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Journal
Surgical Innovation, 20(6)

ISSN
1553-3506

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Publication Date
2013-12-01

DOI
10.1177/1553350613485303

Peer reviewed

Published in final edited form as:
Surg Innov. 2013 December ; 20(6): 625–630. doi:10.1177/1553350613485303.

Understanding the dissemination of sacral neuromodulation

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Abstract

Objectives—To assess trends in the use of sacral neuromodulation and to measure the magnitude of variation in its use across geographic regions.

Methods—We used the State Ambulatory Surgery Database (SASD) from 2002 to 2009 from Florida to identify patients implanted with a neuromodulator. Age and gender adjusted rates of implantation were calculated by year and by geographic region, defined by the Hospital Service Area (HSA). The coefficient of variation was estimated to quantify the magnitude of variation for different time periods.

Results—Adjusted rates of sacral neuromodulation increased significantly from 1.1 per 100,000 population in 2002 to 10.4 per 100,000 population in 2009. The majority of cases were performed for overactive bladder. There was a very large amount of geographic variation in rates of these procedures as evidenced by the high coefficients of variation: 1.67 (2002 and 2003), 1.70 (2004 and 2005), 1.49 (2006 and 2007), and 1.05 (2008 and 2009).

Conclusions—Rates of sacral neuromodulation have increased dramatically over the last decade. However, these rates of utilization are highly variable across regions, with some regions performing large numbers of these procedures, and other regions performing few to no procedures. This range in practice patterns may reflect medical uncertainty surrounding the role of this procedure.

Keywords

Sacral Neuromodulation; voiding dysfunction; variation; trends; population

Introduction

Sacral neuromodulation is a relatively new treatment that is used for multiple different lower urinary tract conditions. It was approved by the U.S. Food and Drug Administration in 1997 for treatment of urge urinary incontinence, in 1999 for treatment of urinary urgency-frequency and nonobstructive urinary retention,(1) and in 2011 for fecal incontinence.(2) It has also been used to treat interstitial cystitis,(3) chronic pelvic pain,(4) neurogenic bladder symptoms,(5) and sexual dysfunction.(6) Since its introduction, over 100,000 sacral neuromodulators have been implanted,(7) at a cost of nearly $2 billion.(8)

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Despite its growing use and popularity, relatively little is known about the dissemination of these devices in community practice. Clinical indications for sacral neuromodulation are not absolute and depend on the preferences of the physician and the patient.(9) In such a setting, decisions on whether or not to implant a neuromodulator are susceptible to a variety of non-clinical factors, including physician training, physician comfort with performing the procedure, patient desires and expectations, community norms regarding preferred treatments, and associated financial incentives. As a direct reflection of the uncertainty surrounding when and in whom to implant, physicians likely vary greatly in their use of sacral modulation.

To examine this issue more carefully, we performed a study to assess trends in implantation of sacral neuromodulators. We used population-based data and leveraged small area variation methods to understand the scope of uncertainty surrounding the use of these devices.

Materials and Methods

Subjects

This study used data from the State Ambulatory Surgery Database (SASD) from 2002 through 2009 from the state of Florida.(10) The SASD is maintained by the Healthcare Cost and Utilization Project (HCUP) and provides patient level discharge data for all ambulatory procedures performed during this time period. We chose the state of Florida for two reasons. First, it is one of the larger and more ethnically diverse states participating in the Healthcare Cost and Utilization Project. Second, it captures discharges from a broad array of practice settings, including freestanding ambulatory surgery centers, where these procedures are commonly performed.

We identified patients ages 18 and older who underwent insertion or replacement of peripheral neurostimulator pulse generator or receiver [Current Procedure Terminology (CPT) Code 64590] between 2002 and 2009. Only these patients undergoing final placement of the sacral neuromodulator were included. Test stimulation procedures phases (CPT codes 64561 or 64585) were not a part of this analysis.

