Research article

Pre-procedural antibiotics for endoscopic urological procedures: Initial experience in individuals with spinal cord injury and asymptomatic bacteriuria

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Objective: The objective of this study was to compare the safety, efficacy, quality-of-life impact, and costs of a single dose or a longer course of pre-procedural antibiotics prior to elective endoscopic urological procedures in individuals with spinal cord injury and disorders (SCI/D) and asymptomatic bacteriuria.

Design: A prospective observational study.

Setting: Hunter Holmes McGuire Veterans Affairs Medical Center, Richmond, Virginia, USA.

Participants: Sixty persons with SCI/D and asymptomatic bacteriuria scheduled to undergo elective endoscopic urological procedures.

Interventions: A single pre-procedural dose of antibiotics vs. a 3–5-day course of pre-procedural antibiotics.

Outcome measures: Objective and subjective measures of health, costs, and quality of life.

Results: There were no significant differences in vital signs, leukocytosis, adverse events, and overall satisfaction in individuals who received short-course vs. long-course antibiotics. There was a significant decrease in antibiotic cost (33.1 ± 47.6 vs. 3.6 ± 6.1 US\$, $P = 0.01$) for individuals in the short-course group. In addition, there was greater pre-procedural anxiety (18 vs. 0%, $P < 0.05$) for individuals who received long-course antibiotics.

Conclusion: SCI/D individuals with asymptomatic bacteriuria may be able to safely undergo most endoscopic urological procedures with a single dose of pre-procedural antibiotics. However, further research is required and even appropriate pre-procedural antibiotics may not prevent severe infections.

Keywords: Neurogenic bladder, Spinal cord injury, Bacteriuria, Antibiotic prophylaxis, Urological surgical procedures

Introduction

In individuals with spinal cord injury and disorders (SCI/D) and neurogenic bladder dysfunction, there is a high prevalence of asymptomatic bacteriuria, upwards of 90%.¹ Asymptomatic bacteriuria is not usually treated in persons with SCI/D due to anatomical and functional abnormalities that confer an increased risk for recolonization.²

It is well known that urological procedures have the potential to induce surgical site infections, bacteriuria, pyelonephritis, and septicemia.³ As such, many studies have explored the need for antibiotic prophylaxis in different urological procedures. Procedures such as transurethral resection of the prostate and core prostate biopsy require antibiotic prophylaxis for all patients; however, the need for prophylaxis is not well established for other procedures such as cystoscopy.⁴ The American Urological Association and European Association of Urology currently recommend a duration of ≤ 24

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hours of antimicrobial prophylaxis for most urological procedures.^{5,6} However, a risk–benefit analysis must be performed for each patient, maintaining a lower threshold for a longer duration of antibiotic administration in high-risk patients. Urinary tract infections are especially prevalent among the SCI/D population with neurogenic bladder and asymptomatic bacteriuria.⁷

Based on this increased risk in our own population of veterans at a large SCI/D unit at a tertiary care medical center, it has been our practice to administer 3–5 days of organism-specific or broad-spectrum antibiotics prior to elective endoscopic urological procedures in an attempt to eradicate asymptomatic bacteriuria. Previous studies have shown that Gram-negative organisms isolated from the urine of persons with SCI/D are resistant to two or more classes of antimicrobial agents.⁸ The reason for the administration of this longer course of antibiotics was a lack of specific antibiotic recommendations or guidelines for individuals with SCI/D undergoing endoscopic urological procedures at the time of our study.

Previous studies evaluating the safety, efficacy, and cost-effectiveness of this or other types of antibiotic administration in individuals with SCI/D undergoing elective endoscopic urological procedures are extremely limited. Vaidyanathan and Soni⁹ examined the effectiveness of empiric gentamicin vs. culture-specific antibiotics in patients with SCI/D undergoing urological procedures and concluded that culture-specific antibiotics were superior; however, the study did not evaluate the length of antibiotic administration or make any consideration for patients with gentamicin-resistant bacterial species. Therefore, the purpose of the current study was to compare the safety, efficacy, quality-of-life impact, and cost of 3–5 days of a pre-procedural antibiotic regimen to a more streamlined approach in which the individuals are administered one dose of pre-procedural antibiotics within 30 minutes of the scheduled endoscopic procedure.

