

Original Article

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Data Gap in Sacral Neuromodulation Documentation: Call to Improve Documentation Protocols

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Purpose: We quantified patient record documentation of sacral neuromodulation (SNM) threshold testing and programming parameters at our institution to identify opportunities to improve therapy outcomes and future SNM technologies.

Methods: A retrospective review was conducted using 127 records from 40 SNM patients. Records were screened for SNM documentation including qualitative and quantitative data. The qualitative covered indirect references to threshold testing and the quantitative included efficacy descriptions and device programming used by the patient. Findings were categorized by visit type: percutaneous nerve evaluation (PNE), stage 1 (S1), permanent lead implantation, stage 2 (S2) permanent impulse generator implantation, device-related follow-up, or surgical removal.

Results: Documentation of threshold testing was more complete during initial implant visits (PNE and S1), less complete for S2 visits, and infrequent for follow-up clinical visits. Surgical motor thresholds were most often referred to using only qualitative comments such as “good response” (88%, 100% for PNE, S1) and less commonly included quantitative values (68%, 84%), locations of response (84%, 83%) or specific contacts used for testing (0%). S2 motor thresholds were less well documented with qualitative, quantitative, and anatomical location outcomes at 70%, 48%, and 36% respectively. Surgical notes did not include specific stimulation parameters or contacts used for tests. Postoperative sensory tests were often only qualitative (80%, 67% for PNE, S1) with quantitative values documented much less frequently (39%, 9%) and typically lacked sensory locations or electrode-specific results. For follow-up visits, <10% included quantitative sensory test outcomes. Few records (<7%) included device program settings recommended for therapy delivery and none included therapy-use logs.

Conclusions: While evidence suggests contact and parameter-specific programming can improve SNM therapy outcomes, there is a major gap in the documentation of this data. More detailed testing and documentation could improve therapeutic options for parameter titration and provide design inputs for future technologies.

Keywords: Urinary incontinence; Retrospective study; Electronic health records; Implantable neurostimulators

- **Research Ethics:** The study was approved by the Institutional Review Board as an exempt study (24 Feb 2020, IRB ID:8595).
- **Conflict of Interest:** No potential conflict of interest relevant to this article was reported.

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INTRODUCTION

Sacral neuromodulation (SNM) is an established therapy for the treatment of lower urinary tract disorders of overactive bladder and retention [1]. SNM devices are surgically implanted, with a lead consisting of 4 equally spaced electrodes (contacts) placed near a sacral nerve along with a subcutaneous pulse generator that delivers therapeutic electrical stimulation through the lead [2]. It is proposed that SNM acts to interfere with afferent sensory neural fibers that mediate sensations of bladder fullness, urgency, or similar information regarding the state of the bladder and lower urinary tract [3].

Stimulation amplitude is dictated by voltage or current depending on the device model and manufacturer [4]. Along with fluoroscopic guidance, the proximity of the lead to the nerve of interest is assessed intraoperatively by performing a motor threshold test. During this test, the stimulation amplitude of each individual contact is increased until a bellows or toe response is observed. Postoperatively, a sensory threshold test is performed in which the patient can verbally respond when the stimulation amplitude reaches a perceptive level and they correlate strongly with motor threshold intensities [5]. A lower amplitude during threshold testing implies the lead is closer to the stimulated nerve because the radius of the electrical field is proportional to the amplitude [4,6]. A positive motor or sensory response at each contact with an amplitude less than 2V is evidence of a well-placed lead [7]. Additionally, a lead that is close to the nerve of interest theoretically requires less energy and decreases the likelihood of off-location stimulation [8]. After lead insertion, the contact pattern of stimulation can be adjusted to titrate the therapy to the individual patient. Generally, a pattern is selected that produces a perineal sensation on the patient and is then adjusted to a subsensory level for therapy delivery [4]. Altering the contact pattern influences both the sensation location and the amplitude required to elicit it during sensory threshold testing and can be used for optimizing and troubleshooting SNM therapy [9].

The overall success rate for SNM ranges from 43% to 85% [10] and revision rates for an initial suboptimal outcome range from 3%–35% [11]. Reasons for therapy failure include lead migration [12,13], hardware failure [11], patient selection [14], and adverse effects such as unwanted stimulation, discomfort, or loss of efficacy, often leading to reprogramming of the device [11]. Reprogramming and documentation of thresholds, efficacy and therapy settings are essential to understanding and im-

proving therapy failures, surgical revisions and device designs needed to address these therapy issues.

