgery, Tottori University Faculty of Medicine.

Compliance with ethical standards

Conflict of interest No author has any conflict of interest.

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