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Original Article

Long-term complications and functionality after continent cutaneous urinary diversion

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ABSTRACT

INTRODUCTION. Data are limited on the functional outcomes of continent cutaneous urinary diversions (CCUD) to guide shared decision-making regarding urinary diversion. The objective of this study was to investigate long-term outcomes for patients who had undergone cystectomy with CCUD construction at a specialised tertiary centre.

METHODS. Data were retrospectively obtained by manual review of 50 medical records of patients who underwent cystectomy with a CCUD from 2010-2023 at a single centre in Denmark. The primary outcome was continence rate, and secondary outcomes included late reinterventions and the associated cumulative risk, late complications and kidney function after cystectomy with a CCUD. Outcomes were presented as the number of patients and the percentage of the patient population, and the median number of days since cystectomy. The cumulative risk of reintervention was calculated as a competing risks analysis.

RESULTS. The median follow-up was 5.7 years (IQR: 2.9-9.7 years). Three-hour continence was reached by 92% of patients at a median of 167 years (IQR: 75-229 days) after surgery. All patients managed clean intermittent catheterisation at a median of 23 days (IQR: 20-33 days) after surgery. A total of 33 patients underwent a reintervention procedure, with an absolute five-year cumulative risk of reintervention of 71% (95% CI: 57-85%).

CONCLUSIONS. Most patients who received a CCUD reached continence within six months of surgery. Two of three patients needed at least one reintervention.

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Radical cystectomy with a urinary diversion is the gold standard treatment for non-metastatic muscle invasive bladder cancer and in some cases high-risk non-muscle invasive bladder cancer [1]. Urinary diversions are also performed for benign indications or for non-urothelial tumours involving the bladder [2]. Patients are often offered a choice between different types of urinary diversions. Therefore, providing accurate information on the functional outcomes of different urinary diversions is crucial in the shared decision-making process. Whereas large studies exist for common diversion types, such as the incontinent ileal conduit and the continent orthotopic neobladder, only limited data exist to guide patients on the expected functional outcomes of continent cutaneous urinary diversion (CCUD). CCUDs are a continent alternative in cases where an orthotopic neobladder is contraindicated, such as tumour involvement of the trigone/bladder neck, the urethra or the prostate [3].

The CCUD is constructed as a low-pressure reservoir with a high capacity, voided by catheterisation through a small cutaneous stoma. Since the first modern CCUD, the Kock pouch, first described in 1969, many modifications have emerged. Currently, the Indiana pouch, which utilises the ascending colon and terminal ileum, is the CCUD performed at our institution [4, 5]. We have previously published short-term complication rates for all patients with bladder cancer undergoing cystectomy at our centre [6]. This study aims to assess the functional outcomes and late complications after the construction of a CCUD at a specialised tertiary centre in Denmark.

Methods

Patients

Patients who received a CCUD were identified from a pre-existing database of all bladder cancer patients having undergone cystectomy at the Copenhagen University Hospital – Rigshospitalet. The study period was defined as January 2010 to December 2023 based on the availability of Electronic Medical Records (EMR). A total of 53 patients were identified. Patients who died before 2017 were excluded due to the unavailability of data after the implementation of a new EMR system in 2017, leaving 46 patients for inclusion. An additional four patients who received a CCUD for other reasons than bladder cancer were identified by procedure codes and were included in the study, totaling 50 patients eligible for analysis.

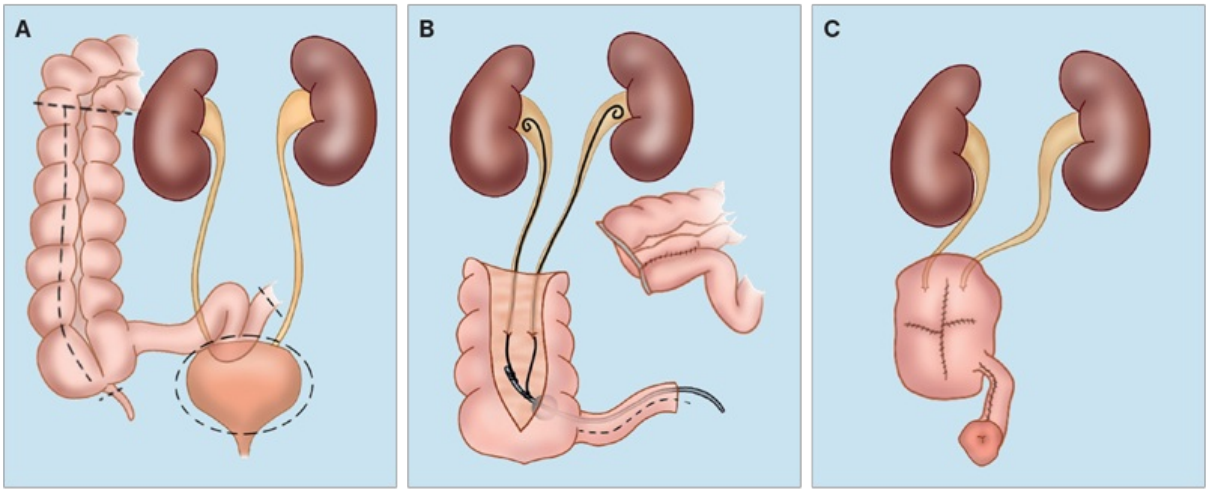
At our institution, CCUDs are performed as an Indiana pouch. To be eligible for the procedure, patients must demonstrate having the mental and physical capacity for clean intermittent catheterisation (CIC), have no pre-existing colonic disease and be suitable for high-risk surgery.