International Classification of Diseases (ICD-9) codes were used to characterize the clinical indications for the procedure. For this purpose, patients were first sorted into 1 of 5 mutually exclusive groups, including neurogenic bladder, interstitial cystitis, non-obstructive urinary retention, urgency incontinence, and dry overactive bladder, as previously described.(9) Collectively, these groups comprised 98.5% of all patients undergoing neuromodulator implantation. The remaining 74 patients (1.5%) were combined and categorized as an “other group”.

Statistical Analysis

We used Poisson regression to estimate trends over time for rates of procedures, both overall and for the individual indications. Rates were adjusted for age and gender based on data from the U.S. Census estimates for Florida.(11)

In order to understand more about time trends, we performed a series of analytic procedures. First, we divided all patients into time 4 time periods (2002-2003, 2004-2005, 2006-2007, and 2008-2009) and evaluated trends in diagnosis, gender, age, race, insurance, socioeconomic class,(12) and Charlson score(13) over time. Differences in these characteristics between time periods were estimated using the Mantel-Haenszel Chi-Square statistic.

Second, we evaluated the extent of variation in rates of implantation between markets over time. Rates were calculated using the indirect method of adjustment for gender and age. We chose the indirect method, as opposed to the direct method, due to the small numbers of procedures in each age/gender category. To measure these local healthcare markets, we used the Hospital Service Area (HSA) as described by the Dartmouth Atlas.(14) Each HSA represents a collection of zip codes in which residents receive their hospital care. The state of Florida has 114 HSAs that range in size from 5,000 to 190,000 inhabitants. We assessed the magnitude of variation between HSAs using the coefficient of variation. The coefficient of variation is the ratio of the standard deviation of the rates to the mean rate.(15) This calculation gives an estimate of variation between geographic regions for a procedure that is standardized to both the population size and the frequency of the procedure. Thus, this value can be used as a means of comparing the amount of variation in rates between different procedures. Higher values of the coefficient of variation are indicative of more variation.

Third, we wanted to determine if patient characteristics differed among HSAs with high implantation rates vs. those with low implantation rates. We suspected that patients in high volume regions would reflect a more diverse group demographically and would demonstrate a wider variety of indications for the procedure. We looked specifically at rates in years 2008-2009, which represented the majority (55.5%) of our cases. We divided HSAs into terciles (i.e., equal number of markets) based on rates. We then contrasted demographic and clinical characteristics across the three groups of HSAs.

Analyses were performed with SAS version 9.3 (SAS Institute, Cary, NC). The probability of a Type I error was set at 0.05 and all testing was 2-sided. The study was classified as exempt by our Institutional Review Board.

Results

A total of 3,857 patients underwent implantation of sacral neuromodulators between 2002 and 2009. During this time period, adjusted rates of these procedures increased from 1.1 per 100,000 population to 10.4 per 100,000 population ($p<0.001$). As shown in Figure 1, rates increased for all clinical indications ($p < 0.001$), except for interstitial cystitis ($p=0.379$) and the “other” category ($p=0.293$). Overactive bladder, both wet and dry, represented the largest group of patients.

Trends in patient characteristics over time are shown in Table 1. Patients who underwent these procedures in later years were more likely to be older and insured by Medicare. Additionally, patients tended to have more comorbid illnesses, as measured by a higher percentage of patients with a Charlson score of 2 or higher. We observed no significant differences in urologic diagnosis, gender, race, or socioeconomic class over time.

Rates of sacral neuromodulator implantation for each HSA are shown in Figure 2 for each of the four time periods. As time advances, there are more HSA's performing these procedures and at higher rates. The median rates of procedures at the HSA level for each time period were 0.9 per 100,000 population (range 0 to 21.8) in 2002-2003, 3.0 per 100,000 population (range 0 to 80.9) in 2004-2005, 4.2 per 100,000 population (range 0 to 95.0) in 2006-2007, and 12.9 per 100,000 population (range 0 to 128.3) in 2008-2009. Figure 3 highlights the differences in rates between the first two years of the analysis (2002-2003) and the last two years of the analysis (2008-2009). The line represents equality in rates between the two time periods and each dot represents an HSA. HSAs located above the line indicate higher rates of utilization in 2008-2009 compared to 2002-2003 (vice versa for HSAs below the line).

