Outcomes of Sacral Neuromodulation in a Privately Insured Population

Running Title: **Sacral Neuromodulation in the Ingenix Dataset**

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Abstract

Objective: In this study we analyzed claims data from the Ingenix database to analyze outcomes of sacral neuromodulation with respect to both provider and patient factors.

Materials and Methods: We used the Ingenix (I3) database to determine demographic, diagnosis, and procedure success information for years 2002-2007 for privately insured patients. Demographic information was obtained, as were the diagnoses given and procedures performed, based on ICD-9 diagnosis codes and CPT procedure codes. Multivariate analysis was performed to identify specific predictors of success, as measured by progression to implantation of a pulse generator.

Results: Overall success, as defined by battery placement, was 49.1%. Fifty-one percent of staged procedures were followed by battery placement compared with 24.1% of percutaneous cases ($p<0.0001$). Among the patient variables analyzed, women were more likely than men to progress to battery placement. After Stage I testing, patients treated by urologists were overall more likely than gynecologists to proceed to battery placement (I3: 54% vs. 47%, $p < 0.0001$)**.** Unlike previous findings in other claims-based data sets, we did not observe a provider-volume relationship in the i3 dataset.

Conclusions: Success of sacral neuromodulation, as defined by proceeding to battery placement, was much better after formal staged procedures, which leads us to question the utility of percutaneous techniques. Outcomes were also better among female patients and among those treated by a urologist. Specialty differences will likely diminish over time as more gynecologists adopt sacral neuromodulation.

Key words: Urology, Gynecology, Implantable Neurostimulators, Medical Specialty, Provider Volume, Claims Data

Introduction

Sacral neuromodulation has demonstrated efficacy in the treatment of many chronic urological diseases refractory to medical therapy, including overactive bladder symptoms, urinary retention, neurogenic voiding dysfunction, and even interstitial cystitis. More recently, sacral neuromodulation has been FDA-approved and proven effective for the treatment of fecal incontinence[1]. Once an invasive procedure involving a large incision over the sacrum, in 2001 the device was modified such that is it now a minimally invasive procedure that is often performed under local anesthesia with intravenous sedation. Patients typically undergo a one or two week testing period to determine whether there is an adequate symptom response (usually defined as a 50% or greater improvement in symptoms[2]) before proceeding to battery placement. Testing is either performed with a permanent lead (formal stage I, often under sedation) or a temporary wire (Peripheral Nerve Evaluation, PNE, usually in the office) which is replaced with the permanent lead and battery after the testing period[3].

Previous studies, both clinical and claims-based, have identified patient factors associated with outcomes of sacral neuromodulation. Variables associated with improved outcomes include female gender, younger age, and a diagnosis of OAB over other types of voiding dysfunctions[3]. However, relatively little is known about the effect of surgeon variables on outcomes of neuromodulation, such as surgeon volume, or case load, and surgeon subspecialty (urology vs. gynecology). Use of claims-based data is an ideal means to measure such surgeon factors in a heterogeneous, broadly distributed population.

At that time we analyzed outcomes of sacral neuromodulation in two claims-based datasets, Medicare and I3 (Ingenix)[3]. We next analyzed specific provider and patient factors affecting outcomes of sacral neuromodulation in the Medicare population[4]. Herein we used the I3 dataset to measure variables that may affect outcomes of neuromodulation in a younger, privately insured population, whose outcomes may differ from that of the Medicare population. We specifically analyzed provider specialty and volume, and patient factors including age, gender, race, and chief urologic diagnosis.

Materials and Methods

The Ingenix (I3) database includes nationwide claims for the employees of 25 large companies (Fortune 500) and their dependents. The Ingenix (I3) database was used to determine demographic, diagnosis, and procedure success information for years 2002-2007 for these privately insured patients. Since all patient data were de-identified, this work was granted an Institutional Review Board exemption from UCLA and RAND Corporation. This time frame was specifically chosen in order for us to make comparisons to our previously conducted work in the Medicare population during a similar time period[3]. Current Procedural Terminology, 4th edition (CPT-4) codes were used to identify procedures performed on each individual, and ICD-9 diagnosis codes were used to identify the clinical indication, as previously described[3]. Patients were assigned a diagnosis of OAB-dry if they carried one or more of the following codes: urgency of urination (ICD-9 code 788.63), urinary frequency (788.41), bladder hypertonicity (596.51), detrusor instability (596.59), or nocturia (788.43) and did not meet any of the criteria for OAB-wet. They were assigned a diagnosis of OAB-wet if they had a code for unspecified urinary incontinence (788.30), urge incontinence (788.31), and/or mixed incontinence (788.33). Patients were also assigned a diagnosis of neurogenic voiding dysfunction, interstitial cystitis, or "other" voiding dysfunction categories, based on relevant ICD-9 codes[3].

