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ORIGINAL ARTICLE

Sacral neuromodulation for fecal incontinence in Latin America: initial results of a multicenter study

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Abstract

Background Sacral neuromodulation (SNM) is a widely used therapeutic option for fecal incontinence (FI). Larger series are mainly from Western countries, while few reports address the results of SNM in less developed or less wealthy countries. The aim of the present study was to evaluate the efficacy of SNM in patients with FI in Latin America.

Methods A retrospective study was conducted on patients with FI who had SNM between 2009 and 2016 at 15 specialized colorectal surgery centers in Latin America. Main outcomes measures were functional outcomes, postoperative complications, requirement of revisional surgery, and requirement of device removal. All patients had failed conservative management and had clinical assessment including recording of the validated Cleveland Clinic Florida Fecal Incontinence Score (CCF-FIS) and, when available, anal manometry and endoanal ultrasound. Patients were followed up for a median of 36.7 (1–84) months.

Results One hundred and thirty-one patients [119 females, median age of 62.2 (range 19–87) years] were included. The most common etiology of FI was obstetric injury ($n=60$; 45.8%). After successful test lead implantation, the stimulator was permanently placed in 129 patients (98.5%). One patient failed to respond in the test phase and one patient did not proceed to permanent implantation for insurance reasons. Nineteen patients (14.7%) had 19 complications including infection ($n=5$, 3.8%), persistent implant site pain ($n=5$, 3.8%), generator/lead dislodgment ($n=5$, 3.8%), malfunctioning device ($n=3$, 2.3%), and hematoma ($n=1$, 0.7%). Reimplantation after the first and second stages was necessary in 2 (1.5%) and 3 patients (2.3%), respectively. The device removal rate was 2.2%. At a median follow-up of 36.7 (range 1–84) months, the CCF-FIS significantly improved from a preoperative baseline of 15.9 ± 2.98 to 5.2 ± 3.92 (95%CI: 15.46 vs 4.43; $p<0.0001$). Overall, 90% of patients rated their improvement as "significant".

Conclusions Sacral nerve stimulation for FI is safe and efficient, even in less wealthy or less developed countries.

Keywords Fecal incontinence · Sacral neuromodulation · Complications · Lead explantation · Device explanation · Migration, Infection

Introduction

Fecal incontinence (FI) is an underreported condition that can profoundly impact an individual's quality of life. FI has a high prevalence among women due to obstetric injury. During vaginal childbirth sphincter injury occurs in up to 65% and occult sphincter defects are seen in 21–43% of cases [1–3]. Although FI may affect up to 50% of the population, only 10–30% of afflicted patients are likely to discuss this problem with their primary physician [4, 5]. In many cases, individuals live with this condition for years before seeking treatment, due to embarrassment or because of the

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assumption that some degree of incontinence is "normal" or lack of knowledge of therapeutic options [1, 6, 7]. These issues result in delayed intervention, which may negatively impact outcomes of treatment. Treatment is challenging for both the general practitioner as well as the colorectal surgeon, given the challenges associated with the various surgical techniques [8–13].

Initial management options can simply include dietary changes and added fiber, bulking and anti-diarrheal agents, as well as perineal exercises. In addition, biofeedback/pelvic floor retraining has proven beneficial. However, in more severe cases of FI where conservative and less invasive management fails, more invasive surgical options may be required including repair (sphincteroplasty), replacement (muscle transposition/interposition, artificial bowel sphincter), augmentation (injectables radiofrequency, slings), stimulation [posterior tibial nerve stimulation, sacral neuromodulation (SNM)] and diversion (continence enema, colostomy).

SNM was only recently launched in Latin America, but the high cost inhibits its use. Other factors slowing the uptake of SNM include patient compliance, lack of resources, and disparity in education.

In light of these challenges, a consensus conference of surgeons who perform SNM in Latin America was convened in February 2016 in Bogotá, Colômbia by the senior author (SDW). The purpose of the conference was to discuss indications and barriers to the use of SNM in these economically challenged countries. The discussion revealed the need for a multicenter study to assess the outcomes of patients who have had SNM for FI. The concept for this multicenter study was by the senior author (SDW). The summit was funded by Medtronic, Inc, although Medtronic had no role in the selection of participants, creation of the agenda, and/or the material presented. Moreover, Medtronic had no role in data analysis related to the study or in the preparation or editing of this manuscript.

Materials and methods

Patients

All patients with FI who had third sacral (S3) SNM between 2009 and 2016 at one of the 15 participating centers in Latin America were identified. All patients had failed conservative management and had clinical assessment including recording of the validated Cleveland Clinic Florida Fecal Incontinence Score (CCF-FIS) and, when available, anal manometry, and endoanal ultrasound [14]. Main outcome measures were functional outcomes, postoperative complications, requirement of revisional surgery, and requirement for device removal.

Patient selection

All patients who had unsuccessful conservative treatment, including dietary modification, antidiarrheal agents, and biofeedback therapy/pelvic floor retraining and who had a CCF-FIS > 12 were considered candidates for SNM. Patients with a very hypotonic sphincter on anorectal manometry, in whom denervation was suspected, were also considered candidates for SNM. Patients who were unresponsive during the test phase and did not undergo stimulator implantation were excluded.

