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Evaluating the role of postoperative oral antibiotic administration in artificial urinary sphincter and inflatable penile prosthesis explantation: a nationwide analysis

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Abstract

Objective—To determine whether postoperative oral antibiotics are associated with decreased risk of explantation following artificial urinary sphincter (AUS) or inflatable penile prosthesis (IPP) placement. Although frequently prescribed, the role of postoperative oral antibiotics in preventing AUS or IPP explantation is unknown.

Materials and methods—We queried the MarketScan database to identify male patients undergoing AUS or IPP placement between 2003 and 2014. The primary endpoint was device explantation within 3 months of placement. Multivariate regression analysis controlling for clinical risk factors assessed the impact of postoperative oral antibiotic administration on explant rates.

Results—We identified 10847 and 3594 men who underwent IPP and AUS placement, respectively, between 2003 and 2014. Postoperative oral antibiotics were prescribed to 60.6% of patients following IPP placement and 61.1% of patients following AUS placement. The most frequently prescribed antibiotics were fluoroquinolones (35.6%), cephalexin (17.7%), trimethoprim/sulfamethoxazole (7.0%), and amoxicillin-clavulanate (3.2%). Explant rates did not differ based upon receipt of oral antibiotics (antibiotics vs. no antibiotics IPP: 2.2% vs. 1.9%, $p=0.18$, AUS: 3.9% vs. 4.0%, $p=0.94$). On multivariate analysis, no individual class of antibiotic was associated with decreased odds of device explantation.

Conclusion—Postoperative oral antibiotics are prescribed to nearly two-thirds of patients but are not associated with reduced odds of explant following IPP or AUS placement. Given the risks to individuals associated with use of antibiotics and increasing bacterial resistance, the role of oral

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antibiotics after prosthetic placement should be reconsidered and further studied in a prospective fashion.

MeSH keywords

Urology; Prostheses and Implants; Device removal; Anti-Bacterial Agents; Urinary Sphincter; Artificial; Penile prosthesis

Introduction

The artificial urinary sphincter (AUS) and inflatable penile prosthesis (IPP) are commonly used prosthetic devices for the management of stress urinary incontinence and erectile dysfunction, respectively. While patient satisfaction with these devices is excellent, infection and subsequent device explantation remain a concern for reconstructive urologists and patients alike. Infection rates vary in the literature from 4.4–13.9% for AUS^{1–3} and 0.6–8.9% for IPP⁴, and the standard treatment of device infection is explantation. This unfortunate outcome is associated with patient dissatisfaction and increased risk to patients who ultimately require removal of the infected device and reimplantation, if desired⁵.

In an effort to prevent infection, postoperative oral antibiotics (PO antibiotics) are commonly prescribed despite a paucity of evidence to support this practice. The American Urological Association (AUA) Best Practice Policy Statement on Urologic Surgery and Antimicrobial Prophylaxis acknowledges that the current urologic literature does not provide adequate evidence to guide the duration of antibacterial therapy after prosthesis placement⁶, but draws on data from orthopedic literature on prosthetic joints⁷ to suggest that prophylaxis should be discontinued within 24 hours of surgery. Despite this, PO antibiotics are prescribed by the majority of urologists following prosthetic surgery⁸. With increasing concerns regarding potential harms from the overuse of antibiotics and the emergence of resistant microorganisms, it is worthwhile to determine if there is any benefit from prolonged PO antibiotic prophylaxis following AUS and IPP placement⁹. To this end, we analyzed a national database to assess the role of PO antibiotics in preventing prosthetic device explantation.

Materials and Methods

Data Source

MarketScan[®] (Truven Health Analytics) is a database containing information on over 62.5 million beneficiaries obtained from employer based commercial health plans in the United States. The database includes longitudinal data captured across inpatient and outpatient encounters, including outpatient prescriptions¹⁰. De-identified individual records contain patient demographics, service dates, length of stay, International Statistical Classification of Disease (ICD) 9 and current procedural terminology (CPT) codes. Data on race, ethnicity, socioeconomic status, operating time, and surgeon case volume are not available.

