Impact of Surgeon Case Volume on Reoperation Rates after Inflatable Penile Prosthesis Surgery

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Purpose: We investigated the impact of surgeon annual case volume on reoperation rates after inflatable penile prosthesis surgery.

Materials and Methods: The New York Statewide Planning and Research Cooperative System database was queried for inflatable penile prosthesis cases from 1995 to 2014. Multivariate proportional hazards regression was performed to estimate the impact of surgeon annual case volume on inflatable penile prosthesis reoperation rates. We stratified our analysis by indication for reoperation to determine if surgeon volume had a similar effect on infectious and noninfectious complications.

Results: A total of 14,969 men underwent inflatable penile prosthesis insertion. Median followup was 95.1 months (range 0.5 to 226.7) from the time of implant. The rates of overall reoperation, reoperation for infection and reoperation for noninfectious complications were 6.4%, 2.5% and 3.9%, respectively. Implants placed by lower volume implanters were more likely to require reoperation for infection but not for noninfectious complications. Multivariable analysis demonstrated that compared with patients treated by surgeons in the highest quartile of annual case volume (more than 31 cases per year), patients treated by surgeons in the lowest (0 to 2 cases per year), second (3 to 7 cases per year) and third (8 to 31 cases per year) annual case volume quartiles were 2.5 ($p < 0.001$), 2.4 ($p < 0.001$) and 2.1 ($p = 0.01$) times more likely to require reoperation for inflatable penile prosthesis infection, respectively.

Conclusions: Patients treated by higher volume implanters are less likely to require reoperation after inflatable penile prosthesis insertion than those treated by lower volume surgeons. This trend appears to be driven by associations between surgeon volume and the risk of prosthesis infection.

Key Words: penile prosthesis, postoperative complications, infection

Abbreviations and Acronyms

ACV = annual case volume

IPP = inflatable penile prosthesis

SPARCS = Statewide Planning and Research Cooperative System

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It is estimated that 1 in 3 men in the United States experiences erectile dysfunction.[1,2] Inflatable penile prosthesis insertion is the preferred treatment for patients with severe erectile dysfunction that does not respond to oral or injectable medication. More than 15,000 prostheses are implanted annually in the United States.[3] Despite advancements in prosthesis engineering and surgical techniques, IPP infection and noninfectious complications such as prosthesis malfunction continue to occur. These complications frequently necessitate reoperation, which is

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associated with increased risks of penile shortening, urethral injury and subsequent infection.[4]

Population based data on IPP surgical outcomes are limited. The majority of the studies describing reoperation rates after IPP surgery are derived from single surgeon, single center data sets or from industry maintained databases. These studies report IPP infection rates of 2% to 5% at 5 years[5–7] and 1.4% to 7% at 10 years.[7–10] Mechanical failure rates are reported in the same studies at 4% to 10% at 5 years[5,6] and 10.3% to 24.0% at 10 years.[7,9,10] More recent publications of population based analyses have provided additional data on IPP practices and outcomes. However, these studies have either grouped inflatable and malleable prostheses together in the analysis,[11] have had few IPP patients,[12] have been limited to a Medicare population[13] or were industry sponsored studies whose findings are not necessarily generalizable.[8,14] To our knowledge no large scale population based study has examined the impact of surgeon experience on IPP reoperation rates.

MATERIALS AND METHODS

Data Source

Our institutional review board deemed our study exempt from formal review. The data for our analysis came from the New York SPARCS database between 1995 and 2014. SPARCS is a comprehensive, all payer administrative database that collects patient, physician and hospital level data from each hospital inpatient admission, emergency room visit and hospital based ambulatory surgery visit in New York State. The data set is de-identified. Individual patients are tracked using a permanent identifier code that is assigned to each patient upon their first encounter at a SPARCS facility. This identifier code allows patients to be tracked across time and location as long as they receive care at any SPARCS facility.

Individual physicians are identified by their state license number, which is recorded for each clinical encounter that occurs within SPARCS. Hospitals are identified by facility name and county. The data set includes demographic information such as insurance status, ethnicity and Zip Code™ of primary residency; coded medical diagnoses; and coded procedures performed including the date of the procedure, the medical license number of the performing surgeon and the facility in which the procedure was performed.

