

# Statewide Success of Staged Sacral Neuromodulation for the Treatment of Urinary Complaints in California (2005–2011)

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**Purpose:** Sacral neuromodulation (SNS) is approved by the Food and Drug Administration as a third-line treatment for refractory overactive bladder, idiopathic urinary retention, and fecal incontinence. Prior to implantation of an implantable pulse generator, all patients undergo a trial phase to ensure symptom improvement. The published success rates of progression from the test phase to permanent implant vary widely (range, 24% to >90%). We sought to characterize success rates using a statewide registry.

**Methods:** Using nonpublic data, we identified SNS procedures using the California Office of Statewide Planning and Development ambulatory surgery database from 2005 to 2011. A successful trial was defined as receiving a stage 2 generator implantation after trial lead placement. Multivariable logistic regression was performed to identify factors associated with staged success.

**Results:** During the study period, 1396 patients underwent a staged SNS procedure, with 962 (69%) subsequently undergoing generator placement. Successful trial rates were 72% for overactive bladder wet, 69% for urgency/frequency, 68% for interstitial cystitis, 67% for neurogenic bladder, and 57% for urinary retention. On multivariate logistic regression, only male sex (odds ratio, 0.51) and urinary retention [odds ratio, 0.54] were significantly associated with lower odds of success, whereas age, race/ethnicity, medical insurance, and placement at an academic or high-volume institution had no association.

**Conclusions:** The “real world” success rates for staged SNS implantation in California are less than those observed by some academic centers of excellence but better than previously reported for Medicare beneficiaries. Successful trial rates for interstitial cystitis and neurogenic voiding dysfunction are similar to refractory overactive bladder.

**Key Words:** California, epidemiology, lower urinary tract symptoms, overactive bladder, sacral neuromodulation, urinary retention

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Sacral neuromodulation (SNS) is approved by the Food and Drug Administration as a third-line treatment for refractory overactive bladder, idiopathic urinary retention, and fecal incontinence.<sup>1–3</sup> In addition to these indications, SNS has been used with moderate success for the treatment of interstitial cystitis/painful bladder syndrome, chronic pelvic pain, neurogenic detrusor overactivity, and nonobstructive urinary retention.<sup>4–11</sup> Prior to implantation of an implantable pulse generator (IPG), all

patients undergo a trial phase to ensure a minimum of 50% symptom improvement. This can be in the form of a definitive quadripolar tined lead (stage 1 SNS procedure) or a nonpermanent percutaneous nerve evaluation (PNE) wire. When successful, the ultimate outcome is the placement of a definitive tined lead and pulse generator.<sup>12</sup>

Following initial Food and Drug Administration approval of the Interstim (Medtronic, Inc, Minneapolis, Minn) SNS device in 1997, rates of successful trial (ie, the proportion of patients who receive stage 2 SNS generator implantation after a successful PNE or stage 1 SNS lead trial) have varied greatly in the reported literature.<sup>13</sup> Initial reports from the Sacral Nerve Stimulation Study Group found that approximately two thirds (63% [98/155 patients]) of patient were eligible for generator placement following PNE.<sup>14</sup> Following the introduction of the quadripolar tined lead in 2002, trial success rates and subsequent stage 2 generator placement have been reported to be greater than 90% in academic-affiliated centers of expertise.<sup>15–20</sup> However, SNS implantation rates are reported to be much lower using claims data in both commercially insured patients (24% PNE and 51% stage 1 SNS) and Medicare patients (35% PNE and 46% stage 1 SNS).<sup>21</sup>

Given this discrepancy in the reported literature, we chose to examine a contemporary statewide database of SNS procedures in an effort to further characterize “real-world” trial success rates of SNS for both on-label and off-label urinary complaints. As part of this analysis, we also sought to identify patient or hospital case volume characteristics that might affect trial success.

## PATIENTS AND METHODS

We reviewed a nonpublic ambulatory surgery database provided by the California Office of Statewide Health Planning and Development (OSHPD, Sacramento, Calif) for the time period January 1, 2005, to December 31, 2011. For each patient encounter, the ambulatory surgery database captures up to 20 procedure codes (*Current Procedural Terminology, fourth edition*) and 25 diagnostic codes (*International Classification of Diseases, Ninth Revision*). In addition, each unique patient has his/her own record linkage number that facilitates longitudinal analysis.

