Reconstructive Urology

Antibiotic Stewardship and Postoperative Infections in Urethroplasties

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OBJECTIVE To determine surgical site infection and urinary tract infection (UTI) rates in the setting of urethroplasty. Given significant variation in the utilization of antibiotics, there is an opportunity to improve antibiotic stewardship. This study aims to elucidate the rate of both UTI and surgical site infection after urethroplasty on a standardized perioperative antibiotic regimen, and to obtain patient and operative characteristics that may predict infection.

METHODS We prospectively treated 390 patients undergoing urethroplasty at 11 centers with a standardized perioperative antibiotic protocol. Patients had a urine culture or urine analysis within 3 weeks of surgery. After surgery, patients were discharged with an indwelling catheter, removed per usual surgeon practice. All were given nitrofurantoin from discharge until catheter removal. Logistic regression analyses were performed to determine the correlation between patient characteristics or operative categories with post-operative infection.

RESULTS The rates of postoperative UTI and wound infection within 30 days were 6.7% and 4.1%, respectively. On multivariate analysis of demographics, comorbidities, and stricture characteristics and repair, only preoperative UTI ($P = .012$), history of cardiovascular disease ($P = .015$), and performing a membranous urethroplasty (0.018) were significant predictors of a UTI within 30 days postoperatively. Location of repair nor graft use increased the risk of UTI. There were no factors predictive of postoperative wound infection.

CONCLUSION A standardized antibiotic protocol was created to narrow and limit excess antibiotic use. This protocol, with clear definitions of UTI and wound infection, allowed determination of accurate infection rates in urethroplasties. Preoperative UTI, even when properly treated, increases the risk of postoperative UTI. UROLOGY 00: 1–6, 2020. © 2020 Elsevier Inc.

Urethral stricture disease has an overall incidence of 0.3% in males[1] and creates a significant social, financial and mental burden on patients that suffer from it.[2] Urethral reconstruction has the highest success rates and is the accepted gold standard treatment.[3] At this time, there are no established guidelines regarding management of antibiotics for patients specifically undergoing urethroplasty. The American Urological Association (AUA) provides best practice guidelines that recommend a urine culture preoperatively and appropriate treatment based on the culture for endoscopic or open surgery involving the urinary tract.[4] For open urologic cases involving entry into the urinary tract, one day of prophylaxis with a first- or second-generation cephalosporin or an aminoglycoside and either metronidazole or clindamycin is indicated in all patients.[5] Despite published guidelines, compliance rates are poor overall at 53%.[6]

A recent survey of reconstructive experts revealed a wide variation in length, type, and number of antibiotics prescribed.[7] We know surgical site infections (SSI) have significant implications in healthcare due to the longer and costlier hospitalizations associated with the complication.[8] Overuse of antibiotics has been linked to increased risk of postoperative *Clostridium Difficile* infection[9] and antimicrobial resistance with global implications.[10] This has led to numerous negative consequences due to additional healthcare costs, prolonged hospital stays, propagation of bacterial resistance, and increased mortality.[6]

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Previous urethroplasty studies have tended to focus on other endpoints such as a successful repair and the need to intervene with additional surgical procedures in the future.[11] A dedicated study was needed to elucidate the rate of both urinary tract infection (UTI) and SSI in patients treated for urethral stricture by using a standardized perioperative antibiotic protocol and controlling for confounders.

Our aim was 3-fold. First, to create a protocol to standardize and minimize antibiotic use in the perioperative setting based on AUA best practice guidelines and clear definitions of urinary tract and wound infections. Second, to report the incidence of postoperative infections in urethroplasties once a standardized perioperative antibiotic protocol has been established. Third, to determine the patient and operative characteristics that may be predictors for infection.

