ORIGINAL ARTICLE – UROLOGIC ONCOLOGY

Perioperative Outcomes of Robot-Assisted Radical Cystectomy with Intracorporeal Versus Extracorporeal Urinary Diversion

Jeremy Yuen-Chun Teoh, FRCSEd[1,2], Erica On-Ting Chan, MBChB[1], Seok-Ho Kang, MD[3], Manish I. Patel, MBBS, PhD[4,5], Satoru Muto, MD, PhD[6], Cheng-Kuang Yang, MD[7], Shingo Hatakeyama, MD, PhD[8], Timothy Shing-Fung Chow, MBChB[1], Alex Mok, MBChB[1], Ruiyun Zhang, PhD[9], Kittinut Kijvikai, MD[10], Lui-Shiong Lee, MBBS, MRCS, MMed[11,12], Haige Chen, PhD[9], Chikara Ohyama, MD, PhD[8], Shigeo Horie, MD, PhD[6], and Eddie Shu-Yin Chan, FRCSEd[1]

[1]S.H. Ho Urology Centre, Department of Surgery, The Chinese University of Hong Kong, Hong Kong, China; [2]European Association of Urology Young Academic Urologists, Urothelial Carcinoma Working Group (EAU-YAU), Arnhem, Netherlands; [3]Department of Urology, School of Medicine, Korea University, Seoul, Republic of Korea; [4]Discipline of Surgery, Sydney Medical School, University of Sydney, Sydney, NSW, Australia; [5]Department of Urology, Westmead Hospital, Westmead, NSW, Australia; [6]Graduate School of Medicine, Department of Urology, Juntendo University, Tokyo, Japan; [7]Division of Urology, Department of Surgery, Taichung Veterans General Hospital, Taichung, Taiwan; [8]Department of Urology, Hirosaki University Graduate School of Medicine, Hirosaki, Japan; [9]Department of Urology, Renji Hospital, School of Medicine, Shanghai Jiao Tong University, Shanghai, China; [10]Division of Urology, Department of Surgery, Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand; [11]Department of Urology, Sengkang General Hospital, Singapore, Singapore; [12]Department of Urology, Singapore General Hospital, Singapore, Singapore

ABSTRACT
Purpose. This study was designed to investigate and compare the perioperative outcomes of intracorporeal urinary diversion (ICUD) versus extracorporeal urinary diversion (ECUD) following robotic-assisted radical cystectomy (RARC) in patients with localized bladder cancer from the Asian Robot-Assisted Radical Cystectomy (RARC) Consortium.

Methods. The Asian RARC registry was a multicenter registry involving nine centers in Asia. Consecutive patients who underwent RARC were included. Patient and disease characteristics, intraoperative details, and perioperative outcomes were reviewed and compared between the ICUD and ECUD groups. Postoperative complications were the primary outcomes, whereas secondary outcomes were the estimated blood loss and the duration of hospitalization. Multivariate regression analyses were performed to adjust potential confounders.

Results. From 2007 to 2020, 556 patients underwent RARC; 55.2% and 44.8% had ICUD and ECUD, respectively. ICUD group had less estimated blood loss (423.1 $\pm$ 361.1 vs. 541.3 $\pm$ 474.3 mL, $p = 0.002$) and a shorter hospital stay (15.7 $\pm$ 12.3 vs 17.8 $\pm$ 11.6 days, $p = 0.042$) than the ECUD group. Overall complication rates were similar between the two groups. Upon multivariate analysis, ICUD was associated with less estimated blood loss (Regression coefficient: -143.06, 95% confidence interval [CI]: -229.60 to -56.52, $p = 0.001$) and a shorter hospital stay (Regression coefficient: -2.37, 95% CI: -4.69 to -0.05, $p = 0.046$). In addition, ICUD was not associated with any increased risks of minor, major, and overall complications.

Conclusions. RARC with ICUD was safe and technically feasible with similar postoperative complication rates as ECUD, with additional benefits of reduced blood loss and a shorter hospitalization.

Bladder cancer is the 11th most common cancer worldwide; more than 550,000 cases are diagnosed every year.[1] Open radical cystectomy (ORC) with pelvic lymph node dissection (PLND) is the current standard for patients with localized muscle-invasive bladder cancer (MIBC).[2,3] However, ORC is a complex and major surgery associated with high perioperative morbidities and prolonged hospital stay.[4,5] In order to shorten the postoperative recovery, minimally invasive approaches in the form of laparoscopic and robot-assisted radical cystectomy (RARC) have been proposed.[6,7] The technical difficulty of minimally invasive radical cystectomy is undoubtedly challenging, but the introduction of the robotic surgery had made the procedure much more feasible, and RARC has gained increasing acceptance worldwide in the past two decades.[8]

Seeing the potential benefits of RARC, this surgical approach also was increasingly adopted in Asian countries. In 2017, a number of Asian expert centers in bladder cancer joined hands and formed the Asian RARC Consortium, aiming to develop an Asian RARC registry to learn more about the potential benefits and harms of RARC through real-world experiences. The Asian RARC registry has collected data from more than 500 patients so far.

