# Sacral neuromodulation in the golden years: Treatment outcomes in elderly 75 years and older

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## ABSTRACT

**INTRODUCTION:** Despite high prevalence and increased severity and burden of overactive bladder (OAB) and fecal incontinence (FI) in the elderly, sacral neuromodulation (SNM) is often overlooked as a potential treatment option for this demographic. In this study, we report the outcomes of SNM in patients aged 75 years or older at the time of surgery.

**METHODS:** We conducted a retrospective cohort study of patients who underwent SNM implantation between 2013 and 2022 performed by a single, high-volume urologist at a tertiary center. Success, complication, and adjunct therapy rates were analyzed by Fisher's or Wilcox rank-sum test as appropriate. We compared outcomes between patients aged 75–79 years and octogenarians.

**RESULTS:** Of 632 patients, 50 were ≥75 years. Patients had a mean age of 78.4±2.6 years and were predominantly female (84%). The indications for SNM were 66% OAB, 16% FI, 16% non-obstructive urinary retention, and 4% pelvic pain. Within the first year, 94% of patients reported satisfaction and improvement in symptoms, while 76% continued to experience improvement beyond one year. SNM insertion led to reduced oral medication use from 68% to 24% ($p<0.0001$). The complication rate was 16% and mostly included device pain. No significant difference was observed in treatment success, complication, or adjunct therapy rate between age groups.

**CONCLUSIONS:** SNM is a safe and effective option in well-selected patients over the age of 75 years. Treatment success rate is comparable to younger cohorts. Advanced age should not preclude third-line therapy options in this population.

## INTRODUCTION

Elderly patients experience a higher incidence and increased severity of overactive bladder (OAB) and fecal incontinence (FI), with disease burden significantly affecting their quality of life.[1] Elders represent a unique population that often presents with comorbidities that raise concerns about treatment adherence and polypharmacy. Second-line treatments, such as anticholinergics, have limitations in terms of tolerability, and their long-term use has been associated with an increased risk of dementia.[2] As the use of anticholinergic medication in elderly patients becomes an increasingly concerning issue, it is crucial to evaluate the effectiveness of third-line treatments for this demographic.

Sacral neuromodulation (SNM) emerged in the 1990s as an alternative option for the minimally invasive treatment of refractory OAB with or without urinary incontinence, non-obstructive urinary retention, and FI.[3] SNM can be successfully implemented in the elderly, and advanced age alone does not negatively predict treatment outcomes;[4,5] however, claims-based studies suggest that healthcare providers historically have been reluctant to recommend SNM to older patients.[6]

Currently, there is limited information about the success rate and risk of complications of SNM in the elderly population and a lack of consensus on the maximum safe age for SNM insertion. Understanding the outcomes of SNM therapy in this demographic can inform decision-making regarding treatment options

KEY MESSAGES

- SNM is a safe and effective therapy in well-selected patients over 75 years with overactive bladder, non-obstructive urinary retention, and fecal incontinence, with a success rate of over 76% beyond 12 months of followup and a 16% complication rate.
- Beta-3 agonist and anticholinergic use were reduced from 68% to 24% ($p<0.0001$) post-SNM therapy.
- SNM can be successfully implemented in elders. Advanced age should not preclude third-line therapy in patients over 75 years.

for this growing population. Therefore, this study aimed to retrospectively assess the success rates and safety of SNM insertion in patients older than 75 years.

## METHODS

### Study design

This retrospective cohort study reviewed medical charts of patients who underwent SNM insertion by a single, high-volume urologist at an academic tertiary hospital (Toronto, Canada) between December 2013 and January 2022. The institutional research ethics board approved data collection as a medical quality review, and the requirement to obtain patient consent was waived.

### Patient population

All patients in this database (n=632) who underwent percutaneous nerve evaluation (PNE) and SNM for bladder or bowel disorders (OAB, chronic non-obstructive urinary retention, FI, constipation, etc.) that lasted for at least six months and failed conservative treatments were screened. Patients were followed at one, three, six, and 12 months post-implantation and yearly after that. We included patients 75 years and older at the time of surgery — lead and internal pulse generator (IPG) implantation (n=51). We excluded patients with followup shorter than 12 months or incomplete medical records (n=1).

### Data collection

The collected data included patient demographics (age and sex), reason for referral, treatment before SNM, requirement of additional staged SNM testing post-PNE, procedural complications, and clinical outcomes (treatment success and adjunct therapies).

