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## Physician use of sacral neuromodulation among Medicare beneficiaries with overactive bladder and urinary retention

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### Abstract

**Objective**—To identify physician-level factors associated with high rates of SNM testing.

**Materials and Methods**—We performed a retrospective cohort study using a 20% sample of national Medicare claims to identify physicians who performed SNM procedures between 2005 and 2010. Physician-level rates of device testing were determined based on the number of patients seen for overactive bladder and urinary retention diagnoses in the office in each calendar year. These rates were then used to fit a Poisson model to examine factors associated with high rates of device testing.

**Results**—The number of physicians performing test procedures increased 4-fold from 2005-2010. Average rates of test procedures increased from 4.0 to 6.4 procedures per physician per year ( $p < 0.001$ ), while rates of device implantation remained stable ( $p = 0.23$ ). Physicians who had higher rates of device testing were associated with lower rates of device implantation (Estimate  $-1.76$ ,  $p < 0.01$ ). Other predictors of physicians with higher test rates included more recent calendar year, testing done in any setting other than an ambulatory surgery center, gynecology subspecialty, and geographic location in the South and West (all  $p$  values  $< 0.01$ ).

**Conclusions**—Over time, physicians are testing more patients but are not implanting more devices. Additionally, there is an inverse relationship between rates of device testing and implantation, suggesting opportunities to improve efficiency and resource utilization.

### Keywords

urology; practice patterns; InterStim; population

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## Introduction

Overactive bladder accounts for over \$65 billion in annual expenditures,<sup>1</sup> affecting up to 43% of men and women<sup>2</sup> with symptoms of urinary urgency, frequency, and incontinence.<sup>3</sup> Unfortunately, many patients are refractory to first and second-line therapies such as behavioral modifications and medications, leading them to seek additional treatments. In 1997 the Food and Drug Administration (FDA) approved the use of sacral neuromodulation for the treatment of refractory overactive bladder and expanded its indications for treatment of non-obstructive urinary retention in 1999.<sup>4</sup> Since that time, over 125,000 devices have been implanted worldwide<sup>5</sup> at a cost of over \$2 billion.<sup>6</sup> While this treatment is effective in some, it is difficult to predict which patients will benefit. For this reason, the procedure is performed in two stages. The first stage, or “test” procedure, determines effectiveness of neuromodulation with implantation of a temporary device. For responders, a second stage procedure is performed wherein the permanent device is implanted.

Because of the uncertainty surrounding who will and will not benefit from neuromodulation therapy, decisions to perform the test procedure are left to clinical judgment, which can be influenced by a variety of clinical and non-clinical factors given the limited evidence base. First and foremost, physicians may be motivated to help their patients who have failed to respond to other treatments. This impetus could prompt physicians to perform the test procedure in a marginal population, or among those patients less likely to respond to neuromodulation given the clinical context. This altruistic motivation, coupled with the low morbidity profile associated with the test procedure, has the potential to encourage high rates of testing. Second, financial incentives inherent in the fee-for-service system could potentially motivate physicians to perform higher rates of sacral neuromodulation test procedures, which are reimbursed 4 to 5 times more than the implant procedure.<sup>7</sup> Further, additional incentives may be garnered through physician ownership of facilities where these procedures can be performed, such as ambulatory surgery centers (ASCs).

To better understand the use of sacral neuromodulation, we performed a retrospective cohort study using a 20% sample of national Medicare claims. Findings from this study will provide important information regarding provider-level utilization of this common and expensive procedure.

## Materials and Methods

We performed a retrospective cohort study of fee-for-service Medicare beneficiaries undergoing sacral neuromodulation test (Stage I) procedures from 2005 to 2010 using a 20% random sample of national Medicare claims. We identified patients ages 66 to 99 in the Carrier file who underwent sacral neuromodulation test procedures by urologists and gynecologists using Healthcare Common Procedure Coding Systems (HCPCS) codes 64561 [percutaneous implantation of neurostimulator electrode array (transforaminal placement)] and 64581 in isolation [incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)]. If a patient had more than one test procedure, we chose the first one to represent the index test procedure. We limited our study to patients eligible for Medicare parts A and B both 1 year before and 1 year after the date of the index test

procedure. We chose to follow patients 1 year prior to the procedure in order to measure comorbidity using established methods.<sup>8</sup> We followed patients 1 year after the index test procedure to allow ample time for assessment of permanent implantation and possible device explant procedures.