Apart from cystectomy and lymph node dissection, urinary diversion is another major step involved in the procedure. While extracorporeal urinary diversion (ECUD) requires a minilaparotomy wound for bowel manipulation and reconstruction, the adoption of intracorporeal urinary diversion (ICUD) may further reduce the surgical trauma in patients undergoing RARC.[9-12] On the other hand, the ICUD approach had been criticized for being too technical and complicated, which might increase operative time, hospital stay, and perioperative complication rates.[13-17] Whether RARC with ICUD confers any perioperative benefits compared with ECUD is currently unknown. In this study, we investigated the perioperative outcomes of ICUD versus ECUD following RARC from our current Asian RARC registry.

MATERIALS AND METHODS

The Asian RARC registry was a multicenter registry involving nine centers in Asia. Consecutive bladder cancer patients who underwent RARC from 2007 to 2020 were included. Patients who underwent ORC or laparoscopic radical cystectomy and patients with metastatic bladder cancer were excluded. A standardized form was devised to record patient characteristics, disease characteristics, intraoperative details, and perioperative outcomes. Intraoperative details included surgical approach, urinary diversion and reconstruction approach, operative time, and estimated blood loss. Perioperative outcomes included duration of hospital stay, 30-day readmission, and postoperative complication. For patients who developed complications, the type of complication was documented and graded according to the modified Clavien-Dindo classification.[18] This study was classed as a service evaluation, and formal consent was not required.

The RARC cohort was divided into two groups and compared: the intracorporeal urinary diversion (ICUD) group, and the extracorporeal urinary diversion (ECUD) group. The primary outcomes were minor, major, and overall postoperative complication rates. Minor complications were defined as grade 1 to 2 complications, and major complications were defined as grade 3 or above complications. Secondary outcomes included the estimated blood loss and the duration of hospital stay. The continuous variables were presented as means and standard deviations, while the binary or categorical variables were presented as frequency and percentages. Baseline characteristics between the two groups were compared by independent t-test for continuous variables and by chi-square test for binary or categorical variables. Further multivariate analysis was performed with logistic regression model for postoperative complications and multiple linear regression model for both estimated blood loss and hospital stay. Data analysis were performed with SPSS version 23. A p value of <0.05 is considered statistically significant.

RESULTS

From 2007 to 2020, there were 556 patients with RARC performed in 9 centers in Asia. Among them, 307 patients (55.2%) had ICUD and 249 patients (44.8%) had ECUD following RARC (Table 1). Patient characteristics, including age, gender, body mass index, history of smoking, history of diabetes, and the use of anti-platelet or anticoagulants, were similar between the two groups. The ECUD group has a higher proportion of ASA 3 or above patients than the ICUD group (19.2% vs. 9.2%, $p < 0.001$).

Concerning the type of urinary reconstruction, neobladder (as opposed to ileal conduit) was more commonly performed in the ICUD group than the ECUD group (48.4% vs. 29.5%, $p < 0.001$). On the other hand, urethrectomy was more commonly performed in the ECUD group than the ICUD group (14.7% vs. 8.5%, $p = 0.026$). The vast majority in both groups received PLND.

Disease characteristics were similar between the two groups. Overall, approximately three quarters of the patients had high-grade tumors. More than half of the patients had T2 or above disease, and approximately one-fifth of the patients had positive nodal status.

TABLE 1 Comparison of patients characteristics, disease characteristics, intraoperative details and perioperative outcomes between ICUD and ECUD group