MATERIALS AND METHODS

We prospectively treated 413 patients undergoing urethroplasty at 11 centers over the course of a year with standard perioperative antibiotics. Of these, 390 patients were included in the analysis, excluding those missing significant data. Patients had a urine culture or urine analysis (UA) within 3 weeks of surgery. If a UA was positive, a urine culture was obtained. A positive UA was determined by presence of bacteria in the absence of epithelial cells, nitrite positivity, or pyuria. A preoperative UTI was defined as any urine culture growing >100K CFU/mL regardless of symptoms in those without a urinary catheter, and >50K CFU/mL regardless of symptoms in those with a urinary catheter. Patients with preoperative UTI were treated for 3-5 days according to culture sensitivities. Those sensitive only to intravenous antibiotics were treated for 24-48 hours. Patients with catheters or suprapubic tubes were included in the cohort per protocol. During the perioperative period, intravenous cephalosporins were given (1st, 2nd, or 3rd generation). Those with a penicillin or cephalosporin allergy were given fluoroquinolones.

After surgery, patients were discharged with an indwelling catheter, to be removed per usual surgeon practice. Nitrofurantoin was continued postoperatively (100 mg BID) until catheter removal to as this was the current practice. Keflex was given for patients allergic to nitrofurantoin. Ciprofloxacin or trimethoprim sulfamethoxazole DS were given on the day of catheter removal to reduce the risk of symptomatic UTI.[20]

Patients were followed postoperatively and the incidence of wound infection and UTI were recorded. Wound infection was defined as any SSI requiring antibiotic treatment or incision and drainage within 30 days of surgery. A postoperative UTI was defined as within 30 days of surgery, or during the duration of catheterization plus 1 week after catheter removal, whichever period was longer. The criteria for UTI was >100K CFU/mL of a single organism and at least one urinary symptom, which included suprapubic pain, flank pain, fever >101F without other identified causes, dysuria that persists >2 days after catheter removal, or frequency or urgency that persists >2 days after catheter removal. A rate of infection was calculated. Univariate and multivariate logistic regression were performed to determine the correlation between clinical variables and infection.

RESULTS

The mean age of participants was 49.1 years old, mean body mass index (BMI) was 30.8 (Supplementary Table 1). The average stricture length was 4.29 cm, and 54.1% of urethroplasties were performed on the bulbar urethra, 26.8% on penile urethra, 19.2% on the meatus or fossa navicularis, and 15.7% on membranous urethra (Table 1). Some patients were operated on more than one location of the urethra. Around 58.5% of urethroplasties utilized a graft, and 24.4% were either excision and primary anastomosis or a nontransecting urethroplasty. 18.9% of these patients have had a previous urethroplasty. Overall, the rate of postoperative UTI and wound infection within 30 days was 6.7% (26/390) and 4.1% (16/390), respectively (Table 2).

When analyzed independently using logistic regression, age ($P = .001$), positive preoperative UTI ($p< .001$), history of hyperlipidemia ($P = .015$), coronary artery disease (CAD) ($P = .001$), and membranous urethroplasty ($P = .019$) were significant predictors of postoperative UTI. History of pelvic radiation ($p= .063$) and peripheral vascular disease ($P = .051$) did not reach statistical significance for predicting postoperative UTI.

For wound infections within 30 days postoperatively (Table 2), history of Benign prostatic hyperplasia ($P = .045$), history of cancer ($P = .020$), and having a perineal urethrostomy creation ($P = .015$) were significant, while history of coronary artery disease ($P = .095$) did not reach significance.

Other risk factors, including BMI, clean intermittent catheterization, previous urethroplasties, history of diabetes, hypertension, HIV, smoking, Chronic Obstructive Pulmonary Disease, were not significant risk factors for postoperative UTI or wound infections. The location of urethroplasty at the meatus, fossa navicularis, penile, or bulbar urethra did not result in significance. The method of urethroplasty, whether it was excision and primary anastomosis, nontransecting urethroplasty, use of a flap, or use of a graft did not increase the risk of postoperative infection.

A chi-square test of independence was performed to explore the relationship between graft use and infection rate. When no graft was used, the rate of postoperative UTI was 6.2%, while it was 6.8% when a graft was used ($P = .808$). The wound infection rate was 4.8% without a graft, and 3.4% with a graft ($P = .512$). Overall, the relation between these variables was found to be not significant (Supplementary Table 2).

