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A population based analysis of contemporary rates of reoperation for penile prosthesis procedures

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Abstract

OBJECTIVES—To perform a population based comparison of inflatable versus semi-rigid penile prostheses to determine contemporary rates of re-operation 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 semi-rigid and inflatable prosthesis procedures performed for erectile dysfunction from 2006-2009 in the state of California were examined. Regression analysis was performed to determine differences between the procedures in terms of infectious and non-infectious 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, 439 semi-rigid). The overall re-operation rate was 7.42%. There was no difference in the overall revision rate between the 2 groups (7.52% semi-rigid, 7.40% inflatable, $p=0.94$). The re-operation rate secondary to infectious complications was 3.6% (4.5% semi-rigid vs 3.23% inflatable, $p=0.18$). The revision rate secondary to non-infectious failure was 2.96% in the semi-rigid versus 4.17% in the inflatable group ($p=0.25$). Medicaid insurance (OR 2.25, CI 1.41, 3.61), African American (OR 1.7, CI 1.20, 2.49) race, age over 80 ($p=0.046$), and diabetes (OR 1.67, CI 1.07, 2.59) were associated with receiving a semi-rigid implant.

CONCLUSIONS—Re-operation rates for infectious and non-infectious failure are equivalent between the semi-rigid and inflatable penile prostheses. Socio-demographic factors appear to significantly influence the type of prosthesis a patient receives.

Keywords

Penile prosthesis; Prosthesis-related infections; device removal; Erectile dysfunction; prosthesis failure

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Introduction

With an estimated 20,000 procedures per year, multi-component, inflatable penile prosthesis placement is the most common treatment for erectile dysfunction refractory to medical therapy¹. 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 shortening². Historically, infection rates have been cited as 3-5%³, however, rates of less than 1% are often quoted in contemporary single surgeon series⁴. Non-infectious failure rates increase over time, with non-infectious survival rates of 97.6 and 93.2% at 3 and 5 years in a contemporary cohort⁵. However, both infectious and non-infectious 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.

While the multi-component penile prosthesis represents the most common surgical therapy for ED, the semi-rigid 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/ non-infectious failure rate. However, there is currently no data in the literature comparing outcomes of malleable versus inflatable prosthesis placement. In addition, the indications for type of prosthesis performed remain poorly defined.

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

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 (HCUP) sponsored by the Agency for Healthcare Research and Quality (AHRQ). CPT and ICD-9 codes were used to identify patients undergoing semi-rigid or inflatable penile prosthesis placement (in both inpatient and ambulatory settings) from 2006 to 2009. Patients with ICD-9 codes indicative of replacement or whom had undergone previous surgery for erectile dysfunction (data starting in 2005) were excluded from the cohort. Table 1 lists the relevant CPT and ICD-9 codes used in our analysis.

HCUP provides all payor discharge level data collection of hospitalizations, outpatient surgeries, and emergency room visits from participating states⁶. The California database was used as it provides data from all three of these locations⁷. Patients are linked amongst 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 to smaller, less geographically isolated states.

Outcome Variable

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

Statistical Analysis

Multi-component and semi-rigid prostheses were initially compared by survival analysis using the Kaplan-Meier approach. To account for possible confounding due to differences in patients receiving the two types of prostheses, Cox proportional hazards modeling was applied. We examine age, race, insurance status, hospital volume (categorized as < 1 case every other month, < 1 case per month, or at least one case per month), and comorbidity (methods of Elixhauser, et al.)⁸ as possible confounding factors for removal or revision of the prosthesis. Race was categorized as white, black, Hispanic, or other. Insurance status was classified as commercial, Medicare, or Medicaid/self-pay.

Using logistic regression, we then used these same variables to explore reasons why patients received multi-component and semi-rigid prostheses.

All data was analyzed using SAS, version 9.2. The study was approved by the institutional review board of Washington University in St. Louis. Statistical significance was defined as $p < 0.05$.

Results

A total of 2263 cases were included in the cohort (1824 inflatable vs. 439 semi-rigid). Table 2 lists baseline demographics and co-morbidities of the two groups. 2 patients were excluded due to incomplete records. The overall reoperation rate was 7.42% (7.40% inflatable, 7.51% semi-rigid, $p=0.94$). The mean time to reoperation was 176.67 days.