In order to quantify the amount of variation, we calculated the coefficient of variation for each of the time periods. The coefficient of variation initially increased and then slowly

decreased over time: 1.67 (2002 to 2003), 1.70 (2004 to 2005), 1.49 (2006 to 2007), and 1.05 (2008 to 2009).

Finally, we wanted to determine whether there were differences in patients who underwent the procedure in high volume HSAs as opposed to in low volume HSAs (table 2). High volume HSAs were more likely perform the procedure on patients who were older, white, insured by Medicare, and of lower socioeconomic class. Clinical indication, gender, and Charlson score did not significantly differ between the three groups.

Discussion

Rates of sacral neuromodulator implantation increased by more than 9 fold in the state of Florida between 2002 and 2009. Although the relative distribution of clinical indications for the procedure evolved over time, overactive bladder was by far the most common reason for implantation. Adoption and utilization of this procedure were substantial during this time period, yielding significant variation across regions at the HSA level.

While the literature on sacral neuromodulation consists of numerous studies and clinical trials attesting to its safety and efficacy,(9, 16-22) this is the first study to describe its adoption in community practice. Given the medical uncertainty and discretion surrounding the indications for implantation, it is not surprising that we observed such widespread variation in rates of utilization.

Interestingly, we found that the use of sacral neuromodulation was dominated by a select few healthcare markets. In 2008 and 2009, only five HSA's performed more than 100 procedures. These HSAs accounted for more than a third (35.2%) of all procedures. Patients who underwent a procedure in these very high volume HSAs tended to be the older, Medicare-insured population. One possible explanation is that providers in these markets are meeting a latent clinical demand. Alternatively, providers might be becoming more comfortable with the procedure and are thereby expanding its indications to a larger patient population. In a similar context, it is possible that some markets may be underutilizing sacral neuromodulation. In 2008 and 2009, 13 HSAs did not perform any of these procedures, while 68 HSA's performed fewer than 20 procedures each.

It is difficult to determine the “appropriate” rate of sacral neuromodulator implantation. While we do expect some degree of variability in rates between adjacent healthcare markets, the variation between regional rates observed in this study is striking. As of 2008 and 2009, the coefficient of variation, a standardized measure of variation, for procedure use was 1.05. To place this finding in context, it is useful to consider the coefficient of variation for other surgical procedures. Hip replacement, the rate of which is largely determined by the incidence of hip fracture,(23) has a coefficient of variation of 0.12, nearly one tenth that of sacral neuromodulation. Values for other procedures include 0.13 for cholecystectomy, 0.26 for hysterectomy, and 0.45 for routine circumcision.(15) Collectively, these data suggest that, at least relative to these other procedures, there is considerable disagreement about who should and should not undergo this procedure.

It is also interesting to note that the observed rates of increase in use of sacral neuromodulation, especially for overactive bladder, occurred during a time when several medications for this indication were released to the market. The significant growth of this surgical procedure in the face of these new drugs suggests that there is great dissatisfaction with these more “conservative” treatments for overactive bladder.

Our findings should be interpreted in the context of a few limitations. First, geographic data were calculated based on the residence address of each patient, rather than treatment

location (i.e., where the surgery was performed). As these procedures are elective and discretionary, we expect that the vast majority of patients undergo such procedures locally, so we do not view this as a significant issue. Additionally, any misclassification would be non-directional and have minimal impact on our findings. Second, because of the nature of the data, it does not include those procedures done in the inpatient or office settings. We believe however, that the majority of the final implantation procedures are performed in the ambulatory surgery setting.(9) Finally, some may worry about the generalizability of our findings beyond the state of Florida. As discussed earlier, we chose to use the state of Florida because it represents one of the most populated and diverse states represented by the HCUP. We found a large amount of variation in this state, and we have no strong reasons to believe that our findings would be different elsewhere.

