# **ORIGINAL RESEARCH—MEN'S SEXUAL HEALTH**

# The Decline of Inpatient Penile Prosthesis over the 10-Year Period, 2000–2010

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## ABSTRACT-

*Introduction.* Across all specialties, economic pressure is driving increased utilization of outpatient surgery when feasible.

*Aims.* Our aims were to analyze national trends of penile prosthesis (PP) surgery and to examine patient and hospital characteristics, and perioperative complications in the inpatient setting.

*Methods.* We analyzed data from National Inpatient Sample. Patients in NIS who underwent PP insertion between 2000 and 2010 were included.

*Main Outcome Measures.* Our main outcomes were the number of inpatient PP procedures, type of prosthesis, patient demographics, comorbidities, hospital characteristics, and immediate perioperative complications.

*Results.* There was a progressive and dramatic decline by nearly half in the number of both inflatable (IPP) and noninflatable (NIPP) inpatient insertions performed from 2000 to 2010 (P = 0.0001). The overall rate of inpatient complications for PP insertion was 13.5%. Patients with three or more comorbidities were found to have a higher risk of complications than patients with no comorbidities (OR = 1.45, 95% CI = 1.18–1.78) (P = 0.0001). Surgeries performed in high-volume hospitals (10 or more PP cases per year) were associated with reduced risk of complications (OR = 0.6) (P < 0.0001). There was a dramatic decrease in inpatient setting for PP placement in high-volume hospitals (32% in 2000 compared with 6% in 2010; P < 0.0001), and when compared with lower volume hospitals. NIPP was more likely performed in younger patients and in community hospitals, and less likely in white patients. Medicaid health insurance was associated with much higher rate of NIPP insertion than other types of insurance. *Conclusions.* The number of PP procedures performed in the inpatient setting declined between 2000 and 2010, likely reflecting a shift toward increasing outpatient procedures. Our data also suggest a better outcome for patients having the procedure done at a high-volume center in terms of inpatient complications. **Alwaal A, Harris CR, Hussein AA, Sanford TH, McCulloch CE, Shindel AW, and Breyer BN. The decline of inpatient penile prosthesis over the 10-year period, 2000–2010. Sex Med 2015;3:280–286.** 

Key Words. Erectile Dysfunction; Penile Prosthesis; Outpatient Surgery; Complications

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#### Introduction

E rectile dysfunction (ED) affects more than half of men between 40 and 70 years of age [1]. Penile prosthesis (PP) placement is the gold standard treatment for ED among men who are unwilling to use, not candidates for, or refractory to medical management [2]. There are two types of PP; noninflatable (NIPP) and inflatable (IPP) types; the latter is associated with generally higher patient and partner satisfaction rates [3]. Utilization of PP appears to be increasing, with approximately 17,540 PP placed in 2000 compared with 22,420 in 2009 [4]. In addition, Medicare records from 2002 to 2012 show a slightly increased performance of IPP from 4615 in 2002 to 5328 in 2010 (see Figure S1) [5].

Over 70% of surgical procedures in the United States are performed in the outpatient setting [6,7]. Outpatient surgery is generally more costeffective with an acceptable safety profile for most procedures [6,8]. While most outpatient surgeries are performed in hospital outpatient departments, utilization of nonhospital ambulatory surgery centers and physician offices for surgical procedures has increased by 300% over the last decade [7,8].

Several large single-center series have demonstrated the safety and economic advantage of PP insertion in the outpatient setting [9–11], with one series showing a 17% reduction in financial cost [12]. We were interested in understanding the national trends in the number and type of inpatient PP and perioperative outcomes of PP performed in the inpatient setting over time. We hypothesized that the number of inpatient PP insertions has declined over time.

#### **Materials and Methods**

## Data Source

For our analysis of inpatient PP, we utilized the National Inpatient Sample (NIS), the largest publicly available, all-payer inpatient care database in the United States [13]. NIS contains data from approximately 1000 hospitals in 37 states and includes 8 million inpatient hospital admissions per year; this sample represents approximately 20% of all hospital admissions in the United States [13].

