Laparoscopy and Robotics

Uretero-Enteric Anastomotic Stricture Following Radical Cystectomy: A Comparison of Open, Robotic Extracorporeal, and Robotic Intracorporeal Approaches

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OBJECTIVES To compare the incidence of benign uretero-enteric anastomotic strictures between open cystectomy, robotic cystectomy with extracorporeal urinary diversion, and robotic cystectomy with intracorporeal urinary diversion. The effect of surgeon learning curve on stricture incidence following intracorporeal diversion was investigated as a secondary outcome.

PATIENTS AND METHODS Patients who underwent radical cystectomy at an academic hospital between 2011 and 2018 were retrospectively reviewed. The primary outcome, incidence of anastomotic stricture over time, was assessed by a multivariable Cox proportional hazards regression. A Cox regression model adjusting for sequential case number in a surgeon's experience was used to assess intracorporeal learning curve.

RESULTS Nine hundred sixty-eight patients were included: 279 open, 382 robotic extracorporeal, and 307 robotic intracorporeal. Benign stricture incidence was 11.3% overall: 26 (9.3%) after open, 43 (11.3%) after robotic extracorporeal, and 40 (13.0%) after robotic intracorporeal. An intracorporeal approach was associated with anastomotic stricture on multivariable analysis (HR 1.66; *P* = .05). After 75 intracorporeal cases, stricture incidence declined from 17.5% to 4.9%. Higher sequential case volume was independently associated with reduced stricture incidence (Hazard Ratio per 10 cases: 0.90; *P* = .02).

CONCLUSION An intracorporeal approach to urinary reconstruction following robotic radical cystectomy was associated with an increased risk of benign uretero-enteric anastomotic stricture. In surgeons' early experience with intracorporeal diversion the difference in stricture incidence was more pronounced compared to alternative approaches; however, increased intracorporeal case volume was associated with a decline in stricture incidence leading to a modest difference between the 3 surgical approaches overall. UROLOGY 00: 1−6, 2020. © 2020 Elsevier Inc.

Benign uretero-enteric anastomotic stricture (UEAS) is a common late complication of radical cystectomy. Various groups have reported an incidence between 2.6% and 13.0%, depending on the definition used.[1-7] Clinical presentation varies with some noted incidentally on imaging, while others are detected due to flank pain, renal dysfunction, nephrolithiasis, or pyelonephritis. Treatment of UEAS is morbid and cumbersome. Open or minimally invasive reimplantation is the gold standard, which entails additional surgery that is often complex with inherent risks. Endoscopic and percutaneous treatment options have been described, but often fail or require additional procedures.[5,8-12] Percutaneous or trans-stomal drainage tubes may cause discomfort, introduce a foreign body that can act as a nidus for infection, and require frequent exchanges, occasionally in an urgent fashion to replace dislodged tubes.[13,14] Given the associated morbidity and risk of renal function decline, there has been significant interest in identifying risk factors for and practices to reduce the risk of UEAS.

Currently, both robot-assisted and open radical cystectomy (ORC) are considered acceptable approaches for bladder extirpation. The randomized, multicenter

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RAZOR trial demonstrated non-inferiority of robotic cystectomy to ORC with regards to oncologic and perioperative outcomes, including similar UEAS rates of 7% and 9%, respectively.[1,15] However, urinary reconstruction in the robotic arm of this trial was completed exclusively by an extracorporeal urinary diversion (ECUD) approach, leaving open the possibility of differences in UEAS rates between an entirely robotic, intracorporeal urinary diversion (ICUD) technique and alternative approaches.

Published comparisons of ICUD and ECUD have focused primarily on short-term perioperative outcomes and have demonstrated similar safety profiles.[16-18] Analysis of UEAS after ICUD is limited. A series from a single high-volume surgeon suggested UEAS may be more common after ICUD compared to ECUD.[4] Compared to ORC and ECUD, ICUD is a relatively new operative approach. The learning curve of adopting a new reconstructive technique may contribute to UEAS formation, but the effect of surgeon experience on UEAS has not been published previously.

