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

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Abstract

Purpose—Little is known about outcomes of sacral neuromodulation (SNM) 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** SNM **test phase** success rate, and to identify 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, Inc – 2002-2007). Utilizing billing codes for the SMN 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, there were 358 patients who received percutaneous test stimulation and 1132 who underwent 2-stage lead placement. Of these, 45.8% of the percutaneous tests and 35.4% of the staged procedures underwent subsequent battery implantation. In the privately insured sample, there were 266 percutaneous procedures and 794 two-staged procedures. Percutaneous procedures were followed by battery placement in 24.1% of cases, whereas 50.9% of the staged procedures resulted in a battery implant. Gender was the only consistent predictor of success, with female patients demonstrating higher success rates in both datasets.

Conclusion—The SNM success rates in these datasets 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 Medicare, indicating a potential age effect.

Introduction

Sacral neuromodulation (SNM) implantable systems (InterSTIM, Medtronic Inc. Minneapolis, MN) were FDA approved for urgency incontinence in 1997. Since that time there have been over 40,000 SNM systems implanted worldwide and the approved indications have expanded to include non-obstructive urinary retention and urgency-frequency syndrome who have failed conservative therapies. 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 percentage 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 52-88% of SNM test procedures were followed by a battery implant[1,2]

Two techniques exist to perform the test phase I: the percutaneous technique (PNE) and the 2-stage surgical technique. In the percutaneous technique, a small percutaneous lead is placed using local anesthetic in the office, test stimulation is done for 3-5 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 conducted for a period of one or more weeks. A second surgery is then performed in which the lead is either 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 two staged 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 two separate populations (Medicare and privately insured individuals), and to 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 dataset includes medical claims for the employess of 25 large (Fortune 500) companies and their dependents from across the United States. Each patient was linked by a unique patient identification number. Current Procedural Terminology, 4th edition (CPT), codes were used to identify all procedures performed on each individual, and International Classification of Diseases, 9th edition (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 (Table 1 online*). All patients in the datasets with a CPT code for a test stimulation in the sacral foramen either percutaneously (64561) or with an incision (64581) were included.

The first two ICD-9 diagnosis codes associated with the procedure were used to categorize patients into one of five mutually exclusive diagnosis groups (Table 1). Any patient with a neurogenic bladder diagnosis (NGB) was placed in the neurogenic category; those with interstitial cystitis (IC) were placed in the IC group unless they had a diagnosis of neurogenic bladder. 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" overactive bladder (OAB) group unless they had one of the preceding diagnoses. The

*Table 1 available online: http://www.med.umich.edu/urology/research/ManuscriptAppendices/Pelletier%20Cameron/Table%201%20UDA%20version%202.pdf

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 urologic diagnosis associated with a procedure that did not fit into one of the above mentioned categories were grouped into the "other" category. Any person who had no urologic diagnosis whatsoever associated with their 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: either a percutaneous test with no other subsequent SNM procedure or one followed by a formal two stage procedure with a test stimulation period between the surgical lead placement and the battery placement. A successful 2-stage test was defined as a 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, then a removal with no battery implant. Individuals 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 Statistical Analysis Software. Descriptive statistics were used to report success and failure of the PNE, two stage procedure alone and two stage performed after failed PNE. A Chi square test was utilized to compare success and failure rates based on the patient variables of age, race/ethnicity, bladder diagnosis associated with procedure and gender. P values of ≤ 0.05 were considered statistically significant.

Results

Medicare Database

There were 358 patients who received percutaneous test stimulation and 1132 underwent 2-stage (permanent) lead placement from 1997 to 2007 in the 5% Medicare sample (Table 2). Fully 91.3% of patients were Caucasian 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%), neurogenic bladder (3.2%) and IC (2.6%). Using the criteria outlined above, 45.8% of the percutaneous tests and 35.4% of the staged tests were found to be successful (resulted in placement of a permanent battery). Only 5.9% of the percutaneous tests were salvaged with a 2-stage surgical technique. If the "other" group, whose urologic diagnoses included stress incontinence, intrinsic sphincter deficiency, and cystitis, is eliminated, the overall success rate improved to 47.5% in the percutaneous group and to 44.9% in the two-stage procedure. Both the percutaneous test and the two-stage procedure achieved more success in females than males (41.6 vs. 27.7%). For the staged procedure, the younger age categories of <65, 65-69, 70-74 and 75-79 were associated with improved success, as was diagnosis (NGB – 56.3% success, retention – 46.7%, "wet" OAB – 46.4%, "other" – 10.3%). None of these factors had a significant impact on the percutaneous success rates.

