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Original Article

A comparative propensity score-matched analysis of perioperative outcomes of intracorporeal vs extracorporeal urinary diversion after robot-assisted radical cystectomy: results from the International Robotic Cystectomy Consortium

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Objective

To compare the perioperative outcomes of intracorporeal (ICUD) vs extracorporeal urinary diversion (ECUD) after robot-assisted radical cystectomy (RARC).

Patients and Methods

We retrospectively reviewed the prospectively maintained International Robotic Cystectomy Consortium (IRCC) database. A total of 972 patients from 28 institutions who underwent RARC were included. Propensity score matching was used to match patients based on age, gender, body mass index (BMI), American Society of Anesthesiologists Score (ASA) score, Charlson Comorbidity Index (CCI) score, prior radiation and abdominal surgery, receipt of neoadjuvant chemotherapy, and clinical staging. Matched cohorts were compared. Multivariate stepwise logistic and linear regression models were fit to evaluate variables associated with receiving ICUD, operating time, 90-day high-grade complications (Clavien–Dindo Classification Grade ≥III), and 90-day readmissions after RARC.

Results

Utilisation of ICUD increased from 0% in 2005 to 95% in 2018. The ICUD patients had more overall complications (66% vs 58%, P = 0.01) and readmissions (27% vs 17%, P = 0.01), but not high-grade complications (21% vs 24%, P = 0.22). A more recent RC era and ileal conduit diversion were associated with receiving an ICUD. Higher BMI, ASA score ≥3, and

receiving a neobladder were associated with longer operating times. Shorter operating time was associated with male gender, older age, ICUD, and centres with a larger annual average RC volume. Longer intensive care unit stay was associated with 90-day high-grade complications. Higher CCI score, prior radiation therapy, neoadjuvant chemotherapy, and ICUD were associated with a higher risk of 90-day readmissions.

Conclusions

Utilisation of ICUD has increased over the past decade. ICUD was associated with more overall complications and readmissions compared to ECUD, but not high-grade complications.

Keywords

intracorporeal, extracorporeal, urinary diversion

Introduction

Radical cystectomy (RC), whether open (ORC) or robot-assisted (RARC), is a morbid and complex procedure that involves simultaneous surgeries on the urinary and gastrointestinal tracts, as well as the retroperitoneum. The majority of perioperative complications and morbidity are diversion-related [1,2]. RARC has been increasingly performed worldwide; with several randomised controlled trials (RCTs) supporting equivalent oncological outcomes and suggesting some benefits in terms of blood loss, transfusion needs, wound complications, and hospital stay [3–5]. However, these RCTs compared ORC and RARC only in terms of the extirpative component (i.e. RC and lymph node dissection). The reconstructive aspect, i.e. the urinary diversion (UD), in all published RCTs was performed via an open (extracorporeal) approach. No RCT has compared the safety of different approaches of UD, i.e., intracorporeal (ICUD) vs extracorporeal (ECUD). RARC with ICUD, as a completely minimally invasive procedure, has the potential to provide benefits in terms of smaller incisions, reduced pain, accelerated bowel recovery, and reduced third-space losses, especially after establishment of the learning curve and reduction in operating times [6,7]. A previous study of an older cohort compared an unmatched cohort of ICUD vs ECUD after RARC and showed that ICUD was associated with a shorter operating time and less blood loss. Although ICUD was associated with more complications, the complication rates significantly decreased over time [8].

The feasibility of RARC and intracorporeal ileal conduit has been previously demonstrated [9,10]. While intracorporeal neobladders have been slower to adopt, as they are more challenging and time-consuming, several techniques have been recently described with promising outcomes [11,12]. Deciding upon the most appropriate approach is usually individually tailored according to the patient and disease characteristics, in addition to the surgeon's training and experience [13]. Utilisation of ICUD has increased over the past decade, especially in high-volume institutions with improved perioperative outcomes over time [8]. However, because of the difference in patient and disease characteristics, outcomes may be affected due to case selection. In this context, in the present study, we aimed to perform a matched analysis, with 3 years more of updates, to compare the perioperative outcomes of ICUD and ECUD after RARC from a multi-institutional, prospectively maintained database, the International Robotic Cystectomy Consortium (IRCC).