Lead placement was either performed as a percutaneous placement (CPT-4 code 64561) or an operative lead placement (Stage I, CPT-4 code 64581). Because of our inability to accurately measure detailed clinical outcomes, such as symptom severity or bother, in claims-based datasets, we defined success as proceeding to battery

implantation (CPT-4 code 64590). This assumes that patients who went on to battery placement met criteria for significant improvement, usually 50% or greater improvement in symptoms[5]. We compared outcomes by provider volume and specialty (urology vs. gynecology). We defined a high volume provider as one who performed in the upper 25th percentile of procedures performed. This corresponded to 30+ procedures over the 2002-2007 time period. Descriptive statistics were used to report success rates, as defined by battery placement. Patient factors analyzed included age, gender, race, and chief diagnosis for which sacral neuromodulation was performed. Multivariate analysis was performed to identify predictors of outcome while controlling for covariates. The chi-square test was used to compare success and failure rates based on patient and provider variables. Statistical analysis was performed with the Statistical Analysis System (SAS®).

Results

In the I3 population, 794 two-stage procedures and 266 percutaneous procedures were performed from 2002 to 2007. As previously described, the sample was 81.3% female and 62.7% Caucasian[3]. The majority of patients were younger than 65 years old (82.2%). OAB was the most common indication for the procedure, followed by urinary retention, IC, and "other" diagnoses[3]. Overall success, as defined by battery placement, was 49.1%. Fifty-one percent of staged procedures were followed by battery placement compared with 24.1% of percutaneous cases ($p<0.0001$)[3].

The top volume quartile of providers was at least 30 cases in 5 years. Physicians in the top quartile performed 84.3% of cases (242 percutaneous trials and 652 operative trials) and those in the lower three quartiles performed 15.7% of cases (24 percutaneous trials and 142 operative trials). The rate of progression to battery placement was significantly different for the top quartile vs. the lower three quartiles (I3, Table 1). However, in multivariate analysis (Table 2), surgeon volume was not a significant predictor of outcomes.

Seventy-three percent of cases were performed by urologists (197 percutaneous trials and 572 operative) and 17.0% were performed by gynecologists (31 percutaneous trials and 149 operative trials). Urologists had higher rates of battery placement after operative trials than gynecologists (I3: 54% vs. 47%, $p < 0.0001$). Multivariate analysis confirmed a higher rate of battery placement for two-staged procedures (OR 2.8, 95% CI 2.0-3.9, Table 2) and overall among urologists (OR 2.3, 95% CI 1.7-3.1, Table 2*)*.

Success rates were greater among female patients than male patients (51.5% vs. 38.5%, $p<0.0001$). In fact, multivariate analysis confirmed a nearly two-fold difference in

outcomes between men and women for both two-staged procedures (OR 1.6, 95% CI 1.1-2.5, Table 2) and overall (OR 2.0, 95% CI 1.4-2.8, Table 2). Patient age, however, did not have a significant impact on outcomes. Those with a diagnosis of neurogenic bladder had worse overall outcomes than OAB-wet (OR 0.4, 95% CI 0.2-0.7, Table 2). For the subset undergoing percutaneous testing, those with OAB-dry actually had a higher rate of battery placement than those with OAB-wet (OR 2.2, 95% CI 1.0-4.5, Table 2).

Discussion

Our findings in I3 demonstrate worse outcomes in the "real world" as compared to data from clinical series, usually conducted by high-volume experts in the field. Fifty-one percent of staged procedures were followed by battery placement compared with 24.1% of percutaneous cases ($p<0.0001$). These findings demonstrate a drastic difference in outcomes between the two techniques. These findings of relatively poor outcomes overall are consistent with our prior work in Medicare from the same time frame, in which 46% of the percutaneous tests and 35% of the staged tests resulted in placement of a permanent battery. However, patients in the I3 dataset had superior outcomes with staged testing and inferior outcomes than Medicare beneficiaries with percutaneous testing. These findings are also consistent with clinical series in the literature[6, 7]. Given that the outcomes of formal stage 1 testing are so much better across both claims-based datasets and clinical series, our findings lead us to question the utility of percutaneous testing as an effective treatment modality,

We also identified a relationship between provider and patient variables and success rates in I3, as measured by proceeding to battery implantation. Patients who underwent lead placement by a urologist were more likely to proceed to battery placement. In our previous analysis of Medicare data, urologists were more likely than gynecologists to proceed to battery placement after operative lead placement (49% vs. 43%, $p < 0.0001$), but gynecologists were more likely than urologists to proceed to battery placement after percutaneous testing (63% vs.44%, $p = 0.005$). The provider-specialty relationship is difficult to define with sacral neuromodulation, since success, as defined by permanent battery placement, is a function of both surgeon and patient

decision-making. The majority of lead placements in both datasets were performed by urologists. The fact that outcomes were better among urologists may be due to that fact that there were more high volume providers, including more fellowship-trained providers, among urologists than gynecologists in the I3 dataset. Alternatively, urologists may have used less stringent definitions of success in deciding to proceed to stage II.

