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Urothelial Cancer

Ileal Conduit Versus Orthotopic Neobladder Urinary Diversion in Robot-assisted Radical Cystectomy: Results from a Multi-institutional Series

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Abstract

Background: Head-to-head comparisons between ileal conduit (IC) and orthotopic neobladder (ONB) in terms of peri- and postoperative outcomes and complications, in the specific setting of robot-assisted radical cystectomy (RARC), are not available.
Objective: To address the impact of the type of urinary diversion (UD, IC vs ONB) on RARC morbidity, as well as operative time (OT), length of stay (LOS), and readmissions.
Design, setting, and participants: Urothelial bladder cancer patients treated with RARC at nine high-volume European institutions between 2008 and 2020 were identified.
Intervention: RARC with either IC or ONB.
Outcome measurements and statistical analysis: Intra- and postoperative complications were collected and reported according to the Intraoperative Complications

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Assessment and Reporting with Universal Standards recommendations and European Association of Urology guidelines, respectively. Multivariable logistic regression models tested the impact of UD on outcomes, after adjustment for clustering at single hospital level.
Results and limitations: Overall, 555 nonmetastatic RARC patients were identified. In 280 (51%) and 275 (49%) patients, an IC and an ONB were performed, respectively. Eighteen intraoperative complications were recorded. The rates of intraoperative complications were 4% in IC patients and 3% in ONB patients ($p = 0.4$). The median LOS and readmission rates were 10 versus 12 d ($p < 0.001$) and 20% versus 21% ($p = 0.8$) in IC versus ONB patients, respectively. At a multivariable logistic regression analyses, the type of UD (IC vs ONB) reached the independent predictor status for prolonged OT (odds ratio [OR]: 0.61, $p = 0.03$) and prolonged LOS (OR: 0.34, $p < 0.001$), but not for readmission (OR: 0.92, $p = 0.7$). Overall, 513 postoperative complications were experienced by 324 patients (58%). At least one postoperative complication was experienced by 160 (57%) IC patients versus 164 (60%) ONB patients ($p = 0.6$). The type of UD reached the status of an independent predictor of UD-related complications (OR: 0.64, $p = 0.03$).
Conclusions: Compared with RARC with ONB, RARC with IC is less prone to UD-related postoperative complications, prolonged OT, and prolonged LOS.
Patient summary: To date, the impact of the type of urinary diversion, namely, ileal conduit versus orthotopic neobladder, on peri- and postoperative outcomes of robot-assisted radical cystectomy is unknown. Based on a rigorous data accrual, which relied on established complication reporting systems (Intraoperative Complications Assessment and Reporting with Universal Standards and European Association of Urology recommended systems), we reported intra- and postoperative complications according to urinary diversion type. Moreover, we found that ileal conduit was associated with lower operative time and length of stay, and yielded a protective effect in terms of urinary diversion–related complications.

1. Introduction

Robot-assisted radical cystectomy (RARC) represents an alternative surgical treatment to open radical cystectomy (ORC) for muscle-invasive or high-risk non–muscle-invasive urothelial bladder cancer (UBC) [1]. Despite increasing diffusion and proficiency in RARC [2,3], radical cystectomy (RC) is still burdened by non-negligible peri- and postoperative morbidity [4,5], and the main driver of complications is the urinary diversion (UD) component [6].

The choice of UD stems from different considerations. The UD must be oncologically safe [7], be technically reproducible, and meet the patient's preference when possible [8]. Ileal conduit (IC) and orthotopic neobladder (ONB) are the most commonly practiced UD [9]. While ONB maximally preserves body image, IC represents the fastest, most commonly performed, and historically least complication-prone UD [8,9]. Health-related quality of life as well as decision regret has profusely been addressed according to different types of UD [10,11]. To date, no head-to-head comparison has been provided in terms of peri- and postoperative outcomes and complications relative to IC versus ONB in the specific setting of RARCs.

The current study addressed the impact of UD (ie, IC vs ONB) on RARC morbidity relying on a large multi-institutional database. Established criteria were fulfilled in collecting and reporting intra- [12] and postoperative [13] complications. We hypothesized that the type of UD might significantly impact peri- and postoperative outcomes of patients treated with RARC.

2. Patients methods

2.1. Study population

The current study relied on a prospectively maintained database that collected data on UBC patients treated with primary RC between 2008 and 2020, at nine European high-volume institutions. For the purpose of the current study, patients aged ≥18 yr with primary histologically confirmed UBC were identified. Of these patients, those who had undergone RARC with either IC or ONB were selected, regardless of UD reconstruction type (intracorporeal [ICUD] or extracorporeal [ECUD]). Only patients with complete baseline, preoperative, perioperative, postoperative, and pathological data, and follow-up ≥90 d were included. These criteria translated into 555 assessable patients (Fig. 1).

Owing to the anonymously coded design of the exploited database, study-specific institutional review board ethics approval was not required.

2.2. Variable definition

The following variables were collected for each patient: age (continuously coded), sex (female or male), body mass index (BMI; continuously coded), smoking habits (active, former, or never smoker), Charlson Comorbidity Index (CCI; not age adjusted), American Society of Anesthesiologists (ASA) Physical Status Classification System, antiplatelet/anticoagulant therapy, previous abdominal surgery, neoadjuvant