We used the physician-year level as the unit of analysis because it allowed us to adjust for the baseline time trend of the test rate. Using physician identification numbers associated with these claims, we generated physician-year level measurements for the number of test procedures by HCPCS codes 64561 and 64581 in isolation (discussed above), the number of device implant procedures (HCPCS code 64590) and the number of device explant procedures (HCPCS code 64595).

Next, we identified International Classification of Diseases, Ninth Edition (ICD-9) codes from the evaluation and management (E&M) visits associated with the test procedure. The following codes accounted for over 90% of the codes associated with these visits: overactive bladder (78831 urge incontinence, 78841 urinary frequency, 78863 urgency of urination, 59651 hypertonicity of bladder, 78833 mixed incontinence, and 78830 urinary incontinence, unspecified) and urinary retention (78820 retention of urine, unspecified, 78821 incomplete bladder emptying, 78829 other specified retention of urine).

We then measured physician-year level rates of test, implant, and explant procedures. The test rate was determined by the number of test procedures divided by the number of patients seen for overactive bladder and urinary retention diagnoses in the office per physician in each calendar year. The implant rate was ascertained by the number of implant procedures divided by the number of test procedures per physician in a calendar year. Finally, the explant rate was determined by the number of explant procedures divided by the number of implantation procedures per physician in a calendar year.

Additional measures were obtained at the physician-year level to enable us to better characterize the physicians in our cohort and their patient mixes. Because the Centers for Medicare and Medicaid Services (CMS) reimburses physicians differently based on the location of the procedure and since physicians can collect additional facility charges if they have ownership in ambulatory surgery centers, we wanted to investigate whether these potential financial incentives affected rates of physician testing. For this reason, we included the primary place of service for the testing procedure, defined as the place (i.e., freestanding ASC, inpatient hospital departments, office, outpatient hospital department) where the plurality of a physician's test procedures were performed. Additional physician-level factors included physician specialty (urology or gynecology) and region (Midwest, Northeast, South, West). Each physician's average patient mix was characterized by age, race, and comorbidity, and aggregated at the physician-year level. Comorbidity was estimated using established methods based on data from the Carrier, Outpatient and Inpatient files in the year preceding the index test procedure.<sup>8</sup>

In order to determine factors that affect physician use of device testing, we constructed a Poisson regression model with the test rate as our dependent variable and the covariates described above as independent variables. We included treatment year as a fixed effect to

adjust for baseline time trends in the test procedure. To look more specifically at the relationship between implant rate and use of freestanding ASCs as the primary place of service, we contrasted rates of implantation between these facilities and others using Wilcoxon rank sum tests. Analyses were performed with SAS version 9.3 (SAS Institute, Cary, NC) and R version 2.11. The institutional review board at the University of Michigan exempted this study from review.

## Results

Characteristics describing the physicians performing sacral neuromodulation test procedures and their average patient populations are shown in Table 1. These results represent a total of 2,081 physician-years of data. The majority of physicians (53.7%) performed the plurality of their test procedures in an outpatient hospital department while 35.2%, 9.0% and 2.1% performed the plurality of their test procedures in the office, freestanding ASC, and inpatient settings, respectively. Most physicians performing test procedures were urologists (79.7%), as opposed to gynecologists, and 43.7% of all test procedures performed in the United States were located in the South. The average patient mix per physician year of data included a mean patient age of 74.6 years (standard deviation 2.9), a mean of 4.6 comorbidities per patient (standard deviation 6.0), and an overwhelming majority were of white race (93.7% of patients). On average, physicians tested 26% of their patients seen with diagnoses of overactive bladder and urinary retention, implanted 55% of the patients whom they tested, and explanted 9% of these devices.