Study population

We identified male patients who underwent urologic prosthetic device implantation from 2003 to 2014, including only patients with a minimum of 6 months of antecedent data and 3 months of follow up data after the index procedure. Antecedent data were required to maximize capture of comorbid conditions. We used CPT codes to identify men who underwent AUS or IPP placement, as summarized in Appendix 1. Two cohorts were generated based on type of device placed (AUS or IPP), and each group was analyzed separately. Patients undergoing combined AUS and IPP placement were excluded.

Patient and Hospital Characteristics

Patient characteristics were extracted including demographics and comorbid disease with a focus on risk factors previously associated with device explantation⁵ as defined in Appendix 2. Charlson comorbidity index (CCI) for each subject was calculated using the standard components¹¹.

The type of intravenous (IV) antibiotic(s) administered was determined using Healthcare Common Procedure Coding System (HCPCS) codes billed in conjunction with the index CPT code, shown in Appendix 3. Perioperative antibiotic regimen was considered to be consistent with AUA guidelines if it included an aminoglycoside or aztreonam plus vancomycin or a first or second generation cephalosporin, or a penicillin with beta-lactamase inhibitor⁶. The type of outpatient antibiotic prescribed was determined from outpatient prescription claims within one week of index procedure, and duration determined as the number of days indicated on outpatient prescription claim.

The primary endpoint was device explantation within 90 days of device placement, as defined by CPT codes (Appendix 1). We included any code that specifies device removal or device removal and replacement through an infected field. We did not include codes for device repair or device removal and replacement, assuming that these codes would be more likely to correspond to device failure or pain rather than an infectious complication. The 90-day endpoint was chosen to coincide with the global period for these procedures and in an effort to capture early infectious complications, which are intuitively more likely to be impacted by the choice of peri- and post-operative antibiotic selection than complications requiring explantation remote from implantation¹².

Statistical Analysis

All statistical analyses were performed using STATA 14.0 (Statacorp, College Station, TX), with two-sided $p < 0.05$ representing statistical significance. Descriptive statistics included mean and standard deviation or median and interquartile range for continuous variables and proportions for categorical variables. Chi square and t-tests were used to assess for differences in baseline characteristics between groups. Temporal trends in PO antibiotic use were assessed using Pearson's correlation coefficient. Multivariate logistic regression analysis was used to assess for factors affecting the odds of device explantation. Covariates included in the multivariate analysis were selected *a priori* and were based upon known or suspected risk factors for device infection based upon prior literature, including CCI, diabetes, hypertension, vascular disease, neurologic disease, and prior device placement. We

additionally controlled for length of stay, geographic region, and year of implantation. Data on certain known or suspected risk factors, including history of radiation, smoking, surgeon case volume, and operative time were not available in the database. MarketScan contains complete and reliable data on outpatient prescriptions, but inpatient intravenous (IV) antibiotic data is only captured on a subset of patients¹⁰. Therefore, we did not include use of guideline IV antibiotics as a covariate in the primary multivariate analysis. However separate analysis was performed on the patient subset with IV antibiotic data available using limited covariates thought to represent the primary competing risk factors, including diabetes, prior device placement, and PO antibiotic prescribed. Multivariate analysis also assessed the likelihood of PO antibiotic prescription based on clinical variables to determine whether higher risk individuals were more likely to receive antibiotics.

Results

Between 2003 and 2014, there were 10847 patients who underwent IPP placement and 3594 who underwent AUS placement who met criteria for inclusion. Mean age at time of device placement was 61.6 years (SD 9.0) for IPP and 67.6 years (SD 10.3) for AUS. Device explantation occurred in 228 patients (2.1%) at a median time of 42 days (IQR 27–58) following IPP placement and in 141 patients (3.9%) at a median time of 41.5 days (IQR 20–61) following AUS placement. Table 1 details baseline characteristics of patients undergoing IPP or AUS placement, stratified by incidence of device explantation.

