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Outcomes of Right Colon Continent Urinary Pouch Using Standardized Reporting Methods

Jeremy B. Myers, MD^{*}, Christopher Martin, MD^{*}, Philip J. Cheng, MD^{*}, Chong Zhang, MS[#], Angela P. Presson, PhD, MS[#], and James M. Hotelling, MD, MS^{*}

^{*} University of Utah Department of Surgery (Division of Urology), Salt Lake City, UT, USA

[#] University of Utah Department of Internal Medicine (Division of Epidemiology and Biostatistics), Salt Lake City, UT, USA

Abstract

Aims—Studies of right colon pouch urinary diversion estimate risk of perioperative complications, 1–50%, and reoperation, 1–69%. This wide range is due to variable outcome measurements and reporting methods; it is also unclear which factors increase risk of complications and reoperation. We sought to characterize the impact of patient specific factors on risk of complications, readmission, and reoperation after right colon pouch urinary diversion.

Methods—Patients undergoing right colon pouch urinary diversion from January 2010 to April 2017 were analyzed. Outcomes included: high-grade complications within 90 days (Clavien-Dindo grade 3), readmission within 90 days, and reoperation at any time during follow-up. Patient specific factors were analyzed to establish any associations with these outcomes.

Results—During the study period 53 patients underwent the procedure; average follow-up was 30 (SD 21.5) months. Ninety-day high-grade complications were 22% and 90-day readmission was 45%. The cumulative rate of any reoperation was 53% and major reoperation was 32%. Diabetes was associated with increased risk of both post-operative complications and reoperation. Larger body mass index and prior abdominal surgery were associated with increased risk of readmission.

Conclusions—Overall the rate of post-operative complications, readmissions, and reoperation was high, but in agreement with other contemporary series. This study helps to further characterize

Correspondence: Jeremy B. Myers, MD, FACS, University of Utah, Department of Surgery (Urology), 30 N 1900 E, RM 3B420, Salt Lake City, UT 84132 Phone: 802-213-2700, jeremy.myers@hsc.utah.edu, twitter: @jeremybmyers.

All work was performed within the University of Utah

Author Contributions:

1. Conception and design: Jeremy Myers
2. Administrative support: Jeremy Myers
3. Provision of study material or patients: Jeremy Myers
4. Collection and assembly of data: Christopher Martin
5. Data analysis and interpretation: Angela Presson, Chong Zhang, Christopher Martin
6. Manuscript writing: All authors
7. Final approval of manuscript: All authors

surgical outcomes after right colon pouch urinary diversion, however; similar to other studies in the literature, the rarity of the procedure limits the power to establish a link between pre-operative patient factors and outcomes.

Keywords

urinary diversion; right colon pouch; radiation; bladder cancer; Indiana pouch

Introduction

Urinary diversion has a high rate of potential complications.¹ A right colon pouch urinary diversion relies upon de-tubularization of the cecum and ascending colon to create a spherical low-pressure reservoir or pouch.² A continent cutaneous catheterizable channel is also created, most often utilizing a segment of terminal ileum or appendix, which a patient catheterizes as the 'efferent channel' to empty the pouch. This procedure is highly complex and has been suggested to have a higher rate of complications compared to ileal conduit.³ However, a Cochrane systematic analysis of urinary diversion did not find any differences in complications between different types of diversions; although this may be due to the heterogenous nature of the literature and low quality of evidence, rather than a true negative finding.⁴

Overall the published series on right colon pouch urinary diversion have shown highly discrepant complication rates.^{3,5-7} Some of this variability is because of lack of any standard inter-study objective outcome measurements. For instance, some studies have reported long-term clinical outcomes, such as rates of urinary tract infections, urinary leakage, or difficulty catheterizing, however; these complications have low inter-study reproducibility due to heterogenous definitions.⁷ Additionally, many of these studies have patients with differing operative indications; for example including patients with neurogenic, oncologic, and radiation related indications for surgery. Due to these reasons, it is unclear which factors, such as prior pelvic radiation or pelvic malignancy, are predisposing factors for complications in these studies.

Another limitation in the literature is the infrequency of right colon pouch urinary diversion.⁸ This results in studies with low statistical power, making risk stratification based on patient-specific factors difficult. As such, it can be difficult to make clinical decisions or counsel patients based on the limited and variable data available. An important and accurately identified metric for comparing outcomes between studies and between diversion procedures is the Clavien-Dindo (Clavien) complication rate in the 90-day post-operative period.^{9,10} Another easy to quantify measurement is the rate of 90-day readmission to the hospital in the same post-operative period. A final very important metric to patients and surgeons is the short and long-term risk of reoperation related to the urinary diversion. An additional operation can be necessary due to treatment of peri-operative complications, such as a wound infection or pelvic abscess, or long-term problems such as operative management of stones, ureteral stenosis, parastomal hernia, or revision of a component of the urinary diversion.