A total 79 (3.49%) patients underwent re-operation for infectious indications (3.23% inflatable vs. 4.56% semi-rigid, $p=0.18$). The mean time to failure for infectious complications was 94.6 days. Additionally, 89 patients (3.93%) underwent re-operation for non-infectious failure (4.17% inflatable vs. 2.96% semi rigid, $p=0.25$). The mean time to failure for non-infectious complications was 225.7 days. There was no significant difference in re-operation rate for overall, infectious, or non-infectious indications between the cohorts (see Figures 1 and 2).

Results of the proportional hazards modeling revealed no significant differences in infection related failures by age group, race, insurance status, comorbidity, or hospital volume. Non-infectious failures were less common in low volume hospitals compared to high volume hospitals (HR 0.62; 95% CI 0.39 , 0.99).

In our exploration of reasons why patients received multi-component versus semi-rigid implants, we found age over 80 (OR 2.18; 95% CI 1.18 , 4.02), African American race (OR 1.72, CI: 1.20, 2.49), any comorbidity (OR 1.55, 1.66, 1.64 and 95% CI 1.17-2.07, 1.22-2.25, and 1.15-2.35 for one, two and three or more comorbidity), and Medicaid/Self

pay insurance status (OR 2.25, CI: 1.41, 3.61) were associated with receiving a semi-rigid instead of a multi-component implant.

Comment

Penile prosthesis implantation represents the primary surgical therapy for erectile dysfunction refractory to medical therapy. Our data represents the first study, to our knowledge, to examine outcomes of penile prosthesis surgery on a population level.

A true knowledge of the re-operation rates of penile prostheses is critical for the prosthetic surgeon as this represents the most dreaded complication of these procedures, particularly in the setting of infection. The current antibiotic impregnated models from the 2 primary manufacturers of penile prostheses became widely available in 2001 (Inhibizone, AMS, Minneapolis, MN, USA) and 2003 (Mentor Corporation, Santa Barbara, CA, USA). Long term revision rates of 1.1⁹ to 1.4%¹⁰ due to device related infections have been reported using data collected from the device manufacturers at the time of implantation/revision. Using the “No Touch” technique, rates of less than 1% have been reported by Eid et al¹¹. However, in a prospective study comparing surgical site skin preparations, our high volume center observed 1 year revision rate of 6%¹². Our current study suggests that the revision rate secondary to infection is at least 3.23% in a population based series of implants, performed in the antibiotic coated era. Possible explanations for this finding include more accurate ascertainment of surgical revisions. The non-infectious complication rate of 3.93% in our series is similar to that reported in the literature, and would be expected to increase with longer follow-up of patients. It is important to note that the early non-infectious failures may not represent mechanical failure of the device, but rather reflect complications related to implantation technique. As longer term follow up becomes available, a more accurate assessment of true device malfunction would be expected to become apparent. Interestingly, patient comorbidity was not associated with infectious or non-infectious failure. The higher rate of comorbidity in the malleable group at baseline was adjusted for in our analysis, and we found no difference after adjusting for these differences. Although diabetes was very common in our cohort (n = 617), this finding is in contrast to those of Wilson et al, in which diabetes mellitus was found to be a clear risk factor for infection². Interestingly, we found no difference in revisions among low or high volume hospitals. Our results provide valuable information for counseling patients regarding the real world rate of revision prior to inflatable penile prosthesis placement.

Currently, there are no accepted guidelines regarding the indications for placement of a semi-rigid versus inflatable penile prosthesis. Traditionally, urologists have recommended semi-rigid prosthesis placement in cases of impaired hand coordination or strength which would limit a patient's ability to operate the pump of an inflatable, multi-component device. An additional purported benefit of the semi-rigid prosthesis is a lower infectious and non-infectious complication rate when compared to the inflatable devices. However, our data contradicts this notion, demonstrating a similar rate of re-operation for both infectious and non-infectious indications in our population based cohort.

