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Minimizing Antibiotic Use in Urethral Reconstruction

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JU Insight

Minimizing Antibiotic Use in Urethral Reconstruction

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Study Need and Importance: Reconstructive urologists performing urethroplasties have had greatly varying practices regarding antibiotic utilization. Despite the American Urological Association recommendations on this issue, adherence to them has been poor due to concern of infection that may potentially negatively affect the outcome. Given the crisis we are currently facing with antibiotic resistance and the need for greater stewardship, a prospective study was necessary to determine whether the usual practice of giving 2–4 weeks of antibiotics truly brought down the rate of wound infections or urinary tract infections.

What We Found: In this prospective, multicenter study, there were 2 phases of the study that were compared. The first phase, in which prolonged antibiotics were utilized, established the usual rate of urinary tract and wound infections. The second phase removed the prolonged antibiotics. When the 2 phases were compared, we showed that prolonged antibiotic utilization did not significantly affect the rate of urinary tract infections nor wound infection.

Limitations: This was not a randomized study as multiple institutions had to maintain the same protocol for the sake of consistency. The presence of a suprapubic tube and the length of postoperative catheterization were not standardized, ultimately leaving it to the surgeon to determine the adequate length. Perioperative skin prep was not standardized, which could have affected the urinary tract infection and surgical site infection rates.

Interpretation for Patient Care: There is understandable hesitancy in decreasing antibiotic utilization for reconstructive cases, particularly with urethral strictures where the patient has likely failed other management strategies and success is critical. Given no significant difference in the rate of urinary tract or wound infection with prolonged antibiotics after a urethroplasty, we recommend more judicious use with 24-hour perioperative antibiotics with additional dosing at the time of catheter removal.

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Minimizing Antibiotic Use in Urethral Reconstruction

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Purpose: There are no established guidelines regarding management of antibiotics for patients specifically undergoing urethral reconstruction. Our aim was to minimize antibiotic use by following a standardized protocol in the pre-, peri- and postoperative setting, and adhere to American Urological Association antibiotic guidelines. We hypothesized that prolonged suppressive antibiotics post-urethroplasty does not prevent urinary tract infection and/or wound infection rates.

Materials and Methods: We prospectively treated 900 patients undergoing urethroplasty or perineal urethrostomy at 11 centers over 2 years. The first-year cohort A received prolonged postoperative antibiotics. Year 2, cohort B, did not receive prolonged antibiotics. A standardized protocol following the American Urological Association guidelines for perioperative antibiotics was used. The 30-day postoperative infectious complications were determined. We used chi-square analysis to compare the cohorts, and multivariate logistic regression to identify risk factors.

Results: The mean age of participants in both cohorts was 49.7 years old and the average stricture length was 4.09 cm. Overall, the rate of postoperative urinary tract infection and wound infection within 30 days was 5.1% (6.7% in phase 1 vs 3.9% in phase 2, p=0.064) and 3.9% (4.1% in phase 1 vs 3.7% in phase 2, p=0.772), respectively. Multivariate logistic regression analysis of patient characteristics and operative factors did not reveal any factors predictive of postoperative infections.

Conclusions: The use of a standardized protocol minimized antibiotic use and demonstrated no benefit to prolonged antibiotic use. There were no identifiable risk factors when considering surgical characteristics. Given the concern of antibiotic over-prescription, we do not recommend prolonged antibiotic use after urethral reconstruction.