A successful lead placement was defined by the presence of bellows or great toe flexion in at least three electrodes with <2 mA current stimulation. Patient satisfaction was measured by asking patients to rate their satisfaction with the treatment during followup. Improvement rate was defined as continuous improvement >50% of baseline symptoms in one or more bothersome parameters, such as urinary frequency, urgency, incontinence episodes, bowel seepage, and bowel warning using bladder and/or bowel diaries. If a patient had both positive satisfaction and met the improvement rate criteria, they were considered a "treatment success." Complications of interest were infection, pain (battery or lead), lead migration, revision, and explantation. Battery replacement was not considered a postoperative complication.

### Statistical analysis

Descriptive statistics were used to summarize demographic and clinical characteristics. Subgroup analysis was performed to evaluate SNM outcomes and the need for adjuvant therapy for patients over the age of 80 and those between 75 and 79 years. Categorical outcomes were assessed using Chi-squared or Fisher's, given excepted cell frequency, and McNemar's test for matched pairs. T-test or Wilcoxon rank-sum analyzed the association of continuous outcomes given normality distribution. Two-sided $p<0.05$ was considered statistically significant. Statistics analyses were performed using Stata version 17BE (StataCorp, TX, U.S.).

## RESULTS

### Baseline characteristics

Of 632 patients underdoing SNM reviewed, 50 were 75 years and older. Patients had a mean age of 78.4±2.6 (75–85) years old and were predominantly female (84%). SNM therapy was indicated for 33 (66%) patients suffering from refractory OAB, eight (16%) from FI, six (12%) from non-obstructive urinary retention, two (4%) from pelvic pain, and one (2%) from chronic constipation. Prior to SNM insertion, four (8%) patients tried pelvic physiotherapy, 34 (68%) patients underwent medical therapy with anticholinergic and/or beta-3 agonists, two (4%) with loperamide (Imodium®), and three (2%) with desmopressin. Nine (20.4%) patients required other third-line therapies, such as intravesical botulinum toxin injection. All patients had

a PNE trial prior to the SNM IPG device and lead implantation. Only 8% of them failed PNE and required a subsequent staged trial: one patient with OAB, two with chronic non-obstructive retention, and one with constipation.

## Procedural outcomes and complications

Within the first year post-SNM insertion, 47 (94%) patients had successful treatment (satisfied and improved symptoms). Beyond the first year of followup, the treatment success rate was 76%. The complication rate was relatively low (16%) in this cohort, with five (10%) implants failing and three (6%) having to be removed. There were no cases of infection, bleeding, lead, or battery migration. Of all patients, 24% needed oral adjunct treatment after SNM insertion with anticholinergic and/or beta-3 agonists and four (8%) with botulinum toxin. Overall, after SNM insertion, oral medication use was reduced from 68% to 24% (p<0.0001). The length of followup post-SNM implantation ranged from 1–8 years.

Treatment success rate after one year of SNM therapy was 100% for patients with pelvic pain, 87.5% for FI, 75.8% for OAB, and 66.7% for chronic urinary retention. Treatment success was not significantly different by reason of SNM indication within (p=0.506) or after a year of followup (p=0.432). During followup, three (6%) patients in our cohort had turned off the IPG device because they did not remember to turn it on or were unable to adjust it. There was no information in medical records on whether these patients had a formal diagnosis of dementia prior to implantation. No patients were diagnosed with dementia during followup.

## Subgroup analysis

The 75–79-year-old subgroup (n=35) had an average age of 77.0±1.4 years, while the 80+ subgroup (n=15) averaged 81.7±1.5 years (p<0.001). There was no difference in sex, etiology of indication for SNM therapy, or treatments used prior to surgery between groups (Table 1). The treatment success rate for octogenarians was 93% within the first year and 73% beyond that. There was no difference in treatment outcomes or need for adjunct therapy for octogenarians when compared to younger elders. Table 2 illustrates SNM outcomes by age group. Similarly, complication rates were mostly battery and lead pain, comprising 6.7% of octogenarians and 5.7% of elders from 75–80 years (Table 3).