Postoperative prophylactic oral antibiotics were prescribed to 6578 (60.6%) patients following IPP placement and 2304 (61.1%) patients following AUS placement. Table 2 summarizes the type and duration of antibiotics prescribed for IPP and AUS. Multivariate regression analysis did not demonstrate any patient demographic or comorbid conditions associated with increased odds of receiving PO antibiotics after either procedure. Utilization of PO antibiotics decreased significantly over the study period for both IPP and AUS, as shown in Figure 1. PO antibiotics were prescribed after 71.5% of IPP cases in 2003 compared to 55.4% in 2014 (p trend <0.01), and after 75.9% of AUS cases in 2003 compared to 56.0% in 2014 (p trend <0.01).

Results of the multivariate analyses assessing the impact of patient factors and antibiotics on odds of device explantation at 90 days are presented in Table 3. For AUS, diabetes (OR 1.86, 95% CI 1.28–2.72, $p<0.01$) and increased age (OR 1.03, 95% CI 1.007–1.05, $p<0.01$) were associated with significantly increased odds of device explantation, and coronary artery disease (CAD) and higher CCI trended toward significance. No class of PO antibiotic demonstrated any benefit, nor did increased antibiotic duration. For IPP, diabetes (OR 1.59, 95% CI 1.14–2.21, $p<0.01$) and prior IPP placement (OR 3.32, 95% CI 1.14–6.99, $p<0.01$) were associated with significantly increased odds of device explantation. No class of PO antibiotic was associated with reduction in explant risk, while longer duration of antibiotics was associated with harm (OR 1.03, 95% CI 1.002–1.05, $p=0.03$).

Data on perioperative IV antibiotic administration was only available for 3008 (27.7%) patients undergoing IPP placement and 970 (27.0%) patients undergoing AUS placement. Explantation rates were similar in these subsets to the overall cohort (IPP: 1.7%, AUS:

4.4%) and did not differ based upon receipt of PO antibiotics. Multivariate analysis in this limited subset of patients did not demonstrate a benefit to receipt of guideline-consistent perioperative IV antibiotics nor PO antibiotics for either device ($p>0.05$ for all), consistent with the results of the analysis on the overall cohort that did not incorporate IV antibiotic data.

Discussion

This study represents the largest to date examining risk factors for AUS and IPP explantation. Furthermore, it is the only study large enough to examine the role of PO antibiotic prophylaxis in altering the risk of prosthetic device explantation independent of multiple risk factors. We failed to demonstrate evidence of a benefit to use of PO antibiotic prophylaxis. On multivariate analysis controlling for comorbid conditions and known risk factors, PO antibiotics did not alter the odds of AUS or IPP explantation. Increased risk of explantation for one or both devices appeared to be associated with increased CCI, diabetes, CAD, and prior device placement. This is consistent with prior literature that motivated selection of these factors as covariates^{13–18}. These risk factors are inherent to the patient and therefore largely non-modifiable prior to surgery.

In contrast, antibiotic selection and duration of therapy comprise a potentially modifiable factor that could influence infection risk. Despite limited evidence, urologists prescribed postoperative PO antibiotics to nearly two-thirds of patients undergoing AUS or IPP placement. This was presumably a well-intentioned effort to reduce the risk of infection, however in general it was not found to be beneficial. Specifically, the data indicate no decreased risk of AUS or IPP infection with any antibiotic, and potentially harm with longer duration of antibiotics following IPP placement. Antibiotics are associated with potential side effects, increased cost of care, and population-wide antimicrobial resistance. As a result, antimicrobial stewardship has become a principal focus of the Centers for Disease Control and Infectious Diseases Society of America as a vitally important objective across medicine^{19,20}. Postoperative antibiotic administration decreased over time in our cohort, suggesting increasing antibiotic stewardship among urologists. This may be related to multiple factors, such as comfort with decreased antibiotic use once the benefits of antibiotic-impregnated devices became apparent²¹, discussion around and publication of the 2008 AUA Best Practice Statement on Antimicrobial prophylaxis⁶, or intensification of a broader effort in the 2000s to reduce antibiotic overuse across medicine²². While there are limitations to a database review, our data suggest that the use of PO antibiotics after prosthetics may not be prudent and should be reconsidered. However, further prospective study is warranted to determine if specific postoperative antibiotics do reduce infectious risk, with a focus on optimal duration of therapy (if any) and patient selection.