Female patients had better outcomes than males, a relationship that was also shown in Medicare and in previous case series[3]. Possibly the presence of a prostate and associated outlet obstruction of varying degrees could result in more treatment-refractory bladder conditions. Outcomes were also worse among those with neurogenic bladder, a finding also supported in the literature[6]. What is not consistent with the literature and our prior work with Medicare is the finding that, in the subset of I3 patients undergoing percutaneous testing, patients with OAB-dry were more likely to proceed with battery placement than those with OAB-wet. Most large series show improved outcomes in the OAB-wet population. Possible explanations for this inconsistency could be the inherent inaccuracies in ICD-9 coding of symptoms, meaning that the populations were not actually pure OAB-dry and OAB-wet. In addition, the sample size of the group who underwent percutaneous testing was small; therefore a larger sample size may have found different relationships between urologic diagnoses and outcomes.

The strong provider-volume relationship we previously observed in Medicare was not demonstrated in the I3 dataset[4]. However, the majority of cases in I3 were performed by high volume providers, which may have contributed to better outcomes overall in I3. Also, we arbitrarily defined a high volume provider as those performing in the upper quartile of providers, a technique used previously by us and others[8]. The upper quartile of

providers in I3 was actually much higher volume than it was in the Medicare population (30 cases over 6 years vs. 5 cases over eleven years in CMS), indicating that many providers in I3 who fell under the 75th percentile were still relatively high volume providers. This might be explained by the possibility that, once physicians complete a learning curve, provider volume may have less of an influence on progression to battery placement. In addition, the I3 population was younger than the Medicare population, and therefore may have demonstrated better outcomes regardless of volume-related provider differences. The younger age of the I3 population may also explain the fact that we did not find a significant impact of patient age on outcomes, as the number of older adults in this population was smaller than that in Medicare.

Our work is among the few claims-based analyses of sacral neuromodulation outcomes using a national dataset. Such analyses shed light into real-world practice patterns in a large, heterogeneous population. However, this work does have limitations. Inherent in claims-based data is a lack of clinical detail. Specifically, we did not have information about degree of improvement and reasons for not proceeding with a staged procedure after a failed PNE. We therefore had to make assumptions that doctors would only proceed to stage 2 if patients were significantly better. However, this was likely the case for the vast majority of patients. Although we chose this dataset in order to make comparisons to Medicare analyses from the same time frame, more recent data might reflect different practice patterns than what we found in 2002-2007; however, there have been no major changes in surgical techniques since this time period, other than the recently developed curved stylet. Possibly future studies will demonstrate better

outcomes with this new modification. We also lacked information on fellowship training, which likely influenced outcomes.

Conclusion

Success of sacral neuromodulation, as defined by implantation of a permanent battery, was greater among women in the I3 dataset than in Medicare, though there was variation in outcomes by patient diagnosis. This suggests that technical factors, including the use of an operative (staged) testing approach, play a role in improving outcomes. Further research may better define the relationship between outcomes of sacral neuromodulation and specific etiology of voiding dysfunction.

References

1. Mirbagheri N, Sivakumaran Y, Nassar N, Gladman MA. Systematic review of the impact of sacral neuromodulation on clinical symptoms and gastrointestinal physiology. *ANZ J SURG.* Aug 5 2015.
2. Dougherty GJ, Dougherty ST, Kay RJ, Landsdorp P, Humphries RK. Identification and characterization of 114/A10, an antigen highly expressed on the surface of murine myeloid and erythroid progenitor cells and IL-3-dependent cell lines. *EXP HEMA TOL.* Sep 1989;17(8):877-882.
3. Cameron AP, Anger JT, Madison R, Saigal CS, Clemens JQ. National trends in the usage and success of sacral nerve test stimulation. *J UROLOGY.* Mar 2011;185(3):970-975.
4. Anger JT, Cameron AP, Madison R, Saigal C, Clemens JQ. Predictors of implantable pulse generator placement after sacral neuromodulation: who does better? *NEUROMODULATION.* Jun 2014;17(4):381-384; discussion 384.
5. Noblett K, Siegel S, Mangel J, et al. Results of a prospective, multicenter study evaluating quality of life, safety, and efficacy of sacral neuromodulation at twelve months in subjects with symptoms of overactive bladder. *NEUROUROL URODYNAM.* Dec 24 2014.
6. Amundsen CL RA, Jamison MG, Webster GD Sacral neuromodulation for intractable urge incontinence: are there factors associated with cure? . *UROLOGY.* 2005;66:746-750.
7. Leong RK, De Wachter SG, Nieman FH, de Bie RA, van Kerrebroeck PE. PNE versus 1st stage tined lead procedure: a direct comparison to select the most