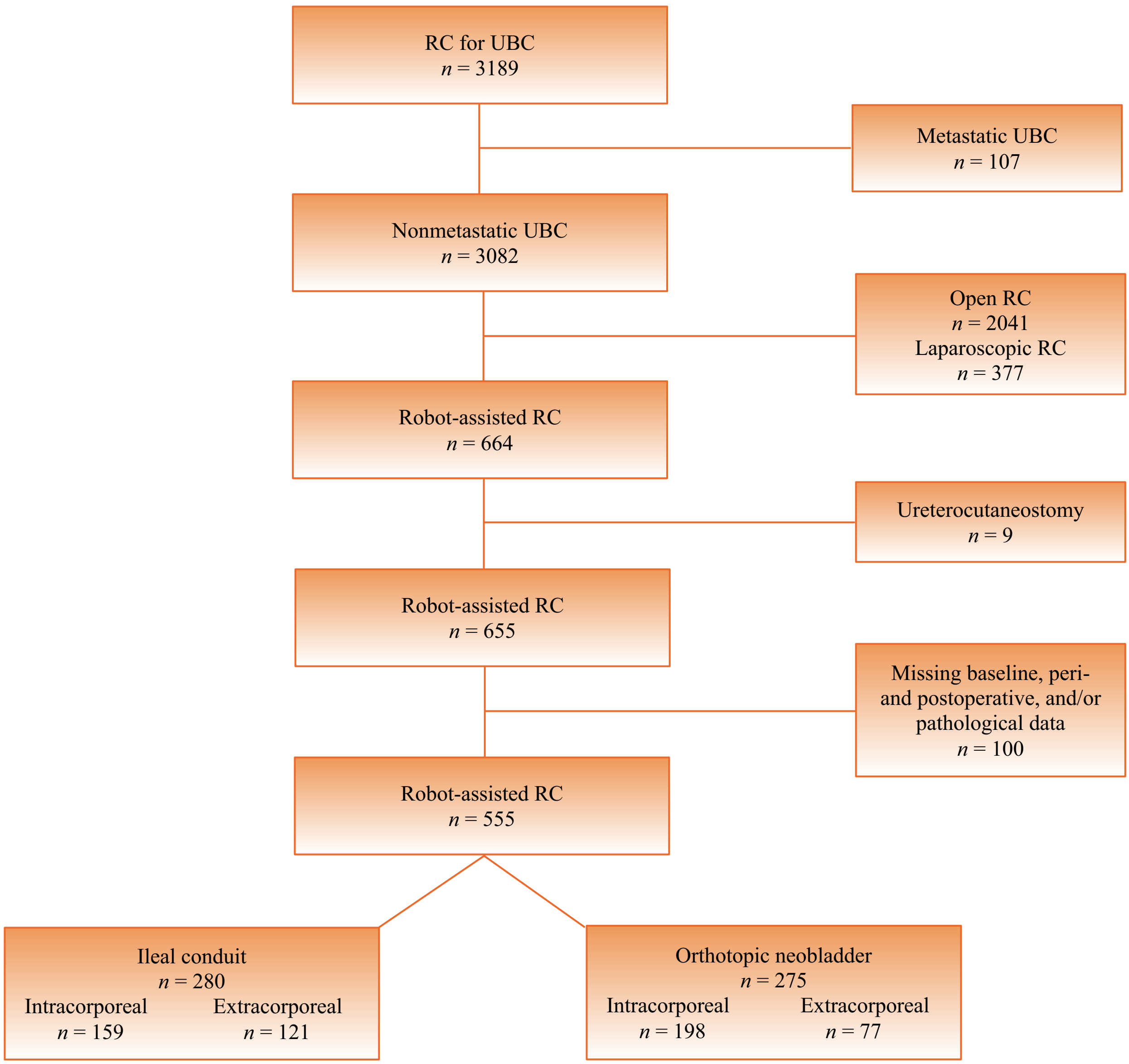

Fig. 1 – Consort diagram of the study population. RC = radical cystectomy; UBC = urothelial bladder cancer.

chemotherapy (NAC), and Enhanced Recovery After Surgery (ERAS) protocol [14]. The eighth edition of the tumor, node, metastasis (TNM) Classification (2017) was used [15].

2.3. *Outcomes*

The primary endpoint of the current study was to evaluate the impact of IC versus ONB on RARC complications. Complications were addressed according to the stratification in intraoperative, early postoperative (≤30 d from surgery), and late postoperative (30–90 d from surgery) complications. Moreover, postoperative UD-related complications were identified and analyzed (definition provided in Table 1 footnote).

Intraoperative complications were collected based on surgery reports and categorized according to the Intraoperative Adverse Incident Classification (EAUiaiC) proposed by the European Association of Urology (EAU) Ad Hoc Complications Guidelines Panel [16]. The quality criteria for accurate and comprehensive reporting of intraoperative adverse events proposed by the Intraoperative Complications Assessment and Reporting with Universal Standards (ICARUS) Global Surgical Collaboration Project were fulfilled (Supplementary Table 1) [12].

Postoperative complications were retrieved based on patient chart review and patient interviews done by medical doctors. Postoperative complications were graded according to the Clavien-Dindo classification system [17]. The quality criteria for accurate and comprehensive reporting of surgical outcomes recommended by the EAU guidelines on reporting and grading of postoperative complications were fulfilled (Supplementary Table 2) [13].

As a secondary endpoint, the impact of IC versus ONB on prolonged operative time (OT), prolonged length of stay (LOS), and readmissions was assessed. Prolonged OT was defined as any OT increase over the 75th percentile (360 min in the current study). Prolonged LOS was defined as any in-hospital stay increase over the 75th percentile (15 d in the current study). Readmission was defined as any adverse event requiring rehospitalization within 90 d from surgery.