	Intracorporeal (n = 307)	Extracorporeal (n = 249)	p value
Age at cystectomy (yr)	66.86 ± 10.99	68.17 ± 13.48	0.212
Gender (female)	47 (15.3%)	27 (10.8%)	0.123
BMI (kg/m^2)	24.47 ± 3.29	24.32 ± 3.37	0.645
History of smoking	150 (50.2%)	132 (53.4%)	0.446
History of diabetes	75 (26.1%)	52 (20.9%)	0.154
Use of anti-platelet/ anti-coagulant	23 (11.8%)	10 (6.8%)	0.126
ASA			
ASA 1	69 (23.4%)	33 (13.8%)	< 0.001
ASA 2	199 (67.5%)	161 (67.1%)	
ASA 3+	27 (9.2%)	46 (19.2%)	
Urinary reconstruction			
Neobladder	147 (48.4%)	66 (29.5%)	< 0.001
Ileal conduit	157 (51.6%)	158 (70.5%)	
Urethrectomy	26 (8.5%)	31 (14.7%)	0.026
Lymph node dissection	304 (99.0%)	245 (98.4%)	0.508
WHO 2004 (high grade)	194 (77.3%)	163 (74.8%)	0.523
Carcinoma in situ	66 (23.5%)	37 (15.5%)	0.022
Pathological T staging			
T0	12 (3.9%)	15 (6.0%)	0.426
Ta and Tis	79 (25.8%)	52 (21.0%)	
T1	49 (16.0%)	42 (16.9%)	
T2 or above	166 (54.2%)	139 (56.0%)	
Presence of positive node	56 (18.4%)	50 (20.7%)	0.511
Operative time (min)	362.80 ± 94.90	329.38 ± 147.81	0.002
Blood loss (ml)	423.08 ± 361.12	541.30 ± 474.32	0.002
Hospital stay (days)	15.70 ± 12.25	17.81 ± 11.61	0.042
30-day readmission	72 (25.1%)	58 (23.5%)	0.666
Presence of complications	157 (51.3%)	118 (47.8%)	0.409
Severity of complications			
No complications	149 (48.7%)	129 (52.2%)	0.327
Minor (Clavien Grade I/II)	111 (36.3%)	75 (30.4%)	
Major (Clavien Grade III+)	46 (15.0%)	43 (17.4%)	

BMI body mass index; *ASA* American Society of Anesthesiologists; *WHO* World Health Organization

Although the ICUD group had a longer operative time than the ECUD group (362.8 ± 94.9 vs. 329.4 ± 147.8 minutes, $p = 0.002$), the ICUD group had less estimated blood loss than the ECUD group (423.1 ± 361.1 vs. 541.3 ± 474.3 mL, $p = 0.002$). The ICUD group also had a shorter hospital stay than the ECUD group (15.7 ± 12.3 vs. 17.8 ± 11.6 days, $p = 0.042$).

Overall complication rates were similar between the two groups (ICUD group: 51.3%, ECUD group: 47.8%; $p = 0.409$). In the ICUD group, 36.3% had minor complications, and 15.0% had major complications. In the ECUD group, 30.4% had minor complications, and 17.4% had major complications. Bowel anastomosis leakage and urinary leakage were uncommon in both the ICUD and ECUD groups; 6.2% of the ICUD group and 4.8% of the ECUD group were found to have ureteric stricture upon follow-up (Table 2).

Upon multivariate analysis, ICUD was associated with less estimated blood loss (Regression coefficient: − 143.06, 95% CI: − 229.60 to − 56.52, $p = 0.001$). On the other hand, a longer operative time (Regression coefficient: 0.54, 95% CI: 0.19–0.90, $p = 0.003$) and a higher T-stage (Regression coefficient: 52.32, 95% CI: 1.45−103.19, $p = 0.044$) were associated with more blood loss (Table 3). ICUD was associated with a shorter hospital stay (Regression coefficient: − 2.37, 95% CI: − 4.69 to − 0.05, $p = 0.046$), but neobladder reconstruction (Regression coefficient: 6.98, 95% CI: 4.44 to 9.53, $p < 0.001$) was

TABLE 2 Type of complications

		Intracorporeal	Extracorporeal
Severity of complications	Minor complications (Clavien I & II)	111 (36.3%)	75 (30.4%)
	Major complications (Clavien III+)	46 (15.0%)	43 (17.4%)
Types of complications	Require ICU care	3 (1.0%)	3 (1.2%)
	Require emergency reoperation	2 (0.7%)	2 (0.8%)
	Intestinal obstruction	5 (1.6%)	4 (1.6%)
	Ileus	27 (8.8%)	28 (11.2%)
	Ureteric stricture	19 (6.2%)	12 (4.8%)
	Urinary tract infection	29 (9.4%)	13 (5.2%)
	Bowel anastomotic leak	10 (3.3%)	3 (1.2%)
	Urine leak	5 (1.6%)	1 (0.4%)

ICU intensive care unit

TABLE 3 Multivariate regression analysis on blood loss

	Coefficient	95% CI		*p* value
		Lower	Upper	
Age	− 1.43	− 5.27	2.41	0.464
Gender	6.19	− 133.87	146.25	0.931
ASA	17.25	− 59.86	94.36	0.660
Pathological T staging	52.32	1.45	103.19	0.044
Positive nodal state	− 85.46	− 199.01	28.09	0.140
Operative time	0.54	0.19	0.90	0.003
Neobladder reconstruction	15.50	− 79.95	110.94	0.750
ICUD	− 143.06	− 229.60	− 56.52	0.001

