

National Trends in the Usage and Success of Sacral Nerve Test Stimulation

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Abbreviations and Acronyms

IC = interstitial cystitis
NGB = neurogenic bladder
OAB = overactive bladder
PNE = percutaneous office technique of neuromodulation
SNM = sacral neuromodulation

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Purpose: Little is known about outcomes of sacral neuromodulation in the general community, with published reports to date limited to case series or randomized, controlled trials. The goal of this analysis was to identify the national sacral neuromodulation test phase success rate and patient factors that contribute to success.

Materials and Methods: Medical claims data were obtained from a 5% sample of Medicare beneficiaries (1997 to 2007) and from employees of 25 large (Fortune 500) companies (Ingenix®, 2002 to 2007). Using billing codes for the sacral neuromodulation procedure, success was defined as progressing from test phase (percutaneous or staged) to battery implantation. The rate of success was compared based on age, race, gender and diagnosis.

Results: In the Medicare sample 358 patients received percutaneous test stimulation and 1,132 underwent 2-stage lead placement, of whom 45.8% and 35.4%, respectively, underwent subsequent battery implantation. In the privately insured sample there were 266 percutaneous procedures and 794, 2-stage procedures. Percutaneous procedures were followed by battery placement in 24.1% of cases, whereas 50.9% of staged procedures resulted in battery implantation. Gender was the only consistent predictor of success, with female patients demonstrating higher success rates in each data set.

Conclusions: The sacral neuromodulation success rates in these data sets are inferior to those published in case series and small randomized, controlled trials. Women had significantly better results than men and privately insured individuals had better results than those with Medicare, indicating a potential age effect.

Key Words: urinary bladder, urination disorders, prostheses and implants, electric stimulation, Medicare

SACRAL neuromodulation implantable systems (InterStim®) were Food and Drug Administration approved for urgency incontinence in 1997. Since that time, there have been more than 40,000 SNM systems implanted worldwide and the approved indications have expanded to include nonobstructive urinary retention and urgency-frequency syndrome for which conservative ther-

apies failed. However, little is known about patterns of use and outcomes of SNM testing in the nation as a whole. Published reports to date have been limited to case series or randomized, controlled trials with a few hundred patients at most.¹

The indications for SNM are not absolute and, therefore, the rate at which the procedure is performed will

depend on the preference of the surgeon and the wishes of the patient. Hence, wide variability in the use of this technology may exist. Success in the literature is often reported as the percent of individuals progressing from stage I to stage II. Recent systematic reviews of the efficacy of SNM for urge incontinence and OAB have reported that 52% to 88% of SNM test procedures were followed by battery implantation.^{1,2}

Two techniques exist to perform the test phase I, including PNE and the 2-stage surgical technique. In the percutaneous technique, a small percutaneous lead is placed using local anesthesia in the office. Test stimulation is done for 3 to 5 days and the lead is then removed. If the test is successful, a permanent lead and battery are then placed simultaneously during a single outpatient operative procedure. The 2-stage surgical technique first involves placement of a permanent lead in the operating room. The lead is initially connected to a temporary external battery with the test stimulation done for 1 or more weeks. A second surgery is then performed in which the lead is removed or it is connected to a permanent subcutaneous battery. In 2001 there was a modification in the staged technique with the introduction of a percutaneously placed tined lead. This tined lead is now used to perform the 2-stage technique and has significantly improved success.³

Our goals were to estimate the success rates of the SNM testing through analysis of administrative claims data from 2 separate populations (Medicare and privately insured individuals) and identify clinical factors that may contribute to success.

METHODS

A 5% random sample of Medicare beneficiaries from 1997 to 2007 and the entire Ingenix database of privately insured individuals from the second quarter of 2002 to the first quarter of 2007 were used as the data sources. The Ingenix data set includes medical claims for the employees of 25 large (Fortune 500) companies and their dependents from across the United States. Each patient was linked by a unique patient identification number. CPT® codes were used to identify all procedures performed on each individual and ICD-9 diagnosis codes associated with the procedure were used to identify the indication. Each of the procedures associated with SNM has a unique CPT code. All patients in the data sets with a CPT code for a test stimulation in the sacral foramen percutaneously (64561) or with an incision (64581) were included.

The first 2 ICD-9 diagnosis codes associated with the procedure were used to categorize patients into 1 of 5 mutually exclusive diagnosis groups. Any patient with an NGB was placed in the neurogenic category. Those with IC were placed in the IC group unless they had a diagnosis of NGB. Those with incomplete bladder emptying or non-obstructive urinary retention were placed in the retention

group unless they had IC or NGB. Those with urgency incontinence or other forms of incontinence except stress incontinence were placed in the wet OAB group unless they had one of the preceding diagnoses. The remaining persons with urgency, frequency and nocturia were placed in the dry OAB group since they did not have a diagnosis of incontinence. All other urological diagnoses associated with a procedure that did not fit into one of the mentioned categories were grouped into the other category. Any person who had no urological diagnosis whatsoever associated with the procedure was excluded since these were likely other types of neuromodulating devices.