#### Inclusion Criteria

All patients in NIS who underwent PP insertion between January 1, 2000 and December 31, 2010

were candidates for inclusion. Subjects were identified using the International Classification of Diseases (ICD-9-CM) procedure codes for insertion of IPP (64.97) and NIPP (64.95). Two urologists (A.A. and B.N.B.) evaluated this data to ensure that the patients included in the analysis did undergo PP insertion and not a different surgery. Some patients were excluded because of major concurrent procedures that would preclude concomitant PP insertion in the same admission, such as radical cystectomy, as it would most likely be a result of an error in coding. We elected to include patients who had PP placement in combination with other minor procedures, including removal of PP prior to replacement (64.96), artificial urinary sphincter insertion (5893), inguinal hernia repair (5300, 5301, 5302, 5303, 5304, 5305, 5314, 5317, 5321), abdominal hernia repair (5341, 5349, 5351, 5359, 5361, 5369), hydrocelectomy (612, 617), circumcision (640), orchiectomy (623, 6241), varicocelectomy (631), vasectomy (6373), and epididymal cyst excision (632). We have also identified PP revision cases through the presence of the PP removal ICD-9 procedure code (64.96) in the same inpatient admission along with one of the two codes of insertion (64.97 or 64.95).

# Predictors

We abstracted demographic data from NIS including patient age (grouped as patients aged 18–44, 45–64, and  $\geq$ 65 years), race (white, black, and other), number of medical co-morbidities such as hypertension (0, 1, 2, and  $\geq$  3) as defined and previously validated by NIS [13], year of operation, hospital size (small, medium, and large), number of PP inserted per year at each hospital (grouped as 1, 2–9, and 10 or more), payer type (Medicare, Medicaid, private insurance, and other), and geographic region (Northeast, Midwest, South, and West) [13].

#### **Outcome Variables**

Our primary outcomes were trends of PP insertion across the different categories according to the type of prosthesis and inpatient complications. In addition, we analyzed trends in the number of inpatient PP insertion performed over the last decade, and examined the change in trends of inpatient PP insertion in terms of patient comorbidity and hospital volume of PP cases/year.

We analyzed the prevalence and type of complications whether surgical or medical. Complications were divided into surgical complications (e.g., wound and genitourinary complications) and

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medical complications (e.g., cardiovascular, respiratory, gastrointestinal, neurologic, and musculoskeletal complications) (see Table S1).

# Statistics

Data analysis was performed using sAs (version 9.2, SAS Institute Inc, Cary, NC, USA). All analyses accounted for the complex survey design and the sampling weights of the NIS. Bivariate logistic regression was used to measure the association between patient and hospital characteristics and the presence of an inpatient complication (yes/no). We also examined the association of patient and hospital factors and type of PP insertion using a chi-squared test. *P* values less than 0.05 were considered statistically significant.

### Results

### National Trends of PP Insertion

Analysis of NIS data revealed a progressive decline of the number of inpatient PP insertions (for both IPP and NIPP) performed from 2000 to 2010, by nearly half (P = 0.0001) (Figure 1). Patients with three or more comorbidities comprised a progressively higher percentage of overall inpatient PPs performed (6% in 2000 to 19% in 2010) (P < 0.0001) (Figure 2), while high-volume hospitals performing 10 or more inpatient PP insertion cases per year performed progressively less over time from 32% in 2000 to 6% in 2010 (P < 0.0001) (Figure 3).

## Inpatient Complications

The overall rate of inpatient complications for PP insertion was 13.5%. Surgical complications were the overwhelming majority representing 82% of them, while medical complications represented 14% and the remaining 4% were patients who experienced combined medical and surgical complications.

Patients with three or more comorbidities were found to have a higher risk of complications than patients with no comorbidities (OR = 1.45, 95% CI = 1.18–1.78) (P = 0.0001). High-volume hospitals (defined as performing 10 or more PP insertion cases per year) were associated with reduced risk of complications (OR = 0.6, 95% CI = 0.5– 0.76) (P < 0.0001). Patient age, race, or hospital size were not associated with risk of complications (Table 1). Replacement of PP comprised 1.13% of inpatient PP insertion cases, with an increased risk of complications (OR 4.93, 95% CI 3.31–7.35).