Materials and methods

Patient population

The study was approved by the Institutional Review Board at the Hunter Holmes McGuire Veterans Affairs Medical Center. Individuals with SCI/D at the Hunter Holmes McGuire Veterans Affairs Medical Center scheduled for elective, endoscopic urological surgical procedures not requiring a skin incision were eligible for this study. All of the study participants included were at least 18 years old, had documented SCI/D, had been followed by the SCI/D unit, and gave informed consent. In addition, the participants

must have had a positive urine culture pre-operatively as defined by $>10^5$ CFU/ml urine or a “contaminated” specimen defined as having two or more bacterial species. None of the participants were immunocompromised due to active chemotherapy, medical immunosuppression, or HIV, and no participants had active infection requiring the use of antibiotics at the time of planned admission/procedure.

Group assignment

An independent, blinded individual, not affiliated with the study, assigned each participant into one of the two groups based on a coin toss; the long-course group received 3–5 days of pre-procedural antibiotic therapy and documentation of clean urine was required prior to performance of the procedure. Clean urine was confirmed via dipstick testing and was considered positive only when the presence of “moderate” or “large” bacteria was identified. The short-course group received a single dose of pre-procedural antibiotic therapy administered 30 minutes prior to the scheduled procedure, and documentation of clean urine was not required prior to the performance of the procedure. Documentation of clean urine was not required for the short-course group due to the proximity of the procedure to the intervention. In both of the groups, the selection of the antibiotics was tailored to the results of the most recent urine culture (maximum of 6 months prior to the procedure). If all of the cultures in the past 6 months showed contamination or the presence of multiple bacterial species, then broad-spectrum antibiotics were administered. All of the cultures were obtained by using clean technique (mid-stream clean catch or collection via a new catheter). In most cases, a repeat urine culture was obtained as soon as possible prior to the initiation of the antibiotics, and these data were used to determine the appropriateness of the selected antibiotics. All of the participants received a minimum of 48 hours of post-procedural antibiotic treatment by using the same agent as was our standard practice at the time of enrollment in the current study.

Pre-procedural data

In the pre-operative period, the individuals were directly interviewed and an additional review of the electronic medical record was completed in order to collect the following data: demographic data (age, sex, race, employment status, marital status, education, home health requirements, and type of residence), SCI/D data (level of spinal cord injury, date and duration of injury, American Spinal Injury Association Impairment Scale classification, the presence of

autonomic dysreflexia, level of assistance with activities of daily living), urological data (type of bladder management, previous history of urological procedures), medical data (the presence of comorbid medical conditions including, but not limited to, diabetes, heart disease, hypertension, renal insufficiency, liver dysfunction, chronic obstructive pulmonary disease, morbid obesity, and major depression), physical exam data (admission vital signs including heart rate, temperature, respiratory rate, and blood pressure), and laboratory data (creatinine and urine culture).

Intra-procedural and post-procedural data

Operative time, estimated blood loss, type of anesthesia, and intra-procedural complications were recorded. All of the participants were monitored for 24 hours post-procedure. This remains our standard practice due to the nature of our referral population. Any participant who experienced an adverse event was followed until medically stable. All of the participants received comprehensive medical care within the same institution and any additional adverse events or re-admissions within 30 days of the scheduled procedure were recorded. The following post-procedural data were collected: physical exam data (vital signs on post-procedural day 1 including heart rate, respiratory rate, temperature, and blood pressure), antibiotic usage (type, frequency, and duration of antibiotic administration), post-procedural day 1 white blood cell (WBC) count, complications (all urinary tract infections with fever, other infectious ailments, or other post-procedural complications), and a local satisfaction survey.

Quality-of-life data

The EQ-5D is a validated instrument that allows participants to rank their overall health state as well as subjective symptom data.¹⁰ The participants were administered this survey prior to the scheduled procedure and asked to complete the same survey on post-procedural day 1.

Data analysis

Demographic, pre-procedural, post-procedural, and EQ-5D data of the short-course and the long-course groups were analyzed by using univariate unpaired *t*-tests for continuous variables or Fishers exact tests for categorical variables. Pre- and post-procedural EQ-5D survey results were also analyzed by using repeated measures of analysis of variance to identify changes in subjects' perceptions of their health pre- and post-procedure. The Common Term Criteria for Adverse Events (CTCAE) was used to grade the adverse events that were observed and treated.