Cohort

We captured data on all patients who underwent IPP insertion in inpatient and ambulatory settings from 1995 to 2014 using the ICD-9 procedure code 64.97 and the CPT codes 54401 and 54405. Patients whose first IPP operation was associated with diagnosis or CPT codes suggestive of prior penile prosthesis surgery (ie diagnosis codes for IPP infection or complication and/or procedure codes for revision surgery) were excluded from analysis. Data analysis was restricted to 1996 to 2014 to enable the determination of annual surgeon case volume preceding IPP placement because prior surgeon experience at the time of IPPs placed in 1995 could not be determined as that was the first year of available data.

Outcomes

The primary outcome was reoperation. Reoperation was defined as surgery for replacement (ICD-9 codes 64.95 and 64.97, and CPT codes 54410 and 54411), repair (CPT code 54408) or removal (ICD-9 code 6496 and CPT code 54406) of the initial prosthesis. The indication for reoperation was defined as infection if the ICD-9 diagnosis code for "infection or inflammation of genitourinary device" (996.65) was used, and as noninfection if any codes for "mechanical complication" (996.30, 996.39, 996.59) or "other complication" (996.76, 996.79) were used. Patients were censored at the date of reoperation or at the end of the study period if they had yet to undergo reoperation.

Independent Variables

Patient level characteristics included age, race (white and nonwhite), insurance (private, Medicaid or other government and Medicare), median household income and comorbidity score. Median household income was abstracted from ZIP Code level data in the 2007 to 2011 American Community Survey 5-year files. Comorbidity was calculated using the validated Elixhauser comorbidity index.[15] The timing of surgery with respect to the availability of antibiotic impregnated prostheses was divided into the pre-antibiotic impregnated IPP era from 1995 to 2003, spanning the introduction of antibiotic impregnated implants from American Medical Systems (Minneapolis, Minnesota) in 2001 and Mentor Corporation (Santa Barbara, California) in 2003, and the post-antibiotic impregnated IPP era from 2004 to 2014.

Average Annual Surgeon Case Volume

The average ACV of the treating surgeon was calculated at each IPP placement to adjust for accrual of surgeon experience throughout the study period. The start of each surgeon's IPP career was defined as the year in which that surgeon placed his or her first IPP within the SPARCS database. The cumulative number of virgin IPP cases performed by the treating surgeon was tabulated from the start of his/her IPP career within the database through the end of the year preceding each IPP placement event. This number was then divided by the duration in years of the treating surgeon's IPP career to determine ACV at the time of each IPP surgery event. The resulting ACVs were then categorized into quartiles.

Statistical Analysis

Demographic and clinical characteristics were compared between patients who did and did not undergo reoperation using the chi-square test and Student's t-tests. Univariate analyses were performed to evaluate factors associated with reoperation for infection and for noninfectious complications. Variables with significant associations were further evaluated with multivariable proportional hazard regression to identify independent predictors of reoperation for infection or noninfectious complications. The presence or absence of diabetes was not included in the multivariable model as diabetes status is incorporated in

the Elixhauser comorbidity index. Statistical significance for all analyses was defined as $p < 0.05$ and all analyses were done using SPSS® 23.0.

RESULTS

We identified 14,969 virgin IPP insertions in the data set from 1996 to 2014. Median followup was 95.1 months (range 0.5 to 226.7) from the time of implant. The overall reoperation rate was 6.4%, and the 5 and 10-year cumulative IPP freedom from reoperation rates were 95.2% and 94.1%, respectively. The incidence of reoperation for infectious and noninfectious complications was 2.3% (343) and 4.1% (617), respectively. The reoperation rate for infection was 4.2% (217 of 5,200) in the era before the routine use of antibiotic impregnated implants and decreased to 1.5% (126 of 8,209) with the widespread use of antibiotic coated prostheses. Median time to reoperation for infection was 3.9 months (IQR 1.0–25.0) and median time to reoperation for noninfectious complications was 27.1 months (IQR 6.0–75.0). Of the reoperations 68% (649 of 960) were performed by the primary surgeon who had placed the original implant and 32% (311 of 960) were performed by another surgeon.

