128

Cameron A P[1], Anger J T[2], Madison R[3], Saigal C S[2], Clemens J Q[1], Urologic Diseases in America Project U D A[3]
1. *University of Michigan,* ***2.*** *University of California, Los Angeles,* ***3.*** *RAND corporation*

NATIONAL TRENDS IN THE USAGE AND SUCCESS OF SACRAL NEUROMODULATION

Hypothesis / aims of study:
There have been over 25,000 sacral neuromodulation (SNM) systems implanted worldwide, however little is known about patterns of use and outcomes of SNM in the general community. The indications for SNM are not absolute, and therefore the rate at which it 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. SNM is performed in two stages. Stage I is a test phase in which a lead is implanted in the third sacral foramen (S3). This is followed by a brief period of stimulation during which the patient rates the effectiveness of therapy with a voiding diary. Typically, if patients have 50% or greater improvement in symptoms, they are offered the battery stimulator implant (stage II). Success in the literature is often reported as the percentage of individuals progressing from stage I to stage II. SNM trials have yielded success rates of 63% [1] for urgency incontinence and "urgency-frequency syndrome", 38% for non-obstructive urinary retention [2], and 52% for interstitial cystitis (IC) [3]. Two techniques exist to perform the test phase I: the percutaneous technique and the 2-stage surgical technique. In the percutaneous technique, a small percutaneous lead is placed using local anaesthetic 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 weeks. A second surgery is then performed in which the lead is either removed, or it is connected to a permanent subcutaneous battery. Our goals in this analysis were to identify the true rate of success of the SNM test phase with the percutaneous technique and the 2-stage technique in the Medicare population.

Study design, materials and methods:
A 5% random sample of Medicare beneficiaries from 1997 to 2007 was used as the data source with each patient 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 in question were used to identify the indication. Fortunately each of the procedures associated with SNM has a unique CPT code (test stimulation- percutaneous 64561 or incision/permanent 64581, battery placement 64590, lead or battery removal 64585/64595). All patients in the dataset with a CPT code for a test stimulation in the sacral foramen (percutaneous 64561 or using an incision 64581) were included. ICD-9 diagnosis codes were used to categorize patients into one of five groups. Any patient with a neurogenic bladder diagnosis (NGB) was placed in the neurogenic category; those with 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 remaining persons with urgency, frequency, and nocturia were placed in the "dry" OAB group since they did not have a diagnosis of incontinence. Successful percutaneous test stimulation was defined as a percutaneous test followed by a simultaneous permanent lead and battery implant. A failed percutaneous test 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 percutaneous test 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.

Results:
In total there were366 patients who received percutaneous test stimulation and 1142 a 2-stage (permanent) lead placement from 1997 to 2007 in this 5% sample. 90.6% of patients were white and 73.6% were female. 45.6% of all percutaneous tests were considered to be successful, 3.0% failed both the percutaneous and 2 stage surgical techniques, and 5.7% of all the percutaneous tests were salvaged with a 2-stage surgical technique. Of those with a 2-stage (permanent) test lead 62.7% failed and were not implanted with a battery. The majority of SNM procedures were performed for "wet" or "dry" OAB. The percutaneous procedure was much more successful in females and when performed by a gynaecologist. The 2-stage procedure also achieved more success in females, when performed by a urologist, on those under the age of 79 and for NGB diagnosis, while the poorest success was seen in patients diagnosed with IC.

Table 1: Success of Sacral neuromodulation in a 5% sample of Medicare 1997-2007

	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 %
Diagnosis											
NGB	16	50.0	37.5	0	12.5	0.066	32	56.3	43.7	**<0.0001**	54.2
IC	9	66.7	22.2	11.1	0		33	33.3	63.6		43.9
Retention	50	44.0	42.0	8.0	6.0		92	46.7	48.9		50.0
"wet" OAB	164	51.2	39.6	6.1	3.0		440	46.6	51.1		50.3
"dry" OAB	114	38.5	55.2	5.3	0.9		234	41.0	56.4		42.6
other	13	23.1	76.9	0	0		311	10.3	89.7		10.8
Age:											
<65	65	52.3	52.3	40.0	0	0.64	277	40.1	58.1	**0.037**	44.5
65-69	78	35.9	35.9	52.6	5.1		199	31.1	66.3		34.9
70-74	71	43.7	43.7	52.1	0		202	44.6	54.0		45.9
75-79	70	54.3	54.3	38.7	4.3		210	37.6	61.4		42.8
80-84	57	43.9	43.9	43.9	5.2		162	26.0	71.6		33.0
85-89	19	47.4	47.4	36.8	5.2		71	24.0	73.2		31.8
90-94	5	40.0	0	60.0	0		19	21.2	78.9		25.0

95+	1	0	0	100	0		2	0	100		-
Race:											
Unknown	3	66.7	33.3	0	0	0.13	4	25.0	75	0.67	42.9
White	335	46.9	44.2	6.0	3.0		1031	35.2	62.9		40.1
AA	12	25.0	75.0	0	0		57	40.4	59.6		37.7
Other	7	14.3	85.7	0	0		22	45.5	54.5		37.9
Asian	3	33.3	33.3	0	33.3		4	50.0	50.0		42.9
Hispanic	6	50.0	33.3	16.7	0		17	35.3	58.8		45.5
NA Native	0	-	-	-	-		7	0	100		-
Sex:											
Male	99	29.3	60.0	5.1	6.1	**0.0004**	299	27.1	71.2	**0.0017**	29.3
Female	267	51.7	40.4	6.0	1.9		843	38.4	59.7		43.7
Provider:											
Urologist	305	44.3	45.6	6.9	3.3	**0.0046**	670	46.2	50.6	**<0.0001**	48.8
Gynaecologist	49	63.2	34.7	0	2.0		161	37.3	62.7		43.3
Other	12	8.3	91.7	0	0		311	11.3	88.7		11.1
Total:	366	45.6	45.6	5.7	3.0		1142	35.5	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 all analysis with Chi square

Interpretation of results:

The overall success rate of SNM of 39.9% is inferior to published results. Outcomes among adults age 80 and over were worse than in younger patients (33% or less). 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.

Concluding message:

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 sacral nerve stimulation test phase in the Medicare population is inferior to that published elsewhere in the literature. Although the Medicare population may represent an older and more disabled population of patients receiving SNM, these findings suggest the need to counsel patients realistically about their chances of success with such a procedure.

References

1. 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. J Urol 1999; 162: 352
2. Jonas U, Fowler CJ, Chancellor MB, Elhilali MM, Fall M, Gajewski JB et al: Efficacy of sacral nerve stimulation for urinary retention: results 18 months after implantation. J Urol 2001; 165: 15
3. Whitmore KE, Payne CK, Diokno AC and Lukban JC: Sacral neuromodulation in patients with interstitial cystitis: a multicenter clinical trial. Int Urogynecol J Pelvic Floor Dysfunct 2003; 14: 305

Specify source of funding or grant	**NIDDK as part of the Urologic Diseases in America Project**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Exemption**
Was the Declaration of Helsinki followed?	**Yes**
This study did not follow the Declaration of Helsinki in the sense that	**It did**
Was informed consent obtained from the patients?	**No**