Continuous variables are reported as means $\pm$ standard deviation. Statistical significance was achieved with $P < 0.05$.

Results

Sixty individuals with confirmed SCI/D and asymptomatic bacteriuria scheduled for elective endoscopic urological procedures were included in this study and were assigned to the long-course ($N = 25$) or the short-course ($N = 35$) groups. Urine cultures were obtained at an average of 11 ± 2.3 days prior to the initiation of pre-procedural antibiotics (median = 5 days, range = 0–79 days). The results from the most recent cultures demonstrated that complete bacterial speciation was available in 39 of 60 (65%) of the participants, and “mixed” or “contaminated” cultures were identified in the remainder. Based on our definition of “appropriate” as either culture-specific antibiotics or the empirical use of broad-spectrum antibiotics for individuals with “mixed” or “contaminated” cultures, appropriate antibiotics were administered in 50 of 60 (88.3%) of the participants. In 10 participants, repeat urine cultures taken just prior to the initiation of the antibiotics showed organisms that were resistant to the selected antibiotics.

Table 1 summarizes the demographic and the clinical characteristics of the participants. There were no differences in any pre-procedural demographic, urological, neurological, or medical variables between the groups. More importantly, the type of bladder management was similar between the groups, and the pre-procedural serum creatinine was similar (1.0 ± 0.5 mg/dl – long course vs. 0.9 ± 0.3 mg/dl – short course, $P = 0.48$).

Table 1 Subject characteristics

Age (years)	55.75 $\pm$ 12.91
Sex, <i>n</i> (%)	
Male	59 (98.33)
Female	1 (1.67)
Race, <i>n</i> (%)	
Caucasian	35 (58.33)
African American	25 (41.67)
Level of injury	
C8 and above	35 (58.33)
T1 and below	25 (41.67)
AIS scale	
A	34 (56.67)
B	11 (18.33)
C	9 (15)
D	6 (10)
E	0 (0)
Urinary management	
Foley	34 (56.67)
Condom catheterization	14 (23.33)
Urinary diversion	5 (8.33)
Intermittent catheterization	6 (10)

AIS, American Spinal Injury Association Impairment Scale.

The majority of the procedures in both the groups were diagnostic cystoscopies performed without anesthesia. More invasive endoscopic procedures were distributed equally between the groups (Table 2). There were no differences in vital signs between the groups (long course vs. short course) or within the groups (pre-procedure vs. post-procedure) (Table 3). In addition, the post-procedural WBC levels were similar ($10.6 \pm 7.5 \times 10^3/\mu\text{l}$ – long course vs. $7.2 \pm 2.5 \times 10^3/\mu\text{l}$ – short course, $P = 0.10$). The route of antibiotic administration was oral in 47% of the participants and intravenous or intramuscular in 53% with no differences between the groups. However, the cost of antibiotics (calculated only as the total drug costs) for the participants in the long-course group was higher (33.1 ± 47.6 US\$ – long course vs. 3.6 ± 6.1 US\$ – short course, $P = 0.013$).

In terms of quality-of-life (EQ-5D) scores, there were no significant differences in the total health score or health state in the long-course and the short-course groups. However, there was a significant difference in the pre-procedural anxiety/depression level. Thirteen participants in the long-course group (46.4%) subjectively reported being “not anxious” vs. 30 participants in the short-course group (85%) ($P = 0.010$). Similarly,

Table 2 Procedure type

	Long course	Short course	P value
Type of procedure (n, %)			
Cystoscopy/stent	21/25 (84.0)	32/35 (91.4)	0.436
Other/invasive*	4/25 (16.0)	3/35 (8.6)	

*Transurethral resection of bladder tumor (2), ureteroscopy with laser lithotripsy (1), diagnostic ureteroscopy (1), sphincterotomy (1), laser lithotripsy of bladder calculus and retrograde pyelogram (1), ureteroscopy with laser lithotripsy and electrohydraulic lithotripsy of bladder calculus (1).