Conclusion

Rates of sacral neuromodulation increased dramatically over the last decade. Growth in the use of this procedure was limited to a few healthcare markets. Generally speaking, regions appear to vary widely in their threshold for implanting sacral neuromodulators as evidenced by the dramatic regional variation. Future research is needed to better determine who should and should not be candidates for use of this new technology.

Acknowledgments

Funding: Thomas Benson Award in Sacral Neuromodulation (AUGS) Elisabeth Pickett Award (SWIU)

References

1. Bolton JF, Harrison SC. Neuromodulation 10 years on: how widely should we use this technique in bladder dysfunction? Current opinion in urology. 2009; 19(4):375–9. Epub 2009/05/19. [PubMed: 19448546]
2. U.S. Department of Health and Human Services. [cited 2011 September 20, 2011] F Medtronic® InterStim® Therapy System - P080025. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm249208.htm2011
3. Marinkovic SP, Gillen LM, Marinkovic CM. Minimum 6-year outcomes for interstitial cystitis treated with sacral neuromodulation. International urogynecology journal. 2011; 22(4):407–12. Epub 2010/09/18. [PubMed: 20848271]
4. Marcelissen T, Jacobs R, van Kerrebroeck P, de Wachter S. Sacral neuromodulation as a treatment for chronic pelvic pain. The Journal of urology. 2011; 186(2):387–93. Epub 2011/06/21. [PubMed: 21683381]
5. Chaabane W, Guillotreau J, Castel-Lacanal E, Abu-Anz S, De Boissezon X, Malavaud B, et al. Sacral neuromodulation for treating neurogenic bladder dysfunction: clinical and urodynamic study. Neurourology and urodynamics. 2011; 30(4):547–50. Epub 2011/04/14. [PubMed: 21488095]
6. Gill BC, Swartz MA, Firoozi F, Rackley RR, Moore CK, Goldman HB, et al. Improved Sexual and Urinary Function in Women with Sacral Nerve Stimulation. Neuromodulation : journal of the International Neuromodulation Society. 2011 Epub 2011/08/23.
7. Medtronic. [cited 2011 September 20, 2011] http://professional.medtronic.com/pt/uro/snm/index.htm2011
8. Siddiqui NY, Amundsen CL, Visco AG, Myers ER, Wu JM. Cost-effectiveness of sacral neuromodulation versus intravesical botulinum A toxin for treatment of refractory urge incontinence. The Journal of urology. 2009; 182(6):2799–804. Epub 2009/10/20. [PubMed: 19837427]
9. Cameron AP, Anger JT, Madison R, Saigal CS, Clemens JQ. National trends in the usage and success of sacral nerve test stimulation. The Journal of urology. 2011; 185(3):970–5. Epub 2011/01/21. [PubMed: 21247596]