sensitive test method to identify patients suitable for sacral neuromodulation therapy. *NEUROUROL URODYNAM.* Sep 2011;30(7):1249-1252.

8. Anger JT, Rodriguez LV, Wang Q, Pashos CL, Litwin MS. The role of provider volume on outcomes after sling surgery for stress urinary incontinence. *J UROLOGY.* Apr 2007;177(4):1457-1462; discussion 1462.

Success of Sacral neuromodulation in I3, 2002-2007											
	Number of perc test procedures	Total successful perc %	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 %
Provider:											
Urologist	197	23.4	53.8	13.2	9.7	0.611	572	57.3	38.1	<0.00	53.8
Gynecologist	31	22.6	48.4	19.4	9.7	1	149	46.3	49.7	01	47.1
Other	38	29.0	60.5	7.9	2.6		73	9.6	86.3		19.4
Total:	266	24.1	54.1	13.2	8.7		794	50.9	44.7		49.1
Provider:											
High Volume	242	26.0	50.4	14.0	9.5	0.001	652	60.4	34.4	<0.00	57.1
Low Volume	24	4.2	91.7	4.2	0.0	7	142	7.0	92.3	01	7.3
Total:	266	24.1	54.1	13.2	8.6		794	50.9	44.7		49.1

Table 1. Success of Sacral Neuromodulation by Provider Volume and Specialty

	Total successful percutaneous			Successful 2-staged (no perc)			Overall Success		
	Odds Ratio	95% CI		Odds Ratio	95% CI		Odds Ratio	95% CI	
High Surgeon volume (vs. low)	0.918	0.471	1.788	1.086	0.776	1.520	1.061	0.791	1.423
Urologist (vs. gynecologist)	0.882	0.449	1.731	2.790	1.981	3.929	2.311	1.713	3.117
White (vs. non-white) patient	0.647	0.355	1.180	1.073	0.793	1.453	1.159	0.891	1.508
Female (vs. male)	1.498	0.718	3.125	1.632	1.077	2.474	*1.986*	*1.404*	*2.808*
Age 55 or less (v >55) years	1.732	0.889	3.376	0.842	0.619	1.147	0.960	0.731	1.260
Diagnosis wet OAB (comparison group)	1.000			1.000			1.000		
Diagnosis NGB (vs. Wet OAB)	0.221	0.027	1.818	0.497	0.237	1.043	0.383	0.200	0.731
Diagnosis IC (vs. Wet OAB)	1.510	0.536	4.250	1.092	0.599	1.990	1.142	0.686	1.900
Diagnosis retention (vs. Wet OAB)	1.199	0.460	3.130	0.923	0.589	1.447	1.079	0.726	1.603
Diagnosis dry OAB (vs. Wet OAB)	2.159	1.029	4.532	1.010	0.716	1.425	1.027	0.759	1.389

Table 2. Multivariate Analysis of Outcomes based on Provider and Patient Variables

Success of Sacral neuromodulation in I3, 2002-2007											
	Number of perc test procedures	Total successful perc %	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 %
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Other	38	29.0	60.5	7.9	2.6		73	9.6	86.3		19.4
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Urologist (vs. gynecologist)	0.882	0.449	1.731		2.790	1.981	3.929		2.311	1.713	3.117
White (vs. non-white) patient	0.647	0.355	1.180		1.073	0.793	1.453		1.159	0.891	1.508
Female (vs. male)	1.498	0.718	3.125		1.632	1.077	2.474		1.986	1.404	2.808
Age 55 or less (v >55) years	1.732	0.889	3.376		0.842	0.619	1.147		0.960	0.731	1.260
Diagnosis wet OAB (comparison group)	1.000				1.000				1.000		
Diagnosis NGB (vs. Wet OAB)	0.221	0.027	1.818		0.497	0.237	1.043		0.383	0.200	0.731
Diagnosis IC (vs. Wet OAB)	1.510	0.536	4.250		1.092	0.599	1.990		1.142	0.686	1.900
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