#### National Trends of Inpatient PP Types

When we analyzed the procedures according to the type of prosthesis inserted, we found NIPP to be more commonly performed in younger patients

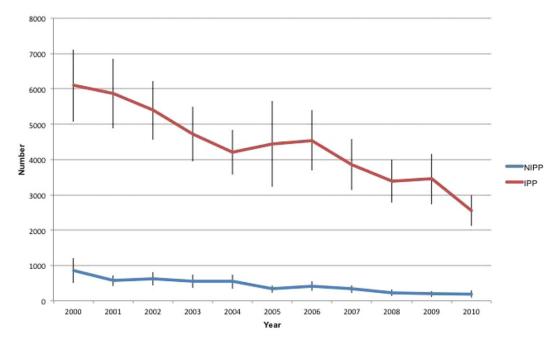


Figure 1 Volume of inpatient PP in the United States from 2000 to 2010. IPP, inflatable penile prosthesis; NIPP, noninflatable penile prosthesis; whiskers, 95% confidence interval

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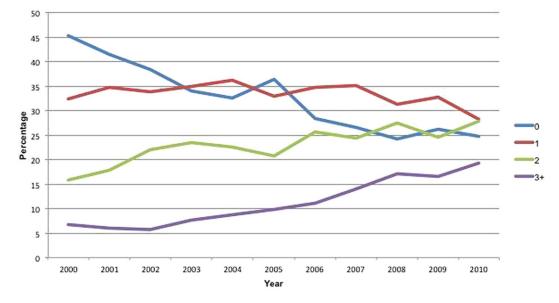


Figure 2 Patient comorbidities of inpatient PP from 2000 to 2010. 0, no comorbidity; 1, one comorbidity; 2, two comorbidities; 3+, three or more comorbidities

(13.4% vs. 9–10%) (P = 0.012) and less likely to be performed in white patients (8.3% vs. 12.3–14.6%) (P < 0.0001). NIPP was also found to be more likely to be performed in community hospitals than academic (12.7% vs. 7.1%) (P < 0.0001), and more likely to be performed in the northeast and the west (15.9% and 12.8%, respectively)

(P < 0.0001). Medicaid health insurance was associated with much higher rate of NIPP insertion (20.9%) than other types of insurance (9–10%) (P < 0.0001). There was no difference in the rate of NIPP insertion when compared by hospital size, patient comorbidity, or PP insertion cases per year (Table 2).

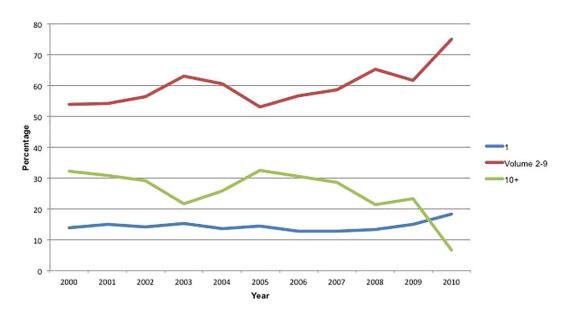


Figure 3 Hospital volume of inpatient penile prosthesis from 2000 to 2010. 1, one case/year; 2–9, two to nine cases/year; 10+, 10 or more cases/year