In 2005, there were 144 physicians performing sacral neuromodulation test procedures. This number grew to 593 in 2010, representing a four-fold increase in the number of physicians performing this procedure over a span of 6 years. During the same time period, the average annual rate of test procedures performed by physicians increased from 4.0 to 6.4 procedures per physician per year ( $p < 0.001$  test for trend). However, as shown in Figure 1, the average rate of implant procedures remained stable (2.1 procedures in 2005 and 2.2 procedures in 2010,  $p = 0.23$  test for trend). Since our data represent a 20% sample of Medicare claims, it can be extrapolated that these numbers are representative of 5 times their actual value, meaning that physician rates of testing increased from 20 to 32 procedures during this time period, representing a net increase of 12 test procedures. Likewise, the average rate of implant procedures remained stable from 10.5 to 11 from 2005 to 2010.

Results of the Poisson regression model predicting physician test rates are demonstrated in Table 2. The model demonstrates an inverse relationship between device testing and implantation, where physicians with lower rates of device implantation are associated with higher rates of devices testing (estimate  $-1.76$ ,  $p < 0.01$ ) (Figure 2). In other words, on average, if a physician's implant rate decreases from 90% to 10%, the physician's test rate increases from 6% to 26%. Other predictors of physicians with high test rates include low explant rates (estimate  $-0.14$ ,  $p < 0.01$ ), younger patient age (estimate  $-0.04$ ,  $p < 0.01$ ), gynecology subspecialty compared to urology subspecialty (estimate  $-0.63$ ,  $p < 0.01$ ), testing being done in any setting other than a freestanding ASC (all  $p$ 's  $< 0.01$ ), and more recent calendar year (2010 compared to 2005, estimate 0.22;  $p < 0.01$ ).

Implant rates for sacral neuromodulation devices were lower among physicians who performed the plurality of their test procedures in a freestanding ASC compared to any other location at 42% compared to 56%, respectively ( $p < 0.001$ ). These findings indicate that physicians operating in freestanding ASCs tend to either perform more test procedures, perform fewer implant procedures, or a combination of the two, compared to physicians who primarily operate in other surgical settings.

## Discussion

Over time, more physicians are performing a greater number sacral neuromodulation test procedures, but on average, they are not implanting more devices. In fact, physicians who test a higher percentage of patients with diagnoses of overactive bladder and urinary retention are less likely to implant devices, demonstrating an inverse relationship between device testing and implanting. Additionally, physicians who operate in freestanding ambulatory surgery centers have lower implant rates compared to physicians operating in other settings.

Our previous work found a significant 9-fold increase in rates of sacral neuromodulation implant procedures among men and women of all ages in the state of Florida from 2002 to 2009.<sup>9</sup> This trend is consistent with our current finding in Medicare data that more physicians are performing these procedures over time. Since sacral neuromodulation was first FDA approved in 1997,<sup>10</sup> it appears that an increasing number of physicians are learning how to perform these procedures and, consequently, more procedures are being done.

As physicians are gaining experience with sacral neuromodulation, they may also become better at patient selection. If this were the case, one would expect to see a narrowing in the gap between the number of test and implant procedures over time. However, our results show the opposite effect. While rates of test procedures are growing significantly over time, rates of implant procedures remain flat resulting in a widening in the gap in rates of these two procedures. This suggests that as physicians become more familiar with the sacral neuromodulation techniques, they may be expanding the indications for sacral neuromodulation testing to patients who may be less optimal candidates.

Our finding that rates of sacral neuromodulation testing are higher among gynecologists compared to urologists is interesting and warrants future investigation. Some hypotheses as to why this may be the case include differences in training, referral patterns, and provider experience. There is also evidence to suggest that urologists tend to be early adopters of new surgical technologies,<sup>11</sup> suggesting that they may as a whole be farther along in their learning curve than their gynecology counterparts.

As previously mentioned, clinical factors exist that may motivate physicians to perform more test procedures. Patients with treatment refractory overactive bladder and non-obstructive urinary retention can be difficult to help and sacral neuromodulation may provide the best, and sometimes only, treatment option that remains. Because the procedure

is minimally invasive and carries relatively low morbidity, there is often minimal risk associated with performing the test procedure.

There are also financial incentives that may influence physician decision-making. The Center for Medicare and Medicaid Services reimburses 4 to 5 times as much for a test procedure compared to an implant procedure,<sup>7</sup> potentially incentivizing increased rates of sacral neuromodulation testing. Additionally, performing the test procedure in an ASC, of which over 90% are at least in part physician-owned,<sup>12</sup> may further incentivize physicians to increase their surgical volume at these centers where they can collect both physician and facility payments. However, findings from this study do not necessarily support this hypothesis, as ASC location of service is not predictive of high rates of physician testing based on our Poisson model.