Surgical procedure

Cystectomy with CCUD was performed as open surgery throughout the entire inclusion period by four surgeons using the same surgical technique. All four were trained onco-urologists with comprehensive experience in reconstructive surgery.

An illustration and a thorough description of the Indiana pouch procedure are provided in **Figure 1**.

FIGURE 1 Illustration of the Indiana pouch procedure. **A**. The ascending colon, including a segment of the distal ileum, is mobilised. The middle colic artery is identified by palpation, and the ascending colon is stabled off orally to the artery. The terminal ileum is stabled 10-15 cm from the ileocecal valve. **B**. A hand-sewn side-to-side ileo-transversal anastomosis is performed. The stable lines are removed from the isolated bowel segment, and the appendix is ligated and removed. The isolated colon is detubularised along its antimesenteric border, making sure to preserve the ileocecal valve, and then folded onto itself to form a spherical reservoir. The sides of the pouch are hand sewn using a running suture, including the entire bowel wall, with 2-0 Vicryl. The ileal limb is narrowed over a 6 mm Hegar, using a gastrointestinal anastomosis stapler to remove excess ileum. It is ensured that the Hegar passes freely to the pouch through a straight, narrow segment. No Lembert sutures are used routinely. The ureters are anastomosed on the posterior aspect of the pouch using interrupted PDS 4-0 sutures over JJ catheters, with no anti-reflux mechanism. A 14 Fr catheter is passed through the ileal limb and attached to the JJ catheters so that, by simple removal of the catheter after three weeks, the JJ catheters are simultaneously extracted. The anterior aspect of the pouch is closed with running 2-0 Vicryl, and the pouch is tested with saline to ensure there is no leakage. The ileal segment with the catheter is passed through the abdominal wall and sutured to the skin to make a flush stoma, usually in the right iliac fossa. **C**. The pouch catheter is irrigated twice daily, and patients are discharged with the pouch catheter in situ. At an outpatient appointment three weeks post-operatively, the catheter with attached JJ catheters are removed. The patient then carries out CIC under supervision to ensure correct technique.



Definition of variables

The Charlson Comorbidity Index (CCI) was evaluated without age adjustment. Due to varying indications for undergoing surgery, “localised tumour” was included in the CCI for cancer patients.

Precise data on alcohol consumption was not available. If present, alcohol overconsumption was documented in the EMR and classified according to the recommendations from the Danish health authorities. Before 2022, overconsumption was defined as > 14 units/week for men and > 7 units/week for women. From 2022, overconsumption was defined as > 10 units/week for all.

Late complications were defined as appearing between 90 days after surgery and the last follow-up and were graded according to the Clavien-Dindo Classification [7]. Time to first continence after catheter removal was

defined as the first mention of continence (no reported leakage for a minimum of three consecutive hours, night and day) in the EMR.

Any leakage at six or 12 months was defined as any instance or period where a leak of urine, regardless of quantity, was mentioned in the EMR at six or 12 months.

Patients have a direct number to the department that they may use as needed, and calls are documented. Personal care items for temporary use were supplied by the department and documented in the EMR. In the absence of any record of leakage, patients were presumed to be continent.

Urinary tract infections (UTIs) were defined as symptomatic UTIs requiring treatment. Recurrent UTI was defined as at least two UTIs within six months or three UTIs within one year, in accordance with Danish national guidelines [8].

The preoperative estimated glomerular filtration rate (eGFR) was defined as the last measurement before surgery, and the post-operative eGFR was defined as the latest available measurement. Chronic kidney disease (CKD) stages were defined using the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative guidelines (K/DOQi): G1-G2 was defined as normal to mildly decreased eGFR > 60 ml/min.; G3a-G3b was mildly to severely decreased eGFR of 59-30 ml/min.; G4 was severely decreased eGFR of 15-25 ml/min. [9].