Ingenix Database

In the privately insured population, there were 266 percutaneous and 794 two-staged procedures performed from 2002 to 2007 (Table 3). The sample was 81.3% female, 62.7% Caucasian, and 82.2% were under the age of 65. OAB was the most common indication for the procedure (49.2%) whereas "other" diagnoses were 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 two-staged group, but in the percutaneous group there was better success with the diagnoses of IC and dry OAB and with younger individuals.

Comparison of two databases

When comparing results in the two datasets, 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 (45.8%) than in the privately insured sample (24.1%, p<0.0001). Conversely, the success rate following staged procedures was greater in the privately insured sample (50.9%) than in the Medicare sample (35.4%, p<0.0001). In both samples, age did not influence the choice of staged vs. percutaneous test.

Discussion

Modern series have reported consistently high success rates of conversion from test phase to battery implant in SNM. A systematic review of urgency incontinence treatment with SNM found **88% of all test phases resulted in the implant of a stimulator (range 26%-100%)**.[1]**, however when better quality series were evaluated the battery implant rate was 52-77%**[2]. Outcomes for urinary retention have had more variable, with successful **test phas**e in up to **75.6**%[4] with the two staged procedure, but as low as 38.4% in percutaneous.[5] In contrast to these results, ours were much lower with an overall mean success of 39.9% in the 5% Medicare sample and 49.1% in the privately insured. The Swiss national registry, another nationally representative sample had similar results to ours with 63% success for staged procedures, and 32% success for percutaneous tests **with 6% of their temporary lead failures salvaged with a two stage procedure**.[6]

Multiple potential explanations may exist to explain the low success rates in this analysis. First, there are inherent difficulties utilizing billing data to estimate success. Second, 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 and it is possible that better results are obtained in such circumstances due to better patient selection and technical improvements that are attained with experience.

Third, there are specific technical improvements that may have impacted the outcomes. For instance, the tined lead introduced in 2002 was shown to have superior results to the originally described percutaneous procedure followed by an 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 this, so this effect is an unlikely explanation for the poor results. Fourth, 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 the success rates in both populations are similarly low, the results for the two different procedures (percutaneous vs. staged) are inconsistent. In Medicare, the percutaneous success rate was greater than the staged, while the converse was seen in Ingenix. The reasons for this inconsistency are not clear. It is possible that those individuals who had a percutaneous test more readily accepted a battery implant believing they would get even more efficacy with the “real” lead and it has been shown that PNE have an increased lack of efficacy after battery placement compared to two-staged[12]. Also the Medicare sample is older than the Ingenix sample, and it is possible that certain age-related factors or other clinical characteristics that are different between the two samples are partly

responsible for these findings. Unfortunately, detailed clinical information is not available to help address these questions.

Many authors have published success rates for SNM in clinical subgroups.[5,11,13-16] The relatively large sample sizes available in our datasets 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 two stage group younger individuals fared better and in Ingenix younger individuals did better with a PNE. In the overall results age remained significant only for the Medicare data. However, the Ingenix population when compared to Medicare had significantly better success overall and are a much younger population. Some authors have shown no difference in success in their patients over 70 years of age[13].

We had significantly higher success in women compared to men patients in both datasets. There were no differences in success based on gender in any previously reported article that evaluated this variable [16] except Amundsen who note 28% success in men and 56% success in women, but without achieving statistical significance. [17] Our improved success in women has previously not been reported most likely since few studies have such large numbers of both 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 the patient's willingness to have the implant and the surgeons 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 nor on the long-term effectiveness of this therapy, which is probably the most important outcome. Long term effectiveness was reported to be between 100-59% in a systematic review that defined effectiveness as >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 utilizing claims data have shown inferior results when compared with the clinical literature[18].