Patients and Methods

A retrospective review of 3000 patients from 28 institutions included in the IRCC database (I-97906) was performed. Patients who had missing data on the diversion approach or technique were excluded. Propensity score matching was used to compare patients who had ICUD vs those who received ECUD, with a calliper width of 0.0075. Matching was based on preoperative parameters that might have affected the decision to choose one approach of diversion over the other including: age, gender, body mass index (BMI), American Society of Anesthesiologists (ASA) score, Charlson Comorbidity Index (CCI), receipt of prior radiation, neoadjuvant chemotherapy (NAC), previous abdominal or pelvic surgery, and preoperative high T stage (≥cT3).

Data were reviewed for institutional volume, year of RARC, operative variables (type and technique of diversion, operating time, blood loss, and blood transfusion), perioperative outcomes (hospital stay, complications, and readmissions), and pathological outcomes (T and N staging, lymph node yield, soft tissue surgical margins, and disease relapse).

Descriptive statistics were used to summarise the data. Multivariate stepwise linear and logistic regression models were fit to evaluate preoperative, operative, and postoperative predictors of receiving an ICUD, operating time, high-grade complications (Clavien–Dindo Classification Grade ≥III) and readmissions within 90 days after RARC. Study data were collected and managed using Redcap electronic data capture tools hosted at Roswell Park Comprehensive Cancer Center. All tests were two-sided, with statistical significance defined

as $P \leq 0.05$. All statistical analyses were performed using Statistical Analysis System (SAS) software (version 9.4, SAS Institute Inc., Cary, NC, USA).

Results

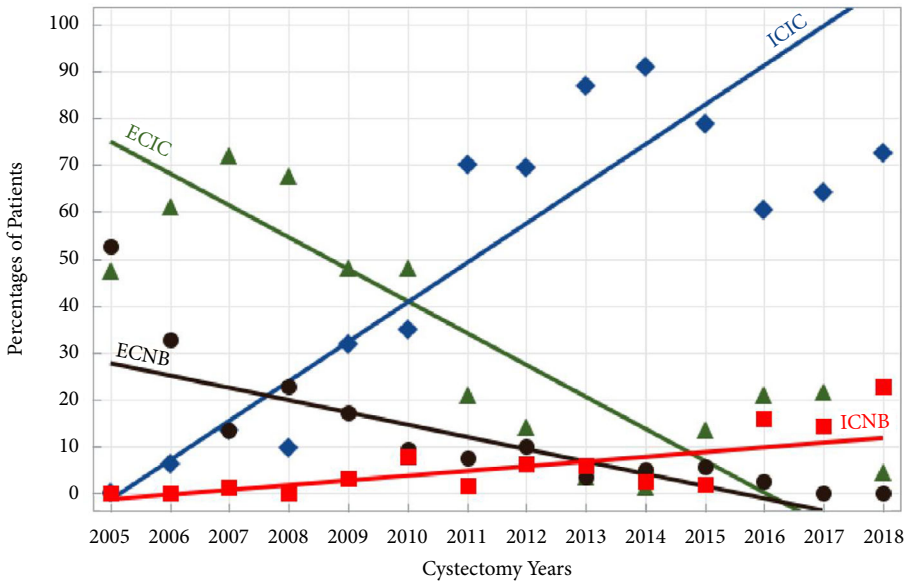
A total of 972 patients were analysed with a median (interquartile range [IQR]) follow-up of 33 (11–70) months. Utilisation of ICUD increased from none in 2005 to 95% in 2018; this increase has been primarily seen for intracorporeal ileal conduits (increased from 0% in 2005 to 73% in 2018) and to a lesser extent for intracorporeal neobladders (increased from 0% in 2005 to 23% in 2018) (Fig. 1). USA institutions started to utilise ICUD more frequently starting in 2009 (35% of all diversions) and increased to 94% by 2018. In contrast, European institutions adopted ICUD earlier in their robotic experience (50% of all diversions in 2007 and reaching 100% in 2018).

ECUD patients received neobladders more frequently (26% vs 9%, $P < 0.01$). On the other hand, ICUD patients had a shorter median operating time (355 vs 401 min, $P < 0.01$), less blood loss (250 vs 400 mL, $P < 0.01$), and received blood transfusions less frequently (9% vs 15%, $P < 0.01$). However, ICUD patients had a 1 day longer hospital stay (9 vs 8 days, $P < 0.01$). They also experienced more complications (66% vs 58%, $P = 0.01$) and readmissions (27% vs 17%, $P = 0.01$); however, both groups showed similar high-grade complication rates (21% vs 24%, $P = 0.22$). The higher incidence of complications and readmissions were more pronounced in the first 30 days after RARC (47% vs 28%, $P < 0.01$) and (15% vs 4%, $P < 0.01$) for ICUD and ECUD, respectively. Patients that had an ICUD had significantly more infectious complications (30% vs 23%, $P = 0.03$) and UTIs (14% vs 8%, $P < 0.01$). Despite the significant increase in the utilisation of ICUD, high-grade complications remained stable over time (Fig. 2). Both groups showed comparable pathological outcomes (Table 1).

