

Evolution toward early stent removal and reduced antibiotic prophylaxis post-cystectomy

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WENZEL JL, CHOU WH, ROBINSON EJ, BASALE S, JONES P, ISHARWAL S, AMLING CL, SAJADI KP, LIU J-J. Evolution toward early stent removal and reduced antibiotic prophylaxis post-cystectomy. *Can J Urol* 2026;33(3):649–656.

Background: The ideal duration of ureteral stents in cystectomy is unknown, with trends toward earlier removal or foregoing them altogether. To reduce the duration of indwelling stents and antibiotics, we modified the cystectomy pathway at our institution from ~2 weeks of stenting with 30 days of antibiotic prophylaxis to stent removal before discharge with prophylaxis ending one day after stent removal. We evaluated rates of urinary tract infection (UTI) and urine leak in cystectomy patients after these changes.

Methods: We performed a retrospective review of patients undergoing cystectomy with ileal conduit diversion at our institution from 2016–2022. Patients were stratified into early vs. late stent removal (postoperative

day [POD] ≤ 5 or > 5). Primary outcomes were the 30-day rate of UTI (positive urine culture with symptoms requiring antibiotics) and urine leak (postoperative drain creatinine measurement $\geq 2 \times$ serum creatinine).

Results: Of 228 patients, 19% had early stent removal. Mean stent removal was POD 4 vs. 18 days in the early vs. late group. The early stent removal group had shorter antibiotic exposure (8.2 vs. 21.9 days, $p < 0.001$). No differences between the early vs. late stent removal groups were seen for postoperative UTI (9.3 vs. 10.8%, $p = 0.77$), urine leak (2.3% vs. 2.2%, $p = 0.96$), or readmission rates (9.3 vs. 11.4%, $p = 0.69$). No difference in the rate of hydronephrosis on postoperative imaging was noted between the two groups.

Conclusions: Iterative decreases in ureteral stent duration as part of a quality improvement initiative enabled reduced postoperative antibiotic exposure without increasing adverse outcomes, including UTI, urine leak, or postoperative hydronephrosis.

Key Words: radical cystectomy, stents, antibiotics, urinary tract infections, *Clostridioides difficile*

Introduction

Ureteral stenting has been a mainstay after urinary diversion by enhancing drainage of the kidney and

preventing urine leaks and associated morbidity.^{1,2} However, recent studies have found associations between stenting and increased rates of urinary infections and ureteroenteric stricture.³ The optimal duration of ureteral stents is an area of active research, with recent trends towards earlier stent removal or forgoing stenting altogether. That said, with evolving robotic techniques for urinary diversion and variable surgeon comfort level, practice patterns for stenting and antibiotic duration vary.

Received date 31 July 2025

Accepted for publication 09 October 2025

Published online 26 June 2026

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Infectious complications, particularly UTIs, are a significant contributor to morbidity following radical cystectomy.⁴ Indwelling ureteral stents can increase the risk of urinary tract infection (UTI) after radical cystectomy, particularly around the time of stent removal.^{5,6} Extended antibiotic prophylaxis following cystectomy has shown conflicting results with regards to reduction in the rates of UTI and urosepsis compared to perioperative antibiotic prophylaxis only.⁷⁻⁹ However, prolonged antibiotic exposure has its own morbidity, including, but not limited to increased antibiotic resistance and risk of *Clostridioides difficile* infection (CDI). At present, there is no consensus among the urological community regarding the utilization of ureteral stents, or the optimal duration of stenting when used after urinary diversion. Furthermore, the utilization and duration of antibiotic prophylaxis to prevent infections while stents are in place after urinary diversion is highly variable. While the American Urological Association recommends a single dose of antibiotic prophylaxis at the time of radical cystectomy only,¹⁰ the European Association of Urology does not provide specific recommendations for these scenarios and leaves it to the discretion of the surgeon.¹¹ Despite the AUA guidelines, studies demonstrate variable practice patterns in the utilization of antibiotic prophylaxis.^{6,12}