The setting of sacral neuromodulation testing is also likely influenced by several non-clinical factors. One such factor may be the availability of resources, such as fluoroscopy. Many office locations are not equipped with fluoroscopy, driving procedures into the operating room, either in a hospital or non-hospital based setting. Additionally, differentials in payment schedules between different settings, i.e. higher physician reimbursement in the office setting compared to in a facility, may further influence choice of location where these procedures are performed. This increase in payment may incentivize physicians to perform more test procedures in the office, or it may serve only to offset additional costs including staff, supplies, and equipment, that are required in the office setting.

Interestingly, patient characteristics did not seem to influence whether or not a physician was associated with a high rate of testing procedures. Patient race and comorbidity also were not significant predictors of high volume testers. While younger patient age was associated with a higher rate of testing, the magnitude of effect was small and unlikely clinically meaningful. These findings suggest non-clinical factors (specialty, region, place of service) play a larger role in test rates than do patient characteristics. Alternatively, clinical factors that are not accounted for in administrative data may also impact testing rates.

This study should be interpreted with certain limitations in mind. First, Medicare data lack clinical information on specific patient and physician level factors that may be of great importance to our study question. Having more information in these areas would certainly further our understanding of why physicians are testing more patients but not implanting more devices. However, the fact that implant rates have remained stable suggests that improved patient selection, guided by growing experience using these unmeasured clinical details, has not occurred. This is perhaps not very surprising, as no data currently exists which can accurately predict success or failure from sacral neuromodulation testing. Second, we do not report test procedures as either percutaneous or staged procedures, but rather report all test procedures as one group. Stratification of results by test type is beyond the scope of this project, but would be interesting to look into in the future. Third, by studying Medicare beneficiaries, our population is inherently limited to older patients, who have been shown to have lower rates of progression from test to implant procedures than their younger counterparts in several studies.<sup>13,14</sup> Nonetheless, the Medicare population represents a large and growing group of patients in which these diagnoses are particularly common. We know

this based on our previous work that looked at the dissemination of sacral neuromodulation in the state of Florida among all age groups and found that approximately 50% of these procedures were performed in patients age 60 and older.<sup>9</sup> Finally, in this study we are limited in our knowledge of the appropriateness of the decisions made by and the motivations of the physicians performing sacral neuromodulation test procedures.

## Conclusions

Rates of sacral neuromodulation test procedures increased while rates of implant procedures remained stable over the course of the study period. Interestingly, physicians who performed high rates of device testing procedures were associated with lower rates of device implantation procedures, raising concerns about ineffective resource utilization surrounding the testing procedure. More research needs to be done to improve patient selection for testing procedures.