Intervention for cancer recurrence was defined as treatment with chemotherapy, radiation therapy, immunotherapy or cancer surgery.

Outcomes

The primary outcome was the rate of continence after cystectomy with CCUD. The secondary outcomes were the rate and cumulative risk of reinterventions, the rate of other late complications and post-operative kidney function.

Statistics

Categorical variables were presented as numbers and percentages, continuous variables as medians and IQR. Outcomes were presented as numbers and percentages of the population and median (IQR) days since surgery. The cumulative risk of reintervention was calculated using a competing-risks analysis, with death before reintervention as the competing risk. The curve was truncated at ten years because only one patient had follow-up data beyond that point. A sub-analysis of patients operated between 2017 and 2023 was performed to test for the effect of survival bias. The reverse Kaplan-Meier was used for calculating the median follow-up. All analyses were performed in SPSS (version 29) and R (version 2024.04.2).

Trial registration: not relevant.

Results

Table 1 presents patient demographics. The median age at surgery was 59 years (IQR: 51-66 years), with equal numbers for males and females. Twelve patients had prior abdominal surgery (24%). The indications for cystectomy with CCUD were non-metastatic bladder cancer in 46 patients (92%), vesico-vaginal fistula in one patient, interstitial cystitis in one patient, melanoma in one patient and radiation-induced cystitis in one patient.

TABLE 1 Patient characteristics.

	Patients, n (%)	Median (IQR)
Total	50 (100)	
Gender		
Male	25 (50)	
Female	25 (50)	
Age at surgery, yrs		59 (51-66)
Preoperative BMI[a], kg/m²		23 (18-27)
Smoking status		
Never	10 (20)	
Active at surgery or prior use	40 (80)	
Overconsumption of alcohol	8 (16)	
Preoperative CCI		
0-1	1 (2)	
2	26 (52)	
3	16 (32)	
4-6	7 (14)	
Preoperative ASA score		
1	4 (8)	
2	34 (68)	
3	12 (24)	
Preoperative morbidity		
Chronic hypertension	13 (26)	
Diabetes mellitus	5 (10)	
Chemotherapy	12 (24)	
Prior pelvic radiation therapy	3 (6)	
Prior abdominal surgery	12 (24)	
Preoperative eGFR, ml/min./1.73 m²		86 (71-96)
Preoperative CKD stage		
G1-G2: eGFR ≥ 60 ml/min./1.73 m²	45 (90)	
G3a-G3b: eGFR 59-30 ml/min./1.73 m²	5 (10)	
Indication for surgery		
Urothelial cancer, highest pre-cystectomy T stage[b]:		
NMIBC (Ta, Tis, or T1)	24 (52)	
MIBC (≥T2 or Tx)	22 (48)	
Benign or non-urothelial cancer[c]	4 (8)	
Highest post-operative urothelial pT stage[b]		
NMIBC: Ta, Tis, or T1	21 (46)	
T2	15 (33)	
≥ T3 or any N+	10 (22)	
Length of index hospitalisation, days		8 (5-11)

ASA = American Society of Anesthesiologists physical status classification system; CCI = Charlson Comorbidity Index; CKD = chronic kidney disease; eGFR = estimated glomerular filtration rate; MIBC = muscle invasive bladder cancer: ≥ T2 or Tx; NMIBC = non-muscle invasive bladder cancer: Ta, Tis, or T1.
a) Out of 49 patients.
b) Out of 46 patients.
c) Including vesico-vaginal fistula, interstitial cystitis, radiation cystitis or melanoma.

Table 2 outlines the functional outcomes. All patients were able to manage CIC after a median of 23 days (IQR: 20-33 days) after cystectomy. Continence was achieved by 92% of patients at a median of 167 days (IQR: 75-229 days) after cystectomy. The incidence of any leakage was 43% after the first six months and 29% after 12 months.

TABLE 2 Functional outcomes and kidney function.