Limitations in data collection prevented a more robust analysis of perioperative IV antibiotic selection. Our data did not shed light on optimal perioperative IV antibiotic selection. A recent study of infected IPPs revealed that microorganisms isolated at the time of explant or salvage were not covered by current guideline antibiotics in up to 38% of cases, which highlights the need for further study and cooperation with infectious disease specialists to optimize perioperative IV antibiotic selection²³. The impact of surgical technique must also

be emphasized, as unrecognized injury to the urethra during AUS placement will almost certainly lead to erosion and infection regardless of antibiotic selection.

Because the rate of explantation is generally low, and multiple risk factors influence explantation risk, analysis of a large nationally representative database with detailed outpatient antibiotic data ascribes unique strength to our study. Nevertheless, our findings must be interpreted within the context of its limitations. Reliance on coding with respect to diagnosis and procedural codes capture culture data from preoperative urine, nor from the time of device explant. However, a recent publication demonstrated poor correlation between organisms identified on preoperative urine culture and at time of subsequent explantation²⁴. Furthermore, although complete removal of a device due to dissatisfaction rather than revision is uncommon in clinical practice, a proportion of 90-day device removals may have been performed for reasons other than infection which would theoretically not be at all related to antibiotic selection. In addition, we were unable to assess patient compliance with prescribed medication regimens. Capture in the database confirms the prescription was filled and purchased, but noncompliance with completing the course of medication would diminish any differences between the antibiotic and non-antibiotic groups. Finally, the MarketScan database does not capture certain factors that have been demonstrated to increase risk of device explantation. For example, smoking status, prior radiation, and surgeon case volume have all been associated with device explantation but are unreliably coded in the database^{16,25,26}. Additional details regarding the duration and severity of diabetes, for example, would also be of use but are not reliably available in the dataset. A randomized placebo-controlled trial could control for many of these factors as well as unmeasured confounders, but the sample size required due to the relative rarity of infection represents a significant challenge requiring coordination across multiple centers. Nevertheless, further prospective study should be pursued in order to validate our findings and truly determine the benefit of PO antibiotic use following urologic prosthetic surgery.

Conclusions

Postoperative oral antibiotics are commonly prescribed following prosthetic device placement, but in general are not associated with reduced risk of explantation within 90 days of surgery. Given the risks to individuals associated with use of antibiotics and increasing antimicrobial resistance, routine use of PO antibiotics after prosthetic placement should be reconsidered and studied prospectively. Further study aimed at optimization of perioperative IV antibiotics specific to AUS and IPP placement is critical, as is education regarding what role, if any, PO antibiotic prophylaxis should have in urologic prosthetic surgery.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Appendix 1

Common procedural terminology codes used for index cases and explantation

Appendix 2

International Statistical Classification of Disease (ICD) 9 codes for identification of comorbid disease

Appendix 3

Healthcare common procedure coding system (HCPCS) codes for perioperative intravenous antibiotics

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Figure 1.
Trends in Prescription of Oral Antibiotics Following Device Implantation Over Time

Table 1

Baseline characteristics stratified by incidence of device explantation within 90 days