Reprogramming the device can restore treatment efficacy in 16%–100% of patients depending on the reason for which it is performed [11]. If reprogramming is not successful, an explant, with the associated morbidities and costs, may be warranted. Successful reprogramming has been achieved by altering different variables on the patient's device such as the stimulating contact point, the frequency, as well as the pulse-width [11]. However, parameters used during successful reprogramming are not widely reported [4,11]. Regular clinical documentation of reprogramming and reprogramming parameters may improve the success of patient outcomes and device efficacy in the future. As an initial project to understand the state of documentation in our clinic, we retrospectively quantified patient record documentation of sacral neuromodulation threshold testing in the electronic health record (EHR) at our institution in order to better identify opportunities for improving therapy outcomes and obtaining potential data for essential design inputs into future SNM technologies.

MATERIALS AND METHODS

We conducted a single-center retrospective study of sensory and motor testing and related documentation with a focus on data captured during, and following, surgical implantation of SNM. The study was approved by the IRB as an exempt study (24 Feb 2020, IRB ID:8595). The documentation source was the patient EHR (Epic Systems Corporation, Verona, WI, USA) for SNM patients receiving device implantations or therapy between January–December 2019. We traced visits or surgeries from this date range to January 2016 to capture prior visit data. Records from 40 patients were identified using surgical and clinical schedules for SNM patients at the university clinic and surgery center. Data were only included from patients that opted into research participation.

The typical patient-care pathway visible from the EHR included: (1) percutaneous nerve evaluation (PNE) temporary lead implantation, or (2) stage 1 (S1) permanent lead implantation under monitored anesthesia, (3) stage 2 (S2), permanent impulse generator implantation under monitored anesthesia, (4) follow-up postoperative clinical visits related to wound check, programming, or therapy efficacy issues, and (5): if warranted, device removal under monitored anesthesia. Routine visits related to SNM such as reprogramming, unwanted sensa-

tions, problems with the SNM device, or poor efficacy were included as follow-up visits. For each visit, we screened and transcribed relevant surgical notes and clinical records regarding SNM sensory or motor testing, documented device therapy settings or descriptions, therapy efficacy remarks or quantification, and notes regarding SNM therapy or efficacy. Because we were specifically interested in clinical documentation, we did not seek out any information stored in corporate databases, clinical programming devices, implanted devices, or other non-EHR locations.

Visit-specific motor and sensory threshold outcomes were assessed using 6 criteria: (1) qualitative mention or description of a threshold test outcome, such as incidental reference to an outcome (e.g., good, adequate); (2) quantitative amplitude threshold; (3) anatomical location of the response, such as a patient-reported perception of stimulation locations or clinician-observed motor locations; (4) inclusion of specific electrode(s) tested; (5) additional test parameters, such as pulsewidth or frequency; (6) discomfort mentioned, such as an uncomfortable sensation experienced during a sensory test. We also recorded whether therapy-use logs, documentation of therapeutic efficacy, and recommended therapy settings such as quantitative parameters and device electrodes were documented.

RESULTS

Patients and Clinical/Surgical Visits

Records from 40 patients, 27 females (68%) and 13 males (32%) were included. The mean patient age was 58.6 years (standard deviation, 15.6 years). Primary clinical symptoms noted in records included urgency (n = 30 of 40, 75%), frequency (n = 27, 68%), urinary retention (n = 7, 18%), and overactive bladder (n = 4, 10%). Twenty-eight patients received new SNM therapy during the study period (70%); 12 (30%) had existing SNM therapy (implanted prior to the study period). For the study duration, Interstim (Medtronic, Minneapolis, MN, USA) was the only U.S. Food and Drug Administration-approved SNM device, and all patients were implanted with these devices. There were 127 visits evaluated. Visits included 25 PNEs, 6 S1 implants, 33 S2 implants, and 8 device removals (Fig. 1). Follow-up visits included 15 post-PNE, 25 post-S2 and 15 follow-up visits that were nonsurgical (not immediately postoperative). The mean number of SNM-related visits/patient was 3.7 (median, 3; range, 1–26) for the 39 months included in the study; the most typical visit series for patients was a PNE implant, PNE