Key Words: anti-bacterial agents, urethroplasty, urethral stricture

Abbreviations and Acronyms

BMI = body mass index
BPH = benign prostatic hyperplasia
CAD = coronary artery disease
PVD = peripheral vascular disease
UTI = urinary tract infection

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Ethics Statement: In lieu of a formal ethics committee, the principles of the Helsinki Declaration were followed.
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The utilization of antibiotics in urethroplasties has been a controversial topic. Because there are no established guidelines regarding its management during urethroplasties, antibiotic usage has varied widely in the peri- and postoperative period, both in the length of time and the type of antibiotic

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given.[1] Of those receiving antimicrobial therapy in the United States 30%–50% were found to be unnecessary, inappropriate or redundant.[2,3] The risks of antibiotic overtreatment are well known, particularly regarding patient harm, medication side effects, propagation of antimicrobial resistance and the resulting increased health care costs.[4,5] This has led to a major public health issue with pervasive use of antibiotic therapy, and antibiotic stewardship has become an important endeavor to reduce harm and lower costs.[6]

The AUA (American Urological Association) provides best practice guidelines that recommend 1 day of prophylaxis with a first- or second-generation cephalosporin or aminoglycoside with metronidazole or clindamycin for all patients undergoing open urological cases.[7] Despite these guidelines, adherence to them has been poor,[8] and given the typically longer indwelling catheterization time utilized in urethroplasties, the practice patterns of reconstructive urologists in postoperative antibiotic utilization have ranged widely from less than 1 week postoperatively to up to 4 weeks.[1] There have been no strong data to support this practice.[9] Catheter associated urinary tract infection (UTI) data derived from radical prostatectomy patients have been observed to be between 6%–7.3% without the use of continuous postoperative antibiotics, and given only at the time of catheter removal.[10,11] UTI or wound infection rates after a urethroplasty historically have not been well studied and ranged from 4.7%–25.6% with a varied definition of a UTI calling into question the true incidence of infection.[12–14] We published our initial multi-center UTI and wound infection rates (cohort A) with the then practice of prolonged postoperative antibiotics while the catheter was indwelling and found a UTI rate of 6.7% and a wound infection rate of 4.1%.[15] Despite the use of continuous antibiotics for urethroplasties during the catheterization period postoperatively, the rate of infection was not much different in comparison to prostatectomies where postoperative antibiotics are not typically given during the entire course of catheterization.

Understanding the potential harm of antibiotic overuse combined with the additional medical cost associated with treating resistant bacteria, we performed a multi-center quality improvement project eliminating prolonged antibiotic use. We conducted a noninferiority analysis to determine if the UTI and wound infection rates differ between the 2 cohorts with/without the extended antibiotic use in urethral reconstruction.

MATERIALS AND METHODS

We had prospectively treated 900 patients undergoing urethroplasty at 11 centers over the course of 2 years with standard pre- and perioperative antibiotics. Patients had a urine culture or urine analysis within 3 weeks of surgery, ordered by the reconstructive urologists team. When the urine analysis was positive, a urine culture was obtained. Preoperative bacteriuria 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. Those with preoperative bacteriuria were treated for 3–5 days preoperatively according to culture sensitivities. Patients sensitive only to intravenous antibiotics were treated for 24–48 hours. During the perioperative period, intravenous cephalosporins were given for a 24-hour period and those with microbial resistance were given targeted antibiotics. Those with a penicillin or cephalosporin allergy were given fluoroquinolones.

After surgery, patients were discharged with an indwelling catheter, to be removed per usual physician practice. For cohort A, the patients were discharged on macrobid 100 mg BID until catheter removal. Keflex was given for patients allergic to macrobid. Two doses of ciprofloxacin 500 mg or trimethoprim-sulfamethoxazole DS were given around the day of catheter removal. For cohort B, the patients only received 2 dosages of peri-catheter removal antibiotics with ciprofloxacin or trimethoprim-sulfamethoxazole.