10. (HCUP). AfHRaQHCaUP. [cited 2012 January 4] Introduction to the HCUP State Ambulatory Surgery Databases (SASD). 2011. Available from: http://www.hcup-us.ahrq.gov/db/state/sasddist/Introduction_to_SASD.pdf
11. Census US. [cited 2011 November 7, 2011] Population estimates for Florida. Available from: http://www.census.gov/popest/intercensal/state/ST-EST00INT-02.html
12. Diez Roux AV, Merkin SS, Arnett D, Chambless L, Massing M, Nieto FJ, et al. Neighborhood of residence and incidence of coronary heart disease. The New England journal of medicine. 2001; 345(2):99–106. Epub 2001/07/14. [PubMed: 11450679]
13. Deyo RA, Cherkin DC, Ciol MA. Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases. Journal of clinical epidemiology. 1992; 45(6):613–9. Epub 1992/06/01. [PubMed: 1607900]
14. Dartmouth. [cited 2011 October 3, 2011] 2011. http://www.dartmouthatlas.org/tools/downloads.aspx
15. Bederman SS, Coyte PC, Kreder HJ, Mahomed NN, McIsaac WJ, Wright JG. Who's in the driver's seat? The influence of patient and physician enthusiasm on regional variation in degenerative lumbar spinal surgery: a population-based study. Spine. 2011; 36(6):481–9. Epub 2011/04/14. [PubMed: 21488247]
16. Bower WF, Moore KH, Adams RD, Shepherd R. A urodynamic study of surface neuromodulation versus sham in detrusor instability and sensory urgency. The Journal of urology. 1998; 160(6 Pt 1):2133–6. Epub 1998/11/17. [PubMed: 9817339]
17. Weil EH, Ruiz-Cerda JL, Eerdmans PH, Janknegt RA, Bemelmans BL, van Kerrebroeck PE. Sacral root neuromodulation in the treatment of refractory urinary urge incontinence: a prospective randomized clinical trial. European urology. 2000; 37(2):161–71. Epub 2000/03/08. [PubMed: 10705194]
18. Schmidt RA, Jonas U, Oleson KA, Janknegt RA, Hassouna MM, Siegel SW, et al. Sacral nerve stimulation for treatment of refractory urinary urge incontinence. Sacral Nerve Stimulation Study Group. The Journal of urology. 1999; 162(2):352–7. Epub 1999/07/20. [PubMed: 10411037]
19. Hassouna MM, Siegel SW, Nyeholt AA, Elhilali MM, van Kerrebroeck PE, Das AK, et al. Sacral neuromodulation in the treatment of urgency-frequency symptoms: a multicenter study on efficacy and safety. The Journal of urology. 2000; 163(6):1849–54. Epub 2000/05/08. [PubMed: 10799197]
20. Peters KM, Feber KM, Bennett RC. A prospective, single-blind, randomized crossover trial of sacral vs pudendal nerve stimulation for interstitial cystitis. BJU international. 2007; 100(4):835–9. Epub 2007/09/08. [PubMed: 17822464]
21. Tjandra JJ, Chan MK, Yeh CH, Murray-Green C. Sacral nerve stimulation is more effective than optimal medical therapy for severe fecal incontinence: a randomized, controlled study. Diseases of the colon and rectum. 2008; 51(5):494–502. Epub 2008/02/19. [PubMed: 18278532]
22. Kessler TM, Buchser E, Meyer S, Engeler DS, Al-Khodairy AW, Bersch U, et al. Sacral neuromodulation for refractory lower urinary tract dysfunction: results of a nationwide registry in Switzerland. European urology. 2007; 51(5):1357–63. Epub 2006/11/23. [PubMed: 17113216]
23. Weinstein JN, B KK, Shawer Morgan T, Wennberg JE. Trends and geographic variations in major surgery for degenerative diseases of the hip, knee, nad spine. Healht Affairs. 2004:81–9.