Successful PNE was defined as a percutaneous test followed by a simultaneous permanent lead and battery implant. A failed PNE was defined as a percutaneous test with no other subsequent SNM procedure or 1 followed by a formal 2-stage procedure with a test stimulation period between the surgical lead placement and the battery placement. A successful 2-stage test was defined as surgical lead placement followed by a battery placement at a later date, whereas a failure was considered a surgical lead placement followed by a lead removal procedure or no battery placement. A failed PNE and permanent lead was considered to occur if a percutaneous test was done, followed by a permanent lead and then a removal with no battery implant. Cases with only lead explantations or only battery implants without a documented lead implant were not included since we could not define them as success or failure.

Statistical analysis was performed using SAS®. Descriptive statistics were used to report success and failure of PNE, the 2-stage procedure alone and the 2-stage procedure performed after failed PNE. The chi-square test was used to compare success and failure rates based on the patient variables of age, race/ethnicity, bladder diagnosis associated with procedure and gender with $p \leq 0.05$ considered statistically significant.

RESULTS

Medicare

A total of 358 patients received percutaneous test stimulation and 1,132 underwent 2-stage (permanent) lead placement from 1997 to 2007 in the 5% Medicare sample (table 1). Fully 91.3% of patients were white and 73.6% were female. The most common indication for the procedure was wet or dry OAB (63.0%), followed by other indications (21.7%), retention (9.5%), NGB (3.2%) and IC (2.6%). Using the criteria outlined, 45.8% of the percutaneous tests and 35.4% of the staged tests were successful (resulted in placement of a permanent battery). Only 5.9% of the percutaneous tests were salvaged with a 2-stage surgical technique. When the other group, in which urological diagnoses included stress incontinence, intrinsic sphincter deficiency and cystitis, was eliminated, the overall success rate improved to 47.5% in the percutaneous group and to 44.9% in the 2-stage procedure.

Table 1. Result of percutaneous and 2-stage tests in Medicare population, 1997 to 2007

	No. Percutaneous (% success)	% Failed Percutaneous			p Value	No. 2-Stage	% 2-Stage, No Percutaneous		p Value	% Overall Success	p Value
		No 2-Stage	Successful 2-Stage	Failed 2-Stage			Successful	Failed			
Diagnosis:											
NGB	16 (50.0)	37.5	0	12.5	0.09	32	56.3	43.8	<0.0001	54.2	<0.0001
IC	9 (66.7)	22.2	11.1	0		30	36.7	60.0		47.4	
Retention	49 (42.9)	42.9	8.2	6.1		92	46.7	48.9		49.6	
Wet OAB	160 (51.3)	39.4	6.3	3.2		435	46.4	51.3		50.3	
Dry OAB	111 (39.6)	54.1	5.4	0.9		233	40.8	56.6		42.9	
Other	13 (23.1)	76.9	0	0		310	10.3	89.7		10.8	
Age:											
Less than 65	62 (53.2)	38.7	8.1	0	0.64	272	40.1	58.1	0.034	44.7	0.0038
65–69	74 (36.4)	51.4	6.8	5.4		196	30.6	66.8		34.7	
70–74	70 (42.8)	52.9	4.3	0		201	44.8	53.7		45.9	
75–79	70 (54.3)	38.6	2.9	4.3		210	37.6	61.4		42.8	
80–84	57 (43.9)	43.9	7.0	5.3		162	25.9	71.6		33.0	
85–89	19 (47.4)	36.8	10.5	5.3		70	24.3	72.9		32.2	
90–94	5 (40.0)	60.0	0	0		19	21.1	78.9		25.0	
95+	1 (0)	100	0	0		2	0	100		0	
Race/ethnicity:											
Unknown	3 (66.7)	33.3	0	0	0.019	4	25.0	75.0	0.76	42.9	0.47
White	332 (46.7)	44.2	6.0	3.0		1,028	35.3	62.7		40.1	
Black	12 (25.0)	75.0	0	0		57	40.4	59.6		37.7	
Other	5 (20.0)	80.0	0	0		15	40.0	60.0		35.0	
Asian	2 (0)	50.0	0	50.0		4	50.0	50.0		33.3	
Hispanic	4 (75.0)	0	25.0	0		17	35.3	58.8		50.0	
North	0	—	—	—		7	0	100		0	
American native											
Gender:											
M	96 (29.2)	59.3	5.2	6.3	0.0004	298	27.2	71.1	0.002	29.3	<0.0001
F	262 (51.9)	40.1	6.1	1.9		834	38.4	59.7		43.7	
Overall	358 (45.8)	45.3	5.9	3.1		1,132	35.4	62.7		39.9	

The percutaneous test and the 2-stage procedure achieved more success in females than males (41.6 vs 27.7%). For the staged procedure, the younger age categories of less than 65, 65 to 69, 70 to 74 and 75 to 79 years were associated with improved success, as was diagnosis (NGB 56.3% success, retention 46.7%, wet OAB 46.4% and other 10.3%). None of these factors had a significant impact on the percutaneous success rates.