Patients were followed postoperatively and the incidence of wound infection and UTI were recorded. Wound infection was defined as any surgical site infection requiring antibiotic treatment or incision and drainage within 30 days of surgery. A 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 1 urinary symptom, which included suprapubic pain, flank pain, fever >101F without other identified causes, dysuria that persists >2 days after catheter removal, frequency or urgency that persists >2 days after catheter removal. Urine cultures were not routinely performed in all postoperative patients without symptoms. All patients for whom data were incomplete regarding UTI or wound infection were discarded, leaving a total of 900 patients. The rate of infection was calculated. Univariate and multivariate logistic regression were performed with SPSS® (IBM®, Armonk, New York) to determine the correlation between

Table 1. *Comparison of UTI and wound infection rates within 30 days with and without postoperative antibiotics*

Postop Antibiotics	No./Total No. UTI within 30 Days (%)	No./Total No. Wound Infection within 30 Days (%)
Only at catheter removal	20/510 (3.9)	19/510 (3.7)
Throughout catheterization	26/390 (6.66)	16/390 (4.1)

According to a chi-square test, UTI and postoperative antibiotic use had no significant association (X2 [1] = 3.434, p=0.064). Similarly, wound infection and postoperative antibiotic use had no significant association (X2 [1] = 0.084, p=0.772).

Table 2. *Urethral stricture and operative characteristics of patients undergoing urethroplasty*

		UTI		Wound	
Variable	Frequency	p Value	Odds Ratio (95% CI)	p Value	Odds Ratio (95% CI)
Age	49.74 (16.80 SD)	0.016	1.024 (1.004–1.043)	0.736	1.003 (0.983–1.024)
BMI	30.76 (11.24 SD)	0.052	1.016 (1.000–1.032)	0.355	0.975 (0.923–1.029)
No. previous direct visual internal urethrotomies	1.29 (1.03 SD)	0.340	0.777 (0.462–1.305)	0.752	0.919 (0.546–1.549)
No. previous dilation	2.40 (3.38 SD)	0.740	1.019 (0.911–1.140)	0.575	1.035 (0.918–1.166)
Stricture length	4.09 (3.58 SD)	0.008	1.100 (1.025–1.181)	0.695	1.023 (0.912–1.148)
Diabetes mellitus	125/957 (13.1%)	0.576	1.271 (0.549–2.944)	0.165	1.851 (0.776–4.416)
Hypertension	103/311 (33.1%)	0.104	2.129 (0.857–5.292)	0.676	0.750 (0.195–2.889)
Hyperlipidemia	58/311 (18.6%)	0.015	3.213 (1.249–8.268)	0.459	1.670 (0.429–6.500)
HIV	4/957 (0.4%)	0.999	0.000 (0–0)	0.999	0.000 (0–0)
CAD	18/311 (5.8%)	0.001	7.128 (2.246–22.622)	0.095	3.944 (0.786–19.789)
Myocardial infarction	19/646 (2.9%)	0.590	1.771 (0.221–14.173)	0.555	1.873 (0.233–15.032)
Cerebrovascular accident	11/646 (1.7%)	0.999	0.000 (0–0)	0.270	3.319 (0.394–27.973)
BPH	28/311 (9.0%)	0.340	1.878 (0.515–6.849)	0.045	4.125 (1.029–16.539)
Chronic obstructive pulmonary disease	16/957 (1.7%)	0.999	0.000 (0–0)	0.999	0.000 (0–0)
PVD	11/957 (1.1%)	0.045	5.053 (1.037–24.613)	0.308	2.977 (0.365–24.286)
Ca	72/957 (7.5%)	0.099	2.145 (0.865–5.315)	0.018	3.081 (1.212–7.832)
Alcohol	0=200/419 (47.7%), 1=206/419 (49.2%), 2=13/419 (3.1%)	0.962	0.975 (0.346–2.746)	0.412	0.667 (0.253–1.755)
Smoking	0=505/803 (62.9%), 1=223/803 (27.8%), 2=75/803 (9.3%)	0.371	0.782 (0.456–1.341)	0.300	1.326 (0.778–2.262)
Previous urethroplasty	52/275 (18.9%)	0.302	0.456 (0.102–2.028)	0.474	0.466 (0.058–3.764)
Previous radiation	38/906 (4.2%)	0.256	2.047 (0.595–7.041)	0.130	2.624 (0.753–9.141)
Fossa navicularis	182/964 (18.9%)	0.097	1.837 (0.896–3.769)	0.025	2.437 (1.116–5.324)
Penile	268/983 (27.3%)	0.522	1.239 (0.643–2.389)	0.192	1.635 (0.781–3.423)
Bulbar	564/1037 (54.4%)	0.888	0.958 (0.528–1.738)	0.133	0.593 (0.299–1.173)
Membranous	137/970 (14.1%)	0.117	1.850 (0.857–3.995)	0.668	1.240 (0.465–3.306)
Excision and primary anastomosis/nontransecting	237/967 (24.5%)	0.258	0.618 (0.269–1.422)	0.465	0.713 (0.287–1.768)
Flap	20/965 (2.1%)	0.773	1.353 (0.174–10.510)	0.076	3.985 (0.864–18.380)
Perineal urethrostomy	56/965 (5.8%)	0.064	2.541 (0.946–6.824)	0.002	4.482 (1.739–11.555)
Dorsal graft	144/316 (45.6%)	0.384	1.498 (0.603–3.722)	0.535	0.673 (0.193–2.348)
Ventral graft	21/316 (7.0%)	0.723	0.689 (0.088–5.404)	0.998	0.000 (0–0)
First stage	97/962 (10.1%)	0.997	0.000 (0–0)	0.493	0.602 (0.141–2.572)
Graft use	496/996 (49.8%)	0.046	1.928 (1.011–3.679)	0.672	0.860 (0.428–1.730)