2.4. *Statistical analyses*

Established recommendations for statistical analyses, reporting, and interpretation of the results were applied [18]. First, descriptive statistics included frequencies and proportions for categorical variables. Medians

Table 1 – Pathological features and perioperative outcomes of 555 urothelial bladder cancer patients treated with robot-assisted radical cystectomy between 2008 and 2020 at nine European high-volume institutions

	Ileal conduit (n = 280)[a]	Neobladder (n = 275)[a]	p value[b]
Operative time (min)	286 (239, 350)	310 (270, 379)	<0.001
Type of reconstruction			<0.001
ICUD	159 (57)	198 (72)	
ECUD	121 (43)	77 (28)	
pT stage			0.1
pT0	69 (25)	63 (23)	
pTa	9 (3)	5 (2)	
pTis	30 (11)	25 (9)	
pT1	18 (6)	57 (20)	
pT2	59 (21)	43 (16)	
pT3	72 (26)	72 (26)	
pT4	23 (8)	10 (4)	
pN stage			<0.001
pN0	193 (69)	227 (83)	
pN+	73 (26)	44 (16)	
pNx	14 (5)	4 (1)	
Number of retrieved nodes	19 (14, 26)	24 (17, 34)	<0.001
Estimated blood loss (cc)	400 (200, 717)	450 (200, 720)	0.4
Intraoperative transfusions	42 (15)	31 (11)	0.2
Intraoperative complications	11 (4)	7 (3)	0.4
Postoperative transfusions	53 (19)	59 (21)	0.5
Number of postoperative transfusions	2 (2, 2)	2 (2, 3)	0.07
Length of stay (d)	10 (8, 13)	12 (9, 17)	<0.001
Length of stay >75%	52 (19)	98 (36)	<0.001
At least 1 postoperative complication	160 (57)	164 (60)	0.6
At least 1 postoperative complication ≤30 d	142 (51)	133 (48)	0.6
CD ≥3	36 (13)	51 (19)	0.08
At least 1 postoperative complication 30–90 d	52 (19)	39 (14)	0.2
CD ≥3	20 (7)	13 (5)	0.3
At least 1 postoperative complication related to urinary diversion[c]	95 (34)	113 (41)	0.07
Readmission ≤90 d	57 (20)	59 (21)	0.8
Death ≤30 d	1 (0.4)	3 (1.1)	0.1
CSM-free survival at 24 mo	238 (85)	228 (83)	0.8

CD = Clavien-Dindo; CSM = cancer-specific mortality; ECUD = extracorporeal urinary diversion; ICUD = intracorporeal urinary diversion; IQR = interquartile range; pN stage = pathological N stage; pT stage = pathological T stage.
[a] Values are expressed as median (IQR) or n (%).
[b] Wilcoxon rank sum test, Pearson's chi-square test, and Fisher's exact test.
[c] Urinary diversion–related complications: anastomosis dehiscence, gross hematuria, hydronephrosis, parastomal hernia, acute renal failure, ureteral anastomosis leak, ureteral anastomosis stenosis, urethral anastomosis leak, urinary fistula, urinary retention, intestinal hernia/evisceration, pyelonephritis, urinary tract infection, anastomotic bowel leak, intestinal perforation, mechanical ileus, paralytic ileus, acidosis, and electrolyte imbalance.

and interquartile ranges were reported for continuously coded variables. Wilcoxon rank sum test, Pearson's chi-square test, and Fisher's exact test examined the statistical significance of differences in medians and proportions, respectively. Estimated annual percentage changes (EAPCs) in the type of UD were displayed graphically.

Second, four separate sets of multivariable logistic regression models were fitted to assess the impact of IC versus ONB on: (1) overall postoperative complications, (2) early postoperative complications, (3) late postoperative complications, and (4) UD-related postoperative complications. Covariates included UD reconstruction (ICUD vs ECUD), age, BMI, CCI, ASA score, previous abdominal surgery, antiplatelet/anticoagulant therapy, ERAS protocol, clinical stage, and NAC. Third, three additional sets of multivariable logistic regression models tested the impact of IC versus ONB on prolonged OT, prolonged LOS, and readmissions. In the latter models, complications and transfusions were added to the abovementioned covariates. For the sake of interpretability of statistically significant results, we additionally calculated adjusted relative risk estimates of outcome probability in IC versus ONB patients. Here, these computations relied on the IC and ONB patients with median values of continuously coded covariates and mode values of categorical covariates.

Fourth, the above methodology was applied in sensitivity analyses, exclusively focused on patients who had undergone robotic UD reconstruction (ICUD-IC and ICUD-ONB). Fifth and last, sensitivity analyses separately focused on patients who received IC and those who received ONB, according to UD reconstruction (ICUD-IC vs ECUD-IC and ICUD-ONB vs ECUD-ONB).

All multivariable regression models, including those in sensitivity analyses, were fitted after adjustment for clustering at single hospital level, using generalized estimation equation (GEE) functions [19]. In all multivariable logistic regression analyses, the number of covariates met the criteria for model overfitting prevention. In all statistical analyses, R software environment for statistical computing and graphics (R version 4.1.2; R Foundation for Statistical Computing, Vienna, Austria) was used [20]. All tests were two sided, with a level of significance set at $p < 0.05$.

3. Results

3.1. Descriptive characteristics

Overall, 555 nonmetastatic UBC patients treated with RARC were included in the study (Table 2). Overall, in 280 (51%) and 275 (49%) patients, an IC and an ONB were performed, respectively. Over time, the rates of ONB increased significantly (EAPC +7.9%, p = 0.03; Fig. 2). Clinically meaningful differences between IC and ONB patients consisted of age (median age: 69 vs 63 yr, p < 0.001), ASA score (ASA 1: 10% vs 13%; ASA 2: 63% vs 72%; ASA 3: 27% vs 14%, p < 0.001), and history of previous abdominal surgery (31% vs 20%, p = 0.003). Relative to their ONB counterparts, IC patients were more frequently submitted to ECUD (43% vs 28%, p < 0.001; Table 1). The median number of retrieved lymph nodes was lower in IC than in ONB patients (19 vs 24,

Table 2 – Baseline characteristics of 555 urothelial bladder cancer patients treated with robot-assisted radical cystectomy between 2008 and 2020 at nine European high-volume institutions