The objective of this study was to compare the incidence of benign UEAS among patients undergoing ICUD to that of patients undergoing ORC or ECUD. Additionally, we sought to examine whether UEAS was a function of surgeons' learning curve with ICUD.

METHODS

A prospectively maintained registry of patients that underwent radical cystectomy at a tertiary care hospital between January 2011 and May 2018 was queried (IRB 131252). Patients that underwent cystectomy for non-malignant indications were excluded. Patients were also excluded if they did not undergo urinary diversion (n = 2) or underwent cutaneous ureterostomies (n = 3).

Operative approach was determined by surgeon preference and shared decision making between surgeon and patient. ORC, ECUD, and ICUD approach cystectomy and lymphadenectomy in standard fashion which have been described previously.[19,20] Bricker end-to-side anastomoses were used in all 3 surgical approaches.[21] Intracorporeally, ureters are mobilized distal to the iliac bifurcation and clipped at the uretero-vesical junction. In conduits and continent cutaneous diversions, the left ureter is passed to the right side through a window in the sigmoid mesentery. After creation of the intestinal diversion, ureters are trimmed back to healthy tissue and partially transected such that a segment of ureter that will be excised is the only ureteral tissue handled. The ureters are widely spatulated and anastomosed over ureteral stents to the intestinal segment using 2 running absorbable sutures. Similarly, ORC and ECUD anastomoses were performed predominantly in a running fashion with 2 semi-continuous sutures with 2 surgeons employing a combined running and interrupted approach. Both double-J and single-J ureteral stents were utilized according to surgeon preference. Single-J stents were typically left in place for 1-2 weeks while indwelling double-Js were typically left in place for 1 month. No operative techniques were altered during the study period with the explicit intent of reducing anastomotic complications.

Anastomotic stricture was defined as hydronephrosis with functional imaging to confirm obstruction (ie, loopogram, antegrade nephrostogram, or mercaptoacetyltriglycine [MAG3] renal scan). In addition, patients with progressive loss of renal parenchyma and hydroureteronephrosis without an alternative explanation (silent obstruction with renal unit loss) were classified as having a stricture. Obstructions were classified as malignant if extrinsic compression by a mass was suspected by cross-sectional imaging or if endoscopic or pathologic evaluation confirmed malignancy. Routine biopsies were not performed for all strictures. Malignant obstructions were reported, but were not included in statistical comparisons between surgical approaches.

Continuous variables were reported as median (interquartile range) and were compared with a Kruskal-Wallis test. Categorical variables were reported as *n* (frequency) and compared with Pearson's $\chi 2$ test.

Our primary objective was to compare the incidence of benign UEAS between open, robotic ECUD, and robotic ICUD surgical approaches. Unadjusted comparisons of stricture-free survival were made using the Kaplan-Meier method with differences measured by log-rank analysis. The earliest date an anastomotic stricture was suspected (and later confirmed) was used as the time-to-event variable, while the date of last cross-sectional imaging was used for censoring in patients without UEAS. Multivariable adjusted hazard ratios for UEAS were calculated using Cox proportional hazards regression models.

Our secondary objective was to characterize the effect of surgical experience on the incidence of UEAS in ICUD. Sequential case number in a surgeon's experience was included in a Cox proportional hazards model as a surrogate for learning curve (first case = 1, second case = 2...). All statistical analyses were performed using SPSS (Version 23.0).

RESULTS

Between 2011 and 2018, 973 patients underwent radical cystectomy for bladder cancer. Five patients who were either not diverted or were diverted with a cutaneous ureterostomy were excluded. Ten surgeons performed radical cystectomies during this time period; 1 surgeon performed ORC only, 4 performed both ORC and ECUD, and 5 surgeons performed all 3 approaches during the time period captured. In 2011, when our institution began its experience with ICUD, 4 cystectomies were approached with an ICUD, 51 ECUD, and 63 ORC. By the end of 2014, ICUD accounted for 132 cases, cumulatively, as compared to 141 ECUD and 206 ORC. By the end of 2017, ICUD accounted for 300 cases, cumulatively, compared to 356 ICUD and 269 ORC. Robotic cystectomy with ECUD was the most common surgical approach (n = 382), followed by ICUD (307) and ORC (279). Baseline characteristics were comparable among surgical approaches (Table 1) with the exception of shorter follow-up and less node-positive disease (≥pN1) in the ECUD group and fewer Indiana Pouches in the ICUD group.