	Patients, n (%)	Median (IQR)	Time post-operatively, median (IQR[c]), days
Surgical reinterventions			
1st	33 (66)		366 (192-581)
2nd	13 (26)		588 (223-1395)
3rd	6 (12)		844 (323-844)
4th	1 (2)		1,378
1st successful CIC	50 (100)		23 (20-33)
Continence			
Achieved 3 h continence	46 (92)		167 (75-229)
Any incontinence at 6 mos.[a]	20 (43)		-
Any incontinence at 12 mos.[b]	12 (29)		-
eGFR at last follow-up, ml/min./1.73 m^2		82 (57-93)	-
CKD stage at last follow-up			
G1-G2: eGFR ≥ 60 ml/min./1.73 m^2	36 (72)		-
G3a-G3b: eGFR 59-30 ml/min./1.73 m^2	12 (44)		-
G4: eGFR 15-29 ml/min./1.73 m^2	2 (4)		-

CIC = clean intermittent catheterisation; CKD = chronic kidney disease; eGFR = estimated glomerular filtration rate.
a) Out of 47 patients.
b) Out of 42 patients.
c) IQR only presented for variables with ≥ 4 observations.

The preoperative median eGFR was 86 ml/min. (IQR: 71-96 ml/min.), with five patients (10%) in CKD stage G3a-G3b, and with the lowest recorded eGFR being 38 ml/min. At the last post-operative follow-up, the median eGFR was 79 ml/min. (IQR: 57-93 ml/min.), with 14 patients (28%) in CKD stage G3a-G4 and the lowest recorded eGFR being 17 ml/min.

Table 3 shows late complications and reinterventions graded according to the Clavien-Dindo Classification. In total, 38 patients (76%) experienced at least one late complication, of whom nine patients (18% of the total population) had one complication, ten patients (20% of the total population) had two complications and 19 patients (38% of the total population) had three or more complications. The most frequent late complications included treatment of recurrent UTIs at one year (n = 12, 26% of patients with CCUD at one year), diagnosis of incisional hernia (n = 10, 20%), revision of pouch ileal segment (n = 10, 20%) and revision of stomal stenosis (n = 8, 16%).

TABLE 3 Late complications and reinterventions using the Clavien-Dindo Classification. One patient may be registered with multiple complications.

	Patients, n (%)	Time post-operatively, median (IQR[d]), days
Clavien-Dindo 1		
Pouch calculi diagnosis	3 (6)	1,207
Incisional hernia diagnosis	3 (6)	1,157
Parastomal hernia diagnosis	2 (4)	1,191
Upper tract calculi diagnosis	2 (4)	1,031
Fistula to functional bowel	2 (4)	565
Clavien-Dindo 2		
Recurring UTI at 1 yr[a]	12 (26)	-
Recurring UTI at 5 yrs[b]	5 (19)	-
Cancer recurrence intervention[a, c]	7 (15)	296 (183-1,444)
Vitamin B_{12} deficiency	7 (14)	1,078 (359-2,486)
Bicarbonate treatment	1 (2)	1,540
Clavien-Dindo 3a		
Lymphocele	1 (2)	220
Clavien-Dindo 3b		
Revision of ileal segment	10 (20)	366 (136-4,037)
Stomal stenosis	8 (16)	291 (163-549)
Incisional and parastomal hernia intervention	8 (16)	581 (445-771)
Cancer recurrence intervention[a]	7 (15)	611 (374-1,906)
Nephrostomy	4 (8)	237 (104-895)
Bowel obstruction	4 (8)	918 (308-1,342)
Ureteral stenting	4 (8)	307 (159-1,849)
Fistula to functioning bowel	3 (6)	239
Intervention of calculi	2 (4)	354
Ureter-pouch anastomosis stenosis	2 (4)	682
Abscess	2 (4)	844
Removal of pouch	2 (4)	874
Removal of clips	1 (2)	366
Total complications		
0	12 (24)	-
1	9 (18)	-
2	10 (20)	-
≥ 3	19 (38)	-

UTI = urinary tract infection.
a) Out of 46 patients.
b) Out of 27 patients.
c) Including chemo-, radiation-, and immunotherapy.
d) IQR only presented for variables with ≥ 4 observations.

A total of 33 patients (66%) underwent at least one reintervention, with a median time of 366 days (IQR: 192-581 days) after surgery for the first reintervention. Supplementary Figure 1 shows the cumulative incidence curve of the first reintervention. The absolute cumulative risk of reintervention was 33% (95% CI: 19.8-46.3%) at one year, 71% (95% CI: 57.3-85.3%) at five years and 78% (95% CI: 62.4-93.6%) at ten years. The most frequent indications for reintervention were a suboptimal course of the pouch ileal segment and stomal stenosis. Ten patients (20%) had a reintervention of the ileal segment, and eight patients (16%) had a revision of the stoma due to stenosis. Two patients (4%) opted to convert functioning CCUDs to an ileal conduit at 215 and 1,533 days after the primary surgery due to a change in preference.