**Table 1. Preoperative patient characteristics**

| | 75–79 years (n=35) | ≥80+ years (n=15) | p |
|---|---|---|---|
| Age, years, mean (SD) | 77.0±1.4 | 81.7±1.5 | <0.001# |
| Sex, n (%) | | | 1.00* |
| Male | 6 (17.1) | 2 (13.3) | |
| Female | 29 (82.9) | 13 (86.7) | |
| SNM indication, n (%) | | | 0.895* |
| OAB | 22 (62.9) | 11 (73.3) | |
| Non-obstructive urinary retention | 5 (14.3) | 1 (6.7) | |
| Fecal Incontinence | 5 (14.3) | 3 (20.0) | |
| Constipation | 1 (2.9) | 0 (0) | |
| Pelvic pain | 2 (5.7) | 0 (0) | |
| Prior treatments, n (%) | | | |
| Oral medication | 23 (65.7) | 11 (73.3) | 0.746* |
| Beta-3 agonist | 6 (17.1) | 2 (13.3) | |
| Anticholinergic | 4 (11.4) | 2 (13.3) | |
| Beta-3 agonist and anticholinergic | 13 (37.1) | 7 (46.7) | |
| Btx-A (%) | 6 (18.7) | 3 (25.0) | 0.687* |
| Pelvic physiotherapy | 3 (8.6) | 1 (6.7) | 0.82* |

*Fisher's exact test. #Unpaired t-test. Btx-A: onabotulinumtoxin A; OAB: overactive bladder; SNM: sacral neuromodulation.

**Table 2. Sacral neuromodulation outcomes**

| | 75–79 years (n=35) | ≥80+ years (n=15) | p |
|---|---|---|---|
| PNE, n (%) | 35 (100) | 15 (100) | |
| Staged SNM insertion n (%) | 3 (8.6) | 1 (6.7) | 1.00 |
| Treatment success <1 year n (%) | 33 (94.3) | 14 (93.3) | 1.00 |
| Treatment success >1 year n (%) | 27 (77.1) | 11 (73.3) | 1.00 |
| Adjunct treatment, n (%) | 12 (34.3) | 7 (46.7) | 0.528 |
| Oral medication | 8 (22.8) | 4 (26.7) | |
| Btx-A | 2 (5.7) | 2 (13.3) | |
| Desmopressin | 1 (2.9) | 1 (6.7) | |
| Acupuncture | 1 (2.9) | 0 (0) | |

All Fisher's exact test. Btx-A: onabotulinumtoxin A; PNE: percutaneous nerve evaluation; SNM: sacral neuromodulation.

**Table 3. Sacral neuromodulation complications**

| | 75–79 years (n=35) | ≥80 years (n=15) | p |
|---|---|---|---|
| Complication, n (%) | 4 (11.4) | 1 (6.7) | 0.705 |
| Pain (battery or lead) | 2 (5.7) | 1 (6.7) | 1.00 |
| Implant site infection | 0 (0) | 0 (0) | 1.00 |
| Migration | 0 (0) | 0 (0) | 1.00 |
| Revision | 2 (5.7) | 0 (0) | 1.00 |
| Removal, n (%) | 2 (5.7) | 1 (6.7) | 1.00 |
| Battery change, n (%) | 1 (2.9) | 0 (0) | 1.00 |

## DISCUSSION

OAB, urinary incontinence, chronic non-obstructive urinary retention, and FI require individualized management in elderly patients that balances effectiveness and safety without the additional threat of incremental burden on cognitive impairment or dementia.[2] Since the late 1990s, SNM has been FDA-approved for minimally invasive treatment for refractory OAB, non-obstructive urinary retention, and FI.[3] While this therapy is approved for patients over 18 years old, there is no maximum implantation age limit recommendation by the International Continence Society (ICS), Canadian Urological Association (CUA), American Urological Association (AUA) and Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) guidelines.[7-9]

The present study highlights the effectiveness of SNM in elders, with a 76% treatment success rate for patients aged 75 years or older at the time of device implantation, followed for at least 12 months and up to eight years.

Overall, in our patient population, both short-term (94%) and long-term (76%) success rates of SNM were comparable or superior to those reported in other SNM studies, irrespective of the initial medical indication.[10-14] Outcomes of SNM for bladder and bowel disorders in elderly patients have also been evaluated by other studies.