Table 3 Vital signs

	Time	Long course	Short course
Systolic blood pressure (mmHg)	Pre	120.4 $\pm$ 24.5	119.4 $\pm$ 16.5
	Post	121.0 $\pm$ 18.9	117.7 $\pm$ 16.4
Diastolic blood pressure (mmHg)	Pre	67.1 $\pm$ 11.8	66.9 $\pm$ 14.2
	Post	68.5 $\pm$ 10.5	66.1 $\pm$ 10.8
Temperature (°C)	Pre	36.6 $\pm$ 0.4	36.6 $\pm$ 0.4
	Post	36.6 $\pm$ 0.5	36.7 $\pm$ 0.6
Pulse (beats/min)	Pre	73.8 $\pm$ 10.6	75.4 $\pm$ 15.3
	Post	76.1 $\pm$ 12.3	72.8 $\pm$ 16.2
Respiratory rate (breaths/min)	Pre	17.8 $\pm$ 1.5	17.9 $\pm$ 1.9
	Post	18.2 $\pm$ 1.8	17.5 $\pm$ 2.3

Pre, pre-procedure; Post, post-procedure.

Table 4 Pre- and post-procedural EQ-5D survey results

	Long course	Short course	P value
Pre-operative EQ-5D survey			
Total health score	8.28 $\pm$ 1.65	8.03 $\pm$ 1.92	0.598
Health state scale score	72.52 $\pm$ 20.23	71.20 $\pm$ 18.87	0.796
Anxiety/depression (n, %)			
Not anxious	13 (46.4)	30 (85.0)	0.010
Extremely anxious	5 (17.9)	0 (0)	
Post-operative EQ-5D survey			
Total health score	7.52 $\pm$ 2.24	7.86 $\pm$ 1.91	0.533
Health state scale score	74.08 $\pm$ 16.69	74.32 $\pm$ 20.35	0.962
Anxiety/depression (n, %)			0.230
Not anxious	17 (70.8)	30 (85.7)	0.230
Extremely anxious	1 (4.2)	0 (0)	

five participants in the long-course group (17.9%) subjectively reported being “extremely anxious” vs. zero participants in the short-course group ($P = 0.010$) (Table 4). In addition, there were no significant changes in the anxiety levels within each group between the pre- and the post-procedural periods (Table 4).

Finally, five adverse events were reported post-procedure (Table 5). However, only two were considered infectious complications. Two participants in the long-course group (8%) had adverse events vs. three participants in the short-course group (8.6%). Of those adverse events, a total of two were deemed Common Terminology Criteria for Adverse Events Grade IV or greater. One participant from the long-course group (4%) was disoriented and was found to have urosepsis requiring intensive care unit admission. Similarly, one participant from the short-course group (2.9%) had hypotension, fever, and chills and was also found to have urosepsis requiring intensive care unit admission.

Discussion

This is the first prospective observational study to evaluate the safety, efficacy, quality-of-life impact, and cost of short-course pre-procedural antibiotics in comparison with long-course pre-procedural antibiotics in individuals with SCI/D undergoing elective endoscopic urological procedures. In this study, we found that there were no differences between the individuals assigned to receive short-course vs. long-course pre-procedural antibiotics with regard to post-procedural measurements of health or adverse events. However, even appropriate pre-procedural antibiotics may not prevent severe complications, including urosepsis.

In terms of quality-of-life measures, we found that the EQ-5D total scores were not significantly different

Table 5 Adverse events

Procedure	Group	Adverse event	CTCAE type	CTCAE grade
Cystoscopy	LC	Diarrhea on day 6 of ABX	Gastrointestinal (diarrhea)	I
Ureteroscopy with laser lithotripsy	LC	Disorientation and urosepsis	Infection (infection with unknown ANC)	IV
Cystoscopy	SC	Autonomic dysreflexia during procedure and lasting 1 day	Cardiac general (hypertension)	II
Cystoscopy	SC	Stomach cramping of 20–30 minutes	Gastrointestinal (abdominal distention/bloating)	II
Sphincterotomy	SC	Hypotension, fever, chills, and urosepsis requiring intubation	Infection (infection with unknown ANC)	IV

CTCAE, Common Terminology Criteria for Adverse Events; LC, long course; SC, short course; ICU, intensive care unit; ABX, antibiotics; and ANC, absolute neutrophil count.