Table 1. Urethral stricture and operative characteristics of 390 men undergoing urethroplasty

	Mean (st dev) or Percentage
Stricture Length	4.29 cm (st dev 3.68)
Location of stricture	
Meatus/Fossa	19.2%
Membranous	15.7%
Penile	26.8%
Bulbar	54.1%
Operative characteristic	
Graft used	58.5%
Dorsal graft	45.6%
Ventral graft	7.0%
Flaps used	1.9%
EPA or nontransecting	24.4%
Perineal urethrostomy	6.9%
1st stage	7.6%

Table 2. Rate of UTI and wound infection within 30 days after urethroplasty

	Frequency	Rate
UTI within 30 days	26/390	6.7
Wound infection within 30 days	16/390	4.1

UTI, urinary tract infection.

When the variables that were significant under univariate logistic regression were entered into one model using multivariate logistic regression, positive preoperative UTI (odds ratio [OR] 6.7; $P = .012$), history of CAD (OR 14.8; $P = .015$) and performing a membranous urethroplasty (OR 7.8; 0.018) remained significantly predictive of a UTI within 30 days postoperatively (Table 3). The most common organism found was *Escherichia coli*, followed by *Staphylococcus aureus* and *Klebsiella pneumoniae* (Fig. 1). There were no factors that were predictive of postoperative wound infections in the multivariate model, though performing a perineal urethrostomy was close to significance ($P = .057$; Table 3).

DISCUSSION

In the practice of antimicrobial administration for urethroplasties during the pre-, peri-, and postoperative phase, there has been significant variability and deviation from the AUA guidelines. A recent survey of reconstructive urologists at 34 institutions suggested significant variation in practice with different antibiotics, duration of treatment, and threshold to treat preoperatively,.[12] Nearly 42% of reconstructive urologists administered 2 or more antibiotics intraoperatively regardless of culture results. Around 61% administer oral antibiotics for 2-4 weeks until catheter removal, though there is no strong data to support this practice. The wide variation reported in all phases of antibiotic use in this survey highlight the need for more specific and judicious use of antibiotics and the difficulty in determining an accurate UTI and SSI rate in urethroplasty. Our study was designed to follow the limited AUA guidelines available, to minimize antibiotic with the use of a predetermined protocol and to determine true incidences of postoperative infections rates in urethral reconstructive surgery.

Using the National Inpatient Sample, Blaschko et al previously demonstrated about a 6.6% complication rate for urethroplasty, however, there was a wide range of definitions of what was included as a complication, including minor issues such as scrotal swelling and spraying of urine; specifically, infection was not described separately.[8] Because of the lack of uniformity, the true rate of significant complications cannot be determined, and does not include data on complications that occur after discharge. Clean-contaminated cases with entry into the urinary tract have an expected rate of surgical wound infection without prophylaxis of about 5%-10%; that is expected to drop to 2%-3% with appropriate prophylaxis.[12] Although this data is helpful, it does not specifically address the unique issues that arise with urethral reconstruction. There is little evidence about the rate of post-urethroplasty infection with appropriate prophylaxis.

The misuse of antibiotics has led to increased patient morbidity, bacterial resistance, and increased costs[6] without any evidence of decreased infection risk in urethroplasty patients.[13] Many urethroplasty surgeons use a combination of 2 IV antimicrobial agents were used even though the AUA best practice statement recommends a single dose of a first- or second-generation cephalosporin before any open surgery involving the urinary tract. After the initial perioperative dose, the statements provide very limited guidance during the postoperative period. Regarding antibiotic use at the time of catheter removal, the guidance is even more elusive stating that antimicrobial therapy may be therapeutic secondary to colonization. The duration of this therapeutic treatment is unclear. Prolonged antimicrobial prophylaxis from the date of surgery through catheter removal 2-4 weeks later is a common

Table 3. Multivariate logistic regression analysis comparing UTI and wound infections to patient characteristics significant on univariate analysis

Comparing UTI to Patient Characteristics				
Variable Compared to UTI	Odds Ratio	*P*-Value	95% C.I. Lower Limit	95% C.I. Upper Limit
Age	0.977	.434	0.921	1.036
CAD	14.862	.015	1.700	129.961
PVD	0.776	.888	0.022	26.923
HLD	1.273	.788	0.220	7.358
Positive preop urine culture	6.538	.012	1.505	28.396
Prior pelvic radiation	3.484	.316	0.303	40.003
Membranous urethroplasty	7.817	.018	1.417	43.128
Comparing Wound Infections to Patient Characteristics				
Variable Compared to Wound	Odds Ratio	*P*-Value	95% C.I. Lower Limit	95% C.I. Upper Limit
CAD	2.223	.401	0.345	14.340
BPH	3.063	.160	0.642	14.607
Cancer	2.955	.173	0.621	14.058
Perineal urethrostomy	4.400	.057	0.956	20.251

CAD, coronary artery disease.

