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

Submitted for publication July 8, 2010.

Supplementary material for this article can be obtained at http://www.med.umich.edu/urology/research/ManuscriptAppendices/Pelletier%20Cameron/Table%201%20UDA%20version%202.pdf.

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† Financial interest and/or other relationship with American Medical Systems.

‡ Financial interest and/or other relationship with Merck, Pfizer, Lilly, Medtronic and Afferent.

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 therapies 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

0022-5347/11/1853-0970/0
THE JOURNAL OF UROLOGY®

Vol. 185, 970-975, March 2011
Printed in U.S.A.
DOI:10.1016/j.juro.2010.10.060

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 nonobstructive 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.