Various efforts to decrease the overall morbidity of radical cystectomy have emerged, including the development of Enhanced Recovery After Surgery (ERAS) pathways and utilization of robotic-assisted approaches.^{13,14} Our institution utilizes a standardized ERAS pathway for our cystectomy patients. Changes to this standardized protocol are uniformly implemented for patients undergoing radical cystectomy, and outcomes are routinely monitored and drive iterative changes as part of ongoing quality improvement (QI). Previously, we standardized our postoperative cystectomy protocol, which consisted of a ureteral stent duration of at least 14 days with antibiotic prophylaxis of 30 days due to observed high rates of postoperative UTI. This extended course of prophylaxis decreased rates of UTI compared to patients who received no prophylaxis or single dose prophylaxis at the time of stent removal only without an increase in CDIs.¹⁵

Because of the potential downsides to prolonged ureteral stenting and antibiotic exposure, we embarked on an iterative quality improvement project to reduce both variables in a multiple phase approach. Our objective was to assess the rate of UTI and urine leak in patients undergoing cystectomy and ileal conduit diversion after these protocol changes.

Methods

Study design

This was a retrospective single-center cohort study of patients undergoing cystectomy with ileal conduit diversion at Oregon Health and Science University (OHSU) from 2016–2022. Following approval from the Oregon Health & Science University's Institutional Review Board (OHSU IRB00006712), patient data were initially collected using National Surgical Quality Improvement (NSQIP) data; additional variables were then manually extracted through the electronic medical record.

All surgeries were performed robotically with either intracorporeal or extracorporeal diversion by four surgeons. Ureteral stents used were 7 Fr in diameter. At our institution, the postoperative protocol went through multiple iterations as a part of various QI initiatives (Figure 1), aiming to decrease antibiotic usage while maintaining appropriate prophylaxis for UTI. In phase 0, prophylactic antibiotics were continued uniformly for 30 days; ureteral stents remained in place until outpatient follow-up around postoperative day (POD) 14–21. In phase I, stents were still removed at outpatient follow-up around POD 14–21, with antibiotics continued until two days after stent removal. In phase II, stents were removed before patients were discharged from the hospital, and antibiotics were continued until the day after stent removal. The decision to implement the changes of phase I occurred in February 2019, and then in January 2020 for phase II.

Antibiotics protocol

Preoperatively, all patients received a single dose of cefoxitin or ampicillin-sulbactam. On POD 1, all patients were started on prophylactic trimethoprim-sulfamethoxazole. If there was an allergy or contraindication, second-line antibiotics given

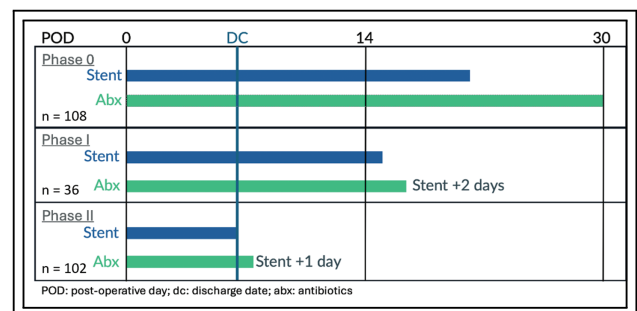


FIGURE 1. Progression in practice patterns for stent removal and antibiotic prophylaxis

included nitrofurantoin, cephalexin, or ciprofloxacin. Urine cultures were collected from the ureteral stents on POD 3. Antibiotics were changed to a culture-driven treatment dose and duration if $>100,000$ colony-forming units (CFUs) of a dominant bacterium were present.

Cohort definition

After data collection, patients were stratified into early or late stent removal. POD 5 was chosen as the cutoff time, as this was our median length of stay (LOS) for cystectomy patients. In addition, within our postoperative cystectomy pathway, this typically represents the most common postoperative day on which a patient was discharged. Therefore, patients who had stents removed on $\text{POD} \leq 5$ were included in the early removal group; those who were removed after POD 5 were included in the late removal group.