demographic or operative categories and infection. Only the variables found to be significant on univariate analysis were used for the multivariate logistic regression model.

RESULTS

The overall (cohorts A and B) rate of postoperative UTI within 30 days was 5.1% (46/900), with a rate of 6.7% (26/390) in cohort A and 3.9% (20/510) in cohort B. The overall rate of postoperative wound infection within 30 days was 3.9% (35/900), with a rate of 4.1% (16/390) in cohort A and 3.7% (19/510) in cohort B (Table 1).

The mean age of participants was 49.7 years old, mean body mass index (BMI) was 30.8 kg/m^2 and the average stricture length operated on was 4.09 cm. Of the urethroplasties 54.4% were performed on the bulbar urethra, 27.3% on penile urethra and 14.1% on membranous urethra; 49.8% of the urethroplasties utilized a graft or flap, and 24.5% utilized an excision and primary anastomosis or nontransecting technique. Of these patients 18.9% have had a prior urethroplasty (Table 2).

A chi-square test of independence was performed to examine the relationship between postoperative antibiotic use and infection rate. There was no significant association found between postoperative antibiotic use and UTI ($p=0.064$). There was no significant association found between postoperative antibiotic use and wound infection (0.772).

When analyzed independently using logistic regression, age ($p=0.016$), BMI ($p=0.052$), stricture length (0.008), preoperative bacteriuria ($p<0.001$), hyperlipidemia ($p=0.015$), coronary artery disease (CAD; $p=0.001$), peripheral vascular disease (PVD; $p=0.045$), perineal urethrostomy ($p=0.064$) and graft use ($p=0.046$) were significant or near significant for postoperative UTI (Table 2). For wound infections within 30 days postoperatively using logistic regression, history of CAD ($p=0.095$), history of benign prostatic hyperplasia (BPH; $p=0.045$), history of cancer ($p=0.018$), stricture location at meatus ($p=0.025$), use of flap ($p=0.076$) and perineal urethrostomy creation ($p=0.002$) were significant or trending towards significance (Table 2).