Benign UEAS occurred in 109 of 968 patients (11.3%) with a median time to diagnosis of 4.67 months (interquartile range 2.1-11.0). UEAS occurred primarily in the left ureter (50.5%), followed by the right (31.2%) and bilateral ureters (17.4%). One UEAS occurred in a transplanted kidney. Among the 3 surgical approaches, UEAS occurred in 26 patients (9.3%) who underwent ORC, 43 patients (11.3%) who underwent ECUD, and 40 patients (13.0%) who underwent ICUD. By crude chi-squared analysis there was no difference in UEAS incidence between ORC vs ICUD (P = .16), ORC vs EDUC (P = .42), and ECUD vs ICUD (P = .48). Laterality and median time to

Table 1. Baseline characteristics by operative approach

	Open (n = 279)	ECUD (n = 382)	ICUD (n = 307)	*P*
Age, median (IQR)	69.4 (62.2-75.7)	69.7 (63.1-75.3)	68.9 (60.6-75.4)	.76
Sex, n (%)				.08
Female	46 (16.5)	63 (16.5)	69 (22.5)	
Male	233 (83.5)	319 (83.5)	238 (77.5)	
Race, n (%)				
Caucasian	255 (91.4)	354 (92.7)	283 (92.2)	.95
African American	15 (5.4)	16 (4.2)	14 (4.6)	
Other	9 (3.0)	12 (3.1)	10 (3.3)	
BMI, median (IQR)	27.5 (24.8-31.0)	28.1 (25.0-31.7)	27.5 (24.0-30.9)	.14
CCI, median (IQR)	3 (2-4)	3 (2-4)	3 (2-4)	.2
Smoking history, n (%)	201 (72.0)	282 (73.8)	224 (73.0)	.88
Neoadjuvant therapy, n (%)	85 (30.5)	141 (36.9)	110 (35.8)	.14
Diversion type, n (%)				**<.001**
Ileal conduit	210 (75.3)	273 (71.5)	261 (85.0)	
Indiana pouch	27 (9.7)	64 (16.8)	6 (2.0)	
Neobladder	41 (14.7)	44 (11.5)	40 (13.0)	
Colonic conduit	1	1	0	
Pathologic stage (pT), n (%)				.77
NMIBC	154 (55.2)	217 (56.8)	162 (52.8)	
MIBC	40 (14.3)	59 (15.4)	46 (15.0)	
Non-OC (≥pT3)	85 (30.5)	106 (27.7)	99 (32.2)	
Positive ureteral margin, n (%)	18 (6.5)	20 (5.2)	12 (3.9)	.38
Nodal disease, n (%)	70 (25.1)	67 (17.5)	71 (23.1)	**.05**
Pre-op hydronephrosis, n (%)	20 (7.2)	30 (7.9)	26 (8.5)	.84
Follow-up (m), median (IQR)	22.0 (8.2-45.8)	10.6 (3.5-27.8)	18.3 (6.2-40.0)	**<.001**
Lost to follow-up (<3 months) n (%)	34 (12.2)	85 (22.3)	50 (16.3)	**<.01**

BMI, body mass index; CCI, Charlson co-morbidity index; ECUD, robotic cystectomy with extracorporeal urinary diversion; ICUD, robotic cystectomy with intracorporeal urinary diversion; IQR, interquartile range; MIBC, muscle invasive bladder cancer; NMIBC, non-muscle invasive bladder cancer; Non-OC, non-organ confined.
P-values ≤ 0.05 were considered statistically significant.

UEAS were statistically similar among surgical approaches (Table 2).