Table 1 shows the characteristics of patients who did and those who did not undergo reoperation for any indication. Table 2 shows the results of univariate Cox regression analyses for reoperation for infection and noninfectious complications.

Table 1. *Patient and surgeon characteristics*

	All Cause Reoperation				
	No		Yes		p Value*
No. pts	14,009		960		
Mean ± SD pt age	61.1 ± 10.3		59.3 ± 11.0		<0.001
No. race (%):					0.227
White	4,886	(34.9)	339	(35.3)	
Nonwhite	7,120	(50.8)	539	(56.2)	
Unknown	2,003	(14.3)	82	(8.5)	
No. Elixhauser comorbidity index (%):					0.013
0	9,219	(65.8)	627	(65.3)	
1	4,006	(28.6)	258	(26.9)	
Greater than 1	784	(5.6)	75	(7.8)	
No. insurance (%):					<0.001
Private	6,207	(44.3)	524	(54.6)	
Medicare	4,192	(29.9)	335	(34.9)	
Medicaid/other government	521	(3.7)	89	(9.3)	
Unknown	3,089	(22.1)	12	(1.2)	
Mean ± SD median household income	$57,766	± $26,209	$55,687	± $25,757	0.022
No. era of initial surgery (%):					<0.001
Before antibiotic coated models	5,200	(37.1)	657	(86.4)	
After antibiotic coated models	8,809	(62.9)	303	(31.6)	
No. ACV (%):					<0.001
0–2	3,430	(24.5)	317	(33.0)	
3–7	3,468	(24.8)	276	(28.7)	
8–31	3,535	(25.2)	186	(19.4)	
Greater than 31	3,576	(25.5)	181	(18.9)	

* Chi-square test (categorical variables) and t-test (continuous variables).

The distribution of IPP cases by ACV is shown in figure 1. Surgeons inserting 0 to 2 IPPs annually accounted for 25% of the cases as did surgeons performing more than 31 implants annually. The remaining 50% were performed by surgeons with an ACV between 2 and 31. The overall reoperation rate correlated inversely with ACV (fig. 2). Reoperation rates were 8.5% in patients treated by surgeons with an ACV of 0 to 2, 7.4% in patients treated by surgeons with an ACV of 3 to 7, 5.0% in patients treated by surgeons with an ACV of 8 to 31 and 4.8% in patients treated by high volume implanters with an ACV greater than 31. Figure 3 illustrates the Kaplan-Meier analysis of freedom from reoperation according to ACV. The 10-year probability of freedom from reoperation varied significantly according to ACV ($p < 0.001$).

Table 3 shows the results of multivariable Cox proportional hazard regression analyzing the impact of ACV on reoperation rates for infectious and noninfectious complications. Annual case volume was independently associated with reoperation for infection but not reoperation for noninfectious complications. Compared with patients treated by surgeons in the highest quartile of ACV (more than 31), patients treated by surgeons in the lowest (0 to 2), second (3 to 7) and third (8 to 31 cases per year) ACV quartiles were 2.5, 2.4 and 2.1 times more likely to require reoperation for IPP infection, respectively.

DISCUSSION

Several population based studies have shown a strong association between surgeon volume and postoperative outcomes in urological and nonurological surgeries.[16–18] Using a cohort of 1,640 Medicare beneficiaries who underwent esophagectomy, Birkmeyer et al found a significant difference in the rates of operative mortality between high and low volume surgeons.[17] Leow et al analyzed 90-day postoperative outcomes of radical cystectomy in a nationwide sample of 49,540 cases, and found a 45% decreased risk of major complications and a 46% decreased risk of mortality in patients treated by very high volume surgeons (7 or more cases per year) compared to those treated by very low volume surgeons (1 case per year).[18] Process of care factors such as comprehensive preoperative testing and intraoperative hemodynamic monitoring have been proposed as mediators of the differences in radical cystectomy outcomes between high and low volume hospitals.[19] Briganti et al analyzed 1,020 radical prostatectomy cases and