Outcome measures and data collection

The primary outcomes were the incidence of UTI (within POD 30) and urine leak. UTI was defined as a positive urine culture with signs (i.e., fever, hypotension, tachycardia, and/or leukocytosis) and symptoms (subjective fevers and chills, nausea/vomiting, and/or flank pain) without another obvious infectious etiology that was treated with antibiotics. Urine leak was defined as a postoperative drain creatinine measurement at least twice the serum creatinine value. An additional subset of patients in the early stent removal group had drain creatinine levels checked at two points: immediately before stent removal, and then within 24 h following stent removal, just prior to drain removal.

Additional data were collected on patient demographics, comorbidities, baseline creatinine, post-operative creatinine, drain creatinine, operative time, LOS, 90-day CDI rates, 30-day readmission rate, and 30-day mortality rate. Postoperative hydronephrosis was also assessed using the first axial imaging available after removal of ureteral stents to assess for potential stricture formation.

Data analysis

Descriptive statistics were performed, with continuous variables expressed as means with standard deviation (SD), while categorical variables were expressed as proportions and percentages. Statistical analysis was performed using the two-sample *t*-tests for continuous variables and the chi-square test or Fisher's exact test for categorical variables. The

criterion for statistical significance was $p < 0.05$. Statistical tests were performed using Statistical Analysis System version 9.4 and Excel (version 2508).

Results

A total of 228 patients underwent robotic cystectomy from 2016 to 2022 at our institution. Of these, 43 (19%) and 185 (81%) were respectively categorized as having early and late ureteral stent removal. Mean stent removal time was POD 4 in the early removal group *vs.* 18 in the late removal group. Mean antibiotic exposure was lower in the early removal group (8.2 ± 10.1 *vs.* 21.9 ± 9.2 days, $p < 0.001$).

There were no significant differences between the groups for age, body mass index (BMI), sex, race, or presence of selected comorbidities (Table 1). Given that the history of pelvic radiation or the presence of a solitary kidney could influence a surgeon to maintain ureteral stents for a prolonged period, we assessed the prevalence of these scenarios and found no difference between the early and late removal groups (8/43 [18.6%] *vs.* 35/185 [18.9%], $p = 0.96$). Operative time was significantly shorter in the early removal group by 0.8 h ($p = 0.003$).

Postoperative outcomes are compared in Table 2. There were no other differences between the groups regarding postoperative outcomes, including LOS, 90-day CDI, and 30-day readmission rates. No deaths occurred within 30 days of surgery. There was no difference between the early and late removal groups with regard to the rate of UTI (4/43 [9.3%] *vs.* 20/185 [10.8%], $p = 0.77$) or urine leak (1/43 [2.3%] *vs.* 4/185 [2.2%], $p = 0.96$). Rates of CDI were similar (1/43 [2.3%] *vs.* 5/185 [2.7%] for early and late removal, $p = 0.88$). Of the 43 patients in the early stent removal group, 26 (57%) had drain creatinine levels measured before and after stent removal. None of these patients had a $\geq 50\%$ increase in drain creatinine following stent removal.

With regards to postoperative hydronephrosis, there was no significant difference in the presence of hydronephrosis reported on first axial imaging when available for the early and late removal groups (10/43 [23.3%] *vs.* 53/185 [28.6%]). Chi-square testing did not show significant differences in the grading of hydronephrosis.

TABLE 1. Demographic data of cystectomy patients

Patient characteristic	Early stent removal (n = 43)	Late stent removal (n = 185)	p-value
Mean age, years (SD)	71 (9.4)	69 (10.7)	0.21
Mean BMI, kg/m ² (SD)	27.5 (5.3)	28.4 (5.6)	0.33
Male sex, n (%)	28 (65.1)	132 (71.4)	0.42
White race, n (%)	40 (93.0)	174 (94.1)	0.79
Presence of selected comorbidities*, n (%)	24 (55.8)	120 (64.9)	0.79
Mean baseline Cr, mg/dL (SD)	1.1 (0.7)	1.1 (0.4)	0.62

Note. *Comorbidities include diabetes mellitus, current smoker, chronic obstructive pulmonary disease, hypertension, immunosuppression, and malnourishment. SD, standard deviation; BMI, body mass index; Cr, creatinine.