On log-rank analysis, UEAS was more common after ICUD than ORC (P = .04). No difference in UEAS incidence was observed between ORC and ECUD (P = .21) or ECUD and ICUD (P = .46). Kaplan-Meier curves are shown in supplemental Figure 1. On multivariable adjusted analysis, ICUD was independently associated with UEAS (Hazard Ratio [HR] 1.66, 95% confidence interval 1.00-2.74; P = .05; Table 3). Higher BMI was also independently associated with UEAS (HR 1.29 per 5 kg/m^2; $P < .01$). No other variable correlated with UEAS.

In the ICUD cohort, the highest volume surgeon performed 182 cases, followed by a second surgeon who performed 71, a third who performed 34, and the remaining 2 surgeons who performed <25 cases. Stricture incidence trended down as surgeons gained experience (as measured by case volume) with intracorporeal diversions (Fig. 1). Prior to a surgeon's 75th case, UEAS incidence was 17.5%, after 75 cases the incidence of UEAS declined to 4.9%, though only 1 surgeon in this series performed >75 cases. Higher sequential ICUD case number was independently associated with a reduced risk of UEAS on multivariable analysis (supplemental Table 1; HR per 10 additional cases: 0.90; P = .02). BMI remained independently associated with UEAS in this model (HR 1.47 per 5 kg/m^2; $P < .01$).

Intervention of any kind was required for 97 of 109 patients (89.0%). Chronic percutaneous or trans-stomal drainage was the most common treatment modality, which was employed in 70 (64.2%) patients. Eight patients (7.3%) required temporary drainage only. Twenty patients (18.3%) underwent ureteral

Table 2. Characteristics of benign uretero-enteric anastomotic strictures by operative approach

	Open (n = 279)	ECUD (n = 382)	ICUD (n = 307)	*P*
Stricture Incidence, n (%)				
Benign	26 (9.3)	43 (11.3)	40 (13.0)	.37
Malignant	7 (2.5)	3 (0.8)	5 (1.6)	.21
Time to stricture (m), median (IQR)	4.5 (1.93-17.8)	4.7 (2.1-10.4)	5.1 (2.2-10.4)	.71
Laterality, n (%)				.32
Left	14 (53.8)	19 (44.2)	22 (55.0%)	
Right	9 (34.6)	13 (30.2)	12 (30.0)	
Bilateral	2 (7.7)	11 (25.6)	6 (15.0)	
Other (transplant)	1 (3.8)			
Intervention required, n (%)	24 (92.3)	36 (83.7)	37 (92.5)	.35

ECUD, robotic cystectomy with extracorporeal urinary diversion; ICUD, robotic cystectomy with intracorporeal urinary diversion.

Table 3. Multivariable Cox proportional hazards regression assessing associations between variables and benign uretero-enteric anastomotic stricture

	Adjusted HR (95% CI)	*P*
Age	1.02 (0.99-1.04)	.14
Male gender	1.64 (0.92-2.95)	.10
BMI	1.05 (1.02-1.09)	**<.01**
Any smoking history	0.92 (0.60-1.43)	.72
Charlson co-morbidity index	0.96 (0.86-1.07)	.44
Pre-op hydronephrosis	0.90 (0.39-2.07)	.80
Surgical approach		
Open	(Ref)	.15
Robotic ECUD	1.33 (0.82-2.18)	.25
Robotic ICUD	1.66 (1.00-2.74)	**.05**
Urinary diversion		
Ileal conduit	(Ref)	.36
Indiana pouch	0.71 (0.33-1.55)	.39
Neobladder	0.64 (0.33-1.26)	.20
pT stage		
NMIBC	(Ref)	.85
MIBC	0.93 (0.53-1.64)	.81
Non-OC (≥pT3)	0.87 (0.54-1.40)	.58
Ureteral margin positive	1.13 (0.49-2.59)	.77

P-values ≤ 0.05 were considered statistically significant.
BMI, body mass index; ECUD, robotic cystectomy with extracorporeal urinary diversion; HR, Hazard ratio; ICUD, robotic cystectomy with intracorporeal urinary diversion; MIBC, muscle invasive bladder cancer; NMIBC, non-muscle invasive bladder cancer; Non-OC, non-organ confined.

reimplantation. Of these, 18 were rendered obstruction-free, 1 was aborted due to extensive abdominal adhesions and continued to require chronic drainage, and 1 patient re-strictured following surgery, which was subsequently observed. Ureteral dilation was used in 37 patients, only 4 (10.8%) of which were rendered obstruction-free. The remaining unsuccessful dilations required either chronic drainage or ureteral reimplantation.