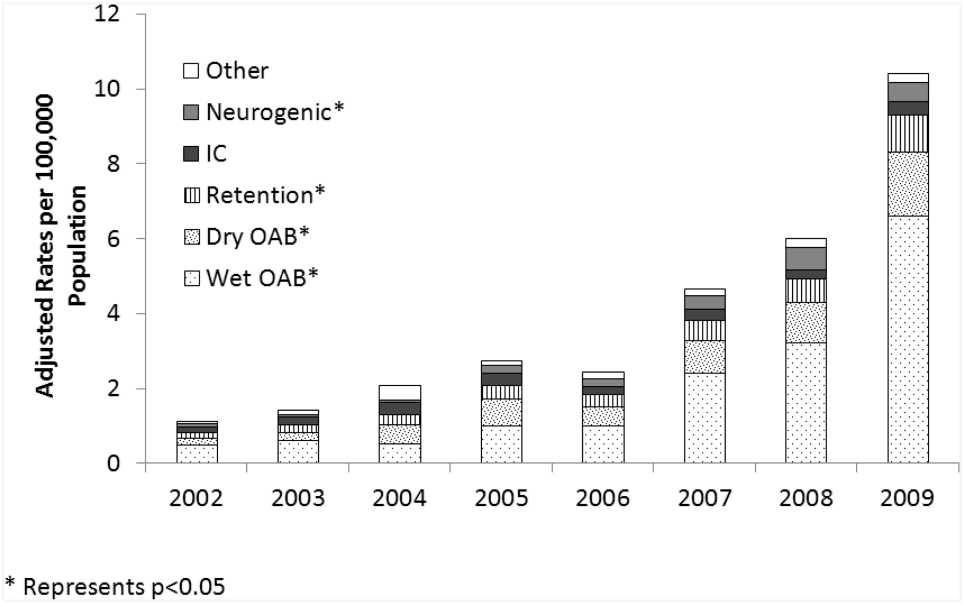

Figure 1. Rates of sacral neuromodulation by indication

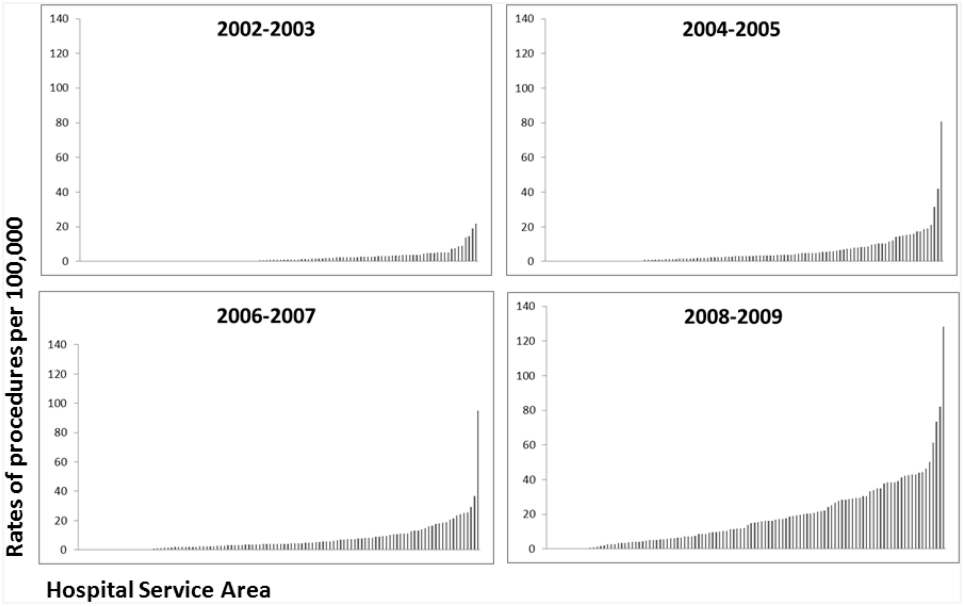

Figure 2.
Rates of implantation of sacral neuromodulators according to HSA for each of the four time periods. *Each vertical line represents the rate of a unique HSA.*