A sub-analysis of patients operated after 2017 is shown in Supplementary Table 1, demonstrating a similar continence rate and lower complication rates. The analysis included 33 patients, of whom 30 (91%) became continent. The types of late complications were similar to those in the original population.

Discussion

In this retrospective long-term follow-up study of 50 patients who underwent cystectomy with CCUD (Indiana pouch), we identified a continence rate of 92% and a reintervention rate of 66%. Studies on other CCUDs have found similar continence rates in the 80-95% range [10-12].

Two other studies have assessed long-term outcomes in patients after CCUD construction [5, 13]. A 2016 systematic review, including 519 patients, reported late complications and long-term functional outcomes. Individual cohort sizes ranged from 26 to 125 patients, with follow-up from 12 to 56 months [5]. A retrospective study from 2024 reported long-term outcomes of 33 patients who underwent an Indiana pouch with a median follow-up of 21.5 years [13]. Although not all studies included in the systematic review provided continence rates, both papers presented high continence rates (95% and 94%) that are comparable to our findings [5, 13]. The same two papers presented reintervention rates of 6-69% and 67%, which are also comparable to the 66% observed in our study. Likewise, the study showed pouch calculi rates of 10% and 18%, which are comparable to the 10% observed in our population. Our finding of 4% ureteral anastomosis strictures was low compared with the 3-27% reported in the two other papers [5, 13].

Complications after CCUD have been reported to be higher than for the ileal conduit and orthotopic neobladder. Among 32 articles included in a meta-analysis of patients receiving a urinary diversion, 21 studies covering 33,742 patients reported long-term post-operative complication rates of 62% for patients receiving an ileal conduit and 60% for patients receiving an orthotopic neobladder [14].

In previous studies, the incidence of incontinence for patients who had previous pelvic radiation therapy was high (approximately 25%). This highlights the need for careful preoperative counselling [5, 15, 16]. Only three patients in our cohort had received radiation to the pelvic area before surgery.

In the present study, stone formation was identified in 4% of patients in the upper urinary tract and 10% in the CCUD, whereas previous reports have documented rates of up to 30% [17-19]. A possible explanation is the use of resorbable sutures rather than staples during pouch construction. Two prevalent late complications were related to the efferent limb: stenosis at the skin stoma in the ileal segment itself. Stomal stenosis is reported in 16-38% of cases in the literature, whereas our observed incidence was in the lower end of this range [16, 19]. Revision of the pouch's ileal segment was reported to occur in as many as 47% of cases in other studies, which is notably higher than the 20% observed in the present study [13, 17].

Among the patients in this study, 18% transitioned from G1-G2 preoperatively to G3a-G4 categories after surgery. Recently, a larger study conducted at our institute investigated the decline in renal function after radical cystectomy with all types of urinary diversions offered at our institute [20]. The study found that the hazard ratio for developing renal insufficiency was 2.4% (95% CI: 1.4-3.9%, $p < 0.001$) for continent diversion types (orthotopic neobladder and CCUD) compared with the ileal conduit [20].

We found a higher overall rate of late complications than in other cohorts. This might be explained by the completeness of data in the Danish EMR or the fact that we included complications that did not require surgical intervention, such as UTIs, contrary to other studies. Conversely, some of the most common late complications were less prevalent in our cohort than in other studies.

This study does not address short-term complications, as these were previously published from an overlapping

database [6]. The study included 729 patients with bladder cancer who had undergone cystectomy with any type of urinary diversion and found no significant difference in the rate of major complications between diversion types within 90 days. Comorbidity, age, and tumour stage are generally lower in patients who receive CCUD, possibly masking an actual higher complication rate. At our institution, patients are counselled that the choice of diversion may increase diversion-related complications.

Limitations

This cohort was treated at a single centre where only selected patients meeting the defined criteria were offered a CCUD, resulting in a selected, small population of relatively healthy individuals. Another limitation was the lack of a prospectively applied standardised definition of leakage and alcohol overconsumption throughout the study period. Generalisability to a wider population may therefore be limited. As inherent to retrospective designs, this study encountered selection and survivorship bias attributable to the inability to include cases where the patient died before 2017. To investigate bias, a sub-analysis was performed, showing similar rates of continence and a lower rate of complications after 2017. This is likely due to the shorter length of follow-up compared with the 2010-2023 population.

Conclusions

In this study, we found that CCUD offered to selected patients produced high rates of three-hour continence and CIC success. Two in every three patients needed at least one intervention within the follow-up period, and one in five patients transitioned from normal kidney function to renal insufficiency. This study adds to information on the benefits and risks of CCUD and may aid physicians and patients in the shared decision-making process when discussing different urinary diversion options.

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