On multivariate analysis, ICUD was significantly associated with an ileal conduit UD (odds ratio [OR] 3.81, 95% CI, 2.45–5.91; $P < 0.01$), and a more recent RC era (2014–2018 vs 2005–2008) (OR 58.87, 95% CI 33.33–103.97; $P < 0.01$) (Table 2).

Operating time was significantly associated with male gender (34 min shorter, $P < 0.01$), older age (1 min shorter/year, $P = 0.03$), BMI (3 min longer for each 1 kg/m^2 increase, $P < 0.01$), ASA score ≥3 (26 min longer, $P < 0.01$), ICUD (31 min shorter, $P < 0.01$), neobladder UD (80 min longer, $P < 0.01$), and RC volume (1 min shorter/procedure, $P < 0.01$) (Table 3).

Fig. 1 Diversion type and approach over time. ECIC, extracorporeal ileal conduit; ECNB, extracorporeal neobladder; ICIC, intracorporeal ileal conduit; ICNB, intracorporeal neobladder.



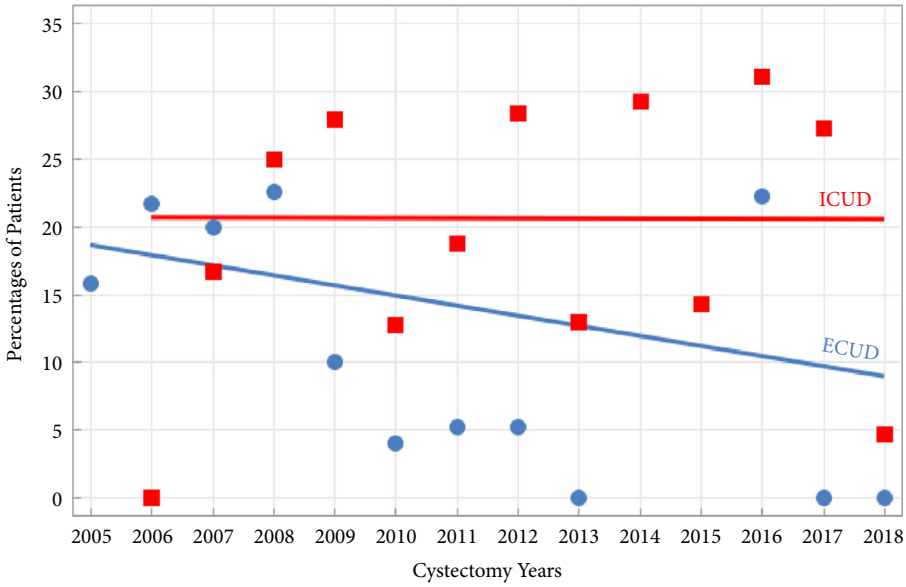
ICIC: Intracorporeal ileal conduit

ECIC: Extracorporeal ileal conduit

ICNB: Intracorporeal neobladder

ECNB: Extracorporeal neobladder

Fig. 2 High-grade complications over time. ECUD, extracorporeal urinary diversion; ICUD, intracorporeal urinary diversion.



ICUD: Intracorporeal urinary diversion

ECUD: Extracorporeal urinary diversion

Longer intensive care unit (ICU) stay (OR 1.11, 95 % CI 1.02–1.20; $P = 0.01$) was associated with increased 90-day high-grade complications. Higher CCI (OR 1.23, 95 % CI 1.05–1.44; $P < 0.01$), prior radiation therapy (OR 2.97, 95 % CI 1.26–6.98; $P = 0.01$), NAC (OR 2.22, 95 % CI 1.15–4.31; $P = 0.02$, and an ICUD (OR 2.47, 95% CI 1.21–5.02; $P = 0.01$) were significantly associated with higher 90-day readmissions (Table 4).