To improve inter-study comparisons, both between continent catheterizable pouches and urinary diversions in general, studies need to present outcomes systematically and consistently. We present our outcomes with right colon pouch using 90-day Clavien complications, risk of readmission, and cumulative risk of reoperation. We also intend to identify patient factors and surgical indications that are associated with complications and reoperation. We hypothesize patients undergoing right colon pouch because of radiation injury will have an increased risk of complications, readmission, and reoperation compared to other etiologies.

Materials and Methods

Study Design

Our study analyzed patients undergoing right colon pouch urinary diversion from January 2010 to April 2017. IRB approval for the study was obtained. Patients were identified using a prospective database for patients undergoing urinary diversion. A Retrospective chart review was used to further characterize preoperative variables of interest, post-operative complications within 90 days, readmission within 90 days, and reoperation in the short or long-term.

Outcomes

There were three outcomes of interest, which included (1) *major complications* in the 90-day postoperative period, (2) *readmission* rate during the 90-day postoperative period, and (3) rate of *reoperation* at any time period. Complications were classified using the modified Clavien grading system.^{9,10} Sepsis was defined using the 1992 CHEST guidelines.¹¹ Major complications were defined as Clavien grade 3. Reoperation included any procedure performed under general anesthesia in the postoperative period and was categorized into any reoperation and major reoperation. Major reoperation was classified as abdominal cavitory surgery after the urinary diversion surgery and examples included: ureteral reimplant, pouch revision, below the fascia catheterizable channel revision, bowel related complications (stenosis, fistula, obstruction requiring exploration), and ventral or parastomal hernia repair.

Variables

We compared pre-operative variables between groups that did or did not experience any of the three outcomes of interest. These preoperative factors included age, gender, body mass index kg/m² (BMI), Charlson Comorbidity Index (CCI), history of diabetes mellitus, prior abdominal surgery, and etiology. Etiology, for comparison of outcomes, was classified as radiation injury versus all other etiologies.

Inclusion / Exclusion criteria

We included adult patients (age > 18 years). Patients who were converted to a right colon pouch from a variety of other urinary diversions such as a Koch Pouch or ileal conduit were excluded. We also excluded anyone that had creation of alternative continent catheterizable pouch such as those constructed from small bowel exclusively (i.e. Skinner T-pouch or a Ghoneim pouch).

Surgical Technique

One surgeon performed all of the right colon pouch urinary diversions (JBM). The well-described techniques for the creation of right colon pouch was utilized.¹² The technique relies upon staple reduction of the terminal ileum, reinforcement of the ileo-cecal valve, and detubularization of the colon. The technique mostly resembles the “Indiana” pouch with minor variations.

Statistical Analysis

Possible pre-operative risk factors associated with the outcomes of interest were analyzed using T-test, chi square, Exact Wilcox, or Fishers statistical analysis testing. Statistical tests varied based on the characteristics of the clinical data point. For example, continuous variables were compared using mean (SD). Multinomial variables were evaluated with the Chi-square test and considered significant at the p values <0.05. Statistical significance was consistently considered at the 0.05 level and all tests were two-tailed. To identify factors associated with any reoperation, as well as major reoperation, a Univariable Fine-Gray competing risk regression model was created using reoperation and death as competing risks. A Kaplan Meier curve was used to summarize the rate of death or any reoperation risk, as well as death or major reoperation risk over time.

Results

There were 63 patients who underwent right colon pouch creation within the study period. Fifty three patients met the study criteria; 10 patients were excluded due to prior urinary diversion (9) and age < 18 years (1). Table 1 summarizes the patient characteristics. The average age was 55.2 (SD 12.2) years, with an average follow up of 30 (SD 21.5) months. Urinary diversion was done for radiation in 17 (32%). At the time of analysis 38 (72%) patients were still alive. The reasons for death included: medical causes / suicide / not determined (10), cancer recurrence (4), and in the peri-operative period (Clavien grade 5 complication) (1). Two patients, who are still alive are not using the pouch, due to psychosocial issues in one and removal of the pouch due to pouch necrosis at 6 weeks postoperatively in another.

Outcomes

Table 2 includes a summary of patients’ postoperative outcomes.