	Artificial Urinary Sphincter				Penile Prosthesis			
	Total (n=3594)	No explant (n=3453)	Explant (n=141)	p-value	Total (n=10847)	No explant (n=10619)	Explant (n=228)	p-value
CCI				0.001				0.002
0	542	528 (97.4)	14 (2.6)		3014	2962 (98.3)	52 (1.7)	
1	1725	1671 (96.9)	54 (3.1)		4737	4642 (98.0)	95 (2.0)	
>1	1327	1254 (94.5)	73 (5.5)		3096	3015 (97.4)	81 (2.6)	
Length of stay*				0.581				0.052
<24 Hours	2734	2624 (96.0)	110 (4.0)		9243	9059 (98.0)	184 (2.0)	
> 24 Hours	860	829 (96.4)	31 (3.6)		1604	1560 (97.2)	44 (2.7)	
Diabetes				<0.001				<0.001
Yes	754	705 (93.5)	49 (6.5)		1819	1760 (96.7)	59 (3.2)	
No	2840	2748 (96.7)	92 (3.2)		9028	8859 (98.1)	169 (1.9)	
Hypertension				0.496				0.56
Yes	1330	1274 (95.8)	56 (4.2)		3753	3670 (97.8)	83 (2.2)	
No	2264	2179 (96.3)	85 (3.7)		7094	6949 (98.0)	145 (2.0)	
Coronary artery disease				0.002				0.06
Yes	686	645 (94.0)	41 (6.0)		1910	1859 (97.3)	51 (2.7)	
No	2908	2808 (96.6)	100 (3.4)		8937	8760 (98.0)	177 (2.0)	
Peripheral vascular disease				0.350				0.42
Yes	65	61 (93.9)	4 (6.1)		372	362 (97.3)	10 (2.7)	
No	3529	3392 (96.1)	137 (3.9)		10475	10257 (97.9)	218 (2.1)	
Neurologic Condition**				0.240				0.83
Yes	58	54 (93.1)	4 (6.9)		82	80 (97.6)	2 (2.4)	
No	3536	3399 (96.1)	137 (3.9)		10765	10539 (97.9)	226 (2.1)	
Prior Device				0.185				<0.001

	Artificial Urinary Sphincter				Penile Prosthesis			
	Total (n=3594)	No explant (n=3453)	Explant (n=141)	<i>p-value</i>	Total (n=10847)	No explant (n=10619)	Explant (n=228)	<i>p-value</i>
Yes	192	181 (94.3)	11 (5.7)		119	111 (93.3)	8 (6.7)	
No	3402	3272 (96.2)	130 (3.8)		10728	10508 (97.9)	111 (2.1)	
PO Antibiotics				0.94				0.18
Yes	2304	2214 (96.1)	90 (3.9)		6578	6430 (97.8)	148 (2.2)	
No	1290	1239 (96.0)	51 (4.0)		4269	4189 (98.1)	80 (1.9)	
Mean PO Antibiotic duration, days (SD)¶	–	5.8 (6.2)	5.8 (5.8)	0.95	–	5.6 (5.9)	6.6 (8.2)	0.01

* Length of postoperative inpatient stay following index device placement

** Neurologic condition includes autonomic disorders, multiple sclerosis, para- and quadriplegia, spinal cord injuries, neurogenic bladder, spina bifida, cauda equina, nerve root disorders.