Ingenix

In the privately insured population, 266 percutaneous and 794, 2-stage procedures were performed from 2002 to 2007 (table 2). The sample was 81.3% female and 62.7% white, and 82.2% were less than age 65 years. OAB was the most common indication for the procedure (49.2%), whereas the other diagnosis was the least (1.3%).

Percutaneous procedures were only successful in 24.1% of cases, compared with 50.9% following staged procedures ($p < 0.0001$). Success rates were greater in females than in males (51.5% vs 38.5%, $p < 0.0001$). There were no differences in success based on diagnosis or age in the 2-stage group but in the percutaneous group there was better success

with the diagnoses of IC and dry OAB, and in younger individuals.

Comparison

When comparing results in the 2 data sets, overall success was greater in the in the privately insured group (39.9% Medicare vs 49.1% Ingenix, $p < 0.0001$). The success rate following percutaneous procedures was greater in the Medicare sample than in the privately insured sample (45.8% vs 24.1%, $p < 0.0001$). Conversely, the success rate following staged procedures was greater in the privately insured sample than in the Medicare sample (50.9% vs 35.4%, $p < 0.0001$). In each sample, age did not influence the choice of a staged vs a percutaneous test.

DISCUSSION

Modern series have shown consistently high success rates of conversion from test phase to battery implantation in SNM cases. A systematic review of urgency incontinence treatment with SNM demonstrated that 88% of all test phases resulted in the implantation of a stimulator (range 26% to 100%).¹ However, when better quality series were evaluated,

Table 2. Results of percutaneous and 2-stage tests in privately insured population, 2002 to 2007

	No. Percutaneous (% success)	% Failed Percutaneous			P Value	No. 2-Stage	% 2-Stage, No Percutaneous		p Value	% Overall Success	p Value
		No 2-Stage	Successful 2-Stage	Failed 2-Stage			Successful	Failed			
Diagnosis:											
NGB	20 (5.0)	70.0	5.0	20.0	0.024	36	36.1	61.1	0.17	27.3	0.006
IC	26 (30.8)	42.3	15.4	11.5		54	51.9	40.7		52.6	
Retention	44 (20.5)	47.7	20.5	11.4		115	48.7	43.5		49.3	
Wet OAB	79 (19.0)	53.2	17.7	10.1		323	51.1	44.6		50.0	
Dry OAB	94 (33.0)	56.4	7.4	3.2		25	54.5	42.7		51.8	
Other	3 (0)	100.0	0	0		11	27.3	72.7		21.4	
Age:											
Less than 18	10 (80.0)	10.0	10.0	0	0.0088	5	40.0	40.0	0.56	78.6	0.36
18–24	6 (16.7)	66.7	0	16.7		29	58.6	41.4		51.4	
25–34	34 (41.2)	35.3	14.7	8.8		100	47.0	48.0		51.2	
35–44	49 (26.5)	51.0	10.2	12.2		156	53.8	42.9		51.0	
45–54	62 (17.7)	59.7	17.7	4.8		186	46.8	47.3		46.0	
55–64	51 (19.6)	54.9	13.7	11.8		183	52.5	43.7		49.8	
65–74	35 (8.6)	65.7	17.1	8.6		83	48.2	44.6		43.8	
75+	19 (21.1)	73.7	0	5.3		51	58.8	41.2		48.6	
Race/ethnicity:											
White	156 (21.1)	53.9	16.7	8.3	0.75	509	50.7	44.2	0.27	49.6	0.11
Black	12 (33.3)	58.3	8.3	0		32	31.3	65.6		34.9	
Asian	4 (25.0)	75.0	0	0		1	0	100.0		20.0	
Hispanic	9 (44.0)	55.6	0	0		17	64.7	35.3		57.7	
Other	0	—	—	—		9	77.8	22.2		77.8	
Unknown	85 (25.9)	52.9	9.4	11.8		226	52.2	44.2		48.8	
Gender:											
F	195 (26.2)	49.2	15.9	8.7	0.031	667	51.9	43.5	0.31	51.5	0.0012
M	71 (18.3)	67.6	5.6	8.5		125	45.6	51.2		38.5	
Unknown	0	—	—	—		1	0	100.0		—	
Overall	266 (24.1)	54.1	13.2	8.6		794	50.9	44.7		49.1	

the battery implantation rate was 52% to 77%.² Outcomes for urinary retention have been more variable, with a successful test phase in up to 75.6%⁴ of 2-stage procedures but as low as 38.4% in percutaneous procedures.⁵ In contrast to these results, ours were much lower with an overall mean success rate of 39.9% in the 5% Medicare sample and 49.1% in the privately insured sample. The Swiss national registry, another nationally representative sample, had results similar to ours with 63% success for staged procedures and 32% success for percutaneous tests with 6% of temporary lead failures salvaged with a 2-stage procedure.⁶