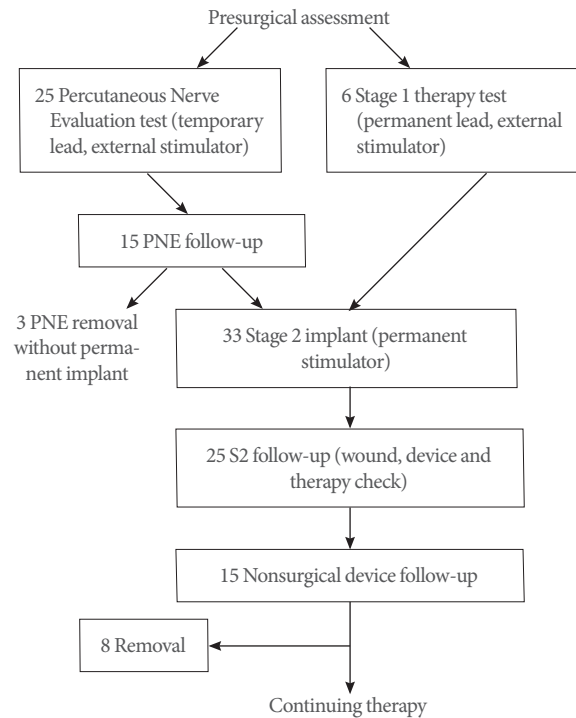


Fig. 1. Patient sacral neuromodulation (SNM) care pathway and records analyzed. Records for 40 patients were reviewed and summarized for the SNM care pathway. A total of 127 visits were included. The number of visit records are shown in the parentheses for each clinical or surgical visit type. PNE, percutaneous nerve evaluation.

follow-up visit, S2 implant, and a single implant follow-up visit.

Motor Threshold Testing

Motor threshold testing for SNM was conducted with patients under local anesthesia or local anesthesia with sedation, thus restricted to surgical implantation events. Qualitative descriptions of motor threshold tests were observed for 88% and 100% of patients during PNE and S1 implantation surgeries, respectively (Fig. 2). Quantitative test information was included for <70% and 90% of these surgeries, respectively. Quantitative amplitude for the motor threshold outcomes were included for <50% of S2 surgeries and often excluded units of measure (e.g., voltage or amplitude). An example includes, “bellows at 0.6.” For all implantation surgeries, there were no consistent parameter data other than stimulation amplitude and location included in motor threshold test outcomes. When they were included in surgical notes, motor locations included bellows (69%), toe (29%), and buttocks (2%). No electrode-specific threshold results were included in the notes. No motor threshold test data

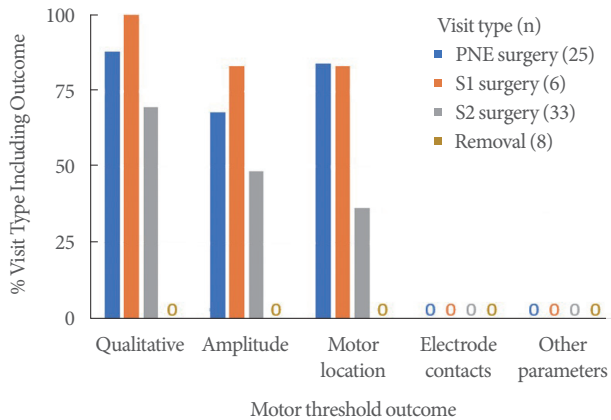


Fig. 2. Sacral neuromodulation (SNM) motor threshold outcomes included in patient records. Within each surgery visit type, % of records including the test outcomes are shown. The number of surgical records is included in the parentheses. Zeros indicate no records included the outcome.

was observed in records for device removal surgeries.

Sensory Threshold Testing

For surgical visits, sensory threshold testing is typically conducted within minutes to an hour after implantation and before postoperative ambulation. Qualitative descriptions for sensory thresholds were found in patient records for 80% and 67% of PNE and S1 implantation documents, respectively (Fig. 3). An example of a qualitative description would be “good sensory response at low amplitude.” Numerical sensory thresholds, however, were included in the records for < 50% of these visits and did not include units of measure, e.g., “sensory response at 1.8.” Likewise anatomical sensory locations were recorded for 68% of PNE visits but for only 4% of other visit types. Postoperative sensory test quantification was noted less frequently for S1 and S2 visits (< 35% and < 10%, respectively). Sensory testing data were also absent from most follow-up visit records (< 10% included quantitative sensory thresholds). Sensory threshold anatomical locations were included in 19 of 40 patients with the most commonly listed locations being vaginal or perineal (n=10), buttocks (n=7), and scrotum or penis (n=2). No records included electrode-specific thresholds of sensory testing that might allow differentiation of optimal therapy delivery or future comparisons in the event of device troubleshooting. No surgical visits for device removal included sensory threshold results (e.g., from testing prior to surgical removal).

