A Population-based Analysis of Contemporary Rates of Reoperation for Penile Prosthesis Procedures

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OBJECTIVE To perform a population-based comparison of inflatable vs semirigid penile prostheses and to determine contemporary rates of reoperation and identify factors impacting the type of prosthetic implanted.

METHODS Patient-level discharge data and revisit files from the Agency for Healthcare Research and Quality for semirigid and inflatable prosthesis procedures performed for erectile dysfunction from 2006 to 2009 in the state of California were examined. Regression analysis was performed to determine differences between the procedures in terms of infectious and noninfectious failure. Regression analysis was performed to identify factors associated with revision and to identify associations between potential risk factors and the type of implant performed.

RESULTS A total of 2263 cases were included in the study (1824 inflatable and 439 semirigid). The overall reoperation rate was 7.42%. There was no difference in the overall revision rate between the 2 groups (7.52% semirigid and 7.40% inflatable; $P = .94$). The reoperation rate secondary to infectious complications was 3.6% (4.5% semirigid vs 3.23% inflatable; $P = .18$). The revision rate secondary to noninfectious failure was 2.96% in the semirigid vs 4.17% in the inflatable group ($P = .25$). Medicaid insurance (odds ratio [OR], 2.25; 95% confidence interval [CI], 1.41-3.61), African American race (OR, 1.7; 95% CI, 1.20-2.49), age >80 ($P = .046$), and diabetes (OR, 1.67; 95% CI, 1.07-2.59) were associated with receiving a semirigid implant.

CONCLUSION Reoperation rates for infectious and noninfectious failure are equivalent between the semirigid and inflatable penile prostheses. Sociodemographic factors appear to significantly influence the type of prosthesis a patient receives. UROLOGY 84: 112–116, 2014. © 2014 Elsevier Inc.

With an estimated 20,000 procedures/year, multicomponent, inflatable penile prosthesis placement is the most common treatment for ED (erectile dysfunction) refractory to medical therapy.[1] Device infection remains the most dreaded complication of penile prosthesis implantation as this inevitably results in additional operations with an increased risk of infection, tissues loss, urethral injury, and penile shortening.[2] Historically, infection rates have been cited as 3%-5%[3]; however, rates of <1% are often quoted in contemporary single-surgeon series.[4] Noninfectious failure rates increase over time, with noninfectious survival rates of 97.6% and 93.2% at 3 and 5 years, respectively, in a contemporary cohort.[5] However, both infectious and noninfectious survival rates are largely based on single institution, retrospective series, and it is unclear if they can be generalized to a larger population of patients.

Although the multicomponent penile prosthesis represents the most common surgical therapy for ED, the semirigid prosthesis is considered an acceptable alternative. The malleable prosthesis has traditionally been offered to patients with impaired strength or coordination and is considered to have a lower infectious or noninfectious failure rate. However, there is currently no data in the literature comparing outcomes of malleable vs inflatable prosthesis placement. In addition, the indications for the type of prosthesis performed remain poorly defined.

Our study is novel as it aimed to evaluate the rate of reoperation for penile prostheses for both infectious and noninfectious indications in a population-based cohort. We further sought to compare the complication rates of inflatable vs malleable prostheses and identify factors associated with the type of implant performed.

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Table 1. The International Classification of Diseases, Ninth Edition (ICD-9) and Current Procedural Terminology (CPT) Codes

Codes	Description
ICD-9	
ED diagnosis codes	
607.84	Impotence of organic origin
302.72	Psychosexual dysfunction with inhibited sexual excitement
607.85	Peyronie disease
607.89	Other specified disorders of penis
607.9	Unspecified disorder of penis
Revision codes	
996.30	Mechanical complication of unspecified genitourinary device implant and graft
996.39	Other mechanical complication of genitourinary device implant and graft
996.59	Mechanical complication of other implant and internal device not elsewhere classified
996.65	Infection and inflammatory reaction due to other genitourinary device implant and graft
996.76	Other complication due to genitourinary device implant and graft
996.79	Other complications due to other internal prosthetic device implant and graft
CPT	
Initial placement	
54,400	Insert semirigid prosthesis
54,401/54,405	Insert self-contained (inflatable) prosthesis
Removal/revision	
54,402	Removal or replacement of semirigid or inflatable penile prosthesis
54,406	Removal of multicomponent penile prosthesis
54,407	Removal, replacement, or repair of multicomponent penile prosthesis
54,409	Revision of penile prosthesis
54,411	Removal/replacement of all components of a multicomponent penile prosthesis through an infected field
54,415	Removal of semirigid or inflatable penile prosthesis without replacement
54,416	Removal/replacement semirigid or inflatable penile prosthesis at the same operative session
54,417	Removal/replacement of semirigid or multicomponent penile prosthesis through an infected field

CPT, Current Procedural Terminology; ED, erectile dysfunction; ICD-9, International Classification of Diseases, Ninth Edition.

MATERIALS AND METHODS

Data Source and Cohort

We examined patient-level discharge data and revisit files from the California Inpatient, Emergency, and Ambulatory Surgery databases from the Healthcare Cost and Utilization Project sponsored by the Agency for Healthcare Research and Quality. Current Procedural Terminology (CPT) and the International Classification of Diseases, Ninth Edition (ICD-9) codes were used to identify patients undergoing semirigid or inflatable penile prosthesis placement (in both inpatient and ambulatory settings) from 2006 to 2009. Patients with ICD-9 codes indicative of replacement or who had undergone previous surgery for ED (data starting in 2005) were excluded from the cohort. Table 1 lists the relevant CPT and ICD-9 codes used in our analysis.

Healthcare Cost and Utilization Project provides all payer discharge level data collection of hospitalizations, outpatient surgeries, and emergency room visits from participating states.[6] The California database was used as it provides data from all 3 of these locations.[7] Patients are linked among the various settings by revisit files. Patients with follow-up care in another state would not be captured in this data set; however, the patient travel across state lines is presumably lower in California compared with smaller and less geographically isolated states.

Outcome Variable

The primary outcome was device removal or revision. Follow-up data were available through 2010. The results were stratified into revisions or removals performed for infectious vs noninfectious indications based on ICD-9 codes.

Table 2. Baseline patient demographics

Variables	Semirigid (%)	Inflatable (%)	*P* Value
Number of patients	439	1824	
Age			
50-54	21.0	79.0	.1210
55-59	18.8	81.2	
60-64	14.6	85.4	
65-69	19.2	80.8	
70-74	19.6	80.4	
75-79	23.1	76.9	
80+	28.4	71.6	
Hospital volume			
Low	22.8	77.2	<.0001
Middle	14.9	85.1	
High	16.0	84.0	
Race			
White	16.4	83.6	.0004
Black	25.6	74.4	
Hispanic	20.5	79.5	
Other/unknown	24.3	75.7	
Insurance			
Medicare	19.5	80.5	.0027
Medicaid/self-pay	31.8	68.2	
Commercial	17.9	82.1	
Comorbidity			
0	15.5	84.5	.0197
1	20.9	79.1	
2	21.8	78.2	
3+	20.5	79.5	

Statistical Analysis

Multicomponent and semirigid prostheses were initially compared by survival analysis using the Kaplan-Meier approach.