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Sacral neuromodulation for refractory lower urinary tract dysfunctions: a single-center retrospective cohort study

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ABSTRACT

Objective. Sacral neuromodulation (SNM) is a technique that electrically stimulates the third sacral spinal nerve root to modulate a neural pathway. In this study, we present our 7-years' experience outcomes and complications of SNM in lower urinary tract dysfunctions.
Materials and Methods. We performed a single-center retrospective cohort study of all patients who underwent InterStim Medtronic SNM device implantation for lower urinary tract dysfunction. All procedures were performed between January 2014 and November 2021 in the Urogynecologycal Center of Villa Sofia Hospital in Palermo by a single expert team. We included 68 patients with refractory lower urinary tract dysfunction who did not adequately respond to primary therapeutical strategies.
Results. We observed a reduction rate of catheterization from a mean of 4.05 to 1.22. In addition, the amount of post-voidal residual decreased from a mean of 520 ml to 187 ml. Among the 41 women in the overactive bladder group, only 36 were included in the follow-up; 24 of the 36 patients (66.6%) had no episodes of leaks; the remaining patients (33.4%) had a significant reduction of leaks. We also recorded a significant reduction in urinary frequency: voids per day decreased from 16.1 at baseline to 6.1. Among the 7 women with BPS, only 5 patients (71.42%) completed the follow-up protocol. They reported satisfaction from the treatment: no patients chronically used pain drugs, and only 1 used occasionally painkillers.
Conclusions. SNM treatment has been found as a potential effective and feasible option for urogynecologycal disorders.

INTRODUCTION

Sacral neuromodulation (SNM) is a technique that electrically stimulates the third sacral spinal nerve root to modulate a neural pathway [1]. In 1997, the Food and Drug Administration (FDA) approved SNM for the treatment of refractory overactive bladder (OAB) and retention-voiding dysfunction (R-VD), commonly associated with several conditions [2, 3]. SNM has also demonstrated a significant role in the treatment for interstitial cystitis/bladder pain syndrome (IC/BPS) [4]. Although the mechanisms through which SNM acts are still debated, accumulating evidence suggests that it modulates the afferent neuronal way, improving sphincter-detrusor contraction.

Lower tract urinary dysfunctions are one of the most important and ongoing health problems worldwide, especially in women [5-8] and may cause a severe impairment of quality of life [9, 10]. Different approaches and interventions have been developed in this peculiar field, all embracing new devices with a broad utility [11-14]. It has been estimated that overall prevalence of OAB symptoms is 12.8% [15], while the prevalence of R-VD varies from 2.7% to 29% [16]. Recent studies show that 2.7% to 6.5% of women have a diagnosis of BPS [17, 18].

In addition, several studies report the safety and efficacy of SNM, and we had previously reported our preliminary experience with SNM in patients with refractory OAB [19]. In this study, we present our 7-years' experience outcomes and complications of SNM in lower urinary tract dysfunctions (LUTDs).

MATERIALS AND METHODS

We performed a single-center retrospective cohort study of all patients who underwent InterStim Medtronic SNM device implantation for lower urinary tract dysfunction.

All procedures were performed between January 2014 and November 2021 in the Urogynecologycal Center of Villa Sofia Hospital in Palermo by a single expert team.

We included 68 patients with refractory LUTDs that did not adequately respond to lifestyle modifications, bladder training, pelvic floor therapy, and pharmacological therapy administered for a duration of at least 8-12 weeks. All LUTD diagnosis were made according to the International Continence Society definitions [20] and included OAB, R-VD and IC/BPS. (in previous treatments) and e ana (in order to exclude other known causes of LUTDs). Exclusion criteria were partial benefit from previous non-interventional therapies, non-adequate compliance to the study protocol. Major health problems which could affect the therapy program and the subsequent follow-up were considered as exclusion criteria as well.

IC/BPS was defined as persistent or recurrent chronic pelvic pain, pressure, or discomfort perceived to be related to the urinary bladder accompanied by ≥ 1 other urinary symptom like an urgent need to void or urinary frequency [21]. R-VD was defined as a complete or incomplete retention or abnormally slow urine flow rate and/or an abnormally high post-void residual without any anatomical obstruction. OAB syndrome was defined as urinary urgency, usually accompanied by frequency and nicturia, with or without urgency urinary incontinence, in the absence of urinary tract infection (UTI) or other obvious pathology.