TABLE 2. Postoperative outcomes and stent removal timing

Postoperative outcome	Early stent removal (n = 43)	Late stent removal (n = 185)	p-value
Mean post-operative Cr, mg/dL (SD)	1.2 (0.9)	1.1 (0.4)	0.27
Mean drain Cr, mg/dL (SD)	1.1 (0.6)	1.4 (2.1)	0.47
Mean operative Time, hours (SD)	5.9 (1.4)	6.6 (1.5)	0.003**
Mean LOS, days (SD)	5.5 (3.3)	5.6 (2.7)	0.79
30-day readmission, n (%)	4 (9.3)	21 (11.4)	0.69
30-day mortality, n (%)	0 (0.0)	0 (0.0)	N/A
Mean antibiotic duration, days (SD)	8.2 (10.1)	21.9 (9.2)	<0.001***
UTI rate, n (%)	4 (9.3)	20 (10.8)	0.77
Urine leak, n (%)	1 (2.3)	4 (2.2)	0.96
90-day <i>C. difficile</i> infection, n (%)	1 (2.3)	5 (2.7)	0.88

Note. Cr, creatinine; SD, standard deviation; LOS, length of stay; UTI, urinary tract infection. Statistical significance: ** $p < 0.01$, *** $p < 0.001$.

Discussion

Our data suggest that decreased duration of both antibiotics and ureteral stenting following cystectomy is not associated with an increase in UTI or urine leak. Additionally, the mean overall duration of antibiotic exposure decreased by 63% after changes to our post-cystectomy protocol. While ureteroenteric stricture rate was not specifically queried as part of this study, a similar number of patients had hydronephrosis on early surveillance imaging.

QI initiatives allow for the systematic identification of issues that arise, as well as implementation of interventions that could improve outcomes. An iterative approach allows for continuing monitoring to ensure that effective interventions are sustained and allows care teams to modify interventions or identify new issues that may arise as a consequence of changes

to clinical protocols.¹⁶ While QI interventions may pertain to site-specific infrastructure and pathways and thus may not always be generalizable, initiatives that test readily implemented interventions may be relevant to the urologic community at large, particularly when an adequately powered, randomized trial is challenging to perform.

We initially sought to address high rates of postoperative UTIs and urosepsis in patients undergoing radical cystectomy at our institution. UTIs affects nearly half of patients and is the largest contributor to morbidity, emergency department visits, and readmissions.^{4,17} In one study, 20% of patients with UTI presented with urosepsis.¹⁸ The greatest risk for both UTI and bacteremia is in the acute postoperative period (POD 4-5), followed by the 24 h following ureteral stent removal.¹⁹ Kolwijck and colleagues showed that over one-third of UTIs happened

within 24 h of stent removal in their cystectomy cohort.⁵ Shigemura and colleagues demonstrated a 6 vs. 18% risk of pyelonephritis when antibiotics were administered prior to stent removal,²⁰ and a review by Antonelli and colleagues showed that 2% of patients developed positive blood cultures when prophylactic antibiotics were given around the time of stent removal vs. 9% when none were administered.⁶

In order to address the high rates of infection observed post-cystectomy and specifically to provide antibiotic coverage for the period around ureteral stent removal, an earlier phase of our QI initiative extended antibiotic prophylaxis to 30 days. We found that 12% of patients on extended antibiotic prophylaxis developed a UTI, compared to 36% of patients not on post-operative antibiotic prophylaxis, or who received it just around the time of stent removal.¹⁵ In this updated study, the rate of UTI was similar to the extended prophylaxis group for both the early and late stent removal groups (4/43 [9.3%] vs. 20/185 [10.8%], respectively), and lower than what is reported in the cystectomy literature. When antibiotics were limited to perioperative prophylaxis, Kolwijck et al. observed a UTI rate of 28%, which contributed to one quarter of the cases of postoperative sepsis.⁵ Our findings support stent removal as a high-risk period for UTI, given that there were no significant differences in UTI despite reduced antibiotic exposure in our early stent removal group. Collection and subsequent treatment of urine cultures from the stents on POD 3 may have also contributed to our overall low rates of UTI.