Conclusion

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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Table 1
Diagnosis categories and procedure codes

Diagnosis	ICD-9 code
Neurogenic Bladder:	
Neurogenic bladder NOS	596.54
Cauda equina syndrome with neurogenic bladder	344.61
Interstitial cystitis:	
Interstitial cystitis	595.1
Urinary retention:	
Retention of urine, unspecified	788.20
Atony of bladder	596.4
Incomplete bladder emptying	788.21
Other specified retention of urine	788.29
Wet OAB:	
Unspecified urinary incontinence	788.30
Urge incontinence	788.31
Mixed incontinence	788.33
Dry OAB:	
Urgency of urination	788.63
Urinary frequency, frequency of micturition	788.41
Hypertonicity of Bladder	596.51
Detrusor instability	596.59
Nocturia	788.43
Other:	
Incontinence without sensory awareness	788.34
Stress incontinence, female	625.6
Intrinsic sphincter deficiency	599.82
Female genital symptoms NOS	625.9
Other specified disorders of bladder	596.8
Other abnormality of urination, Other	788.69
Stress incontinence male	788.32
Other urinary incontinence	788.39
Slowing urinary stream	788.62
Chronic cystitis NEC	595.2
Cystitis NOS	595.9
Urinary System Symptom NEC	788.9
Procedure	**CPT Code**
percutaneous test stimulation	64561

Diagnosis	ICD-9 code
test stimulation with incision (2-stage test)	64581
Battery placement	64590
Lead removal	64585
Battery removal	64595

NOS= not otherwise specified, NEC= not elsewhere classified

Abbreviation Key: CPT= Current Procedural Terminology, 4th edition, IC= interstitial cystitis, ICD-9= International Classification of Diseases, 9th edition, NGB=neurogenic bladder, PNE= percutaneous office technique of neuromodulation, OAB= overactive bladder, SNM=sacral neuromodulation

Table 2

Result of percutaneous and two-staged tests in the Medicare population 1997-2007

	Number of perc test procedures	Total perc success %	Failed perc no 2-stage %	Failed perc with successful 2-stage %	Failed both %	P value	Number of 2-stage tests	Successful 2-stage with no perc %	Failed 2-stage no perc %	P value	Overall success rate %	P value
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:												
<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
Caucasian	332	46.7	44.2	6.0	3.0		1028	35.3	62.7		40.1	
AA	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	
NA Native	0	-	-	-	-		7	0	100		0	
Sex:												

	Number of perc test procedures	Total perc success %	Failed perc no 2-stage %	Failed perc with successful 2-stage %	Failed both %	P value	Number of 2-stage tests	Successful 2-stage with no perc %	Failed 2-stage no perc %	P value	Overall success rate %	P value
Male	96	29.2	59.3	5.2	6.3	0.0004	298	27.2	71.1	0.002	29.3	<0.0001
Female	262	51.9	40.1	6.1	1.9		834	38.4	59.7		43.7	
Total:	358	45.8	45.3	5.9	3.1		1132	35.4	62.7		39.9	

perc=percutaneous, NGB=neurogenic bladder, IC=interstitial cystitis, “wet” OAB= overactive bladder with urgency incontinence, “dry” OAB= overactive bladder with no incontinence, AA=African American, NA= North American

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Table 3

Results of percutaneous and two-staged tests in a privately insured population 2002-2007

	Number of perc test procedures	Total perc success %	Failed perc no 2-stage %	Failed perc with successful 2-stage %	Failed both %	P value	Number of 2-stage tests	Successful 2-stage with no perc %	Failed 2-stage no perc %	P value	Overall success rate %	P value
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:												
<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:												
Caucasian	156	21.2	53.9	16.7	8.3	0.75	509	50.7	44.2	0.27	49.6	0.11
AA	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	44.4	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	
Sex:												
Female	195	26.2	49.2	15.9	8.7	0.031	667	51.9	43.5	0.31	51.5	0.0012

	Number of perc test procedures	Total perc success %	Failed perc no 2-stage %	Failed perc with successful 2-stage %	Failed both %	P value	Number of 2-stage tests	Successful 2-stage with no perc %	Failed 2-stage no perc %	P value	Overall success rate %	P value
Male	71	18.3	67.6	5.6	8.5		125	45.6	51.2		38.5	
Unknown	0	-	-	-	-		1	0	100.0		-	
Total:	266	24.1	54.1	13.2	8.6		794	50.9	44.7		49.1	

perc=percutaneous, NGB=neurogenic bladder, IC=interstitial cystitis, “wet” OAB= overactive bladder with urgency incontinence, “dry” OAB= overactive bladder with no incontinence, AA=African American, NA= North American