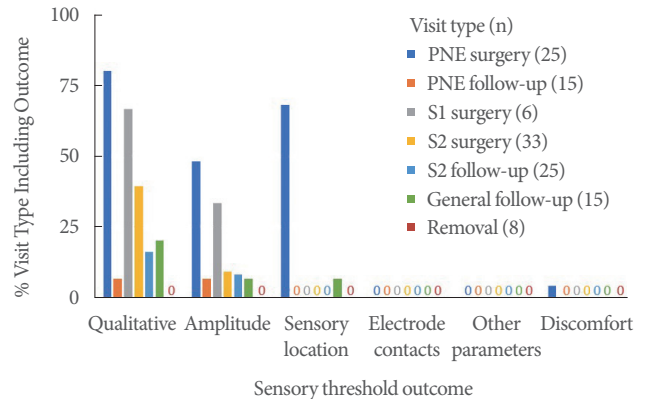


Fig. 3. Sacral neuromodulation (SNM) sensory threshold outcomes included in patient records. Within each visit type, % of records including the test outcomes are shown. The number of records for each visit type is in parentheses. Zeros indicate no visit records included the outcome.

Parameters of Therapy

Patient records also typically lacked information regarding the specific stimulation parameters recommended or used for medical therapy. Eight of 119 possible visits (7%) that could have included therapy setting information actually did. Stimulation amplitude was noted for 6 (5%) visits but units (mA or V) were not included in these records. No records included specific identification of the lead electrodes used or polarity that were programmed to deliver the therapy (e.g., 0-, 3+), although there were references to an undefined therapy programs (e.g., ‘used program 1’) in 6 visit records (5%). There was no inclusion of therapy parameters such as stimulation contacts, frequency, duty cycle. In general, patient records did not include information that would allow parameter based efficacy differentiation or troubleshooting based upon thresholds (e.g., comparisons of efficacy across parameters, optimization of selected lead electrodes, or relative therapy impacts).

Efficacy Documentation

Specific efficacy descriptions or quantification relative to SNM therapy or parameters were often lacking in patient records. Of the 95 visits that took place after initial lead implantation (i.e., excluding PNE and S1 implantation visits), 28 (29%) of patient visit records included a qualitative description of efficacy ‘greatly improved’ or ‘no improvement,’ and 18 records (16%) included some attempt to quantify symptomatic changes, such as noting a ‘50% reduction’ or ‘70% improvement in symptoms.’

Measured across the 40 patients, 20 (50%) included some quantitative description of efficacy. Within these 20 patients, 16 (80%) included numerical descriptions of symptom improvement.

DISCUSSION

The absence and inconsistency of quantitative documentation of device parameters and threshold testing data in our study make it difficult to understand the importance of the data's potential link to patient outcomes or to facilitate SNM technology improvements. As mentioned previously, loss of efficacy can result in eventual device explant with the associated risks of general anesthesia and added financial costs. Device reprogramming, including frequency and pulse-width alterations, can often restore therapy efficacy [11]. However, data for parameters associated with successful reprogramming are infrequently reported. Without these data, we will not know which parameters are actually effective for restoring therapy efficacy after reprogramming.

The International Continence Society best practice statement recommends recording the motor and sensory responses and the stimulus thresholds in the patient's medical record for S2 surgical visits. However, it does not make a recommendation for specifying the contacts associated with the stimulus amplitude, recording the frequency and pulse-width used, nor recording sensory threshold stimulus amplitude at each contact, frequency, and pulse-width after troubleshooting [7]. Dudding et al. [11] highlighted that these parameter data are important for reprogramming and it is our belief that they should be recorded at each threshold that elicited a motor or sensory response. These, along with the duty cycle and contacts programmed for therapy should all be included in the patient's medical record or device at critical times following implant and whenever threshold testing or device troubleshooting is performed.

The financial costs of reprogramming have not been formally quantified at this time and the national average reimbursement rates could not be elucidated from a search of a publicly available Medicare reimbursement database [15] for procedure codes related to device programming (95970-95972). However, codes for 64585 and 64595 (removal of lead and pulse generator, respectively) showed the costs for removal of an SNM device, excluding anesthesia, are \$3,937–\$6,825 depending on the type of facility the removal takes place. Assuming the cost of

device reprogramming is less than device removal, improved therapy reprogramming may decrease financial costs associated with SNM.