Table 2. *Univariable analysis of reoperation*

	Infectious Complication		Noninfectious Complication	
	HR (95% CI)	p Value*	HR (95% CI)	p Value*
Age (continuous)	0.97 (0.98—0.99)	0.003	0.97 (0.96—0.98)	<0.001
Race:				
White	1.0	Ref	1.0	Ref
Nonwhite	1.2 (0.9—1.6)	0.1	1.1 (0.9—1.3)	0.3
Elixhauser comorbidity index:				
0	1.0	Ref	1.0	Ref
1	1.0 (0.8—1.3)	0.8	1.0 (0.8—1.2)	0.9
Greater than 1	1.7 (1.1—2.4)	0.01	1.5 (1.1—2.0)	0.01
Insurance:				
Private	1.0	Ref	1.0	Ref
Medicare	1.2 (0.9—1.5)	0.1	0.9 (0.7—1.0)	0.9
Medicaid/other government	2.0 (1.3—2.9)	<0.001	1.5 (1.1—1.9)	0.01
Median household income	0.9 (0.8—1.0)	0.1	0.96 (0.94—1.0)	0.66
Era of initial surgery:				
After antibiotic coated models	1.0	Ref	Not applicable	Not applicable
Before antibiotic coated models	2.2 (1.8—2.7)	<0.001	Not applicable	Not applicable
ACV:				
Greater than 31	1.0	Ref	1.0	Ref
0—2	2.5 (1.8—3.6)	<0.001	1.2 (0.9—1.4)	0.2
3—7	2.4 (1.7—3.5)	<0.001	0.9 (0.8—1.2)	0.8
8—31	1.6 (1.1—2.4)	0.01	0.6 (0.5—0.8)	<0.001

* Cox regression analysis.

observed that high volume surgeons uncovered significantly more nodal metastases than their low volume counterparts, despite using the same template for node dissection.[20] Vickers et al analyzed outcomes after radical prostatectomy and demonstrated that the probability of recovery of erectile and urinary function was significantly higher among patients treated by higher volume surgeons.[21]

To our knowledge no other population based study has specifically examined the effect of surgeon experience on reoperation rates after IPP surgery. We observed an almost linear inverse relationship between surgeon ACV and the likelihood of requiring reoperation. This relationship was driven by differences in reoperation for IPP infection. The differences that we observed are clinically important and affect the majority of patients who undergo IPP surgery. We observed that 75% of patients were treated by surgeons below the highest quartile of ACV (31 cases per year or less), and that these patients were 2.1 to 2.5 times more likely to require reoperation for IPP infection than patients treated by surgeons in the highest quartile of ACV (more than 31 cases per year). In terms of absolute risk reduction, patients treated by high volume implanters in the top quartile of ACV were 0.9% to 2.1% less likely to require reoperation for IPP infection.