DISCUSSION

In this retrospective review of 968 cystectomy patients, robotic cystectomy with ICUD was identified as an independent risk factor for UEAS (HR 1.66; *P* = .05). Despite this finding, the absolute difference in stricture incidence between the 3 operative approaches was relatively narrow (ORC 9.3%, ECUD 11.4%, ICUD 13.0%); similarly, the Kaplan-Meier curves suggest the differences between groups were not pronounced. Early in surgeons' experience with ICUD, UEAS was more common, though the incidence of UEAS declined as surgeons gained experience with the operation.

The etiology of increased UEAS in ICUD is unclear. Factors that have been suggested include compromised vascularity from excessive dissection of the ureters under magnification, increased ureteral manipulation during reconstruction, lack of haptic feedback leading to crush and stretch injury of the ureter, and urine leak following difficult reconstruction.[22] Prior to this study, emerging data hinted at an association between ICUD and UEAS. Ahmed et al reported a retrospective, single-surgeon series that compared 269 ICUD and 138 ECUD cases.[4] Their group identified ICUD as an independent risk factor for UEAS with an overall incidence of 16% in ICUD diversions compared to 6% in the ECUD group. The results of our multi-surgeon study corroborate this surgeon's experience. Randomized data from the ongoing iROC trial (NCT 03049410) will provide further insight on whether ICUD is an independent risk factor for anastomotic stricture formation.[23]

Robotic cystectomy with ECUD has also been examined as a risk factor for UEAS. The only randomized trial in this space, the RAZOR trial, compared robotic ECUD to ORC.[1,15] Strictures occurred in 9% of robotic cases compared to 7% in open, though stricture was not an outcome of interest and comparative statistical analyses were not performed. In a retrospective series comparing 103 robotic ECUD cases and 478 ORC cases, Anderson et al argued that no difference existed between the groups (12.6% vs 8.5%, respectively), though their study may have been underpowered to conclude that no difference existed.[2] In our cohort ECUD was not an independent risk factor for UEAS.

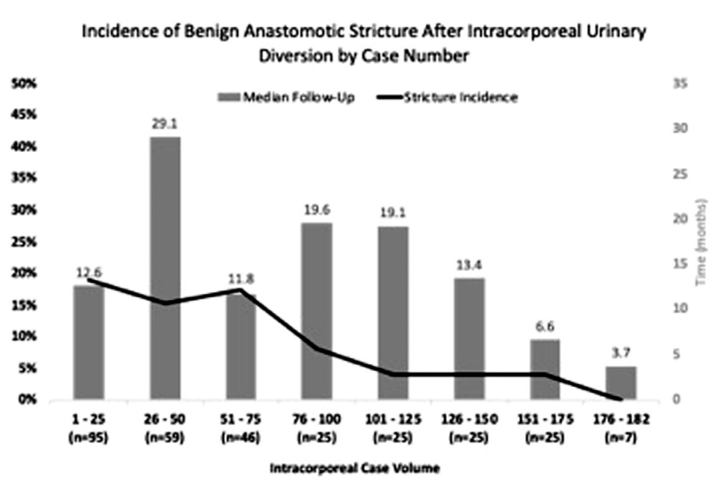

Figure 1. Incidence of benign anastomotic stricture after intracorporeal urinary diversion per 25 cases in surgeons' experience.