Our initial query included all adult men and women, 18 years or older, with eligible procedure codes related to SNS (PNE [64561], SNS stage 1 tined lead placement [64581], SNS stage 2 pulse generator placement [64590], remove/revise SNS lead [64585], or remove/revise SNS generator [64595]) with an associated urologic diagnosis. Patients with no record of a documented first stage (PNE or stage 1 tined lead placement) or subsequent generator placement (SNS stage 2, or simultaneous lead and IPG placement) were excluded. We also excluded patients with only 1 procedure code (battery change only, lead revision only, explant only). The code sequence for the primary and subsequent procedures was then used to identify patients who underwent a staged series of procedures. A staged procedure was any patient receiving a lead placement followed by either lead removal or generator placement. The subsequent placement of a pulse generator after lead implantation was defined as a successful trial. Following

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IPG placement, all included codes were evaluated for subsequent removal within the time period of 2005 to 2011.

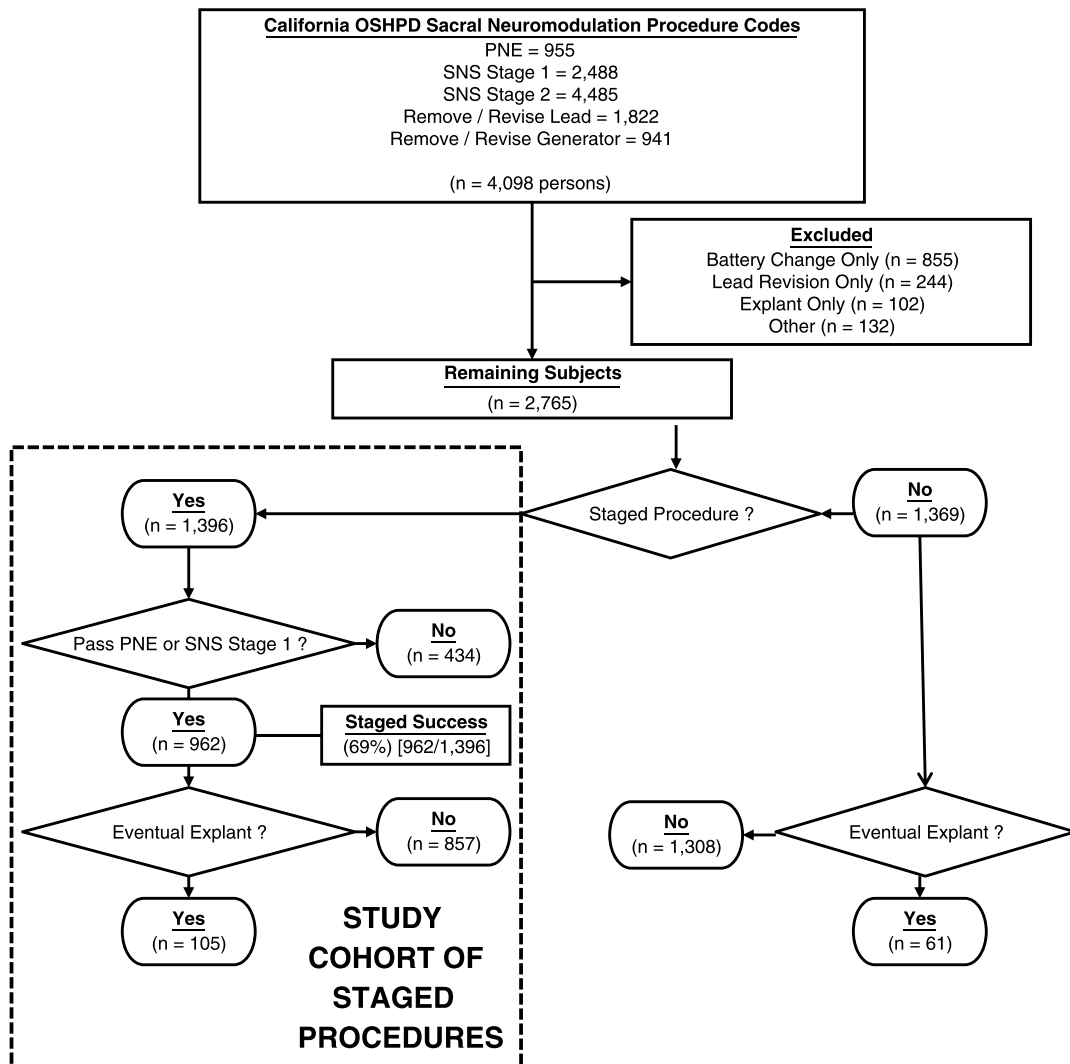
Our analysis of the OSHPD database included an assessment of sex, age, race/ethnicity, insurance status, diagnosis, academic affiliation of the placement institution, and placement facility SNS case volume. As performed by prior investigators,<sup>21</sup> we used known *International Classification of Diseases, Ninth Revision* diagnosis codes associated with SNS procedures to categorize each patient into 1 of 5 mutually exclusive diagnostic groups according to the following hierarchy: (1) neurogenic bladder, (2) interstitial cystitis, (3) urinary retention, (4) overactive bladder with urgency urinary incontinence (OAB-wet), and (5) urgency/frequency. Academic affiliation was defined as the presence of a urology or gynecology residency training program at the site where the procedure was performed. Facility volume was broken down into 4 mutually exclusive categories based on staged case volume over the entire study period (<10, 10–19, 20–39, and ≥40). Individual surgeon volume was unable to be assessed because of database limitations.