Stent duration itself can also predict UTI and complications. Beano et al. found that late stent removal (mean removal POD 15.5) was associated with significantly higher readmission rates (odds ratio [OR] = 2.6, $p = 0.02$) and UTI (OR = 2.4, $p = 0.03$) compared to their early stent removal group (mean removal time POD 5), despite giving antibiotics to both groups around the time of stent removal.³ In the late stent removal group, patients received a 5 day course of fluoroquinolones two days prior to stent removal, while “high-risk” patients received antibiotics until stent removal. In the early stent removal group, patients were given a single intravenous dose of ceftriaxone prior to removal. Their data suggests that presence of the stent itself could be a significant contributor to UTI, as both groups received antibiotics around the time of stent removal. UTI rates in both the late and early groups (37.8 vs. 19.2%) were notably higher than in our study. The difference could be due to our maintaining antibiotics the entire duration of stenting and tailoring prophylaxis to urine cultures. There are

many reasons to decrease antibiotic exposure in this population, including antimicrobial resistance, cost, potential for medication side effects or interactions, CDI, and efficacy of subsequent immunotherapy. Although our study did not assess drug resistance, lower antibiotic duration could reduce the risk of developing multiple-drug resistant organisms, which is especially relevant in this population that remains at high risk for UTI long term, with 23% of patients experiencing UTI requiring hospitalization.²¹ Shorter antibiotic duration could also decrease the risk of side effects such as gastrointestinal upset and simplify patients’ medication regimens at discharge. Additionally, patients undergoing perioperative immunotherapy have poorer outcomes if they have had recent antibiotic exposure, perhaps due to alterations in the gut microbiome. Antibiotics received concurrently with neoadjuvant pembrolizumab were associated with lower rates of complete response and recurrence-free survival in patients with muscle invasive bladder cancer.²² Cancer registry data from the United Kingdom have also shown increased mortality with antibiotic use in bladder cancer patients.²³ Given that immunotherapy has become a backbone of systemic therapy for both localized and metastatic urothelial carcinoma, the implications of antibiotic exposure could be significant.

In addition, both antibiotic exposure and gastrointestinal surgery place cystectomy patients at high risk for CDI, which increases the risk for prolonged hospitalization and readmission.²⁴ Studies using NSQIP data have found 30-day incidence postoperative CDI in radical cystectomy patients to be 3.6%, which was significantly higher than that of patients admitted for other urologic procedures.^{24,25} Antibiotic exposure >7 days was an independent predictor of risk for CDI infection in radical cystectomy patients.²⁶ We did not see a change in rate of CDI in our early removal group despite decreased antibiotic exposure, although the low incidence of CDI in our cohort (6/228, 2.6%) limited statistical power to detect significant differences.

Given the contribution of stenting to infectious risk, the necessity of ureteral stenting is being questioned. Prior research has shown that although there was no impact on ureteral stricture rate, placing ureteral stents across the ureteroenteric anastomosis resulted in less dilation of the pelvicalyceal system, earlier return of bowel function, and lower incidence of early metabolic derangements.^{1,2} However, given that stents induce peri-ureteral inflammation and pose an infectious risk, some surgeons are omitting

ureteral stents for urinary diversions, both to reduce UTIs and potentially ureteroenteric stricture formation.^{27,28} In a recent retrospective study by Tallman and colleagues, stented patients who had undergone robotic cystectomy (average stent duration of 7–10 days with antibiotics given at the time of stent removal) had significantly higher 30-day UTI rates than patients without stents (19% vs. 0%, $p = 0.007$).²⁸ Stented patients also had higher rates of composite ureteroenteric anastomosis complications (20% vs. 9.5%, $p = 0.2$), which included urine leaks, UTI, or sepsis events, and 30-day readmission (19% vs. 9.8%, $p = 0.3$), though these results did not meet statistical significance. While these data support the safety of a stentless approach for urinary diversion, they also suggest that single-dose antibiotic prophylaxis may not be adequate to reduce UTI rates.