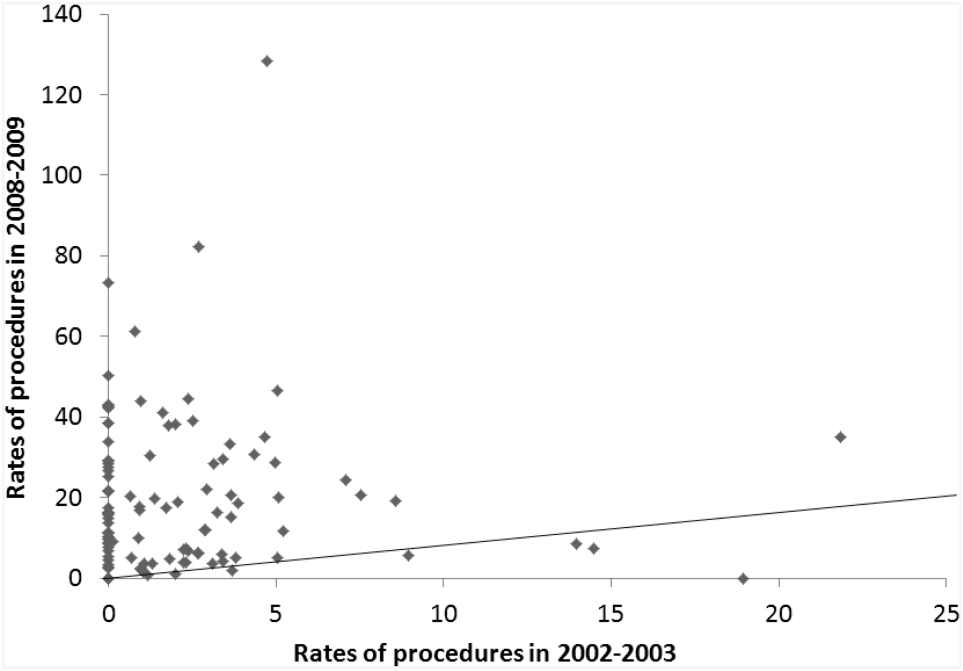

Figure 3.

The relationship between rates of sacral neuromodulation in 2002-2003 and 2008-2009. *The line represents equality between rates; if the dot representing the HSA is located above the line, enrollees in that HSA experienced higher rates of utilization in 2008-2009 compared to 2002-2003*.

Table 1

Patient characteristics based on the time period wherein implantation occurred. Numbers are expressed as percents.

	02-03	04-05	06-07	08-09	P value
N	242	573	875	2167	
Diagnosis					
Neurogenic	3.7	6.5	1.8	3.9	0.379
Interstitial Cystitis	7.0	8.9	6.3	3.9	
Retention	19.4	15.4	13.9	10.8	
Wet OAB	53.3	37.2	48.6	58.2	
Dry OAB	15.3	29.0	20.0	19.0	
Other	1.2	3.1	3.2	1.2	
Gender					
Male	15.3	19.6	21.3	19.4	0.451
Age category					
18-39	21.9	13.3	7.4	5.9	<0.001
40-59	30.2	36.3	28.7	20.0	
60-79	37.6	39.3	46.9	52.0	
80+	10.3	11.2	17.0	22.2	
Race					
White	91.7	89.0	92.9	91.9	0.882
Black	5.0	4.3	3.3	3.7	
Other	3.3	6.7	3.8	4.4	
Insurance					
Medicare	45.9	52.4	62.4	71.5	<0.001
Private	45.0	39.8	31.6	25.3	
Other	9.1	7.9	6.0	3.2	
Socioeconomic Class					
Low	25.5	32.1	31.6	33.8	0.184
Intermediate	37.2	36.6	36.0	32.6	
High	37.2	31.2	32.5	33.6	

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	02-03	04-05	06-07	08-09	P value
Charlson Score					
0	85.1	77.1	76.0	71.1	<0.001
1	12.4	16.4	17.6	21.5	
2	0.8	4.9	5.1	5.8	
≥3	1.7	1.6	1.3	1.6	

Table 2

Demographic characteristics based on terciles of low, medium, and high rates of implantation of sacral neuromodulators in 2008 and 2009.

	Low	Medium	High	P value
N	150	615	1407	
Diagnosis				
Neurogenic	10.7	6.3	6.9	0.858
Interstitial Cystitis	4.7	3.9	3.8	
Retention	12.0	13.3	9.5	
Wet OAB	44.0	52.7	62.1	
Dry OAB	26.0	22.8	16.6	
Other	2.7	1.0	1.1	
Gender				
Male	20.1	15.8	21.0	0.073
Age category				
18-39	8.7	7.0	5.1	<0.001
40-59	30.0	22.9	19.8	
60-79	45.3	50.4	53.2	
80+	16.0	19.7	23.8	
Race				
White	79.3	91.9	93.2	<0.001
Black	6.0	4.8	2.9	
Other	14.7	3.4	6.9	
Insurance				
Medicare	60.7	66.5	74.8	<0.001
Private	34.7	30.1	22.3	
Other	4.7	3.4	3.0	
Socioeconomic Class				
Low	30.6	30.5	35.5	0.049
Intermediate	27.1	37.3	31.3	
High	42.4	32.2	33.2	
Charlson Score				
0	73.3	74.2	69.6	0.307
1	16.0	19.2	23.0	
2	9.3	4.9	5.8	
≥3	1.3	1.8	1.6	