The sequence of procedure codes in our inclusion cohort was grouped into possible combinations by primary and subsequent procedures. The sequences were then individually reviewed by

each of the authors, and a group consensus was used to determine the classification of each sequence (staged vs unstaged, subsequent generator implant, and subsequent IPG explant). Office procedures are not captured by the OSHPD database, and therefore PNE procedures performed in the office were not available for analysis. No comparison was made between staged and unstaged groups given the absence of office PNE in our cohort and missing data in the unstaged classification. Data analysis was performed using STATA Statistical Software (Release 14; StataCorp LP, College Station, Tex). Logistic regression was performed using a univariate and multivariate approach to evaluate our primary outcome (successful staged trial) for each covariate strata.

**RESULTS**

During the 7-year time period studied, there were 4098 individuals identified with procedure codes related to SNS for urologic conditions. After excluding battery change, lead revision, and explant-only codes, 2765 patients remained (Fig. 1). From this group, we were able to classify 1396 patients by their staged sequence of SNS procedure codes. The remaining 1369 individuals did



**FIGURE 1.** CONSORT diagram for California OSHPD database of SNS procedure codes. Staged success is defined as the number of patients proceeding to SNS stage 2 after passing a PNE or SNS stage 1 trial.

not have a staged sequence of procedure codes and were classified as unstaged. In patients undergoing a staged trial, 962 (69%) proceeded to pulse generator implantation. In staged individuals, 105 (10.9%) eventually underwent generator explant. Our SNS cohort was made up primarily of females (77%), with the majority (67.5%) 60 years or older. The cohort was predominantly white (74%), with Medicare insurance (60%), and carried a diagnosis of OAB-wet (54%) (Table 1). Sacral neuromodulation devices were placed at 116 distinct locations with approximately half of the staged trials done at 8 institutions (7 with academic affiliations) with the highest case volume ( $\geq 40$  cases over the study period). Approximately two thirds (63.8%) of our cohort underwent procedures at non-academic-affiliated institutions. When performed at a nonacademic institution, only 37% of SNS procedures were done in a staged fashion compared with 74% of those placed at academic institutions.

The crude rates of staged trial success were similar across most covariate strata, with the exception of sex and urologic diagnosis. Male patients were noted to have less success than their