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Characteristic		Patients, n (%)	Complications, n (%)	OR (95% CI)	P value
Age	18–44	2,523 (5.2)	383 (15.17)	1.00	0.53
	45-64	22,128 (45.57)	2,952 (13.34)	0.86 (0.66-1.12)	
	65+	23,905 (49.23)	3,211 (13.43)	0.87 (0.67-1.13)	
Race	White	25,346 (66.56)	3,431 (13.54)	1.00	0.27
	Black	6,881 (18.07)	899 (13.07)	0.96 (0.79–1.16)	
	Other	5,851 (15.37)	680 (11.63)	0.84 (0.68-1.04)	
Comorbidity	0	16,540 (34.07)	2,179 (13.18)	1.00	0.0001
	1	16,310 (33.59)	1,974 (12.11)	0.91 (0.79-1.05)	
	2	10,778 (22.2)	1,504 (13.95)	1.07 (0.91–1.26)	
	3 or more	4,927 (10.15)	888 (18.02)	1.45 (1.18–1.78)	
Payer	Medicare	27,142 (56)	3,727 (13.73)	1.00	0.33
	Medicaid	1,069 (2.2)	180 (16.8)	1.27 (0.87-1.86)	
	Commercial	18,683 (38.5)	2,443 (13)	0.95 (0.83-1.07)	
	Other	1,661 (3.4)	196 (11.8)	0.84 (0.61-1.16)	
Hospital size	Small	4,234 (8.75)	557 (13.16)	1.00	0.06
-	Medium	12,618 (26.06)	1,495 (11.85)	0.89 (0.66–1.19)	
	Large	31,564 (65.19)	4,479 (14.19)	1.09 (0.84–1.43)	
Region	Northeast	10,103 (20.8)	1,222 (12.1)	1.00	0.09
Ŭ	Midwest	8,403 (17.3)	1,163 (13.88)	1.17 (0.91–1.5)	
	South	19,803 (40.8)	2,893 (14.6)	1.24 (1–1.5)	
	West	10,246 (21.1)	1,268 (12.4)	1.03 (0.83–1.28)	
Hospital type	Community	23,587 (48.7)	3,120 (13.2)	1.00	0.56
	Academic	24,830 (51.3)	3,412 (13.7)	1.04 (0.9–1.21)	
Volume (PP cases/year)	1	6,982 (14.38)	1,170 (16.75)	1.00	<0.0001
· · · · · · · · · · · · · · · · · · ·	2–9	28,494 (58.68)	3,976 (13.96)	0.82 (0.69-0.97)	
	10+	13,079 (26.94)	1,400 (10.70)	0.61 (0.5–0.76)	

 Table 1
 Patient and hospital characteristics and complication rates for penile prosthesis insertion

CI, confidence interval; N = number; OR = odds ratio; PP = penile prosthesis. Bold results = statistically significant, p < 0.05.

#### Discussion

While there are several treatments available for ED, PP remains a valuable and effective option

when others have failed or are contraindicated [2]. Little data are available to estimate the overall number of PPs inserted [14]. Market research data and Medicare records for performance of IPP have

Table 2	Comparison between	patient and hospital	characteristics and	type of	penile prosthesis pe	erform
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Characteristic	Category	IPP n (%)	NIPP n (%)	P value
Age	18–45	2,179 (86.6)	338 (13.4)	0.0123
	45-65	19,849 (89.75)	2,268 (10.25)	
	65+	21,659 (90.65)	2,235 (9.35)	
Race	White	23,237 (91.7)	2,099 (8.3)	<0.0001
	Black	5,871 (85.4)	1,004 (14.6)	
	Other	5,127 (87.7)	720 (12.3)	
Number of comorbidities	0	14,833 (89.7)	1,696 (10.3)	0.242
	1	14,816 (90.9)	1,489 (9.1)	
	2	9,674 (89.8)	1,099 (10.2)	
	3 or more	4,365 (88.7)	557 (11.3)	
Payer	Medicare	24,488 (90.3)	2,638 (9.7)	<0.0001
	Medicaid	845 (79.1)	224 (20.9)	
	Commercial	16,872 (90.4)	1,801 (9.6)	
	Other	1,483 (89.3)	178 (10.7)	
Hospital size	Small	3,938 (93)	296 (7)	0.105
	Medium	11,424 (90.54)	1,194 (9.46)	
	Large	28,202 (89.4)	3,336 (10.6)	
Region	Northeast	8,500 (84.1)	1,603 (15.9)	<0.0001
·	Midwest	7,704 (91.8)	688 (8.2)	
	South	18,559 (93.7)	1,244 (6.3)	
	West	8,924 (87.2)	1,307 (12.8)	
Hospital type	Academic	21,668 (92.9)	3,151 (7.1)	<0.0001
	Community	21,897 (87.3)	1,675 (12.7)	
Volume (PP cases/year)	1	6,125 (87.8)	852 (12.2)	0.262
	2–9	25,842 (90.7)	2,636 (9.3)	
	10 +	11,720 (89.7)	1,354 (10.3)	

IPP = inflatable penile prosthesis; n = number; NIPP = non-inflatable penile prosthesis. Bold results = statistically significant, p < 0.05.