	Ileal conduit, (*n* = 280[a]; 51%)	Neobladder (*n* = 275[a]; 49%)	*p* value[b]
Age (yr)	69 (62, 75)	63 (56, 67)	<0.001
Sex (male)	220 (79)	240 (87)	0.007
Body mass index (kg/m^2)	26 (24, 29)	26 (24, 28)	0.3
Smoking habits			0.6
Active	76 (27)	80 (29)	
Former	104 (37)	91 (33)	
Never	100 (36)	104 (38)	
Charlson Comorbidity Index			0.4
0	30 (11)	23 (8.4)	
1	23 (8.2)	15 (5.5)	
2	81 (29)	85 (31)	
≥3	146 (52)	152 (55)	
ASA score			<0.001
1	27 (10)	37 (13)	
2	177 (63)	199 (72)	
3	76 (27)	39 (14)	
Anticoagulant/antiplatelet therapy	49 (18)	34 (12)	0.1
History of previous abdominal surgery	86 (31)	54 (20)	0.003
Neoadjuvant chemotherapy	141 (50)	126 (46)	0.3
ERAS protocol	160 (57)	168 (61)	0.4
Clinical stage			0.027
cT1N0M0	66 (24)	66 (24)	
cT2N0M0	142 (51)	158 (57)	
cT34N0M0	43 (15)	40 (15)	
cTanyN + M0	29 (10)	11 (4)	

ASA = American Society of Anesthesiologists score; ERAS = Enhanced Recovery After Surgery; IQR = interquartile range.
[a] Values are expressed as median (IQR) or *n* (%).
[b] Wilcoxon rank sum test and Pearson's chi-square test.

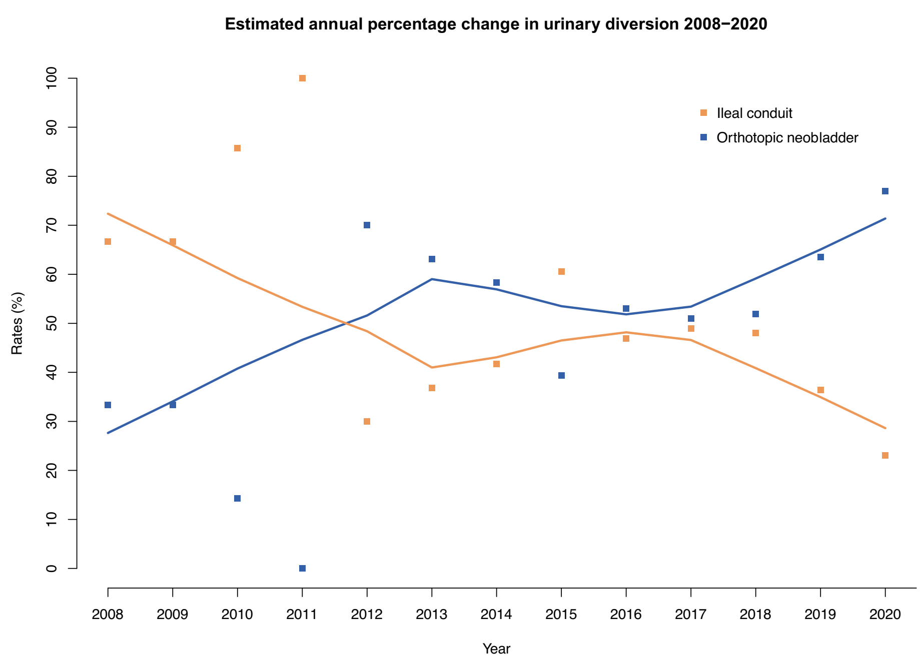

Fig. 2 – Estimated annual percentage change (EAPC) in urinary diversion between 2008 and 2020. EAPC, ileal conduit: –6.5% (95% confidence interval: –11.4, –1.8, *p* = 0.03); EAPC, orthotopic neobladder: +7.9% (confidence interval: +2.1, +15.0, *p* = 0.03).

$p < 0.001$), whereas IC patients harbored positive nodal stage more frequently (26% vs 16%, $p < 0.001$; Table 1).

3.2. *Intraoperative complications, OT, LOS, and readmission*

Eighteen intraoperative complications were recorded (Tables 1 and 3). Of those, the most frequent were vascular injuries (*n* = 12, 67%), followed by nerve injuries (*n* = 3, 17%) and gastrointestinal injuries (*n* = 2, 11%). According to EAUiaiC, 13 (61%) intraoperative complications were of grade 1 and five (39%) of grade 2 (Table 3). The rates of intraoperative complications were 4% in IC patients and 3% in ONB patients ($p = 0.4$). Supplementary Table 1 reports the ICARUS criteria satisfied and defines the quality of our intraoperative adverse event collection analysis (ten out of 13 criteria were satisfied).

Table 3 – Description of intraoperative complications in 555 urothelial bladder cancer patients treated with robot-assisted radical cystectomy between 2008 and 2020 at nine European high-volume institutions, according to the Intraoperative Adverse Incident Classification (EAUiaiC)

Description of the complication and EAUiaiC grade		Ileal conduit (*n* = 280)		Neobladder (*n* = 275)	
18 complications in 18 patients		*n*	%	*n*	%
Vascular injury (*n* = 12)	Injury of internal iliac artery managed with immediate repair[a], grade 1	2	0.7	0	0
	Injury of internal iliac vein managed with immediate repair[a], grade 1	2	0.7	1	0.4
	Injury of external iliac vein managed with immediate repair[a], grade 1	1	0.4	1	0.4
	Pelvic bleeding with no specified origin, grade 1	3	1.4	2	0.7
Nerve injury (*n* = 3)	Injury of obturator nerve, grade 2	1	0.4	2	0.7
Genitourinary injury (*n* = 1)	Partial injury of ureter managed with running suture, grade 1	1	0.4	0	0
Gastrointestinal injury (*n* = 2)	Hematoma of the mesentery requiring partial bowel resection[b], grade 2	0	0	1	0.4
	Injury of the rectum managed with immediate repair[b], grade 2	1	0.4	0	0

Grade 1: an event requiring additional/alternative procedure in planned intraoperative steps, not life threatening or involving part or full organ removal; the event was addressed in a controlled manner with no long-term side effects.
Grade 2: an event requiring major additional/alternative procedure in operative approach but not immediately life threatening; the event was addressed in a controlled manner, however may have short- or long-term side effects.
No conversion from robot-assisted to open radical cystectomy was recorded.
[a] Not requiring vascular surgeon intervention.
[b] Not requiring general surgeon intervention.