Major Complications—Overall 73% of patients had a complication of any grade. Clavien grade 3 complications occurred in 22% of patients in the 90-day time period. Patients with a complication, experienced a mean of 1.7 complications. There was an 8% rate of wound infection and a 17% rate of sepsis. The only significant associations between preoperative variables and risk of major complications (Clavien grade 3) was a history of diabetes (36.4 % versus 9.5%, p=0.048).

Readmission—The 90-day readmission rate for patients was 45%. There was an increased risk of readmission associated with higher BMI (mean 30.7 versus 25.9, p=0.012) and prior abdominal surgery (83.3% versus 55.2%, p=0.029) (Table 3).

Reoperation—The cumulative rate of any reoperation or procedure under general anesthesia, over the study time period, was 53%. Major reoperation occurred in 32% of patients. The mean time to the first reoperation / procedure was 15.1 (SD 15) months and the time to major reoperation was and 20 (SD 17.1) months. Patients that had a reoperation over the study period, required a mean of 1.9 operations. Diabetes was associated with a hazards ratio of 2.5 (1.01–6.26, $p=0.048$) for major reoperation (Table 4).

Kaplan Meier plot revealed that 38 (72%) patients died or had any reoperation at 72 months and 28 (53%) of patients died or had major reoperation at 72 months.

Discussion

Our study found that postoperative complications, readmission, and risk of reoperation are high for patients undergoing right colon pouch urinary diversion. Any reoperation occurs in 53% and major reoperations in 32%. Several patient factors increased risk of these outcomes including: diabetes, BMI, and prior abdominal surgery.

In our study, we did not establish an association between radiation injury and increased complications. In contrast to our findings, some previous studies have shown that prior radiation is a risk factor for complications after other types of urinary diversion.^{13,14} However, similar to our study results, in right colon pouch specifically, the difference in overall risk of complications was not significant with radiation.¹⁴ In right colon pouches, radiation only increased certain complications, such as the need for percutaneous nephrostomy or ureteral reimplantation. This association makes sense since pelvic radiation potentially damages the quality of the distal ureteral supply and thereby may increase the rates of ureteral complications. For instance, in men undergoing urinary diversion, after prostate cancer radiotherapy we did indeed find a high rate of ureteral stenosis (12%) than reported in the literature in urinary diversion.¹⁵ The literature on the impact of radiation therapy on urinary diversion outcome is mixed, however; and other studies, involving a high proportion of patients with preoperative radiation, have reported equivalent complications compared to other contemporary cohorts.^{14,16,17} It is obvious to any pelvic surgeon that the complexity of patients with radiation injury is very high. It may be, in our study with such a small cohort of patients, that we lacked sufficient power to show an association between radiation injury and complications or that surgical maneuvers were used, such as omental and rotational muscle flaps which modified those patients' risk to approximate that of non-radiated patients.

Older age, also has been previously identified as a risk factor for complications after urinary diversion, however, it was not identified as a risk factor in our study.¹⁸ If age is a risk factor for complications or reoperation we may have failed to identify this risk due to selection bias. In order for older patients to undergo right colon pouch urinary diversion, they would need to present with excellent functional status, otherwise they would be counseled to undergo a simpler surgery, such as an ileal conduit.

Previous studies have clearly illustrated that significant potential complications can arise after right colon pouch urinary diversion.⁷ However, many of these studies did not report

complications and outcomes in a consistent manner, which makes both inter-study and inter-procedure comparison difficult. For example, Webster et al. only reported anatomic and metabolic complications, but failed to include infections, interventions, and reoperations.¹⁹ Comparatively, some studies such as Wiesner et al. focused their efforts on specific issues such as continence, stenosis, and stricture rates rather than overall complications.⁷ Likewise Holmes et al. reported prospective rates of difficulty catheterizing using their own measurement system.²⁰ While Holmes et al. should be praised in their efforts to characterize such an important aspect of patients' lives, catheterization difficulties are complex issues and their measurement system was neither validated nor made available with their manuscript.²⁰ Two recent studies by Bazargani and Liedberg have been undertaken with more standard reporting methods.^{6,21} Both of these studies focused on 90-day complication rates and risk of repeated procedure. However, the rates between the studies were quite dissimilar. Bazargani et al found a 64% complication rate with 14% of patients requiring a repeat procedure for those receiving right colon pouches.⁶ Comparatively, Liedberg found a 23% 90-day complication rate, but the rate of reoperation (54%) was much higher, likely due to their longer length of follow up.²¹ Additionally, Liedberg et al. found that patients receiving their diversion for benign reasons were more likely to have a complication than those undergoing treatment for oncologic reasons. We did not analyze this subset of patients. In our series, we also reported surgical complications, such as hernia repair and lysis of adhesions for bowel obstruction. While these may not be perceived as specific to the right colon pouch urinary diversion, a patient would rarely differentiate them as unrelated to the surgery to create the urinary diversion. We feel it is important to report the overall surgical burden to patients after urinary diversion rather than just those that involve the pouch directly.