SNM was performed in two stages: all patients underwent a test period (tined-lead evaluation [TLE]) under x-ray followed by a permanent InterStim II device (Medtronic Inc) implantation. Patients were considered for permanent SNM device implantation only if there was a ≥ 50% improvement in any of the symptoms and confirmed by objective measures of voiding diary. During stage 1, a test electrode (TLE) was placed percutaneously unilaterally into the sacral foramen S3 (S2-S4) under local anesthesia or analgesic sedation. During stage 2, a battery-powered implantable pulse generator (IPG) was positioned in the fatty tissue of the gluteal region on the side of the electrode and connected to the test electrode under local anesthesia or analgesic sedation [22].

After implant surgery, a Medtronic's Specialist programmed the IPG with variable parameters in amplitude (V), rate (Hz), width (s), and stimulus duration depending on urinary dysfunction and patient's response. These parameters were changed as needed on follow-up. The patients were taught how to turn their stimulator on or off and adjust its amplitude. All patients were followed for 1, 3, 6, 12 months and annually, or as clinically indicated, thereafter following device implantation.

The primary outcome was a percentage of overall symptoms improvement and device retention at final follow-up. All patients who failed SNM (no clinical improvement or device intolerance due

to significant complications or patient's request) had their devices removed. Secondary outcomes included: pads used in 24 hours before and later implantation, number of catheterizations in 24 hours before and later operation, use of painkillers in 24 hours before and after implantation, post-operative complications, and re-operation rates. The following complications were evaluated: pain, lead migration, skin erosion, seroma, hematoma, wound dehiscence, cellulitis, deep wound infection, abscess, and device malfunction.

Data analysis

Data analysis was performed in all test responders. Percentage and absolute value were calculated for episodes of leaks, voiding, pads and catheterization. The t-test and Wilcoxon test were used to compare continuous variables, Fisher test for categorical variables. The IBM SPSS statistics 26V was used as software package.

RESULTS

Between January 2014 to November 2021, we evaluated 68 female patients with an average age of 54 years old (range 23-70 years old): 41 patients (60.29%) had OAB syndrome with urinary incontinence, 20 patients (29.41%) had R-VD, while 7 patients (10.29%) had BPS.
We recorded a post-operative complication rate of 4.41%: in 2 patients there was a wound abscess, while in 1 patient a migration of the lead occurred. In the two patients with abscess, the lead was removed and not reimplanted due to inefficacy, so they were not included in the follow-up group; while in the other patient with migration of the lead, another one was reimplanted.
The average of follow up was 43 months. Among 68 implanted subjects, 3 were lost at follow-up (4.41%), 9 patients (13.23%) declined to be enrolled. Indeed, 54 of 68 patients (79.41%) were included in the follow-up protocol. Among these patients included in the follow-up, only in 3 patient (5.55%) NMS was removed due to inefficacy after a median period of 36 month.

Overactive bladder

Among 41 OAB group, only 36 were included in the follow-up. 24 of the 36 patients (66.6%) had no episodes of leaks, the remain patients (33.4%) had a significant reduction of leaks. We also recorded a significant reduction in urinary frequency: voids per day reduced from 16.1 at baseline to 6.1.

Retention-voiding dysfunction

Among the 20 women in the R-VD group, only 13 (65%) were included in the follow-up. We observed a reduction rate of catheterization from a mean of 4.05 to 1.22. In addition, the amount of post-voidal residual decreased from a mean of 520 ml to 187 ml.

Bladder pain group

Among the 7 women in bladder pain group, only 5 patients (71.42%) completed the follow up protocol. They reported satisfaction from the treatment: no patients chronically used pain drugs, and only 1 used occasionally painkillers.