**TABLE 1.** SNS Population Demographics (n = 2765)

	Overall		Staged		Unstaged	
	n	(%)	n	(%)	n	(%)
<b>Sex</b>						
Female	2135	(77.2)	1092	(78.2)	1043	(76.2)
Male	630	(22.8)	304	(21.8)	326	(23.8)
<b>Age, y</b>						
<40	205	(7.4)	126	(9.0)	79	(5.8)
40–49	279	(10.1)	163	(11.7)	116	(8.5)
50–59	415	(15.0)	216	(15.5)	199	(14.5)
60–69	585	(21.2)	286	(20.5)	299	(21.8)
70–79	759	(27.5)	369	(26.4)	390	(28.5)
80–89	479	(17.3)	224	(16.0)	255	(18.6)
$\geq 90$	43	(1.6)	12	(0.9)	31	(2.3)
<b>Ethnicity</b>						
White	2039	(73.7)	971	(69.6)	1068	(78.0)
Hispanic	324	(11.7)	173	(12.4)	151	(11.0)
African American	124	(4.5)	68	(4.9)	56	(4.1)
Asian	72	(2.6)	48	(3.3)	24	(1.8)
Other	206	(7.4)	136	(9.7)	70	(5.1)
<b>Insurance</b>						
Medicare	1663	(60.1)	815	(58.4)	848	(61.9)
Health maintenance organization	702	(25.4)	377	(27.0)	325	(23.7)
Private	321	(11.6)	161	(11.5)	160	(11.7)
Self-pay	33	(1.2)	15	(1.1)	18	(1.3)
Medi-Cal	29	(1.0)	18	(1.3)	11	(0.8)
Other	17	(0.6)	10	(0.7)	7	(0.5)
<b>Diagnosis</b>						
OAB-wet	1488	(53.8)	739	(52.9)	749	(54.7)
Neurogenic bladder	267	(9.7)	121	(8.7)	146	(10.7)
Interstitial cystitis	177	(6.4)	119	(8.5)	58	(4.2)
Urinary retention	249	(9.0)	155	(11.1)	94	(6.9)
Urgency/frequency	552	(20.0)	244	(17.5)	308	(22.5)
Other	32	(1.2)	18	(1.3)	14	(1.0)
<b>Academic affiliation</b>						
Nonacademic	1765	(63.8)	653	(46.8)	1112	(81.2)
Academic	1000	(36.2)	743	(53.2)	257	(18.8)

**TABLE 2.** Staged Success Rate (n = 1396)

	Success		
	n	(%)	n/N
<b>Sex</b>			
Female	790	(72.3)	790/1092
Male	172	(56.6)	172/304
<b>Age, y</b>			
<40	85	(67.5)	85/126
40–49	105	(64.4)	105/163
50–59	148	(68.5)	148/216
60–69	200	(69.9)	200/286
70–79	260	(70.5)	260/369
80–89	156	(69.6)	156/224
$\geq 90$	8	(66.7)	8/12
<b>Ethnicity</b>			
White	678	(69.8)	678/971
Hispanic	114	(65.9)	114/173
African American	46	(67.6)	46/68
Asian	28	(58.3)	28/48
Other	96	(70.6)	96/136
<b>Insurance</b>			
Medicare	567	(69.6)	567/815
Health maintenance organization	255	(67.6)	255/377
Private	111	(68.9)	111/161
Self-pay	11	(73.3)	11/15
Medi-Cal	18	(64.3)	18/28
<b>Diagnosis</b>			
OAB-wet	532	(72.0)	532/739
Neurogenic bladder	81	(66.9)	81/121
Interstitial cystitis	81	(68.1)	81/119
Urinary retention	89	(57.4)	89/155
Urgency/frequency	168	(68.9)	168/244
Other genitourinary	11	(61.1)	11/18
<b>Academic affiliation</b>			
Nonacademic	453	(69.4)	453/653
Academic	509	(68.5)	509/743
<b>Facility volume over study period</b>			
<10 cases (79 facilities)	150	(67.3)	150/223
10–19 cases (20 facilities)	184	(67.9)	184/271
20–39 cases (9 facilities)	162	(74.6)	162/217
$\geq 40$ cases (8 facilities)	466	(68.0)	466/685

female counterparts (56.6% vs 72.3% respectively,  $P < 0.001$ ). The diagnosis of OAB-wet had the highest staged trial success rate (72%), whereas urinary retention had the lowest staged trial success rate (57%) ( $P < 0.001$ ) (Table 2). These differences remained significant during multivariable logistic regression modeling, with both male sex and a diagnosis of urinary retention being associated with a similar ~50% decrease in odds of success (odds ratios [ORs], 0.51; 95% confidence interval [CI], 0.38–0.67; and 0.54; 95% CI, 0.37–0.79, respectively). Age, race/ethnicity, insurance status, institutional academic affiliation, and institutional case volume were not associated with increased odds of staged trial success rate (Table 3).