Opportunities for the Future

We recognize that thorough SNM threshold testing and transferring patient data to the EHR may pose a significant clinical burden [16]. A study by Vaganée et al. [17] found that contact-specific sensory threshold testing can be completed within 15 minutes for each patient. However, physician follow-up visits are often only scheduled for 15 minutes and require counseling patients on topics beyond threshold testing. Furthermore, the data generated by testing the 4 available electrodes is significant, including up to 100 values. These complex data must currently be recorded as free-text in the EHR by a trained staff member [7]. Furthermore, once the data is transferred, it is not easy to visualize trends since it usually exists in a procedure note or clinical note. One possible solution is to enable an interface between the device and the EHR. This would automate data transfer and allow physicians to quickly reference previous device parameters while troubleshooting device problems.

Another opportunity to reduce the burden of device and therapy monitoring would be through the development of an application that a patient could use to troubleshoot their device. Loss of efficacy could be quantified in a module for entering patient bladder diary data existing within the application. If a patient loses therapy efficacy and is not experiencing pain or another immediately concerning adverse event, the app could toggle between different parameter settings for a specified period of time to assess the effectiveness of the reprogramming, similarly to the reprogramming method described by Dudding et al. [11]. If after a certain number of attempts efficacy was not restored, or if the patient were experiencing pain or adverse effects (unwanted stimulation from the device), they would be prompted to make an appointment with their physician. Some troubleshooting visits are simply due to the device not being turned "on" [11], thus time and financial costs could be reduced with the thoughtful development of useful software.

Data from patient devices or an application could exist in a queryable database, which would augment clinical tracking and research efforts in investigating the influence of stimulation parameters on SNM outcomes. This would provide information needed for the design and improvement of future SNM devices. Studies suggest altering the contact, frequency and pulse-width of the devices can lead to improved efficacy in patients experi-

encing specific troubleshooting scenarios [11]. If this troubleshooting data existed in a database, it could be analyzed in a similar manner to EHR bioinformatics studies which could corroborate existing research. These data may also provide information about the stimulation habits of patients not undergoing device reprogramming. Suppose patients only stimulate using 2 of the 4 possible contact orientations. In fact, it has been shown that the majority of patients have contact “2” as the anode and contact “0” as the cathode [18,19]. This may suggest that next-generation devices do not need to include 4 contacts. Furthermore, not all patients undergoing an implant achieve intraoperative motor threshold responses <2V [11]. Despite this, some still have a beneficial response from the treatment. If successful therapy parameter trends exist in nontypical patients, it could potentially be elucidated with a database.

Limitations

While unique, we recognize that our study has significant limitations. We are a relatively small, single center in the United States and it is unknown whether SNM testing and documentation in patient records is more complete at larger centers, centers from different geographies, or centers with different EHRs. Although this information is unknown, no other studies have attempted to quantify the presence of threshold testing results, frequency, pulse-width, and duty cycle as they relate to clinical outcomes at their institution. Additionally, at the time of the study, our institution did not have standardized methods for data capture and as such cannot temporally tie threshold testing and parameter data to efficacy outcomes. However, numerous studies have shown that the results of threshold testing and patient device reprogramming can restore therapy efficacy and improve patient outcomes [11]. All patients undergoing SNM therapy in our study utilized devices from a single manufacturer and technical stage of device development (2016–2019). As automating the capture of SNM data becomes commonplace, the field must ensure the data are appropriate as well as scientifically and clinically meaningful.

In conclusion, current SNM records inconsistently document acute stimulation testing, therapy parameters, and efficacy details at our center. Given existing SNM document on best practices, we suspect documentation at other institutions is also suboptimal. These data are important tools for improving patient therapy [7,11], and can be valuable design inputs for implantable clinical technologies [6,20]. Our results reveal a significant opportunity to address these data needs in the clinic

through increased quality and frequency of threshold testing documentation, parameter documentation, and efficacy tracking in SNM patients.