Lastly, our study suggests that racial and socio-economic disparities exist with regards to the type of prosthesis a patient receives. The finding that patients with higher comorbidity burdens are more likely to receive a semi-rigid prosthesis seems appropriate, as these patients are more likely to have impaired hand strength/coordination or may be advised to undergo semi-rigid prosthesis placement based on the perceived lower infectious risk. However, our multivariate model also identified age, black race, and Medicaid/self pay insurance status as significant predictors for receiving a semi-rigid prosthesis. This may reflect the lower cost of this implant, however, it remains concerning since the multi-component implant is considered the “gold-standard” surgical treatment for erectile dysfunction by many surgeons. Since lower socioeconomic status is associated with the highest risk of having erectile dysfunction¹³, the improved access to care with healthcare reform provides an opportunity for the urologic community to identify and eliminate these disparities.

Limitations of our study include the retrospective nature, as a review of administrative data. Our study showed no difference in failure rates between malleable and inflatable penile prostheses. Two factors could affect these results. First, the maximum follow up of 4 years in our cohort may not have been long enough to allow the development of mechanical complications in patients treated with inflatable prostheses. Second, our study may have been underpowered to show a true significant difference between the two types of implants. Although the study population was large, the rate of revisions was low, and the absolute difference in complications between malleable and inflatable prosthesis small. Performance of power calculations show that a study population of our size has 90% power to show an absolute difference of 2% in either mechanical or infectious complications. As the absolute difference in complications did not reach this level, we can say with certainty that absolute differences in mechanical or infectious complications would not be as high as 2% between the types of prostheses. However, the observed difference of about 1% between the types of prostheses may in fact be statistically significant in a larger study population.

Furthermore, the use of diagnosis codes to define reasons for failure is dependent upon proper coding at the time of surgery, which may not always be accurate. Our data set is also limited to the state of California, and may not reflect the overall population in the United States or elsewhere. Lastly, some patients may have had follow up outside of the state of California, which would not be captured in this database. However, this would result in an increase in the actual failure rate as compared to our current results.

Conclusions

With similar overall revision rates at approximately 7.5%, we found no difference in the rate of failure for infectious and non-infectious indications between semi-rigid and inflatable penile prostheses. However, racial and socio-economic disparities appear to exist with respect to the type of implant a patient receives. Our results assist urologists in providing appropriate counseling for patients and provide the background for further explorations into disparities in penile implants.

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Figure 1.
Survival analysis comparing failure due to non-infectious indications

Figure 2.
Survival analysis comparing failure due to infectious indications

Table 1

ICD-9 and CPT Codes

ICD-9 Code	Description
ED Diagnosis Codes	
607.84	Impotence of organic origin
302.72	Psychosexual dysfunction with inhibited sexual excitement
607.85	Peyronie's 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 Codes	Description
Initial Placement	
54400	Insert semi-rigid prosthesis
54401/54405	Insert self contained (inflatable) prosthesis
Removal/Revision	
54402	Removal or replacement of semi-rigid or inflatable penile prosthesis
54406	Removal multicomponent penile prosthesis
54407	Removal, replacement or repair of multicomponent penile prosthesis
54409	Revision of penile prosthesis
54411	Removal/replacement of all components of a multi-component penile prosthesis through an infected field
54415	Removal of semi-rigid or inflatable penile prosthesis without replacement
54416	Removal/replacement semi-rigid or inflatable penile prosthesis at the same operative session
54417	Removal/replacement of semi-rigid or multi-component penile prosthesis through and infected field

Table 2

Baseline Patient Demographics

	Semi-Rigid	Inflatable	p-value
Number of Patients	439	1824	
Age			
50-54	21.0%	79.0%	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%	<0.0001
Middle	14.9%	85.1%	
High	16.0%	84.0%	
Race			
White	16.4%	83.6%	0.0004
Black	25.6%	74.4%	
Hispanic	20.5%	79.5%	
Other/Unknown	24.3%	75.7%	
Insurance			
Medicare	19.5%	80.5%	0.0027
Medicaid / Self Pay	31.8%	68.2%	
Commercial	17.9%	82.1%	
Comorbidity			
0	15.5%	84.5%	0.0197
1	20.9%	79.1%	
2	21.8%	78.2%	
3+	20.5%	79.5%	