Evaluating the Role of Postoperative Oral Antibiotic Administration in Artificial Urinary Sphincter and Inflatable Penile Prosthesis Explantation: A Nationwide Analysis

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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 end point 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 10,847 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%, $P = .18$, AUS: 3.9% vs 4.0%, $P = .94$). 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 antibiotics after prosthetic placement should be reconsidered and further studied in a prospective fashion. UROLOGY ■■: ■■–■■, 2017. © 2017 Elsevier Inc.

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. Although 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 IPP,[4] 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 desired.[5]

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 placement,[6]

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but draws on data from orthopedic literature on prosthetic joints[7] 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 surgery.[8] 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 placement.[9] 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 prescriptions.[10] 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 S1. 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 explantation[5] as defined in Appendix S2. Charlson comorbidity index (CCI) for each subject was calculated using the standard components.[11]

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 S3. 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 penicillin with beta-lactamase inhibitor.[6] The type of outpatient antibiotic prescribed was determined from outpatient prescription claims within 1 week of index procedure, and duration determined as the number of days indicated on outpatient prescription claim.

The primary end point was device explantation within 90 days of device placement, as defined by CPT codes (Appendix S1). 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 postoperative antibiotic selection than complications requiring explantation remote from implantation.[12]

Statistical Analysis

All statistical analyses were performed using STATA 14.0 (Statacorp, College Station, TX), with two-sided $P < .05$ representing statistical significance. Descriptive statistics included mean and standard deviation (SD) 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 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 IV antibiotic data are only captured on a subset of patients.[10] 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 10,847 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 (interquartile range 27-58) following IPP placement and in 141 patients (3.9%) at a median time of 41.5 days (interquartile range 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