IC patients experienced lower median OT than ONB patients (286 vs 310 min, $p < 0.001$; Table 1), whereas there was no statistically significant difference between IC and ONB patients in terms of estimated blood losses (400 vs 450 ml, $p = 0.4$), nor intraoperative transfusions (15% vs 11%, $p = 0.2$). The median LOS and readmission rate were 10 versus 12 d ($p < 0.001$) and 20% versus 21% ($p = 0.8$) in IC versus ONB patients, respectively. Additionally, in Supplementary Table 3, perioperative outcomes were reported according to UD reconstruction type.

At multivariable logistic regression analyses (Table 4), the type of UD (IC vs ONB) reached the independent predictor status for prolonged OT (odds ratio [OR]: 0.61, 95% confidence interval [CI]: 0.38, 0.95; $p = 0.03$) and prolonged LOS (OR: 0.34, 95% CI: 0.21, 0.56; $p < 0.001$). In IC and ONB patients, with median values of all continuously coded covariates and mode values of all categorical covariates, adjusted relative risk estimates for prolonged OT were 22.5% versus 32.4% in IC versus ONB patients (difference: 9.9%). Similarly for prolonged LOS, adjusted relative risk estimates were 6.5% versus 16.2% in IC versus ONB patients (difference: 9.7%). Conversely, the type of UD did not reach the independent predictor status for readmission (OR: 0.92, 95% CI: 0.56, 1.51; $p = 0.7$).

These results were virtually perfectly replicated in sensitivity analyses focused on ICUD patients (Supplementary Table 4). UD reconstruction did not reach the independent predictor status of none of the outcomes of interest, with the exception of prolonged LOS in patients who received IC (Supplementary Table 4).

3.3. Postoperative complications

Overall, 513 postoperative complications were experienced by 324 patients (58%). At least one postoperative complication was experienced by 160 (57%) IC patients versus 164 (60%) ONB patients ($p = 0.6$; Table 1).

All postoperative complications were recorded according to the standardized criteria published by the EAU guidelines [13]. Supplementary Table 2 reports the criteria satisfied and defines the quality of our complication collection analysis (13 out of 14 criteria were satisfied). Statistically signif-

Table 4 – Multivariable logistic regression analyses predicting prolonged operative time, prolonged length of stay, and readmission after robot-assisted radical cystectomy

Characteristic	Operative time >75%			Length of stay >75%			Readmission		
	OR	95% CI	*p* value	OR	95% CI	*p* value	OR	95% CI	*p* value
Urinary diversion, IC vs ONB	0.61	0.38, 0.95	**0.03**	0.34	0.21, 0.56	**<0.001**	0.92	0.56, 1.51	0.7
Reconstruction, ICUD vs ECUD	2.87	1.54, 5.39	**<0.001**	2.60	1.40, 4.97	**0.003**	0.94	0.58, 1.53	0.8
Age	0.99	0.97, 1.02	0.5	0.98	0.95, 1.01	0.2	1.01	0.99, 1.04	0.9
Body mass index	0.99	0.94, 1.02	0.8	1.01	0.97, 1.06	0.3	1.00	0.99, 1.01	0.9
Charlson Comorbidity Index	0.80	0.68, 1.03	0.1	1.05	0.90, 1.21	0.6	0.87	0.74, 1.01	0.1
ASA score, 3 vs ≤2	0.86	0.48, 1.51	0.6	1.33	0.74, 2.35	0.3	–	–	–
Prior Abdominal Surgery	1.33	0.81, 2.15	0.3	1.88	1.14, 3.08	**0.01**	1.69	1.02, 2.76	**0.04**
Antiplatelet/anticoagulant therapy	0.96	0.51, 1.75	0.9	1.13	0.61, 2.05	0.7	1.30	0.71, 2.30	0.4
ERAS protocol	0.69	0.37, 1.31	0.3	0.34	0.18, 0.66	**0.001**	–	–	–
cStage, cT3–4N0M0 vs ≤cT2N0M0	2.53	1.53, 4.18	**<0.001**	1.50	0.84, 2.67	0.2	0.73	0.40, 1.30	0.3
Neoadjuvant chemotherapy	0.69	0.35, 1.55	0.5	0.74	0.46, 1.19	0.2	0.85	0.53, 1.36	0.5
Complications[a]	3.39	1.49, 6.01	**<0.001**	5.08	2.98, 8.86	**<0.001**	9.15	5.10, 17.43	**<0.001**
Transfusions	1.40	0.80, 2.41	0.3	2.83	1.68, 4.77	**<0.001**	0.66	0.38, 1.12	0.1

ASA = American Society of Anesthesiologists score; CI = confidence interval; cStage = clinical stage; ECUD = extracorporeal urinary diversion; ERAS = Enhanced Recovery After Surgery; IC = ileal conduit; ICUD = intracorporeal urinary diversion; LOS = length of stay; ONB = orthotopic neobladder; OR = odds ratio; OT = operative time.
[a] "Complications" consisted of (1) "intraoperative complications" for OT >75%, (2) "at least one postoperative complication ≤30 d" for LOS >75%, and (3) "at least one postoperative complication" for readmission.

icant differences between IC and ONB patients were recorded in terms of genitourinary (11% vs 24%, $p < 0.001$) and gastrointestinal (19% vs 12%, $p = 0.03$) complication rates (Table 5). The rate of UD-related complications was lower in IC than in ONB patients (51% vs 56%), albeit without reaching a statistically significant difference ($p = 0.08$).