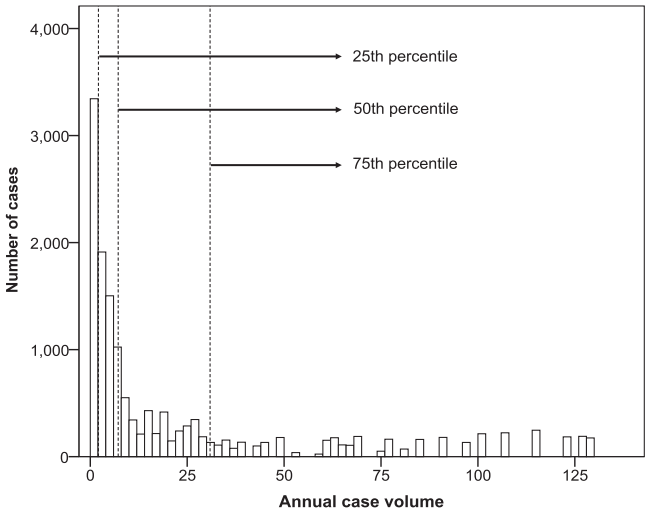

Figure 1. ACV distribution

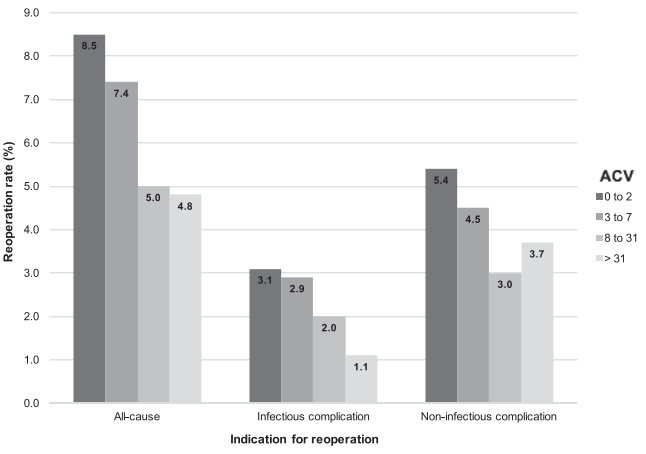

Figure 2. Reoperation rates for all cause, infectious and noninfectious complications by ACV.

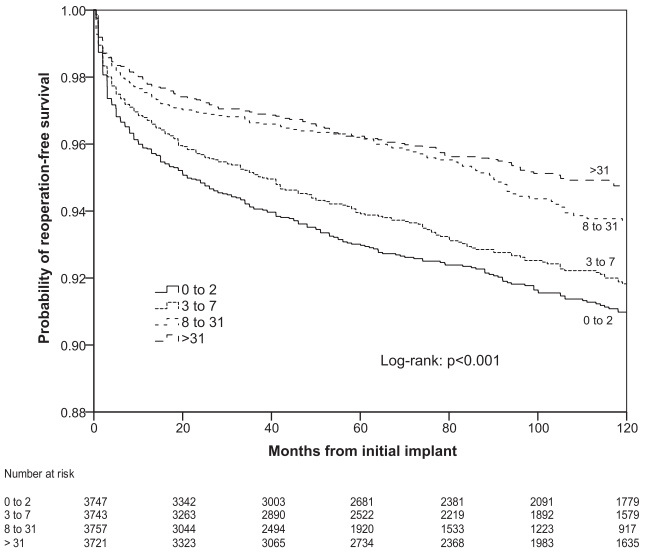

Figure 3. Kaplan-Meier analysis of freedom from reoperation by ACV.

A variety of single center, single surgeon studies have similarly reported better reoperation-free survival for patients treated by high volume implanters.[22,23] Operative factors could explain this relationship. Higher volume surgeons work with more experienced operating room personnel, who are presumably less likely to inadvertently contaminate an exposed device, and these teams may be more likely to adhere to stringent procedure protocols that are believed to reduce the risk of IPP infection. Adherence to a set of best practices for infection prophylaxis, such as obtaining a negative preoperative urine culture, has been shown to significantly reduce the risk of IPP infection.[24] Adherence to perioperative antibiotic prophylaxis recommendations and standardization of perioperative antimicrobial therapy might also be better with higher volume surgeons.[22] Furthermore, operative time may also be shorter for more experienced surgeons operating with more experienced teams at higher volume centers, which could result in lower infection rates by minimizing ambient prosthesis exposure.[23]

Table 3. *Cox regression multivariable analysis of reoperation*

	Infectious Complication*		Noninfectious Complication†	
	HR (95% CI)	p Value	HR (95% CI)	p Value
ACV:				
Greater than 31	1.0	Ref	1.0	Ref
0—2	2.5 (1.7—3.7)	<0.001	1.2 (0.9—1.4)	0.2
3—7	2.4 (1.6—3.6)	<0.001	0.9 (0.8—1.2)	0.7
8—31	2.1 (1.4—3.1)	0.01	0.8 (0.6—1.0)	0.1

* Adjusted for age, race, comorbidity, insurance and era of index surgery.
† Adjusted for age, comorbidity and insurance.

We did not observe a relationship between surgeon experience and rates of reoperation for noninfectious complications after IPP surgery. Dubocq et al performed a single center retrospective review of 366 IPP cases, another study that examined the impact of surgeon experience on IPP mechanical failure rates, and similarly found no difference between high and low volume implanters.[25] The absence of an association between surgeon experience and noninfectious IPP failure is not surprising. Surgeon experience has no impact on the physical mechanical properties of prostheses and, therefore, would not be expected to have an impact on the likelihood of mechanical failure. In addition, we speculate that although lower volume implanters might be more prone to errors in pump placement or device sizing, lower volume implanters might also be less likely to perform a repeat operation in a patient with suboptimal but noncatastrophic IPP outcomes such as glans hypermobility or pump migration.