Discussion

There is growing evidence that supports the utilisation of RARC as a viable alternative to ORC. However, in all RCTs comparing both approaches, UD after RARC was performed using an open technique. RCTs have addressed the questions about the oncological outcomes after RARC, but have also left unanswered questions about whether RARC with ICUD is superior to ORC or not [14]. Bearing in mind that many of the complications after RC are diversion-related, it remains unclear which diversion approach (ICUD vs ECUD) is ideal after RARC [13,14].

Earlier studies have reported only 3% utilisation of ICUD in the USA [15]. Our present data show that the utilisation of ICUD has increased over the past decade, reaching 95% of all RARCs amongst IRCC institutions in 2018. Later RC era (2009 onwards) was associated with receiving an ICUD. In agreement with prior reports, a 'stepwise' approach to RARC allowed safe incorporation of ICUD, especially ileal conduits, without compromising perioperative outcomes [9]. After achieving the learning curve and optimising the technique for the extirpative aspect of the procedure, ICUD has become more popular [8].

While the adoption of RARC has the promise of improved perioperative outcomes and enhanced patients' recovery, much of the criticism to the procedure has been attributed to the longer operating times and steep learning curve. These operations times were anticipated to be longer with the adoption of an intracorporeal approach to UD, especially with construction of a continent reservoir. Utilisation of orthotopic continent reservoirs was only 17% and was significantly higher amongst the ECUD group. However, utilisation of intracorporeal neobladders has increased, reaching 23% of ICUDs by 2018. Orthotopic UD is extremely challenging and has a steep learning curve [2]. Similar to prior reports, male gender, age and higher annual RARC volume were associated with shorter overall operating time [16,17]. With increased experience and comfort with the robotic platform, operating times for RARC have decreased over time [16–18]. Patients who had an ICUD had shorter operating times (difference of 46 min). Moreover, on multivariable analysis, ICUD was associated with a shorter operating time. This could be a result of increased comfort and experience with ICUD and the flattening of the learning curve, surgeon-related factors, additional time of undocking of the robot and preparing the patient for ECUD, or other unknown variables. Other studies have reported a shorter operating time for ECUD; that study was from a single centre comparing two surgeons one performing ICUD and the other

Table 1 Perioperative and pathologic outcomes.

Preoperative variables	ECUD	ICUD	All	*P*-value
Number (%)	486 (50)	486 (50)	972	1
Age years, mean ± SD	68 ± 11	69 ± 10	68 ± 10	0.14
Males, *n* (%)	377 (78)	374 (77)	751 (77)	0.88
BMI (%), kg/m^2	27 ± 5	28 ± 6	27 ± 6	0.92
ASA ≥3, *n* (%)	240 (49)	238 (49)	478 (49)	0.95
CCI, mean ± SD	3 ± 2	3 ± 2	3 ± 2	0.34
Prior abdominal surgery, *n* (%)	218 (46)	182 (50)	400 (48)	0.24
Prior radiation, *n* (%)	20 (6)	24 (7)	44 (6)	0.53
NAC, *n* (%)	96 (20)	91 (19)	187 (19)	0.75
cT≥3, *n* (%)	75 (15)	63 (13)	138 (14)	0.31
Perioperative Outcomes				
Neobladder, *n* (%)	127 (26)	42 (9)	169 (17)	< 0.01
Operative time, median (IQR), min	401 (340, 468)	355 (295, 420)	373 (310, 446)	<0.01
Blood loss, median (IQR), mL	400 (200, 600)	250 (100, 400)	300 (150, 500)	<0.01
Transfusion, *n* (%)	70 (15)	29 (9)	99 (12)	<0.01
Any Complication, *n* (%)	222 (58)	322 (66)	544 (63)	0.01
30-d Complications, *n* (%)	106 (28)	226 (47)	332 (38)	<0.01
90-d Complications, *n* (%)	133 (35)	255 (52)	388 (45)	< 0.01
High grade Complications, *n* (%)	77 (24)	100 (21)	177 (22)	0.22
30-d High grade Complications, *n* (%)	33 (10)	56 (12)	89 (11)	0.65
90-d High grade Complications, *n* (%)	39 (12)	66 (14)	105 (13)	0.67
Category of Complications				
Bleeding	4 (1)	8 (2)	12 (1)	0.52
Cardiovascular	14 (4)	24 (5)	38 (4)	0.41
Gastrointestinal	78 (20)	112 (23)	190 (22)	0.36
Genitourinary	67 (17)	93 (19)	160 (18)	0.60
Infections	88 (23)	145 (30)	233 (27)	**0.03**
Wound	45 (12)	64 (13)	109 (13)	0.54
Neurological	6 (2)	18 (4)	24 (3)	0.06
Pulmonary	23 (6)	40 (8)	63 (7)	0.24
Thromboembolic	22 (6)	34 (7)	56 (6)	0.49
Any Readmission, *n* (%)	30 (17)	72 (27)	102 (23)	**0.01**
30-d Readmissions, *n* (%)	8 (4)	40 (15)	48 (11)	<0.01
90-d Readmissions, *n* (%)	11 (6)	49 (19)	60 (14)	<0.01
90-d Mortality, *n* (%)	16 (3)	12 (2)	28 (3)	0.57
Adjuvant Treatment, *n* (%)	80 (20)	78 (18)	158 (19)	0.54
Hospital stay, median (IQR), days	8 (6, 11)	9 (7, 13)	8 (6, 12)	<0.01
Pathologic Outcomes				
≥pT3, *n* (%)	191 (42)	194 (41)	385 (41)	0.69
LNY, mean (SD)	21 ± 12	20 ± 10	21 ± 11	0.44
pN+ve, *n* (%)	117 (24)	107 (22)	224 (23)	0.49
Positive soft tissue margins, *n* (%)	43 (11)	37 (8)	80 (9)	0.29
Any recurrence, *n* (%)	146 (30)	129 (27)	275 (28)	0.26
Local recurrence, *n* (%)	63 (13)	68 (14)	131 (13)	0.71
Distant recurrence, *n* (%)	109 (22)	88 (18)	197 (20)	0.11