No statistically significant differences were recorded between IC and ONB patients after stratification according to the time of complication (patients with at least one early complication: 51% vs 48%, $p = 0.6$; patients with at least one late complication: 19% vs 14%, $p = 0.2$; Table 1).

Overall, four patients (0.7%) died during the hospitalization. Specifically, one IC patient (0.4%) died from myocardial infarction, and three ONB patients (1.1%) died from cerebral stroke, massive pulmonary embolism, and myocardial infarction (Table 1). Additionally, in Supplementary Table 3, postoperative complications were reported according to UD reconstruction.

At multivariable logistic regression analyses after adjustment for clustering at single hospital level, type of UD (IC vs ONB) was not an independent predictor of overall, early, or late postoperative complications (all $p > 0.1$, Table 6), but reached the status of an independent predictor of UD-related complications (OR: 0.64, 95% CI: 0.43, 0.96; $p = 0.03$). Here, adjusted relative risk estimates in IC versus ONB patients with median values of all continuously coded covariates and mode values of all categorical covariates were 21.3% vs 29.6% (difference: 8.3%).

Sensitivity analyses on ICUD patients reported virtually the same results (Supplementary Table 4). UD reconstruction did not reach the independent predictor status of any of the outcomes of interest when we exclusively focused on patients who received IC (Supplementary Table 4) and ONB (Supplementary Table 4).

Remarkably, patients on antiplatelet/anticoagulant therapy ($n = 83$, 15%) experienced significantly higher rates of intraoperative (10% vs 2%, $p = 0.003$), postoperative (75% vs 56%, $p = 0.001$) and UD-related complications (45% vs 36%, $p = 0.02$), when compared with their counterparts not receiving the same treatment. Antiplatelet/anticoagulant therapy was unfavorably associated with complications according to all stratifications, except for late complications (ORs from 1.52 to 2.73, all $p \leq 0.01$; Table 6). Conversely, the ERAS protocol was associated with a protective effect in terms of overall, early, and UD-related complications (ORs from 0.20 to 0.35, all $p < 0.001$; Table 6).

4. Discussion

The current study aimed to provide the first ever reported head-to-head comparison between the two most performed UD (IC vs ONB) in a large multi-institutional series of patients treated with RARC for nonmetastatic UBC. We hypothesized that the type of UD may significantly impact peri- and postoperative morbidity, OT, LOS, and hospital readmission of such a population. Our hypothesis was only partially confirmed.

First, we observed that ONB rates increased significantly during the study interval (2008–2020), with an estimated annual increase slightly below +8% ($p = 0.03$). These findings agreed with the literature reporting how in several large centers, including the Memorial Sloan Kettering and the University of Southern California, ONB has become the diversion of choice for most patients undergoing RC [21,22].

Second, relative to perioperative outcomes, we observed that IC was associated with shorter OT (286 vs 310 min, $p < 0.001$) and shorter median LOS (10 vs 12 d, $p < 0.001$) relative to ONB. Once accounted for multiple confounders, especially the type of reconstruction (ICUD vs ECUD) and complications (respectively, intraoperative and early postoperative), IC was associated with a protective effect toward both prolonged OT and LOS. Conversely, no effect on readmission was detected according to the UD type.

Unfortunately, despite best intentions, the limited number of events prevented the current study from conducting multivariable analyses on intraoperative complications. However, a detailed collection of intraoperative complications and corresponding management was provided, according to which, no statistically significant difference between IC and ONB patients was detected. Notably, the current study is the first endorsing the intraoperative adverse events reporting system proposed by the ICARUS Global Surgical Collaboration Project in the specific setting of RARC [12].

Third, in the current study, 90-d postoperative complications were collected and reported according to the EAU standardized quality criteria for accurate and comprehensive reporting of surgical outcomes [13], which were proved to avoid missing critical information that could lead to an underestimation of complications after major surgeries such as RC or prostatectomy [23,24].

Postoperative complications were stratified not only according to early (<30 d) and late (30–90 d), but also, and more remarkably, between UD related and not related complications. The rate of RARC patients having experienced at least one postoperative complication was lower in IC patients than in their ONB counterparts (57% vs 60%), and the same occurred in terms of UD-related complications (34% vs 41%). In both scenarios, the difference did not reach statistical significance ($p = 0.6$ and $p = 0.07$, respectively). However, at multivariable logistic regression models, the type of UD was significantly associated with UD-related postoperative complications, with the protective effect of IC being translated into an OR of 0.64 ($p = 0.03$).

Unfortunately, similar reports concerning RARC patients do not exist, with the current study being the first to undertake this mission. Therefore, direct means of comparisons for our data are not available. Moreover, these results are only partially comparable with previous reports on ORC, in which predictors of UD-related complications were not addressed, the EAU standardized reporting system [13] was not exploited, and the regression models were not adjusted for potential discrepancies among different centers [25,26].

Fourth, in the current study, the impact of IC versus ONB on RARC perioperative outcomes and morbidity remained virtually unchanged when the analyses performed on the entire population were repeated in the specific cohort of

Table 5 – Description of postoperative complications in 555 urothelial bladder cancer patients treated with robot-assisted radical cystectomy between 2008 and 2020 at nine European high-volume institutions