Table 3. *Multivariate logistic regression analysis comparing UTI to patient characteristics significant on univariate analysis*

Variable compared to UTI	Significance	Odds Ratio (95% CI)
Age	0.298	1.027 (0.977–1.079)
BMI	0.912	0.994 (0.892–1.108)
Stricture length	0.933	1.008 (0.831–1.224)
Hyperlipidemia	0.422	1.878 (0.404–8.742)
CAD	0.392	2.268 (0.348–14.783)
PVD	0.818	1.606 (0.028–90.593)
Ca	0.751	0.719 (0.04–5.497)
Fossa navicularis	0.692	0.665 (0.088–5.007)
Perineal urethrostomy	0.811	1.354 (0.112–16.324)
Graft used	0.494	0.570 (0.114–2.859)

Table 4. *Multivariate logistic regression analysis comparing wound infections to patient characteristics significant on univariate analysis*

Variable Compared to Wound	Significance	Odds Ratio (95% CI)
CAD	0.441	2.120 (0.313–14.367)
BPH	0.151	3.193 (0.654–15.579)
Ca	0.174	3.015 (0.614–14.811)
Fossa navicularis	0.326	2.050 (0.490–8.585)
Flap	0.999	0.000 (0–0)
Perineal urethrostomy	0.154	3.332 (0.638–17.394)

Other risk factors, including number of previous direct visual internal urethrotomies, number of previous dilations, history of diabetes mellitus, hypertension, hyperlipidemia, HIV, myocardial infarction, cerebrovascular accident, chronic obstructive pulmonary disease, alcohol use, smoking, intermittent catheterizations, prior urethroplasty and prior radiation were not significant for risk for postoperative UTI or wound infections. The method of urethroplasty, whether it was excision and primary anastomosis, nontransecting urethroplasty or use of a flap did not increase the risk of infection.

When the variables that were significant under univariate logistic regression were entered into 1 model using multiple logistic regression, no factors were significantly predictive of a UTI within 30 days postoperatively (Table 3). There were no factors that were predictive of postoperative wound infections (Table 4).

DISCUSSION

The overuse of antibiotics has led to a growing concern and reality of bacterial resistance, and thus the call for judicious and thoughtful utilization by physicians. Barriers to successful antibiotic stewardship have reportedly been due to diagnostic uncertainty, fear of not adequately covering the causative pathogen and underappreciation of the toxicity of antibiotics, leading to increased use of multiple broad-spectrum antibiotics.[16,17] This is mirrored in urological reconstruction practice with a wide range of antibiotics used, including aminoglycosides, fluoroquinolones, penicillin based and in many cases with double coverage.

The reasoning for postoperative antibiotic utilization is understandable for urethroplasty procedures. The catheter is typically left in for a longer period of time compared to other urological surgeries, anywhere between 1 to 3 weeks depending on whether buccal mucosa or other augments were utilized.[18–21] An indwelling catheter has been shown to increase the risk of bacterial colonization by 5%–10% each day that it is maintained[22] and, given that it can be challenging to distinguish colonization versus true infection, antibiotic prophylaxis has been utilized to try to eliminate the likelihood of infection with the increased length of catheterization. In addition, the common utilization of buccal mucosa and the pathogens that arise from the oral cavity can lead to an even more diverse antimicrobial practice pattern.

To date, this is the first prospective urethroplasty study performed with a standardized antibiotic protocol that directly compares the risk of postoperative infection with and without prolonged antibiotic utilization. A prior study by Manjunath et al suggested that antibiotic prophylaxis after urethroplasty may offer no benefit, given that there was no significant difference in stricture recurrence or wound complications between patients who had a positive and negative urine culture.[14] Additionally, Ofoha et al showed that the level of training of the surgeon seemed to have more of an impact on stricture recurrence, while infection was found to be insignificant.[23] There have not been any conclusive data to show that infections lead to urethral stricture recurrence, but concern over infection is seemingly the rationale for prolonged antibiotics. While it is ultimately the goal to ensure that a urethroplasty succeeds by minimizing any complications such as infection, the question of whether antibiotics truly reduce infections in the postoperative setting has not been answered previously.