¶ Antibiotic duration 0 days if no PO antibiotic was prescribed

Table 2

Postoperative oral antibiotic prescription data

	Artificial Urinary Sphincter		Penile Prosthesis	
	Patients Prescribed, n (%)	Duration prescribed in days, mean ($\pm$ SD)	Patients Prescribed, n (%)	Duration prescribed in days, mean ($\pm$ SD)
Overall	2304 (64.1)	9.2 ($\pm$ 6.1)	6578 (60.6)	9.4 ($\pm$ 5.3)
Ciprofloxacin	686 (29.8)	8.8 ($\pm$ 0.2)	1979 (30.1)	9.6 ($\pm$ 0.1)
Levofloxacin	554 (24.1)	8.9 ($\pm$ 0.18)	1927 (29.3)	9.4 ($\pm$ 0.1)
Trimethoprim- Sulfamethoxazole	286 (12.4)	12.3 ($\pm$ 0.7)	730 (11.1)	9.2 ($\pm$ 0.2)
Cephalexin	725 (31.5)	8.7 ($\pm$ 0.2)	1829 (27.8)	8.9 ($\pm$ 0.1)
Amoxicillin- Clavulanate	118 (5.1)	8.3 ($\pm$ 0.3)	343 (5.2)	8.9 ($\pm$ 0.2)
Cefpodoxime	2 (0.1)	8.5 ($\pm$ 1.5)	3 (0.1)	6.3 ($\pm$ 0.7)
Nitrofurantoin	20 (0.9)	18.8 ($\pm$ 4.5)	8 (0.1)	13.4 ($\pm$ 2.7)
Tetracycline	18 (0.8)	9.8 ($\pm$ 1.8)	90 (1.4)	13.2 ($\pm$ 1.6)
Macrolide	6 (0.3)	4.5 ($\pm$ 0.7)	25 (0.4)	7.7 ($\pm$ 0.9)
Clindamycin	24 (1.0)	10.1 ($\pm$ 1.2)	39 (0.6)	8.6 ($\pm$ 0.7)
Penicillin	28 (1.2)	10.5 ($\pm$ 1.5)	58 (0.9)	12.2 ($\pm$ 1.6)

Table 3

Multivariate* logistic regression for factors associated with device explantation within 90 days

	Artificial Urinary Sphincter			Inflatable Penile Prosthesis		
	OR	95% CI	P	OR	95% CI	P
Age	1.03	1.007–1.05	<0.01	0.99	0.99–1.01	0.33
Hypertension	0.96	0.67–1.39	0.83	1.03	0.77–1.36	0.85
PVD	1.13	0.39–3.24	0.83	1.05	0.54–2.04	0.88
LOS 24 hrs (ref <24 hrs)	0.90	0.52–1.23	0.31	1.39	0.98–1.96	0.06
Diabetes	1.86	1.28–2.72	<0.01	1.59	1.14–2.21	<0.01
CAD	1.48	0.99–2.20	0.06	1.31	0.95–1.83	0.10
Neurologic condition**	2.42	0.80–7.30	0.12	1.04	0.25–4.29	0.96
CCI (ref = 0)						
1	1.18	0.65–2.16	0.59	1.12	0.80–1.58	0.50
>1	1.71	0.94–3.13	0.06	1.22	0.83–1.80	0.30
Prior Device	1.02	0.51–2.01	0.96	3.32	1.58–6.99	<0.01
PO Antibiotic duration (days)	1.01	0.97–1.05	0.54	1.03	1.002–1.05	0.03
PO antibiotics (ref = none)						
Fluoroquinolones†	1.13	0.66–1.93	0.66	0.91	0.61–1.36	0.64
Trimethoprim-Sulfamethoxazole	0.42	0.14–1.26	0.12	1.06	0.58–1.94	0.85
Cephalexin	0.68	0.36–1.30	0.25	1.01	0.65–1.58	0.96
Amoxicillin-Clavulanate	1.08	0.39–2.99	0.89	1.69	0.89–3.30	0.11
Other‡	0.83	0.24–2.94	0.78	0.73	0.34–2.34	0.59

CAD- coronary artery disease, PVD- peripheral vascular disease, LOS – length of stay, CCI – Charlson comorbidity index

* Controlling for geographic region and year

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** Neurologic condition includes autonomic disorders, multiple sclerosis, para- and quadriplegia, cauda equina pathology, spinal cord injury (all levels), neurogenic bladder, muscular atrophy, spina bifida, nerve root injury

† Ciprofloxacin or levofloxacin

£ All antibiotics received by fewer than 100 patients (cefodoxime, nitrofurantoin, tetracycline, macrolide, penicillin)