	Overall (n = 555)[a]	Ileal conduit (n = 280)[a]	Neobladder (n = 275)[a]	p value[b]
Overall complications	513	246	267	
Overall urinary diversion–related complications	273 (53)	124 (51)	149 (56)	0.08
Genitourinary	96 (17)	30 (11)	66 (24)	<0.001
Anastomosis dehiscence	1 (0.2)	0 (0)	1 (0.4)	
Gross hematuria	1 (0.2)	0 (0)	1 (0.4)	
Hydronephrosis	8 (1.4)	5 (1.8)	3 (1.1)	
Parastomal hernia	2 (0.4)	2 (0.7)	0 (0)	
Acute renal failure	11 (2.0)	1 (0.4)	10 (3.6)	
Ureteral anastomosis leak	12 (2.2)	6 (2.1)	6 (2.2)	
Ureteral anastomosis stenosis	19 (3.4)	10 (3.6)	9 (3.3)	
Urethral anastomosis leak	12 (2.2)	0 (0)	12 (4.4)	
Urinary fistula	14 (2.5)	4 (1.4)	10 (3.6)	
Urinary retention	11 (2.0)	0 (0)	11 (4.0)	
Other	5 (0.9)	2 (0.7)	3 (1.1)	
Wound related	13 (2.3)	8 (2.9)	5 (1.8)	0.6
Intestinal hernia/evisceration	9 (1.6)	6 (2.1)	3 (1.1)	
Superficial wound dehiscence	4 (0.7)	2 (0.7)	2 (0.7)	
Hematologic	113 (20)	58 (21)	55 (20)	0.9
Anemia	111 (20)	57 (20)	54 (20)	
Thrombocytosis	1 (0.2)	1 (0.4)	0 (0)	
Others	1 (0.2)	0 (0)	1 (0.4)	
Infectious	113 (20)	49 (18)	64 (23)	0.09
Abdominopelvic abscess	5 (0.9)	3 (1.1)	2 (0.7)	
Deep wound infection	3 (0.5)	1 (0.4)	2 (0.7)	
Pneumonia	3 (0.5)	2 (0.7)	1 (0.4)	
Pyelonephritis	16 (2.9)	10 (3.6)	6 (2.2)	
Sepsis	15 (2.7)	6 (2.1)	9 (3.3)	
Superficial wound infection	1 (0.2)	1 (0.4)	0 (0)	
Urinary tract infection	69 (12)	26 (9.3)	43 (16)	
Other	1 (0.2)	0 (0)	1 (0.4)	
Gastrointestinal	84 (15)	52 (19)	32 (12)	0.025
Anastomotic bowel leak	2 (0.4)	1 (0.4)	1 (0.4)	
Clostridium difficile colitis	4 (0.7)	1 (0.4)	3 (1.1)	
Diarrhea	6 (1.1)	4 (1.4)	2 (0.7)	
Dyspepsia	1 (0.2)	0 (0)	1 (0.4)	
Emesis	4 (0.7)	3 (1.1)	1 (0.4)	
Gastrointestinal bleeding	2 (0.4)	1 (0.4)	1 (0.4)	
Intestinal perforation	2 (0.4)	2 (0.7)	0 (0)	
Mechanical ileus[c]	18 (3.2)	11 (3.9)	7 (2.5)	
Paralytic ileus[d]	45 (8.1)	29 (10)	16 (5.8)	
Vascular/lymphatic	27 (4.9)	9 (3.2)	18 (6.5)	0.08
Deep venous thrombosis	4 (0.7)	1 (0.4)	3 (1.1)	
Lymphedema	1 (0.2)	1 (0.4)	0 (0)	
Lymphocele	10 (1.8)	5 (1.8)	5 (1.8)	
Massive pulmonary embolism[e]	5 (0.9)	2 (0.7)	3 (1.1)	
Submassive pulmonary embolism[f]	6 (1.1)	0 (0)	6 (2.2)	
Other	1 (0.2)	0 (0)	1 (0.4)	
Cardiac	17 (3.1)	12 (4.3)	5 (1.8)	0.1
Acute heart failure	1 (0.2)	1 (0.4)	0 (0)	
Hypertension	3 (0.5)	1 (0.4)	2 (0.7)	
Myocardial infarction	4 (0.7)	3 (1.1)	1 (0.4)	
Tachyarrhythmia	8 (1.4)	6 (2.1)	2 (0.7)	
Other	1 (0.2)	1 (0.4)	0 (0)	
Pulmonary	7 (1.3)	3 (1.1)	4 (1.5)	0.7
Pneumothorax	1 (0.2)	1 (0.4)	0 (0)	
Respiratory failure/insufficiency	6 (1.1)	2 (0.7)	4 (1.5)	
Metabolic	27 (4.9)	14 (5.0)	13 (4.7)	0.9
Acidosis	12 (2.2)	5 (1.8)	7 (2.5)	
Dehydration	4 (0.7)	1 (0.4)	3 (1.1)	
Electrolyte imbalance	9 (1.6)	6 (2.1)	3 (1.1)	
Other	2 (0.4)	2 (0.7)	0 (0)	
Neurological	16 (2.9)	11 (3.9)	5 (1.8)	0.2
Lethargy	2 (0.4)	0 (0)	2 (0.7)	
Sensory peripheral neuropathy	2 (0.4)	2 (0.7)	0 (0)	
Cerebrovascular event	4 (0.7)	2 (0.7)	2 (0.7)	
Other	8 (1.4)	7 (2.5)	1 (0.4)	

[a] Values are expressed as median (IQR) or n (%).
[b] Pearson's chi-square test and Fisher's exact test; p values tested differences in the distribution of the complications' categories.
[c] Defined as clinical and radiographical findings of bowel obstruction requiring medical or surgical intervention.
[d] Defined as postoperative nausea or vomiting with associated abdominal distension requiring stoppage of oral intake and intravenous fluid and/or nasogastric tube placement.
[e] Defined as pulmonary embolism without hemodynamic instability, not requiring thrombolysis but anticoagulation alone.
[f] Defined as pulmonary embolism with hemodynamic instability, requiring thrombolysis.

