RESEARCH LETTER

Failures of Sacral Neuromodulation for Incontinence

Sacral neuromodulation (SNM) is increasingly used to treat lower urinary tract symptoms and bowel symptoms refractory to conventional therapy.1 The US Food and Drug Administration approved the device in 1997, and the device was modified in 2006, which included a 50% reduction in size and an improvement in leads to decrease lead migration. These changes at least partially explain the more than 3.5-fold increase in the number of SNM procedures in the following 5 years.2 While guidelines based on small clinical studies with highly selected patients report 50% or greater symptom improvement in most patients,1,3,4 an early safety report using real world data found that a large number of reinterventions occurred in the Medicare population.2

The indications for SNM use are growing despite the lack of evidence. Hence, we sought to determine the reintervention rate associated with treatment failures and device malfunctions at 1, 3, and 5 years after surgery. The secondary aim was to evaluate the volume-outcome relationship.

Methods | We used data from 2008 to 2015 from the Statewide Planning and Research Cooperative System, with longitudinal records of all procedures conducted in New York. Patients who underwent the SNM second-stage procedure (InterStim; Medtronic) as well as treatment failures and device malfunctions were identified using Current Procedure Terminology, Fourth Edition, International Classification of Diseases, Ninth Revision, and International Statistical Classification of Diseases and Related Health Problems, Tenth Revision codes. We evaluated the reintervention (ie, revision, replacement, or removal) rate of SNM within 1 year, 3 years, and 5 years following the initial procedure and analyzed principal diagnoses during reinterventions. We defined high hospital and surgeon volumes based on the upper quartile and used multivariable generalized linear mixed models to account for hospital clustering (Figure). This protocol was reviewed and approved by the institutional review board at Weill Cornell Medical College. Because deidentified information from the Statewide Planning and Research Cooperative System database was used, informed consent was waived.

Results | A total of 4946 patients underwent the SNM procedure between 2008 and 2015. The mean (SD) age was 60.7 (16.2) years, and 3943 patients (79.7%) were female. The primary indication for SNM was wet overactive bladder (n = 2534 [51.2%]). Reinterventions were conducted for 592 of 4313 patients (13.7%) within 1 year, for 767 of 2920 (26.3%) within 3 years, and for 575 of 1514 (38.0%) within 5 years following SNM placement. The most common principal diagnoses for reintervention were related to treatment failure (278 of 592 patients [47.0%]) and device malfunction (280 of 592 [47.3%]) at 1 year. At 5 years, 190 of 575 reinterventions (33.0%) were related to treatment failure and 367 of 575 (63.8%) to device malfunctions (Table). There were no significant differences between high vs low volume hospitals or surgeons.

Figure. Box Plot of the Average Annual Hospital and Surgeon Volumes

The box indicates the interquartile range; the line, the median; the point, the mean; the error bars, 95% CIs.

Table. Principle Diagnoses During Readmission for Reintervention*

<table>
<thead>
<tr>
<th>Principle Diagnosis</th>
<th>Reintervention Within 1 y (592 of 4313 [13.7%])</th>
<th>Reintervention Within 3 y (767 of 2920 [26.3%])</th>
<th>Reintervention Within 5 y (575 of 1514 [38.0%])</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device malfunction</td>
<td>280 (47.3)</td>
<td>452 (58.9)</td>
<td>367 (63.8)</td>
</tr>
<tr>
<td>Treatment failure</td>
<td>278 (47.0)</td>
<td>286 (17.3)</td>
<td>190 (33.0)</td>
</tr>
<tr>
<td>Pain</td>
<td>20 (3.4)</td>
<td>14 (1.8)</td>
<td>NR</td>
</tr>
<tr>
<td>Infection</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

Abbreviation: NR, not reportable.
*Values for categories with 10 or less diagnoses are not reported.
*aThe denominators for 1-year, 3-year, and 5-year reintervention rates were different because patients who did not have enough follow-up time were excluded.
Our previous study using limited 5% Medicare data reported an 11.3% reintervention rate at 90 days and a 33% rate at 5 years. In a 5-year follow-up study of patients implanted with SNM for overactive bladder, Siegel et al also reported only a 67% therapeutic success rate. We extend these results in, to our knowledge, the first large-scale, all-inclusive statewide study demonstrating high SNM device failure. We found that device malfunction was the second most common indication for early reinterventions and the predominant indication at 5 years. Moreover, our results demonstrate that even in the hands of high-volume surgeons, the invasive surgical reintervention rate remains very high.

Limitations include generalizability to the entire US population, despite inclusion of all ages and data from all of New York, with its diverse population and practices. Use of billing codes may introduce some misclassification but is a valid method, particularly for reinterventions.

Conclusions | Sacral neuromodulation is associated with a very high rate of failure, as measured by reinterventions, that occur at alarming rates within 5 years of placement. A device registry is urgently needed in this setting to advise stakeholders and assist future innovations.

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Surgeon Practice Patterns of Arthroscopic Partial Meniscectomy for Degenerative Disease in the United States: A Measure of Low-Value Care

Arthroscopic partial meniscectomy (APM) is one of the most common surgical procedures in the world. However, the value of APM has come under intense scrutiny. Multiple randomized clinical trials, including the shame surgery-controlled Finnish Degenerative Meniscal Lesion Study (FIDELITY), revealed no benefit from the procedure in patients with degenerative meniscal tears compared with exercise and physical therapy. Evidence that may support an APM-only procedure (APM not associated with a ligament, cartilage, or meniscus repair) is for a small subset of patients with an acute traumatic meniscal tear, but these typically occur in younger, non-Medicare patients. Despite this, APM-only procedures continue to be common among Medicare beneficiaries. To better understand the disparity between the medical evidence and current orthopedic practice, we designed this study to measure surgeon practice patterns of APM-only procedures.

Methods | Using 2016 Centers for Medicare and Medicaid Services data, we evaluated the prevalence of APM-only procedures as a proportion of all knee arthroscopies (Current Procedural Terminology [CPT] codes 29866-29889) performed by a surgeon. We excluded patients with septic knee lavage and drainage (CPT code 29871). Arthroscopic partial meniscectomy-only procedures were identified by CPT codes 29880 (medial and lateral meniscus) and 29881 (medial or lateral meniscus). We defined low-volume surgeons as those performing 10 or fewer arthroscopies annually in the Medicare population (Johns Hopkins University institutional review board approval 00085313). Informed consent was waived for this study due to it being a database study.

Results | We identified 121,624 knee arthroscopies in the Medicare population performed by 12,504 surgeons. We found wide practice variation in the national distribution of surgeons by the proportion of knee arthroscopies they performed that were APM-only procedures, regardless of the indication (Figure). Arthroscopic partial meniscectomy-only procedures comprised 66.7% (81,102 of 121,624) knee