© 2015 The Authors. *Sexual Medicine* published by Wiley Periodicals, Inc. on behalf of International Society for Sexual Medicine. shown an overall increased utilization of PP over the last decade, despite the introduction of type 5 phosphodiesterase inhibitors [4,5]. Our data indicate that during that same period of time, inpatient hospitalizations for PP have declined, likely suggesting that more PP procedures are being performed in outpatient settings. There is a growing trend toward increasing the utilization of outpatient surgery, which has been shown for many procedures to be safe and effective at reducing healthcare costs by shortening hospital stay [15].

We analyzed the trends of patient and hospital characteristics associated with inpatient PP insertion over the last decade. With time, there was an increase in the percentage of patients with three or more comorbidities (Figure 2). Also, there was a significant drop in the percentage of inpatient PP by hospitals performing 10 or more PPs per year, from 32% in 2000 to only 6% in 2010. This is likely representing that sicker patients are more likely to need inpatient care rather than the outpatient option and that high-volume centers are confident enough with the procedure to perform it in outpatient settings (Figure 3).

The overall perioperative inpatient complication rate was 13.5%. This complication rate is slightly higher than the previously reported rates of 7–10% for PP surgery [16,17]. Race and age were not associated with the complication rate. However, high-volume (PP cases/year) hospitals had a lower complication rates than other hospitals (P < 0.0001). Since high-volume hospitals are performing less inpatient PP insertions with time, it is possible that our reported higher complication rate is due to performance of this procedure by predominantly less experienced surgeons, who are performing it in an inpatient setting.

To our knowledge, there have been no previous studies looking at a national-level data analysis of patient and hospital characteristics related to NIPP. NIPP was surprisingly performed slightly more in younger patients. It was also more likely to be performed in the West and the Northeast. White patients tend to be more likely to have IPP than NIPP (see Table 2), possibly reflecting a better socio-economic status for those patients. Community hospitals tend to perform more NIPP than academic hospitals, possibly due to patient characteristics and/or insurance issue. By far, inpatient NIPP was more likely to be performed in Medicaid patients (20.9%) than other types of health insurance, which could be explained by the fact that Medicaid usually covers NIPP, not IPP. Hospital size, comorbidity, or volume of inpatient PP cases/year were not associated with the type of inpatient PP performed.

There are limitations in our study. First, NIS only contains inpatient data, and do not include 23-hour stay. While our aim was to analyze inpatient PP use, having comparative outpatient data would have strengthened our findings. Second, the reported complication rates are for the inpatient admission only and do not reflect long-term complications or readmissions. Third, we were limited by the ICD-9 coding system, which is not a detailed system to catalogue complications. Therefore, we could not comment on complication details such as device malfunction or erosion. Furthermore, administrative data from NIS do not provide granular data regarding health status and disease states. In addition, we were unable to assess the severity of complications using a standardized system such Clavien-Dindo.

#### Conclusions

The number of inpatient PP procedures is declining over the years, likely reflecting a shift toward increasing outpatient procedures. Our data suggest a better outcome for patients having the procedure done at a high-volume center in terms of inpatient complications, and a possible shift in these highvolume centers to performing the procedure as an outpatient. Therefore, consideration can be made for referring these cases to high-volume centers in order to have a better outcome and reduce financial expenditure. Further research and analysis are much needed, particularly a nationwide outpatient data analysis, in order to analyze the overall trends and complications of PP insertion.

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*Conflict of Interest*: Benjamin N. Breyer is an advisor to American Medical Systems.

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#### Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Figure S1 Medicare records for performance of IPP from 2002 to 2012 [4].

Table S1 ICD-9-CM codes for postoperative complications.