Table 6 – Multivariable logistic regression analyses predicting intraoperative, overall postoperative, early postoperative, late postoperative, and urinary diversion–related postoperative complications after robot-assisted radical cystectomy

Characteristic	Postoperative complications			Urinary diversion–related postoperative complications			Early postoperative complications			Late postoperative complications		
	OR	95% CI	*p* value	OR	95% CI	*p* value	OR	95% CI	*p* value	OR	95% CI	*p* value
Urinary Diversion, IC vs ONB	0.66	0.44, 1.06	0.1	0.64	0.43, 0.96	**0.03**	0.76	0.49, 1.16	0.2	1.28	0.78, 2.12	0.4
Reconstruction, ICUD vs ECUD	0.95	0.55, 1.68	0.9	1.07	0.64, 1.82	0.8	0.41	0.23, 1.04	0.1	1.10	0.69, 1.90	0.6
Age	1.01	0.99, 1.03	0.5	1.01	0.99, 1.03	0.5	1.00	0.97, 1.02	0.8	1.00	0.98, 1.03	0.7
Body mass index	1.01	0.99, 1.05	0.6	1.03	0.99, 1.08	0.1	1.01	0.99, 1.06	0.5	1.01	0.98, 1.02	0.6
Charlson Comorbidity Index	0.99	0.88, 1.12	0.9	0.98	0.87, 1.10	0.7	0.78	0.68, 1.13	0.2	0.92	0.79, 1.06	0.3
ASA, 3 vs ≤2	1.10	0.67, 1.79	0.7	0.68	0.41, 1.10	0.1	1.34	0.79, 2.28	0.3	–	–	–
Prior abdominal surgery	0.95	0.62, 1.46	0.8	1.17	0.77, 1.78	0.5	1.28	0.81, 2.01	0.3	1.33	0.79, 2.19	0.3
Antiplatelet/anticoagulant therapy	2.00	1.17, 3.49	**0.01**	1.52	1.13, 2.08	**0.01**	2.73	1.54, 4.93	**<0.001**	1.30	0.69, 2.36	0.4
ERAS protocol	0.22	0.12, 0.38	**<0.001**	0.35	0.20, 0.59	**<0.001**	0.20	0.11, 0.34	**<0.001**	–	–	–
cStage, cT3–4N0M0 vs ≤cT2N0M0	1.51	0.95, 2.43	0.08	1.13	0.70, 1.81	0.6	2.50	1.51, 4.17	**0.01**	1.01	0.56, 1.74	0.9
Neoadjuvant chemotherapy	1.20	0.81, 1.76	0.4	1.16	0.79, 1.70	0.5	0.89	0.58, 1.35	0.6	1.25	0.77, 2.02	0.4

ASA = American Society of Anesthesiologists score; CI = confidence interval; cStage = clinical stage; ECUD = extracorporeal urinary diversion; ERAS = Enhanced Recovery After Surgery; IC = ileal conduit; ICUD = intracorporeal urinary diversion; ONB = orthotopic neobladder; OR = odds ratio.

ICUD patients. These observations are in general agreement with the study of Mazzone et al. [4], in which a significant impact on peri- and postoperative outcomes of RARC was associated with the type of UD (IC vs ONB) but not with the type of reconstruction (ICUD vs ECUD). The latter finding was also confirmed in our sensitivity analyses, where the impact of the type of reconstruction (ie, ICUD vs ECUD) on outcomes of interest was addressed in IC and ONB patients separately.

Taken together, our observations suggest that RARC is a highly skill-demanding surgery, still burdened by conspicuous peri- and postoperative morbidity, even in third referral centers. Both types of UD are prone to significant complications, occurring in both the early and the late postoperative phase. IC might provide a reduction in RARC postoperative morbidity, but, maybe for sample size criticisms, we have been able to intercept a significant protective effect of IC only in terms of UD-related complications.

This study presented several remarkable limitations. The retrospective nature of the exploited data represented the foremost limitation of the study. A potential source of selection bias consisted of the multi-institutional nature of the current study, which could have introduced heterogeneity in surgical procedure and perioperative patient care protocols. However, such heterogeneity should have partially been mitigated by the high experience shared among the involved institutions. Moreover, multivariable regression analyses and GEE aimed to reduce the potential selection biases related to the comparison between IC and ONB patients. Indeed, IC and ONB patients had significant differences relative to baseline characteristics of note. For instance, relative to ONB patients, IC patients at baseline were older, and harbored more unfavorable ASA scores and clinical stage. Such differences might not have been controlled completely by multivariable regression and might have partially obliterated the statistical significance related to IC on some outcomes of interest (ie, readmission and postoperative complications). However, a prospective clinical trial testing for differences in surgical outcomes between IC and ONB RARC patients is unlikely to ever be designed and completed. In consequence, rigorous retrospective analyses of data derived from high-volume institutions, as the current analyses, would still represent the best substitute of a clinical trial for a period of time.

Second, information relative to surgical volume were not available. However, our findings were derived from institutions with a high annual caseload and from surgeons highly experienced in RARC. In consequence, the effect of surgical volume on the endpoints of interest might be considered marginal in this case. Third, since our data were derived from centers of excellence, these results might not be applicable to smaller centers with limited surgical volumes. Fourth, paucity of events precluded the assessment of independent predictors of intraoperative complications. In consequence, further studies are warranted in order to address this gap of knowledge. Fifth, the current study addressed only peri- and postoperative outcomes in a cohort of RARC patients, without the inclusion of individuals who underwent ORC or laparoscopic RC. Moreover, no cost analyses were performed. Therefore, comparisons relative to morbidity, functional outcomes, or costs according to different surgical approaches for RC could not be provided, and the reported observations cannot apply to patients submitted to ORC or laparoscopic RC. Last but not least, indeed, the decision to perform a specific UD was based on surgeon's as well as patient's preference, and this point may have introduced a bias in the reported results.

5. Conclusions

RARC is a major surgical procedure associated with significant morbidity, even in centers of excellence. The UD component is one of the main drivers of RARC morbidity. Relative to RARC with ONB, RARC with IC is less prone to UD-related postoperative complications, prolonged OT, and prolonged LOS.

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Acquisition of data: All authors.
Analysis and interpretation of data: Tappero, Dell'Oglio, Di Trapani.

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Appendix A. Supplementary data

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