We demonstrate that stepwise changes to our postoperative ERAS protocol have enabled us to continuously improve outcomes while ensuring that we minimize morbidity. Due to discomfort among our institution's surgeons with moving universally to stentless diversion, we have moved to considering the removal of stents starting at POD 3 or omitting them altogether in low-risk patients to identify if we can further reduce antibiotic exposure. We are continuing to monitor postoperative complications such as ureteroenteric stricture and UTI as these changes are enacted.

Our study has several important limitations. These include a relatively small sample size and an uneven distribution between the early and late stent removal groups. We felt that uneven groups with a more stringent cutoff date for stent removal (5 days) were preferable to choosing a cutoff that would yield more evenly distributed groups (e.g., 10 days), given that POD 5 was our median length of stay, which is a clinically relevant time to consider stent removal. Furthermore, because we continued to test and treat patients for positive urine cultures obtained postoperatively throughout the duration of our protocol, it is not possible to separate the potential contribution of this intervention from decreased stent duration in maintaining our low UTI rates.

Lastly, since the study is based on retrospective review of the data, we cannot totally exclude the potential for unmeasured confounders as a source of selection bias. We did assess various patient characteristics and did not find obvious differences between the groups aside from operative time, which was significantly shorter in the early removal group by 0.8 h. On closer examination, this discrepancy was likely driven by surgeon variation in mean operating time; one surgeon began performing cystectomies

in 2020 and consistently had the shortest operating times. In addition, another surgeon had a general trend towards shorter operating times, likely reflecting increased efficiency over time. Finally, the small size of the early removal group limits overall statistical power in detecting true differences in outcomes, such as CDI.

Conclusions

In this retrospective, single-institution study stemming from an iterative QI initiative regarding postoperative cystectomy care, reduced antibiotic exposure and indwelling ureteral stent duration were not associated with increased UTI rates or urine leaks. A notable limitation of this study was the relatively small proportion of patients who underwent early ureteral stent removal after the most recent QI iteration. Further prospectively designed studies or randomized controlled trials would be needed to elucidate whether the timing of stent removal and duration of antibiotic prophylaxis can be further optimized or even omitted.

Acknowledgement

Not applicable.

Funding Statement

The authors received no specific funding for this study.

Author Contributions

Conceptualization: Paul Jones, Sudhir Isharwal, Christopher L. Amling, Kamran P. Sajadi, Jen-Jane Liu; Methodology: Solange Bassale, Paul Jones, Jen-Jane Liu; Analysis: Jessica L. Wenzel, Eric J. Robinson, Wesley H. Chou, Solange Bassale, Paul Jones, Jen-Jane Liu; Drafting: Jessica L. Wenzel, Wesley H. Chou; Revisions: Jessica L. Wenzel, Eric J. Robinson, Wesley H. Chou, Solange Bassale, Kamran P. Sajadi, Jen-Jane Liu; Supervision: Jessica L. Wenzel, Jen-Jane Liu. All authors reviewed the results and approved the final version of the manuscript.

Availability of Data and Materials

The data used for this study are available from the corresponding author, Wesley H. Chou, upon reasonable request.

Ethics Approval

Ethics approval was provided by the Oregon Health & Science University's Institutional Review Board through protocol OHSU IRB00006712.

Conflicts of Interest

Sudhir Isharwal reports receipt of honoraria and travel accommodation reimbursements, and consulting roles with Intuitive and Angiodynamics. He also reports stock in Lantheus. Jen-Jane Liu reports research funding from EnGene Pharmaceuticals and Merck. Otherwise, the authors have no conflicts of interest to report.

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