AUTHOR CONTRIBUTION STATEMENT

Conceptualization: *KAH, DN*

Formal analysis: *RV, DN*

Methodology: *DN*

Project administration: *DN*

Writing - original draft: *CMH, NAN*

Writing - review & editing: *CMH, RV, KAH, RG, CSF, JE, NAN, DN*

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REFERENCES

1. Bosch JL, Groen J. Sacral nerve neuromodulation in the treatment of patients with refractory motor urge incontinence: long-term results of a prospective longitudinal study. *J Urol* 2000;163:1219-22.
2. Wöllner J, Hampel C, Kessler TM. Sacral neuromodulation: surgery illustrated. *BJU Int* 2012;110:146-59.
3. De Wachter S, Vagane D, Kessler TM. Sacral neuromodulation: mechanism of action. *Eur Urol Focus* 2020;6:823-5.
4. Lehur PA, Sørensen M, Dudding TC, Knowles CH, Wachter S, Engelberg S, et al. Programming algorithms for sacral neuromodulation: clinical practice and evidence—recommendations for day-to-day practice. *Neuromodulation* 2020;23:1121-9.
5. Lee J, Osann K, Noblett K. Comparison of motor and sensory response of InterStim® for overactive bladder syndrome. *Female Pelvic Med Reconstr Surg* 2013;19:317-21.
6. Zirpel L, Su X, Wotton J, Reinking N, Steiner A, Nelson DE, et al. AB291. SPR-18 Correlation of sacral nerve lead targeting and urological efficacy: motor mapping, electrode position, and stimulation amplitude. *Transl Androl Urol* 2016;5(Suppl 2):AB291.
7. Goldman HB, Lloyd JC, Noblett KL, Carey MP, Botero JCC, Gajewski JB, et al. International Continence Society best practice statement for use of sacral neuromodulation. *NeuroUrol Urodyn* 2018;37:1823-48.

8. Matzel KE, Chartier-Kastler E, Knowles CH, Lehur PA, Muñoz-Duyos A, Ratto C, et al. Sacral neuromodulation: standardized electrode placement technique: standardized electrode placement for SNM. *Neuromodulation* 2017;20:816-24.
9. Tilborghs S, Van de Borne S, Vaganée D, De Win G, De Wachter S. The influence of electrode configuration changes on the sensory and motor response during (re)programming in sacral neuromodulation. *Neuromodulation* 2021 Dec 18:S1094-7159(21)06171-7. <https://doi.org/10.1016/j.neurom.2021.09.001>. [Epub].
10. Ammirati E, Giammò A, Manassero A, Carone R. Neuromodulation in urology, state of the art. *Urol J* 2019;86:177-82.
11. Dudding TC, Lehur PA, Sørensen M, Engelberg S, Bertapelle MP, Chartier-Kastler E, et al. Reprogramming sacral neuromodulation for sub-optimal outcomes: evidence and recommendations for clinical practice. *Neuromodulation* 2021;24:1247-57.
12. Deng DY, Gulati M, Rutman M, Raz S, Rodríguez LV. Failure of sacral nerve stimulation due to migration of tined lead. *J Urol* 2006;175:2182-5.
13. Guzman-Negron JM, Derisavifard S, Goldman HB. Sacral neuromodulation lead twisting causes migration and loss of efficacy. *Female Pelvic Med Reconstr Surg* 2020;26:e13-5.
14. Peters KM, Killinger KA, Gilleran JP, Bartley J, Wolfert C, Boura JA. Predictors of reoperation after sacral neuromodulation: a single institution evaluation of over 400 patients. *Neurourol Urodyn* 2017;36:354-9.
15. Planning an outpatient procedure? [Internet]. Lawrence (KS): Medicare.gov; [cited 2022 Jan 24]. Available from: <https://www.medicare.gov/procedure-price-lookup/>.
16. Burks FN, Diokno AC, Lajiness MJ, Ibrahim IA, Peters KM. Sacral neuromodulation reprogramming: is it an office burden? *Int Urogynecology J* 2008;19:1137-40.
17. Vaganée D, Van de Borne S, Fransen E, Voorham J, Voorham-van der Zalm P, De Wachter S. Repeatability of tools to assist in the follow up and troubleshooting of sacral neuromodulation patients using the sensory response. *Neurourol Urodyn* 2019;38:801-8.
18. Cattle KR, Douglas L, Kiff ES. Programming InterStim™ for faecal incontinence. *Colorectal Dis* 2009;11:485-8.
19. Vaganée D, Kessler TM, Van de Borne S, De Win G, De Wachter S. Sacral neuromodulation using the standardized tined lead implantation technique with a curved vs a straight stylet: 2-year clinical outcomes and sensory responses to lead stimulation. *BJU Int* 2019;123(5A):E7-13.
20. Snellings AE, Grill WM. Effects of stimulation site and stimulation parameters on bladder inhibition by electrical nerve stimulation. *BJU Int* 2012;110:136-43.