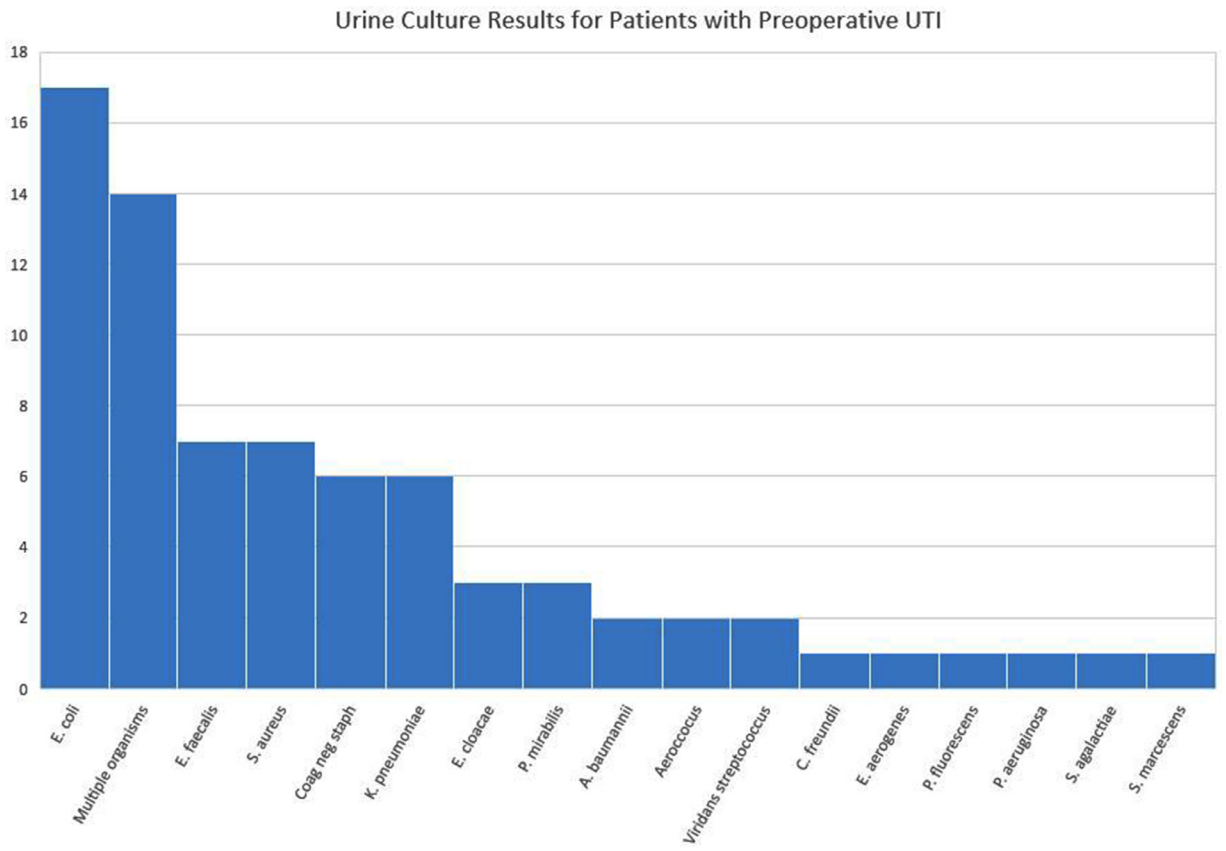

Figure 1. Urine culture results for patients with preoperative UTI. UTI, urinary tract infection.

practice in order to guard against infection during the early healing period. However, it is unknown whether this is beneficial or not in reducing the rate of infections or improving urethroplasty success.