Multiple potential explanations may exist to explain the low success rates in this analysis. 1) There are inherent difficulties using billing data to estimate success. 2) Randomized, controlled trials and single institution case series are typically limited to content experts with focused practices who see relatively large numbers of patients with refractory voiding dysfunction. It is possible that better results are obtained in such circumstances due to better patient selection and technical improvements that are attained with experience.

3) Specific technical improvements may have impacted the outcomes. For instance, the tined lead introduced in 2002 was shown to have results superior to those of the originally described percutaneous procedure followed by open implantation of the permanent lead sutured to the presacral fascia.^{5,7–9} However, only 11% of the Medicare procedures in this analysis were performed before 2002, so this effect is an unlikely explanation for the poor results.

4) Not all failures to implant are necessarily test failures. The reported rate of patients with clinically successful trials with 50% improvement in symptoms who elect to not have the implant for other reasons varies from 7% to 26%.^{7,9–11}

While success rates in the 2 populations were similarly low, the results for the 2 procedures (percutaneous vs staged) were inconsistent. In the Medicare group, the percutaneous success rate was greater than for the staged procedure, while the converse was seen in the Ingenix sample. The reasons for this inconsistency are not clear. It is possible that individuals who had a percutaneous test more readily accepted a battery implant, believing that they would get even more efficacy with the real

lead. It has been shown that PNE has an increased lack of efficacy after battery placement compared to the 2-stage procedure.¹² Also, the Medicare sample was older than the Ingenix sample. It is possible that certain age related factors or other clinical characteristics that were different between the 2 samples were partly responsible for these findings. Unfortunately, detailed clinical information is not available to help address these questions.

Many investigators have reported success rates for SNM in clinical subgroups.^{5,11,13-16}

The relatively large sample sizes available in our data sets allowed us to compare outcomes across these various subgroups. We did not observe any consistent difference in success based on age. In the Medicare population only in the 2-stage group younger individuals fared better and in the Ingenix group younger individuals did better with PNE. In the overall results age remained significant only for the Medicare data. However, when compared to the Medicare group, the Ingenix population had significantly better success overall and is a much younger population. Some investigators have noted no difference in success in their patients older than 70 years.¹³

We had significantly higher success in female compared to male patients in the 2 data sets. There were no differences in success based on gender in any previously reported article that evaluated this variable¹⁶ except that by Amundsen et al, who noted 28% success in men and 56% success in women but without achieving statistical significance.¹⁷ To our knowledge our improved success in women has previously not been reported, most likely since few studies have such large numbers of men and women to allow for adequate comparison.

There are several limitations to this analysis. We defined success as a patient receiving a battery implant after test stimulation with the assumption that all patients who had a battery implanted had the requisite 50% improvement in symptoms. In

clinical practice, battery implantation also depends on patient willingness to have the implant and the surgeon desire to implant the device. We do not have an estimate of the number of patients with clinical improvement who decide not to have the implant for other reasons. We also have no information on clinical improvement seen in patients or on the long-term effectiveness of this therapy, which is probably the most important outcome. Long-term effectiveness was reported to be between 100% and 59% in a systematic review that defined effectiveness as greater than 50% improvement of symptoms.¹

There are also inherent limitation to all claims based research that is reliant on codes, with errors in coding and billing resulting in errors in the analysis. To our knowledge there have been no previous analyses of SNM outcomes using administrative billing data. However, reviews of other surgical procedures using claims data have shown inferior results compared with the clinical literature.¹⁸

CONCLUSIONS

Although claims based data are limited by a lack of detailed clinical information, they identify real world treatment patterns and outcomes of care for a large heterogeneous population. We found the success rate of SNM test phase in the Medicare and privately insured populations to be inferior to that published in case series and small, randomized, controlled trials. These findings suggest the need to counsel patients realistically about their chances of success with such a procedure. Women had significantly better results than men and privately insured individuals had better results than Medicare, indicating a potential age effect. Although data from the literature suggest a large difference in success rates between percutaneous and permanent lead approaches, our findings suggest that less of a gap exists.

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