**DISCUSSION**

Our analysis of a large cohort undergoing SNS testing in California from 2005 to 2011 finds that approximately 70%

**TABLE 3.** Logistic Regression Analysis for the Outcome Staged Success (n = 1396)

	Univariate Model			Multivariate Model		
	OR	95% CI	P	OR	95% CI	P
<b>Sex</b>						
Female	Ref	—	—	Ref	—	—
Male	0.50	0.38–0.65	<0.001	0.51	0.38–0.67	<0.001
<b>Age, y</b>						
<40	Ref	—	—	Ref	—	—
40–49	0.87	0.53–1.43	0.59	0.89	0.52–1.52	0.67
50–59	1.05	0.66–1.68	0.84	1.03	0.62–1.73	0.90
60–69	1.12	0.72–1.76	0.62	1.19	0.70–2.03	0.52
70–79	1.15	0.75–1.78	0.53	1.16	0.66–2.04	0.61
80–89	1.11	0.69–1.77	0.67	1.15	0.63–2.08	0.65
≥90	0.97	0.28–3.39	0.96	0.95	0.25–3.60	0.93
<b>Ethnicity</b>						
White	Ref	—	—	Ref	—	—
Hispanic	0.84	0.59–1.18	0.30	0.87	0.61–1.23	0.42
African American	0.90	0.53–1.53	0.71	0.92	0.54–1.58	0.76
Asian	0.61	0.34–1.09	0.10	0.75	0.40–1.38	0.35
Other	1.16	0.61–2.23	0.65	1.16	0.59–2.27	0.67
<b>Insurance</b>						
Medicare	Ref	—	—	Ref	—	—
Health maintenance organization	0.91	0.70–1.19	0.50	1.05	0.72–1.52	0.82
Private	0.97	0.67–1.40	0.88	1.11	0.70–1.79	0.66
Self-pay	1.20	0.38–3.81	0.75	2.13	0.44–10.19	0.35
Medi-Cal	1.53	0.50–4.70	0.46	2.02	0.54–7.51	0.29
<b>Diagnosis</b>						
OAB-wet	Ref	—	—	Ref	—	—
Neurogenic bladder	0.79	0.52–1.19	0.26	0.91	0.59–1.41	0.67
Interstitial cystitis	0.83	0.55–1.26	0.38	0.70	0.44–1.11	0.13
Urinary retention	0.53	0.37–0.75	<0.001	0.54	0.37–0.79	<0.01
Urgency/frequency	0.86	0.63–1.18	0.35	0.90	0.64–1.26	0.53
Other genitourinary	0.61	0.16–2.39	0.48	0.46	0.11–1.95	0.29
<b>Academic affiliation</b>						
Nonacademic	Ref	—	—	Ref	—	—
Academic	0.96	0.77–1.21	0.73	0.91	0.63–1.30	0.59
<b>Facility volume over study period</b>						
<10 cases	Ref	—	—	Ref	—	—
10–19 cases	1.03	0.70–1.50	0.88	1.00	0.67–1.40	0.98
20–39 cases	1.43	0.94–2.17	0.09	1.39	0.88–2.21	0.16
≥40 cases	1.04	0.75–1.43	0.83	1.16	0.74–1.84	0.51

achieve staged trial success and proceed to pulse generator implantation. Sacral neuromodulation patients are predominantly female (77%), older than 60 years (67.5%), and undergoing treatment at a nonacademic medical center (64%).

When stratified by diagnosis, OAB-wet, urgency frequency, interstitial cystitis, and neurogenic bladder all achieve similar trial success rates (67%–72%), whereas patients with urinary retention are less likely to proceed to a generator implant (57%). Sex also served as a predictor of successful trial, with men having significantly lower odds of success (OR, 0.51) compared with women. Insurance class, patient age, and race/ethnicity were not associated with differing staged success rates. Similarly, staged success was not different among procedures performed with academic affiliations or at higher-volume centers.