DISCUSSION

In the field of IC/BPS, few studies investigate about the efficacy of NMS and the indications remain still unclear. In our study, we provided evidence that NMS could be a safe and efficacy procedure and an alternative treatment to pharmacological and behavior therapy in patient with IC/BPS. The success rate of this group in our study was 71.42% after a median follow-up period of 42 months. To date, only smaller observational studies were published so far, with the success rate ranging between 48% and 72% [23, 24].
A retrospective study conducted by Kaaki and Gupta show a success rate of 75% after a median follow-up of 3 years in patients with OAB [25]. In addition, a retrospective study by Ismail *et al*. conducted in 34 patients with idiopathic OAB reported a success rate of 63% after a median follow-up of 9.7 years. This relatively lower success rate could be a function of a long follow-up period [26, 27]. Another retrospective cohort study by Singh *et al*. in 65 refractory OAB patients reported a success rate of 91%. The higher improvement rate could be attributed to a shorter follow-up period [28].
In our study, in the OAB group we observed a success rate of 66.6% after a median follow-up period of 42 months, comparable with other approaches [10].
In the R-VD group, we observed a significant decrease in catheterization, from a value of 4.05 at

baseline to 1.22, with success rate of 65% after a median follow-up period of 42 month, similar to other available techniques [29,30]. Jonas *et al*. in a trial of randomized patients with urinary retention reported statistically and clinically significant improvements in the SNM group: 83% of patients with SNM had greater than 50% improvement in catheter volume per catheterization, compared to 9% of the control group at 6 months [28].
Approximately 5.55% of our patients underwent removal of the device after a median period of three years. In a similar study, Peeters *et al*. reported that 18% of 217 patients with SNM for various LUTDs, at mean follow-up of 3.9 years, required device removal, and 41% of 217 patients required re-intervention, with the majority occurring after less than 2 years of follow-up [31].
Two of the patients underwent device removal due to inefficacy, while one because she had to undergo MRI. Now this problem could be resolved using a rechargeable SNM device, approved in September 2019 with a conditional safety for 1.5 Tesla full body MRI and 3 Tesla head MRI [32].
We also investigated some concomitant factors including pelvic organ prolapse, concomitant stress urinary incontinence, diabetes, fecal incontinence, urodynamic parameters, and patients' demographic data (such as age, race, and Body Mass Index), and we did not find any significant predictors of NMS success.
On the one hand, the analysis of the factors associated with SNM is still mixed and inconclusive, probably because of the differences in patient populations and types of factors evaluated across studies. Indeed, Kaaki and Gupta [25], Ismail *et al*. [26] and Starkman *et al*. [33] did not find any significant predictors of SNM success. On the other hand, a study has reported age under 55 years to be significantly associated with a higher cure rate [34]. While one study found SNM to be more successful in patients with more severe incontinence [35], another one reported that SNM is equally effective in treating both less severe and more severely affected groups [36]. Furthermore, one study found increasing Body Mass Index to be associated with a lower likelihood of success with SNM [37].
We had a post-operative complication rate of 4.41. Regarding this point, Peters *et al*. showed that 64.9% of 407 patients with SNM developed complications in a follow-up period of 4 years [38], while Sukhu *et al*. showed a complication rate of 30%-40% within 5 years of permanent implantation [39].

Strengths and limitations

Our study adds evidence with positive results for the SNM administration in LUTDs, with a follow-up of almost 42 months. However, our main limitations rely on the moderate number of patients, the retrospective design of the study, and the non-targeted population. Moreover, the record of the right perception of symptoms was difficult and the medium-term follow-up may affect the real efficacy on long-term follow-up. For this reason, results can be low-powered and request observational study support to strengthen the SNM efficacy for our group of patients. Future perspectives of our center consist in targeting the population for every single LUTDs symptom presentation.

CONCLUSIONS

The efficacy of SNM in urological disorders has been investigated in several studies, and the main indications remain treatments of urgency, urinary retention. Few studies investigated about the effectiveness of SNM in patients with bladder pain syndrome.
Our study, despite its limitations, adds new elements in the growing evidence base on the medium-term safety and efficacy of SNM in refractory lower urinary dysfunctions. Nevertheless, other studies from other centers and with larger sample sizes are needed to validate our findings.

COMPLIANCE WITH ETHICAL STANDARDS

Authors contribution

S.C., G.B.: Writing – original draft, writing – review & editing; P.S., E.G., T.P., G.C., F.P., C.M., G.G.: Data curation and review & editing.

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Study registration

N/A.

Disclosure of interests

The authors declare that they have no conflict of interests.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Data sharing

All data are provided within the document.

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