In order to improve urologists' ability to counsel patients, consistency in reporting outcomes and complications should be encouraged. Given the small sample size and heterogeneous indications for urinary diversion, multi-institutional cohorts and more detailed outcome reporting methods are necessary to improve the characterization of patient outcomes. The Clavien classification system,²² which is the most common system used to grade post-operative complications, uses a 1–5 scale. The Clavien system, however; does not assess the cumulative burden of complications when multiple complications occur in one patient. Patients who experience multiple complications are graded by the highest complication they experience. For instance, a patient that has a bout of sepsis and goes to the intensive care unit (Clavien grade 4) and quickly recovers is considered to have had a worse complication than a patient with a bowel leak that has to have multiple percutaneous drainage procedures and ultimately undergoes a bowel resection with fistula closure after 6 months (Clavien grade 3b). Most surgeons would consider the latter patient to have had a much worse burden of complications. Recently the Comprehensive Complication Index, which uses a continuous scale from 1–100, has been validated. This scale weights complications based upon their severity and the total score is a sum of all the weighted complications a patient experiences.²³ Multiple recent trials have suggested this may be more sensitive than traditional measurements of complications in predicting outcomes, and this index may be a useful tool to utilize in complex patients, such as those undergoing urinary diversion in the future.²⁴ In our study, we did not attempt to use the Comprehensive Complications Index because

capturing all of the low-grade complications that would be used to calculate the score would require a prospective study design.

Our retrospective study has important limitations. The cohort size, though large for this relatively uncommon procedure, was almost certainly underpowered to identify risk factors for complications. The study is also limited by its retrospective nature. Many complications may not have been captured during chart review or if they occurred at outside hospitals. This is why we did not attempt to use the Comprehensive Complications Index. Another limitation is the lack of quality of life data. Characterization of complications and associated risk, while important in shared decision making, pales in comparison to the importance of patient-reported function and satisfaction. Studying prospective patient-reported function and satisfaction is an important effort of our research group (the Neurogenic Bladder Research Group, NBRG.org) in patients with radiation injury and neurogenic patients undergoing bladder reconstructive surgery.

Conclusions

There is a high rate of complications, readmissions, and reoperation after right colon pouch urinary diversion. The overall reoperation rate was about 50% after right colon pouch urinary diversion. Several patient factors increased the risk of complications, readmission, and reoperation. Overall, our study helps to further characterize the risks associated with this procedure but did not identify significant differences in risk associated with radiotherapy. This study highlights a knowledge gap about urinary diversion complications which would best be addressed with a multi-institutional prospective studies. Future studies should also combine a more comprehensive analysis of complications with quality of life measures before and after surgery. Prospective studies analyzing patient reported outcome measures after urinary diversion are currently underway with our research group, the Neurogenic Bladder Research Group.

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Figure 1:
 Kalpan Meier plot showing time to (a) any reoperation or (b) major re-operation; death is competing risk

Table 1:

Characteristics of 53 patients undergoing right colon pouch urinary diversion

Pre-op Variables	N=53
Age-mean (SD)	55.2 (12.2)
<u>Gender</u>	
Female	29 (55%)
Male	24 (45%)
BMI-mean (SD)	28.2 (8.6)
Diabetes	8 (15%)
Charlson Comorbidity Score-mean (SD)	4.2 (2.3)
Prior abdominal surgery	36 (68%)
<u>Etiology</u>	
XRT injury	17 (32%)
Cancer	16 (30%)
Neurogenic bladder	11 (21%)
IC / Other	9 (17%)
Pre-op creatinine ng/dl-mean (SD)	1 (0.8)
Operative Characteristics	
OP time (hours)-mean (SD)	8.5 (1.6)
EBL(ml)-mean (SD)	500 (400)
LOS (days)-mean (SD)	9.9 (4)

SD (standard deviation), BMI (body mass index kg/m^2), XRT (radiation), IC (interstitial cystitis), OP (operative), EBL (estimated blood loss), LOS (length of stay). Missing variables – BMI (2), Pre-op creatinine (4).