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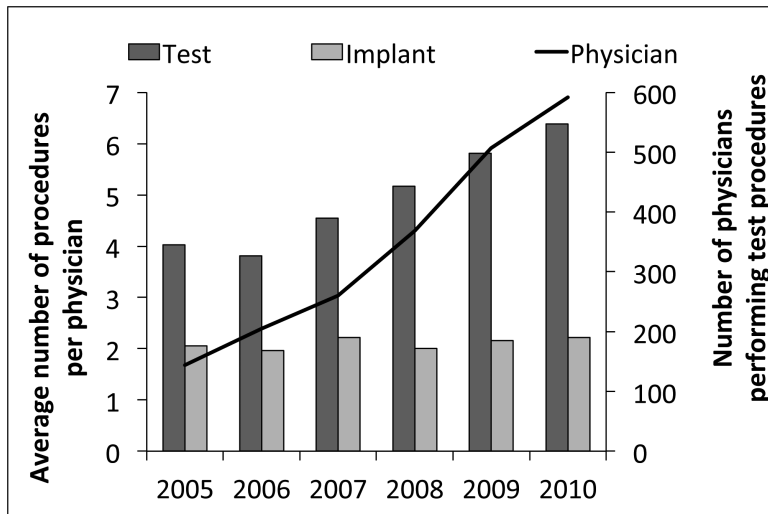
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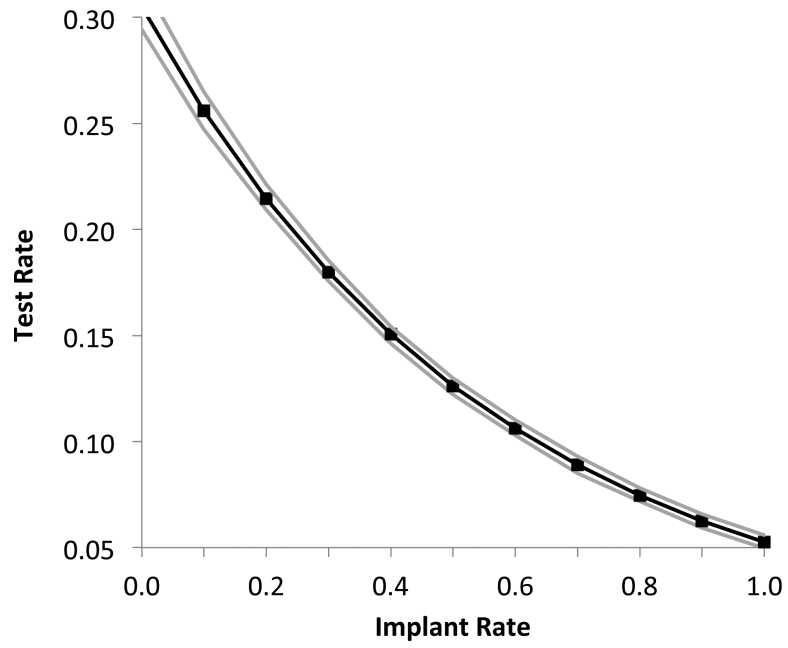
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**Figure 1.**  
Temporal trends in the use of sacral neuromodulation from 2005 to 2010.



**Figure 2.** Inverse relationship between testing and implantation rates (light gray bars represent 95% CIs)

**Table 1**

Descriptive information on physicians performing sacral neuromodulation test procedures and their composite patient characteristics (unit of analysis is at the physician-year level).

Characteristics	Value
Place of Service for test procedure, N (%)	
Freestanding ambulatory surgery center	187 (9.0)
Inpatient hospital department	43 (2.1)
Office	733 (35.2)
Outpatient hospital department	1118 (53.7)
Physician specialty, N (%)	
Gynecologist	422 (20.3)
Urologist	1659 (79.7)
Region, N (%)	
Midwest	554 (26.6)
Northeast	329 (15.8)
South	910 (43.7)
West	288 (13.8)
Patient age, mean (SD)	74.6 (2.9)
White, mean (SD)	93.7 (0.1)
Comorbidity, mean SD	4.6 (6.0)
Test rate (#test/#dx per physician), mean SD	0.26 (0.51)
Implant rate (#implant/#tests per physician), mean SD	0.55 (0.31)
Explant rate (#explant/#implant per physician), mead SD	0.09 (0.30)

**Table 2**

Poisson regression model depicting factors associated with higher rates of sacral neuromodulation test procedures.

	Estimate	SE	P value
Year			
2005	--	--	--
2006	0.04	0.05	0.43
2007	-0.12	0.05	0.02
2008	0.14	0.05	<0.01
2009	0.25	0.05	<0.01
2010	0.22	0.05	<0.01
Place of Service for test procedure			
Freestanding ambulatory surgery center	--	--	--
Inpatient hospital department	0.41	0.09	<0.01
Office	0.22	0.03	<0.01
Outpatient hospital department	0.31	0.04	<0.001
Physician specialty			
Gynecologist	--	--	--
Urologist	-0.63	0.02	<0.01
Region			
Midwest	--	--	--
Northeast	-0.10	0.03	<0.01
South	0.08	0.02	<0.01
West	0.14	0.04	<0.01
Patient age	-0.04	0.004	<0.01
White	0.09	0.11	0.44
Comorbidity	-0.0009	0.003	0.73
Implant rate (#implant/#tests per physician)	-1.76	0.05	<0.01
Explant rate (#explant/#implant per physician), mead SD	-0.14	0.03	<0.01