Abbreviations: ASA, American Society of Anesthesiology Score; BMI, Body Mass Index; CCI, Charlson Comorbidity Index; IQR, Inter Quartile Range; N, Number; SD, Standard deviation. Bold values indicate statistical siginificance.

Table 2 Multivariable logistic regression model for predictors of receiving ICUD.

Variable	OR (95% CI)	*P*
Ileal conduit	3.81 (2.45–5.91)	<0.01
RC era 2009–2013 vs 2005–2008	13.17 (8.52–20.36)	<0.01
RC era 2014–2018 vs 2005–2008	58.87 (33.33–103.97)	<0.01

Table 3 Multivariable linear regression model for operative time.

Variable	Operating time estimate, min	*P*
Intercept	395	<0.01
Male gender	−34	<0.01
Age	−1	0.03
BMI	3	<0.01
ASA score ≥3	26	<0.01
ICUD	−31	<0.01
Neobladder	80	<0.01
Annual RC volume	−1	<0.01

performing ECUD. The longer operating time found may be due to surgeon difference rather than of the UD approach [19]. Interestingly, age was associated with shorter operating time. This could be explained by the fact that surgeons tend to increase efficiency when operating on older patients to reduce anaesthetic risks. Another explanation may be a less thorough lymph node dissection and low utilisation of continent UD, both of which can

Table 4 Multivariable logistic regression model for predictors of 90-day high-grade complications, and readmissions.

	OR (95% CI)	P
90-day high-grade complications		
ICU stay	1.11 (1.02–1.20)	0.01
90-day readmissions		
Prior radiation therapy	2.97 (1.26–6.98)	0.01
Higher CCI	1.23 (1.05–1.44)	<0.01
NAC	2.22 (1.15–4.31)	0.02
ICUD	2.47 (1.21–5.02)	0.01

significantly increase operating time [16,20]. On the other hand, higher BMI, ASA score ≥3, and receiving neobladders were associated with longer operating times. These factors may add to the surgical and anaesthetic complexity of RARC, with more time spent in port placement, careful dissection, management of comorbidities, and construction of the continent reservoir [17,21]. Other studies found that more extensive lymph node dissections and female gender were also associated with longer operating times. The latter is likely attributed to additional time required in organ sparing and/or vaginal reconstruction [22].

Perioperative blood transfusion has been correlated with recurrences and cancer-specific mortality [23]. ICUD patients had significantly less blood loss and transfusion rates compared to those who underwent an ECUD. Future efforts of the IRCC will be made to investigate any long-term differences in cancer-specific outcomes that could be related to differences in blood loss.

ICUD patients had a longer hospital stay compared to those who received an ECUD. A recent study from IRCC showed similar findings [8]. However, an earlier report from the IRCC found no difference in the hospital stay between both groups [7,8]. The longer hospital stays demonstrated may be related to broadening of patient selection as more experience is gained with the robotic platform, and inclusion of more centres worldwide with varying experiences and postoperative pathways. Also, this may be related with the significantly higher infectious complications.