The definition of a UTI preoperatively has varied significantly depending on the study, ranging from any positive urine culture to a symptomatic culture that grows >100K CFU/HPF. Because of this, the reported rates of UTI in men with urethral stricture disease have ranged widely from 6% to 42%.[14] The postoperative definition of UTI can have more confounding variables particularly with the addition of a catheter. An indwelling catheter maintained for several weeks postoperatively increases the risk of bacterial colonization by up to 10% each day.[15] It can be a challenging task to distinguish the truly infected individuals from those who are colonized and having catheter discomfort or bladder spasms. Our study demonstrates the incidence of UTI and surgical site wound infection based on strictly defined criteria.

Because of the lack of data within urethroplasty patients, catheter associated UTI data is instead usually derived from radical prostatectomy patients given the similar need for prolonged catheter placement after urethral reconstruction. The UTI rate observed in one study was 7.3% without any postoperative antibiotics, with reduction to 3.1% with the addition of 3 days of ciprofloxacin.[16] Our study showed a UTI incidence of 6.7% despite antibiotic use in the postoperative period. The higher incidence of UTI in comparison to prostatectomy could be explained by the fact that patients undergoing a urethroplasty is inherently at higher risk of UTI given the longer period of an indwelling urethral catheter, and preoperative risk factors such as urinary stasis, recurrent UTI, previous urologic instrumentations, intermittent catheterizations and most importantly a 25% incidence of positive preoperative urinary cultures.

Previous studies have indicated an infection rate of 4.7%-17.4%[17,18] when using an onlay technique. We specifically looked at onlay versus anastomotic urethral reconstruction and found no difference in infection rate.

It is important to be judicious with antibiotic use given the previously described overuse and risks inherent with bacterial resistance and superbugs phenomena. The development of our perioperative antibiotic protocol significantly reduced the amount and variation of antibiotics for use in urethroplasty. By implementing a systematic and reproducible protocol, we were able to determine a more representative rate of preoperative positive UTI's (20.4%) as well as postoperative UTI (6.7%) and wound infection (4.1%) rate.

This multicenter, prospective cohort study identifies the incidence of infections, and its patient and clinical characteristic predictors. The limitations of this study are the exclusion of 23 patients in the study due to insufficient information. This is not a randomized study as every institution had to maintain the same protocol for the sake of

consistency. Data regarding the presence of a suprapubic tube prior to surgery was not factored into postoperative UTI rates. The length of postoperative catheterization was not standardized and left to the surgeon depending on the case, which could have affected the postoperative UTI rates. Perioperative skin prep was not standardized within the protocol, which may have affected the UTI and SSI rates although most institutions have best practice-operative protocols they adhere to. Treatment of positive preoperative urine cultures was not routinely confirmed with another repeat urine culture as per AUA guidelines for asymptomatic patients.[19]

There is currently no data to support the extended use of antibiotics for the entire 2-3 week postoperative duration after urethroplasty. Nitrofuration was chosen for its specificity to the urinary system in an attempt to sterilize the urine (not for tissue penetration) to facilitate healing. Our protocol reflected the common practice of the majority of the reconstructive urologists at the time and this protocol is still being investigated for potential optimization. A study previously showed that 25% of patients after urethroplasty and catheterization would have a positive urine culture within 30 days despite antibiotic prophylaxis.[10] Despite the presence of a positive culture, it was not associated with stricture recurrence or wound complications. Prolonged antibiotic prophylaxis may offer no benefit after urethroplasty and is the next research question to be answered in the next trial.

CONCLUSION

With a controlled antibiotic protocol and clearly defined definition of infection, the overall UTI rate for urethroplasties was 6.7%, while the wound infection rate was 4.1%. The location of the repair, the length of the stricture, prior failed procedures, and the use of a graft did not result in a statistically significant increase in infection rates. Positive preoperative UTI, history of CAD, and performing membranous urethroplasty were significantly correlated with postoperative UTI, while no independent factors were predictive of wound infections.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.urology.2020.10.065.