Table 2:

Outcomes in 53 patients undergoing right colon pouch urinary diversion

Outcomes	N=53
Postop complications (within 90 days)*	
Minor complications (1&2)	27 (51%)
Major complications (3–5)	11 (22%)
3a	4 (8%)
3b	4 (8%)
4	2 (4%)
5	1 (2%)
Complications per patient – mean (SD) [#]	1.7 (1.3)
Readmission (within 90 days)	24 (45%)
Reoperation	
Any reoperation	28 (53%)
Major reoperation	17 (32%)
Reoperations per patient – mean (SD) [#]	1.9 (1.3)
Minor reoperations	
Stomal revision	11 (21%)
Endoscopic stone surgery	4 (8%)
Upper tract	3
Pouch	1
Endoscopic treatment incontinence	2 (4%)
Major reoperations	
Ureter (total)	5 (9%)
Bilateral re-implant	2
Unilateral re-implant	2
Nephrectomy for ureteral stenosis	1
Catheterizable channel revision (total)	5 (9%)
Obstruction	4
Incontinence	1
Bowel (total)	4 (8%)
Obstruction	2
Fistula / perforation	2
Hernia repair (parastomal)	3 (6%)
Deep wound drainage	3 (6%)
Pouch removal	1 (2%)

Standard deviation (SD)

* Complications defined by Clavien-Dindo grades: 3a (intervention not requiring general anesthesia), 3b (intervention under general anesthesia), 4 (life-threatening complications requiring ICU management), 5 (death).

[#] number of complication or reoperations per patient in patients that had complications or reoperations, reoperation was at any time during the follow up period, Major reoperations defined as entry into the abdominal cavity.

Table 3:

Comparison of patients experiencing major complications and readmission within 90 days of surgery

Variables	Total (n=53)	Clavien 3 (n=11)	Clavien < 3 (n=42)	P-value	Readmit	No Readmit	P-value
Age-mean (SD)	55.2 (12.2)	54.9 (11)	55.3 (12.6)	0.92	54.5 (12.1)	55.8 (12.4)	0.69
Gender-female	29 (55%)	8 (72.7%)	21 (50%)	0.31	12 (50%)	17 (58.6%)	0.53
BMI-mean (SD)	28.2 (8.6)	30.9 (11.9)	27.4 (7.5)	0.49	30.7 (9.5)	25.9 (7.1)	0.012
Diabetes	8 (15%)	4 (36.4%)	4 (9.5%)	0.048	2 (8.3%)	6 (20.7%)	0.27
Charlson Comorbidity Score-mean (SD)	4.2 (2.3)	4 (2)	4.2 (2.4)	0.74	3.9 (2.3)	4.4 (2.4)	0.38
Prior abdominal surgery	36 (68%)	9 (81.8%)	27 (64.3%)	0.47	20 (83.3%)	16 (55.2%)	0.029
<u>Etiology</u>							
XRT injury	17 (32%)	2 (18.2%)	15 (35.7%)	0.47	5 (20.8%)	12 (41.4%)	0.11
Pre-op creatinine ng/dl-mean (SD)	1 (0.8)	0.8 (0.4)	1 (0.8)	0.38	0.8 (0.3)	1.1 (1)	0.55

SD (standard deviation), BMI (body mass index kg/m²), XRT (radiation). Missing variables – BMI (2), Pre-op creatinine (4).

Table 4:

Hazard ratio of any and major reoperation

Variables	HR Any Reoperation (n=28)	P-value	HR Major Reoperation (n=17)	P-value
Age (1 year increase)	1.01(0.99~1.04)	0.34	1.01(0.97~1.05)	0.64
Gender-female	0.96(0.46~2.03)	0.92	0.89(0.35~2.27)	0.81
BMI (1 unit increase)	0.98 (0.94,1.03)	0.43	1.00 (0.94,1.05)	0.91
Diabetes	1.18(0.49~2.87)	0.71	2.51(1.01~6.26)	0.048
Charlson Comorbidity Score-mean (1 unit increase)	0.99(0.88~1.12)	0.86	0.98(0.82~1.17)	0.83
Prior abdominal surgery			0.91(0.35~2.40)	0.85
<u>Etiology</u>				
XRT injury	1.63(0.74~3.58)	0.22	2.18(0.82~5.78)	0.12
Pre-op creatinine ng/dl (1 unit increase)	0.75(0.45~1.25)	0.27	0.74(0.37~1.47)	0.39

HR (hazard ratio), BMI (body mass index kg/m²), XRT (radiation)