ASA American Society of Anesthesiologists; *CI* confidence interval; *ICUD* intracorporeal urinary diversion

associated with a longer hospital stay (Table 4). Upon multivariate analysis, ICUD was not associated with any increased risks of minor, major, and overall complications (Table 5). Older age and neobladder reconstruction were both significant factors associated with higher rates of

minor and overall complications. A higher T stage was associated with a high rate of minor complications (OR: 1.29, 95% CI: 1.00–1.65, $p = 0.047$).

DISCUSSION

The robotic approach in performing radical cystectomy has gained increasing popularity worldwide. There was an increase in the adoption of robotic approach to perform cystectomy from 0.6% in 2004 to 12.8% in 2010 in the United States.[19] The European Association of Urology guidelines recognized robotic surgery for cystectomy as having ergonomic advantages, shorter hospitalization, less blood loss, and transfusion rates.[20] In 2019, a Cochrane review by Rai et al. showed that RARC was associated with a lower rate of blood transfusion, shorter hospital stay, and similar rates of major and minor complications compared with ORC.[21] Time to recurrence also was similar between RARC and ORC. However, among the five randomized, controlled trials being included, four of them performed ECUD and the remaining study performed either ECUD or ICUD at the surgeon's discretion.

TABLE 4 Multivariate regression analysis on duration of hospital stay

	Coefficient	95% CI		*p* value
		Lower	Upper	
Age	− 0.01	− 0.11	0.10	0.893
Gender	− 2.52	− 6.19	1.15	0.178
ASA	0.23	− 1.78	2.25	0.820
Pathological T staging	0.23	− 1.11	1.58	0.733
Positive nodal state	1.59	− 1.48	4.66	0.309
Operative time	− 0.01	− 0.02	0.01	0.314
Neobladder reconstruction	6.98	4.44	9.53	< 0.001
ICUD	− 2.37	− 4.69	− 0.05	0.046

ASA American Society of Anesthesiologists; *CI* confidence interval; *CUD* intracorporeal urinary diversion

TABLE 5 Multivariate regression analysis on presence of complications

	Odd ratio	95% CI Lower	95% CI Upper	p value
Overall complications				
Age	1.04	1.02	10.6	< 0.001
Gender	0.93	0.50	1.74	0.814
ASA	0.82	0.58	1.17	0.277
Pathological T staging	1.32	1.05	1.67	0.017
Positive nodal state	0.78	0.46	1.33	0.361
Operative time	1.00	1.00	1.00	0.596
Neobladder reconstruction	1.87	1.20	2.92	0.005
ICUD	1.18	0.79	1.75	0.420
Major complications				
Age	1.00	0.98	1.03	0.862
Gender	0.73	0.29	1.82	0.495
ASA	1.08	0.68	1.71	0.742
Pathological T staging	1.12	0.82	1.51	0.484
Positive nodal state	0.56	0.26	1.23	0.149
Operative time	1.00	1.00	1.00	0.887
Neobladder reconstruction	0.99	0.55	1.77	0.963
ICUD	0.99	0.58	1.68	0.960
Minor complications				
Age	1.04	1.02	1.07	< 0.001
Gender	1.13	0.58	2.20	0.718
ASA	0.78	0.54	1.13	0.182
Pathological T staging	1.29	1.00	1.65	0.047
Positive nodal state	1.06	0.61	1.84	0.833
Operative time	1.00	1.00	1.00	0.739
Neobladder reconstruction	2.08	1.29	3.35	0.003
ICUD	1.24	0.81	1.91	0.319

ASA American Society of Anesthesiologists; *CI* confidence interval; *ICUD* intracorporeal urinary diversion

Therefore, these results largely represented the potential benefits of RARC plus ECUD over conventional ORC, instead of RARC with ICUD.

In the past, due to the complexity and the technical difficulty of bowel manipulation, anastomosis, and reconstruction, urinary diversion is commonly performed with an extracorporeal approach. With the introduction of robots, laparoscopic staplers, and barbed sutures, ICUD has become feasible within a reasonable operative time.[16,17,22] With an intracorporeal approach, the surgical trauma related to the urinary diversion procedure may be further reduced.[13-17] The abdominal wounds could be miniaturized, especially in female patients where the cystectomy specimen could be delivered transvaginally. The postoperative recovery also might be optimized.