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EDITORIAL COMMENT

The prevention of infectious complications is a universal endeavor in surgery. However, it is true that not a great deal of research has been carried out specifically in the field of urethral reconstruction, where little standardization and a widespread practice variability exists among experts in the prevention and treatment of posturethroplasty infections.

In this scenario, this study has the merit of presenting the results of a predefined and consensual antibiotic-use protocol, applied to a cohort of 390 patients undergoing urethroplasty. The authors found rates of 6.7% in urinary tract infections (UTI) and 4.1% in surgical site infections within 30 days of surgery. Postoperative UTI correlated with prior UTI, history of coronary artery disease, and membranous urethroplasty, but predictive factors for surgical site infections were not found. This is interesting data indeed, illustrating the value of standardized protocols for antibiotic use, so I congratulate and thank the authors for this significant contribution.

While this is an interesting proposal, some aspects of this protocol may be the subject for optimization. Specifically, performing preoperative urine culture within 3 weeks before surgery may be risky, since it is common for patients to suffer recolonization, particularly those with an indwelling catheter. Under the presented protocol, it is possible that some patients in this cohort had a positive urine culture at the time of surgery.

Also, no urine culture was obtained before removing the catheter. It is known that after 3 weeks, the risk of colonization is high, and therefore, the culture could be positive with nosocomial bacteria, resistant to the empiric ciprofloxacin or trimethoprim-sulfa regime predefined in the protocol.

We see 4 occasions when infectious complications can occur in a patient with urethral stricture. The first is at the time of the preoperative diagnostic urethrography, the second at the time of surgery, then at the time of postoperative urethrography, and finally at the time of catheter removal (it is common for the latter two to coincide). Unlike focusing on a predefined rigid antibiotic regime, the protocol at our institution aims to ensure sterile urine on each occasion. To achieve this, we usually obtain a culture 2-3 days prior to each procedure. If positive, we would administer 1 or 2 doses of an antibiotic selected according to the sensitivity study. Replacing a long-standing suprapubic tube with a fresh catheter may also help to clear colonization. If sterile urine cannot be assured, we would consider postponing the procedure. The results of this study tend to support this policy, as the presence of preoperative UTI was a strong predictor of postoperative UTI.

Although efforts to reduce infectious complications should also include protocols for skin preparation, timing of administration of the prophylactic antibiotic prior to the surgical incision, and use of a close urine drainage system, this study provides a valuable point of comparison to develop local protocols for antibiotic use. However, significant variability may exist in the bacteriological profile of each community and that of each institution, so it is recommendable for each antibiotic protocol to be personalized accordingly.

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EDITORIAL COMMENT

The editorial comments address important hurdles that exist with the standardization of antibiotic use for urethral reconstruction. Because of the overuse of antibiotics and the extreme resistance seen in practice, the need for standardization has been evident. The common practice of giving broad spectrum antibiotics without any substantiating evidence for its use has made it even more important to address this issue. We reported the infectious outcomes of an American Urological Association guideline compliant protocol for urethral reconstructive cases focused on judicious use of antibiotics.

The editorial comments raise concerns for recolonization after preoperative treatment with antibiotics, particularly given our results that a positive preoperative urinary tract infection correlated with a postoperative urinary tract infection. However, it is also the goal of this study to minimize the unnecessary usage of antibiotics, and that includes overtesting. It is within the American Urological Association guidelines that a post-treatment test for cure should not be performed for asymptomatic patients, and no specific guidelines exist regarding the need for a repeat culture for preoperative patients. Because of this guideline as well as feasibility, the protocol did not include a repeated urine culture to ensure sterility prior to urethral reconstruction. It is a worthwhile point that additional urine culture testing after preoperative antibiotic treatment may help prevent these infections.

Individual practice patterns led to overuse and wide variation in antibiotic coverage for similar urethral reconstructive cases.[1] We can benefit from more standardized protocols that are based on evidence and adherence to national guidelines. Protocols designed to wisely choose antibiotic use in conjunction with perioperative timing of antibiotics, sterile operative technique, proper skin prep, and closed system catheter drainage will help minimize postoperative infections while avoiding antibiotic overuse. Our manuscript is a first step to enable more widespread use of data-driven protocols for urethral reconstruction.

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