We compared our reoperation rates to those of previous population based studies. Grewal et al retrospectively reviewed 1,824 virgin IPP cases with 4 years of followup from a California database, and found similar overall reoperation (7.4%) and noninfectious complication (4.2%) rates.[12] However, their rate of device infection was higher (3.2%). In a retrospective review of 7,666 penile surgery cases during a 13-year period from a different statewide database from California, Mirheydar et al observed much higher all cause, infectious and noninfectious complication rates at 12.0%, 3.8% and 8.2%, respectively.[11] However, a direct comparison is difficult because the authors grouped inflatable and malleable prostheses together. Other large population studies used industry registries. Carson et al examined 39,005 IPPs inserted during a 7.7-year period from the AMS data set[14] and Serefoglu et al analyzed 11-year postoperative outcomes of 36,391 from the Mentor Corporation database.[8] These studies revealed much lower infectious complication rates (1.2% and 2.0%, respectively).

In addition to a retrospective design, this study has other limitations that stem from using a large database. Diagnosis codes were used to identify the cohort as well as IPP complications, and we acknowledge the possibility of misclassification and miscoding. Because SPARCS does not capture followup that occurred outside of New York State or at nonparticipating institutions within New York State (such as private surgical centers), our analysis may underestimate the true incidence of infectious and noninfectious complications after IPP. The inability of SPARCS to capture care outside of New York is a potential source of bias. High volume implanters may be more likely to attract patients from

out of state who may be more likely to be treated locally if they require reoperation. Conversely, high volume implanters may be more likely to treat more complex patients who are at higher risk for subsequent reoperation. Although we attempted to account for this in our model by including the Elixhauser comorbidity index, this metric may be overly general and may not adequately reflect patient complexity. The database also lacks granularity on the surgical approach, model of IPP placed, patient use patterns, operative time and preoperative protocols (eg skin prep and antibiotics). Nevertheless, this study is among the largest, nonindustry, population based analyses of surgical complications after IPP surgery and is the only such study to examine the impact of surgical volume on outcomes.

CONCLUSIONS

Patients treated by higher volume implanters are less likely to require reoperation after IPP surgery than those treated by lower volume surgeons. This finding appears to be driven by an association between surgical case volume and the risk of prosthesis infection.

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EDITORIAL COMMENT

Onyeji et al report on some of the best available penile implant data (14,969 patients with an 8-year median followup) with infection and mechanical failure rates of 2.5% and 3.9%, respectively. Not surprisingly, the authors found higher infection rates with lower volume surgeons. In reality, the

overall implant complication rate is likely higher than the reported 6.4%, as undoubtedly many patients were lost to followup as they travelled outside the New York system. The fact that only 68% of all the implant revisions from this cohort were performed by the original surgeon illustrates potential loss to followup, the Achilles' heel of most implant outcome studies to date. Importantly this study offers the strongest evidence to date that antibiotic coated devices reduce infection as the hazard ratio was more than doubled for noncoated devices. A properly performed prospective penile implant registry involving all implant manufacturers with meticulous patient followup remains essential.

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REPLY BY AUTHORS

A strength of the New York SPARCS database is the ability to track patients longitudinally across care provided by different providers. The discovery that only 68% of patients who required penile prosthesis revision surgery in New York were treated by their original surgeon is an important observation that illustrates a potentially suboptimal practice pattern. However, this observation does not necessarily reflect a high likelihood of patients being lost to followup that would result in an underestimation of penile prosthesis surgical revision rates.

Repeat analysis of our cohort revealed that only 1,196 of 14,969 (8%) patients resided outside of New York State at their original implant surgery. Therefore, we do not believe that treatment of out of state patients was a significant confounder in our study. However, SPARCS does not include all surgical facilities in New York State. In particular, private surgical centers do not participate in SPARCS. Patients treated initially at a SPARCS facility who underwent revision surgery at a private surgical center would not be visible to the system. Therefore, we agree with Dr. Köhler that the true failure rate of penile prosthesis surgery is likely higher than the 6.4% rate reported in our study. We also agree strongly that a large prospective study or registry is critically important for understanding the long-term outcomes of penile prosthesis surgery.