Our study shows that the use of antibiotics made no difference in the infectious outcome ($p=0.064$), and in fact was trending towards decreased UTI and wound infection rates when postoperative antibiotics were not given. Drawing from our prior publication by Kim et al the only identifiable risk factor for a postoperative UTI was a positive preoperative urine culture.[15] There is no clear evidence that infections lead to urethral stricture recurrence. We have shown here postoperative antibiotics do not result in decreased UTI rates after urethroplasty. There appears to be no benefit to the prolonged postoperative antibiotics currently in practice.

The limitations of this study are the exclusion of 141 patients in the study, excluded due to lack of data regarding UTI and wound infections. This was not a randomized study as every institution had to maintain the same protocol for the sake of consistency. The 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. Although there may have been slight variation between surgeons in the length of catheter duration, each surgeon remained consistent between the 2 cohorts with the only change being the removal of prolonged postoperative antibiotics. Perioperative skin prep was not standardized within the protocol, which may have affected the UTI and surgical site infection rates, although most institutions have best practice-operative protocols they adhere to. Confirmation of clearance of positive preoperative urine cultures was not routinely performed with another repeat urine culture, as per AUA guidelines for asymptomatic patients.

CONCLUSIONS

The use of a standardized protocol minimized antibiotic use in the pre-, peri- and postoperative setting and demonstrated no benefit to prolonged antibiotic use. No statistical difference was seen between the 2 cohorts' postoperative UTI or wound infection rates with an overall rate of 5.1% and 3.9%, respectively, when extended antibiotics were eliminated. No identifiable risk factors were seen when considering surgical characteristics. Given the continued concern of antibiotic over-prescription and the potential harm and cost associated with it, we do not recommend prolonged antibiotic use after urethral reconstruction.

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EDITORIAL COMMENT

Antibiotic overuse and bacterial resistance have been described as a "crisis" and represent a major cause of worldwide morbidity and mortality.[1] Antibiotic stewardship—the judicious use of antibiosis—is therefore of great importance, particularly amongst high-risk patients. The authors present timely data on how to safely limit antibiotics in patients undergoing urethroplasty. They convincingly demonstrate that antibiosis at the time of catheter removal is not inferior to continuous postoperative antibiosis in reducing urinary

tract and wound infection following urethroplasty. These data provide specific guidance for reconstructive urologists in the setting of mounting evidence across surgical and urological disciplines to minimize the use of antibiotics in catheterized patients. Prophylaxis at the time of catheter removal is likely not necessary in the setting of nonurological surgery where there is intact urothelium, even with prolonged catheterization.[2] Similarly, 3 days of antibiosis at the time of catheter removal was equivalent to 24 hours in the post-prostatectomy population.[3] While Kim et al do not examine the rate of resistant bacteria among the groups, there is no doubt that fewer antibiotics in the aggregate will decrease antibiotic resistance. The heterogeneity of the study mimics the clinical milieu we face in treating stricture patients, particularly as it pertains to preoperative urinary tract infections. As the authors note, the preoperative urine culture plays an important predictive role. There may, therefore, be a role for further tailoring of antibiosis, particularly in those with no history of infection. We also wonder whether patients who developed a urinary or wound infection postoperatively had resistance to the prophylactic antibiotic.

This study helps validate the clinical practice of established reconstructive urologist, and perhaps more importantly provides support for those fresh out of training to deviate from the practices of their mentors.

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REPLY BY AUTHORS

We appreciate the editorial comments. It is certainly difficult to deviate from the set protocols that have been felt to work in the past, and likely even more challenging when there are no specific guidelines or data to support its change.

The consequences of antibiotic overuse are not easily noticeable when looking at the individual patient or an individual's practice. This is particularly true for relatively uncommon surgical procedures such as the urethroplasty. The discovery of widespread overuse of antibiotics in urethral surgery led to the need to follow American Urological Association guidelines and develop a protocol to limit antibiotic use.[1,2] We were able to demonstrate in this latest study that the prior common practice of prolonged prophylaxis antibiotics did not decrease postoperative infections rates.

Many things in medicine we accept as a given with little additional thought. A good reminder to us all is to question the status quo and be in a constant state of assessment and improvement.

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