between participants assigned to short-course vs. long-course antibiotics. However, when the individual components of EQ-5D were examined separately, we identified a significant difference between the pre-procedural anxiety/depression levels between the two groups. Individuals assigned to the long-course antibiotics were significantly more anxious pre-procedure than individuals who were scheduled to receive the short course. As individuals who were assigned to the long-course antibiotics were counseled that a longer course of antibiotics could possibly increase the risk of antibiotic-associated complications and antibiotic resistance, we surmise that these factors could have contributed to the increased pre-procedural anxiety/depression levels. However, it is important to emphasize that all of the patients received the same detailed discussion of risks and benefits prior to randomization. In addition, although the route of antibiotic administration did not differ between the groups, it is possible that more invasive routes (i.e. intramuscular or intravenous) could have led to heightened levels of anxiety. Several studies have examined the psychological risk factors for prolonged hospital stays and post-operative complications in surgical inpatients. de Groot *et al.*¹¹ showed that pre-operative specific anxiety had a positive contribution to post-operative anxiety, physical complaints, and prolonged hospital stay. In addition, Kalkman *et al.*¹² developed and validated a prediction model for early post-operative pain in surgical inpatients and demonstrated that including measures of pre-operative anxiety provided a better predictability of post-operative pain.

It has been an accepted practice to administer antibiotics pre-operatively in an attempt to sterilize the urine prior to urological procedures in patients with bacteriuria or indwelling catheters.¹³ However, previous studies regarding the appropriate length or type of antibiotics have been mainly restricted to individuals

without pre-existing risk factors such as neurogenic bladder dysfunction. Briffaux *et al.*¹⁴ evaluated a single pre-operative dose of antibiotics randomized against a 3-day course of antibiotic prophylaxis for transrectal prostate biopsy. Similarly, McEntee *et al.*¹⁵ examined whether a single dose of gentamicin reduced post-operative infections in patients with indwelling catheters undergoing transurethral prostatic resection. However, the study was randomized against a placebo.

The main outcome of the current prospective study was a demonstration that there were no differences in adverse events between individuals receiving short and long courses of antibiotics. Of the five adverse events that occurred, only two were graded as CTCAE Grade IV requiring intensive care unit admission. These two adverse events (one from each group) involved more invasive urological procedures that have greater inherent risks (ureteroscopy, sphincterotomy). The majority of procedures in the study were diagnostic cystoscopies. Therefore, we consider that the CTCAE Grade IV adverse events were due more to the nature of the procedure than to the length of antibiotic treatment. In addition, none of the individuals undergoing simple cystoscopy had an adverse event greater than a CTCAE Grade II. In fact, one individual, assigned to the long-course antibiotics group, had an adverse event directly related to increased antibiotic use, namely diarrhea.

We recognize several limitations to our study, primarily that the study was underpowered. Therefore, we caution against making any definitive conclusions about the safety of short- vs. long-course antibiotics. However, this initial experience suggests that, on a limited scale, complete eradication of asymptomatic bacteria may not be required for individuals with SCI/D who undergo elective, endoscopic urological procedures. We surmise that the results are probably more

applicable to minimally invasive, office-based procedures in which violation of the urothelial barrier does not occur. In addition, 59 of our 60 study participants (98.33%) were male. This is expected, as our Veteran patient population is predominately male. However, Bennett *et al.*¹⁶ previously reported that females with spinal cord injury on intermittent catheterization have a higher rate of urinary tract infections (53%) as compared with males (18%). In the light of this higher prevalence, future studies are required to determine if short-course antibiotic treatment is equally safe and effective in women with SCI/D. Furthermore, there was inequality in the number of individuals assigned to each treatment group (25 – long course; 35 – short course) due to random chance associated with the coin-flip assignment scheme.

On a limited scale, our study suggests that a single dose of pre-procedural antibiotics may be as safe and effective as a 3–5-day course of pre-procedural antibiotics in preventing post-procedural infections and other adverse events. In addition, a short course of pre-procedural antibiotic treatment was associated with lower costs and reduced pre-procedural anxiety.

Conclusion

Although limited in scale, the results of our prospective study suggest that individuals with SCI/D and asymptomatic bacteriuria may potentially be able to safely undergo most endoscopic urological procedures with a single dose of pre-procedural antibiotics. However, additional research is required.

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Disclaimer statements

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Conflicts of interest The authors declare no conflict of interest.

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