Our findings are similar to other reports where success rates in females have been noted to be higher than in males.<sup>21,22</sup> The overall staged trial success rate in our study is higher than success rates reported by others evaluating Medicare-based and commercial insurance-based cohorts. Cameron et al<sup>21</sup> noted staged trial success rates of 35% in a Medicare cohort spanning 1997 to 2007, whereas Suskind et al<sup>3</sup> noted a 55% success rate in a Medicare cohort spanning 2005–2010. Commercially insured patients did not fare much better, with a reported staged trial success rate of 51% for the years 2002–2007.<sup>21</sup> The discrepancy in staged success rates (35%–70%) among the various cohorts is surprising, especially because insurance status did not appreciably affect staged trial success in our cohort, and a large proportion of our cohort was indeed Medicare based (60%). It is possible that the differences in study periods may contribute to the differences in staged

trial success rates in the Medicare cohorts, as our more contemporary cohort included mostly timed lead stage 1 trials throughout the study period (timed leads were introduced in 2002) and generally have a higher success rates than monopolar PNE trials.<sup>15,21,23</sup> However, this does not explain the differences in the privately insured population examined by Cameron et al,<sup>21</sup> which spanned an analysis time of 2002–2007, or the cohort of Suskind et al<sup>3</sup> spanning 2005–2010. As both our analysis and theirs used a claims-based methodology, the reasons for any appreciable differences are unclear. We find it reassuring that our results are similar to the original 63% staged success rate reported by Schmidt et al<sup>14</sup> in one of the original publications on SNS.

It is notable that the OSHPD data show that staged procedures are performed more often in academic institutions compared with nonacademic institutions (74% vs 37%, respectively). This large difference in technique could be attributable to reimbursement advantages, patient preference favoring an office-based procedure, or something else altogether. Unfortunately, our study design makes it impossible for us to investigate this further. Given that more SNS procedures are being done by nonacademic centers than academic centers, and given that studies on PNE success vary considerably in the literature, we feel that this area likely deserves future evaluation.

Our study is limited to the time period that the data set encompasses. As our analysis goes up only to the year 2012, we cannot evaluate the OSHPD “real-world” efficacy of SNS for fecal incontinence, for which SNS was approved in 2012. In addition, because of the nature of the OSHPD data set, we are unable to track office-based PNE placements, which contribute to the large number of implants classified as “unstaged” (which comprise at least 50% of the procedures done within the study period). As a result, we cannot assess the overall success rate of PNE trials, the number of patients who fail a PNE trial who ultimately cross over to have a timed lead stage 1 SNS trial, or the prognostic implications of a failed PNE with respect to success for a timed lead stage 1 SNS trial. Finally, our analysis does not address the potential effect of individual physician experience on SNS trial success as the database lacks provider-level data. As certain high-volume centers have reported success rates approaching 90%, physician experience may affect SNS success rates (although our proxy measure of facility case volume showed no differences in rates of “success”).<sup>15–20</sup> Other potential variables that might affect outcome of stage 1 trial such as patient selection, surgical technique, and nerve activation thresholds may be important, but cannot be assessed from a large administrative data set. It should also be noted that our definition of success only encompasses the placement of a generator after lead implantation, not long-term clinical success (although implantation should be done only in those with >50% symptom improvement during the testing phase).

Despite these limitations, our study has important strengths. As California is home to 15% of the American population, the OSHPD data set captures a very large number of patients, regardless of insurance status or age. The OSHPD data set has the added benefit of unique patient record linkage numbers that allow follow-up even with a change in hospitals as long as the patients seek care within California. Such cross-institution follow-up (specifically for revision procedures) is not available in single-center studies. In addition, given that the testing phase of an SNS device is generally 1 to 3 weeks, the chance of loss to follow-up (ie, the patient moves to a new state) is low. The OSHPD data set, which identifies the location of service, permits comparison of success rates of academic versus nonacademic institutions, something that has not been previously reported. Finally, we used the same hierarchical diagnosis scheme used by prior study authors in an attempt to create consistency with prior published works.

## CONCLUSIONS

Although not as successful as some single-institution series of SNS success rates, the 70% staged success rates for SNS in the state of California are higher than previously reported in other administrative data sets. A broader understanding of timed lead staging success can help guide patients in neuromodulation decision making based on patient sex and diagnosis-related SNS indications.

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