While high-quality studies comparing ICUD and ECUD following RARC is lacking, we conducted this study to analyze real world data from the Asian RARC registry. Although this was a retrospective study, patient and disease characteristics were largely comparable between the ICUD and the ECUD groups. We believe our real world data is important in assessing if the efficacy is generalizable and translatable to real life practice. Our study showed that minor, major, and overall complications rates were similar between the two groups. These results had significant implications proving that an intracorporeal approach is equally safe and feasible as an extracorporeal approach, which is consistent with previous studies.[14,16,23] Although the mean operative time for the ICUD group was on average 33 minutes longer, we believe this is considered acceptable without imposing significant harm to our patients. In addition, ICUD was associated with less estimated blood loss and shorter hospital stay compared with ECUD. ICUD was associated with better postoperative recovery, and this could be regarded an advantage over ECUD. On the other hand, neobladder reconstruction was a significant factor associated with a long hospital stay, minor and overall complication rates. Although neobladder reconstruction could avoid the need of a stoma, its associated risks of a prolonged hospital stay and postoperative complications must be explained to our patients.

It was noted that the centers participating in this Asian RARC Consortium were dedicated to urological cancers, and the surgeons involved were all experts in managing bladder cancer. This may partially attribute to our study result that RARC with ICUD was associated with less blood loss, shorter hospitalization, and comparable complication rates. There is certainly a steep learning curve for performing RARC with ICUD, which is regarded as one of the most challenging robotic-assisted surgeries in urology.[24] A 30-case experience was generally needed to attain an acceptable level of proficiency. The intracorporeal approach of urinary diversion added further challenges in RARC.[25] A study by Collins et al., which evaluated an individual surgeon's series of 47 RARC with intracorporeal neobladder, found that the perioperative outcome improved with increasing experience. The operative time significantly reduced from a median of 565 minutes in the first 10 cases to 345 minutes in the last 7 cases, with rate of converting to open down from 30% to 0% and overall complication down from 70 to 30%.[26] A study from the International Robotic Cystectomy Consortium also suggested that experience improved lymph node yield in RARC with PLND.[27] The impacts of learning curve in the perioperative outcome of RARC with ICUD should not be overlooked. In addition, although the rates of minor, major, and overall complications did not differ significantly between the two groups, urinary diversion-related

complications, such as bowel anastomotic leakage, urinary leakage, and ureteric strictures, were not uncommon. Despite the favorable perioperative outcome of RARC with ICUD demonstrated in our study, the essentiality of close supervision and mentoring at the initial stage of adopting RARC with ICUD has to be reiterated to optimize the perioperative outcome before reaching the learning plateau.

Although the results of our study are promising, high-quality studies are needed to define the role of RARC plus ICUD in patients with MIBC. The iROC study is a multicenter, randomized trial comparing RARC plus ICUD and ORC.[28] It aims to recruit 320 patients with a primary outcome of number of days alive and out of hospital within the first 90 days from surgery. The initial results of the first 30 patients showed that RARC with ICUD was safe and well tolerated by the patients.[29] Patient recruitment has been completed, and the final study results are eagerly awaited.

There are several limitations in this study. First, it was a retrospective study with compromised level of data accuracy. The study results might be biased by the potential confounding factors, but the best effort has been made to adjust for those factors with various multivariate analyses. Second, there is no standard study protocol for the surgical procedure and the postoperative management. Variations in the clinical practice across centers may affect our results. Nevertheless, our study results are arguably more reflective of the true effects of ICUD in a real-world setting. Third, although perioperative outcomes are promising with ICUD, data on survival outcomes remained to be explored. This is, however, beyond the scope of this study on perioperative outcomes, and we plan to report the survival outcomes at a later stage with more mature data.

This is the first collaborative paper developed from the Asian RARC Consortium. Despite the limitations addressed above, we believe the study results were interesting and shed lights on the potential benefits of ICUD over ECUD. RARC plus ICUD could potentially be the best possible minimally invasive approach in treating MIBC, but high-quality clinical trials are needed to determine whether this would become the standard surgical approach in the future.

CONCLUSIONS

Results from the Asian RARC Consortium demonstrated that RARC with ICUD was a safe and technically feasible approach in performing the radical cystectomy with similar postoperative complication rates as RARC with ECUD. RARC with ICUD also was associated with better perioperative outcomes, including reduced blood loss and shorter length of hospital stay.

APPENDIX 1

See Table 6.

TABLE 6 RARC case breakdown by place (n = 556)

Participated centers	No. of cases
Singapore	20
Hong Kong	82
Taiwan	46
Hirosaki, Japan	53
Juntendo, Japan	57
Korea	177
Thailand	23
China	38
Australia	60

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