The present study shows that patients who received ICUD had more complications and readmissions especially in the first 30 days. Most of the complications after RC were diversion-related, and with increased utilisation of ICUD and broadening of the patient selection, more complications after ICUD were observed. Standardised reporting of complications after RARC has led to better reporting of complications and readmissions, which may explain the increase or difference in reporting between the ICUD and ECUD groups [24]. Despite the marked increase in the utilisation of ICUD, high-grade complications remained stable. Propensity score matching is useful here to minimise the effect of patient selection bias, especially early in the ICUD experience; however, residual confounding may still be present despite the matching. The ICUD cohort had infectious complications more frequently compared with the ECUD cohort, namely UTIs. The difference in the rates of infections may be explained by differences in the enhanced recovery after surgery (ERAS) or prophylactic antibiotics protocols, as well as resistance to antibiotics. The increased utilisation of ICUD may be associated with more complications as a result of performing more, rather than the approach to UD per se. Similarly, lower complications associated with ECUD could be a result of decreased utilisation. Prior studies have shown an association between ureteric strictures and ICUD, which may explain the higher rates of UTIs associated with ICUD [25]. In a single-centre study, ureteric strictures developed in 12%, 16% and 19% of 51 patients (13%) at 1, 3 and 5 years after RARC, respectively, at a median (IQR) time of 5 (2–11) months after RARC. Or the difference may be due to different protocols implemented at different hospitals as to the use of antibiotics and stents. The iROC study (ClinicalTrials.gov Identifier: NCT03049410) comparing ORC vs RARC with ICUD is currently enrolling in the UK to evaluate whether ICUD confers additional benefits or not [26].

On multivariate analysis, ICUD was associated with 90-day readmissions; but not 90-day high-grade complications. Higher CCI, prior radiation therapy and NAC were significantly associated with 90-day readmissions. Patient selection criteria amongst the higher RARC volume institutions in the IRCC database were broader and they operated on sicker and older patients with more advanced disease, which may explain the higher rate of readmissions. A recent study from the IRCC looking at perioperative outcomes after NAC, showed that NAC was associated with higher 90-day readmissions. Further analysis has highlighted that anaemia due to NAC was the cause in 40% of the cases [27]. The iROC study comparing ORC vs RARC with ICUD is currently enrolling in the UK to evaluate whether ICUD confers additional benefit or not [26].

In agreement with the present study, a previous unmatched analysis from IRCC showed that healthier patients, who received RARC at higher volume institutions in a more recent era, were more likely to receive an ICUD [8]. The effect of the learning curve was demonstrated in both studies, where patients who received RARC in a more recent era were more likely to receive an ICUD and had shorter overall operating times.

To our knowledge, this is largest reported series of ICUD. We performed a matched analysis to reduce patient selection bias and provide a fairer comparison between the two approaches. However, several limitations exist. The

inherent limitations to retrospective analysis should be acknowledged. The variability among the IRCC institutions in terms of surgical techniques and preferences, ERAS protocols, institutional follow-up protocols, and pathology reporting represents another limitation. Whether RARCs were performed for curative, salvage or palliative reasons are not captured in the IRCC. Under-reporting of readmissions was encountered, and therefore, the results should be interpreted with caution. The IRCC includes mainly high-volume institutions and experienced surgeons, which may limit the generalisability of the results.

Conclusion

Utilisation of ICUD has increased over the past decade and this trend is primarily observed for ileal conduits. ICUD was associated with a shorter operating time. Complications and readmissions after ICUD were higher, but not high-grade complications.

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Conflicts of Interest

Carl Wijburg Freelance Proctor Intuitive Surgical. Alexandre Mottrie Proctor of Intuitive. Jihad kaouk Intuitive Surgical and Endocare Speaker. Morgan Roupert Advisory Board of SANOFI, ASTELLAS, IPSEN, MEDAC, ROCHE, & MERCK.

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Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; CCI, Charlson Comorbidity Index; ERAS, enhanced recovery after surgery; ICU, intensive care unit; IQR, interquartile range; IRCC, International Robotic Cystectomy Consortium; NAC, neoadjuvant chemotherapy; OR, odds ratio; (O)(RA)RC, (open) (robot-assisted) radical cystectomy; RCT, randomised controlled trial; (EC)(IC)UD, (extracorporeal) (intracorporeal) urinary diversion.