The UEAS incidence was consistent with published rates from a randomized cystectomy trial as well as with other high-volume centers' series, ranging from 7.6% to 13%.[1-4] Other high-volume series with ample follow-up report much lower UEAS rates of 2.6%-4.3%.[5-7] The source of this difference is unclear, though variations in diagnostic criteria for UEAS, patient identification methods, and differing patient populations may contribute to differences in published rates. Regardless, the essential principles of gentle tissue handling, preservation of periureteral tissue, adequate ureteral spatulation, and a tension-free, watertight mucosa-to-mucosa anastomosis must be respected to minimize the risk of UEAS.

Prior published learning curve analyses focused on robotic cystectomy with ECUD.[24-27] The International Robotic Surgery Consortium concluded that it takes 20-30 cases to improve operative time, lymph node yield, and positive surgical margin rate.[24,27] To date, no learning curve data as it pertains to stricture formation has been reported. Our data suggest that UEAS incidence may also be affected by surgeon experience. Our learning curve findings must be interpreted within the context of a retrospective series limited to 3 surgeons who performed >25 intracorporeal cases and a single surgeon who has performed >75. Despite these limitations, the decline in incidence of UEAS demonstrated in Figure 1 was notable and increasing case number was associated with a lower risk of UEAS formation in our multivariable analysis.

We found BMI to be strongly associated with UEAS on multivariable analysis. BMI has been identified as a risk factor for UEAS in several large series,[4,6] though the literature is not unanimous on this point.[2] We hypothesize that higher-BMI patients may have thicker, less mobile mesenteries and a longer distance their conduits must traverse for stoma formation, possibly leading to increased stretch and ischemia on the uretero-enteric anastomoses. More work is needed in this area to investigate this phenomenon. Risk factors identified by other groups include ASA class, nodal status, suture technique, Bricker versus Wallace approach, and prior radiation, though the data on each of these variables is heterogeneous and conflicting.[22] Of these risk factors, Charlson co-morbidity index (correlate of ASA) and nodal status were not associated with UEAS in our cohort. Amin et al found a strong association between prior abdominal surgery and UEAS[6]; we did not assess this variable.

Though not the focus of our project, the failure rate of stricture dilation (89.2%) was striking. Other groups have reported much greater success with endourologic management, ranging from 45% and 80%.[5,8-12] The difference in success may be due to surgical approach; the overwhelming majority of patients in our cohort were balloon-dilated by interventional radiology, while the other studies demonstrated success with combinations of endourologic techniques. Ureteral reimplantation rendered 90% of patients obstruction-free, though only a minority of patients underwent definitive reimplantation, possibly reflecting the morbidity of the operation, the competing health and oncologic issues facing bladder cancer patients, or patients' desires to avoid additional major abdominal surgery. Most stricture patients in our series were managed indefinitely with percutaneous or trans-stomal drainage, emphasizing the significant morbidity of anastomotic stricture and the need to reduce the incidence of this burdensome complication.

The retrospective design of our study introduces an inherent selection bias. Though our groups appeared similar, unaccounted for differences in suture technique, stent-type, stent duration, prior pelvic radiotherapy, prior abdominal surgery, urine leak, or urinary infection may affect our conclusions, though the impact of each of these factors is debated and conflicting. As a tertiary center, many patients referred to us from a distance subsequently follow-up with a local urologist, limiting long-term follow-up. External records linked to Epic EHR were reviewed and survival analyses accounting for follow-up time were used to mitigate the impact of this limitation. Furthermore, stricture formation tends to be a late complication, with a small proportion presenting up to 5 years after cystectomy. Our cohort spans 7 years of experience, but our cohort is relatively young with a median of 22 months of follow-up. While including ten surgeons is a strength of our primary endpoint analysis, only 3 surgeons performed more than 25 intracorporeal diversions, severely limiting the generalizability of our learning curve conclusions. Additionally, follow-up beyond case 150 was limited, possibly leading to underestimation of UEAS rates in the most recent cases.

In this large retrospective review, robotic cystectomy with an intracorporeal approach was a risk factor for benign UEAS, with the caveat that stricture incidence appeared to decline to rates similar to alternative approaches with increased surgeon experience.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.urology.2020.06.047.

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