The success rate of SNM for patients ≥70 years was 58.3% for OAB and 59.6% for urinary retention.[5] A study followed 30 SNM patients with a median age of 69 years old for FI.[15] The researchers found the treatment to be effective (incontinent episodes/two weeks reduced from a median of 10 to 2 episodes, $p<0.001$) and yielded a similar rate of improvement as other age groups.[15] Similarly, a multicenter study conducted in 2020 compared the clinical effect of SNM on patients with refractory voiding dysfunction between the ages of 40–64 and over 64 years old.[16] They found no difference in success rates between the two age groups and suggested that age alone should not be a liming factor for SNM indication. These outcomes suggest that SNM in elderly patients is similar to the general population regardless of medical indication.

Furthermore, the present study showed no difference in long-term effectiveness after SNM; octogenarians had a treatment success rate of 73% compared to the 77% improvement of elders 75–79 years. Lee et al[17] and Greenberg et al[18] evaluated octogenarians at the time of stage I and observed no significant difference in the success rate of SNM between elderly and younger patients. At a mean 17-month followup, the success rate in octogenarians was 72%.[17] Similarly, Faris et al divided their study population into age groups covering individual decades of life and did not find any significant variation in the outcomes of SNM across these groups.[19] Lastly, besides symptom relief, SNM can potentially have an incremental impact on quality of life and psychological well-being since elders have a higher risk of social isolation and decreased quality of life due to incontinence.[20]

While there are risks associated with any surgical procedures, our study also showed that the complication rate (16%) was consistent with the literature data.

A prospective, multicenter study evaluated outcomes of SNM due to OAB and reported 15% implant size pain at the five-year followup.[21] Moreover, in our study, SNM insertion led to reduced oral medication use from 68% to 24% ($p<0.0001$). Most implanted patients did not continue or restart anticholinergic or beta-3 agonist medications.

A study published in the *Journal of Urology* in 2019 looked at the rate of discontinuation of medication after SNM insertion in OAB patients.[22] After excluding patients with non-obstructive chronic underactive bladder and those with SNM devices removed one year or less postoperatively, they found that approximately 80% of the cohort did not need adjunct medication treatment in the future.

Our study included OAB patients but also non-obstructive chronic underactive bladder patients, FI patients, pelvic pain disorder, and chronic constipation patients, and that could be a reason that our numbers are slightly higher. In summary, the rate of patients with adjunct treatment was less than in the literature, which suggests that SNM with older patients is efficient, and the rate of adjunct treatment is not higher than in younger patients.

### Limitations

There are, however, limitations to the present study, the first being its retrospective nature.

Second, the level of satisfaction and improvement were self-reported and did not use validated questionnaires. Patients did not undergo a cognitive assessment or geriatric assessment score for us to identify the functionality of these aging patients and how it could have affected treatment compliance/outcome. Similarly, patients' comorbidities were not assessed or controlled for in this study. Furthermore, it should be noted that our study sample consists of selected elderly patients, and our analysis aimed to gain insight into the individual decision-making process retrospectively, thus reducing the generalizability of results.

Nonetheless, this study adds to the evidence of the safety and effectiveness of SNM treatments in septuagenarians and octogenarians. To our knowledge, this study evaluated long-term SNM outcomes from the eldest cohort at the time of implantation in the literature. Also, we had a long followup for each patient, and we were able to show overall good effectiveness with low complications.

Future studies evaluating the effectiveness of SNM in this population should include cognitive and geriatric assessments to evaluate elders' functional ability. This data will be pivotal in informing the cognitive and functional thresholds for SNM in the golden years and to offer a pool of evidence toward adjusting clinical and societal recommendations.

## CONCLUSIONS

SNM is a safe and effective option in well-selected patients over the age of 75 years with OAB, FI, and chronic non-obstructive urinary retention. The treatment success rate is comparable to younger cohorts. Advanced age alone should not preclude SNM during treatment counselling. This study does not suggest a higher complication, revision, or explantation rate in the elderly.

COMPETING INTERESTS: Dr. Bhojani is a consultant/investigator for Boston Scientific, Procept BioRobotics, and Olympus. Dr. Zorn is a consultant/investigator for Boston Scientific and Procept BioRobotics. Dr. Chughtai is a consultant for Boston Scientific, Olympus, Procept, and Prodeon. Dr. Elterman is a consultant/investigator for Boston Scientific, Procept Biorobotics, Olympus, Urotronic, Prodeon, and Zenflow. All other authors do not report any competing personal or financial interests related to this work.

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