This study was exempt from Institutional Review Board approval in Latin America. All patients gave written informed consent prior to surgery.

Follow-up consisted of office visits and telephone interviews regarding the CCF-FIS and questions related to the patient's quality of life and their perception of overall improvement at 1 and 2 weeks and 1 and 3 months after implantation. All patients completed a bowel diary at baseline and during the test phase.

Surgery

All participating surgeons had the same didactic and "hands-on" cadaver lab training prior to, and proctoring during, their initial SNM procedures.

Percutaneous nerve evaluation (PNE) is not available in Latin America; therefore, all patients had a first stage procedure with the electrode placed through the S3 foramen connected to the external generator for a 2–3-week period. All surgeons were trained to insert the lead into the S3 foramen for optimal results. Leads were inserted following a path very close and parallel to the S3 nerve. This optimal placement allows all 4 electrodes to produce a motor and sensory response, and each response was obtained by electrical stimulation at very low voltage. Patients were placed in the prone position after fluoroscopic location of the S3 foramen. Under local anesthesia, the needle was inserted parallel to the midline as far cephalad and medially as possible within the foramen. Once the lead was positioned, each of the 4 electrodes was tested documenting the amplitude threshold at which the appropriate motor responses were seen, all less than 2 V. Although both left and right S3 nerve testing was undertaken, S4 testing was not considered.

Successful test lead implantation was defined as a reduction of > 50% in FI episodes during the test phase. Two weeks following temporary stimulator placement, under local or intravenous sedation, definitive implant of the pulse generator was performed. The implant was inserted into a subcutaneous pocket deep in Scarpa's

fascia, over the superior area of the gluteus maximus and distal to the iliac crest. All patients received preoperative prophylactic antibiotics (the majority were given vancomycin).

Data collection

Data from each participating surgeon at the 15 centers were collected and entered onto a single database, maintained by the lead author (LO). Data included patient demographics (Table 1), CCF-FIS, operative details, manometry data, and postoperative complications. Main outcome measures included functional outcomes, postoperative complications, and requirement of revisional surgery and/or device removal.

Statistical analysis

Statistical analysis was performed using Instat2. A p value of < 0.05 was considered significant. The Mann–Whitney test was utilized for analysis of any change in the pre- and post-SNM CCF-FIS.

Table 1 Number of patients per center

Surgeon	Number of cases
CML	23
LO	14
JACS	4
GH and JCR	20
JPA	11
JCSR	6
VHGG	11
MLT	18
GR	4
SMR	3
LM	4
EV	3
DL	2
VGF	8

CML Carlos Miguel Lumi, *LO* Lucia Oliveira, *JACS* Javier Alejandro Carrera Siachogue, *GH* Gonzalo Hagerman, *JCR* Juan Carlos Reyes, *JPA* Javier Perez-Aguirre, *JCSR* Juan Carlos Sanches-Robles, *VHGG* Victor Hugo Guerrero–Guerrero, *MLT* Marla L. Torres, *GR* Guillermo Rosato, *SMR* Sthela Murad Regadas, *LM* Luciana Marzan, *EV* Eduardo Vieira, *DL* Doryane Lima, *VGF* Valdomiro Garbugio Filho

Results

One hundred thirty-one patients [119 (90%) females; median age: 62.2 (range 19–87) years] had SNM at 15 participating centers in Latin America (Table 1). The median number of vaginal deliveries was 1.6 (range 0–11). After successful test lead implantation, the stimulator was successfully placed in 129 patients (98.5%), who were included in this analysis. The generator was not implanted in 2 patients, due to lack of response in the test phase in one patient and due to insurance issues in the other.

The etiologies of FI are listed in Table 2, with the majority related to obstetric trauma (60; 45.8%). Of these, 22 (36.6%) had SNM without having had a prior sphincteroplasty. The median follow-up was 36.7 (range 1–84) months.

At follow-up, the CCF-FIS significantly improved from a preoperative baseline of 15.9 ± 2.98 to 5.2 ± 3.92 (95% CI 15.46 vs 4.43; $p < 0.0001$) (Fig. 1). Overall, 90% of patients rated their improvement as "significant". Figure 2 shows statistically significant improvement in both frequency of FI episodes and urgency at baseline and after the test phase from the patients' bowel diaries ($p < 0.001$, unpaired t test).

Complications occurred in 19 (14.7%) patients (Table 2). Reimplantation after the first and second stages was necessary in 2 (due to electrode dislodgement) and 3

Table 2 Patient Demographics

Variables	Patients $n = 129$
Mean age (years)	62.2 (range 19–87)
Gender (M:F)	12:119
Etiology	
Obstetric (%)	60 (45.8%)
Neurologic disease	40
Low anterior resection syndrome	13
Post-surgery/trauma	11
Congenital	4
Post-rectal prolapse	2
Inflammatory bowel disease	1
Preoperative manometry assessment	
Mean resting pressure (range)	23.9 (9–65) mmHg
Mean squeeze pressure (range)	48 (14–156) mmHg
Complications	$n = 19$
Infection	5 (3.8%)
Dislodgement	5
Persistent pain	5
Malfunction	3
Hematoma	1

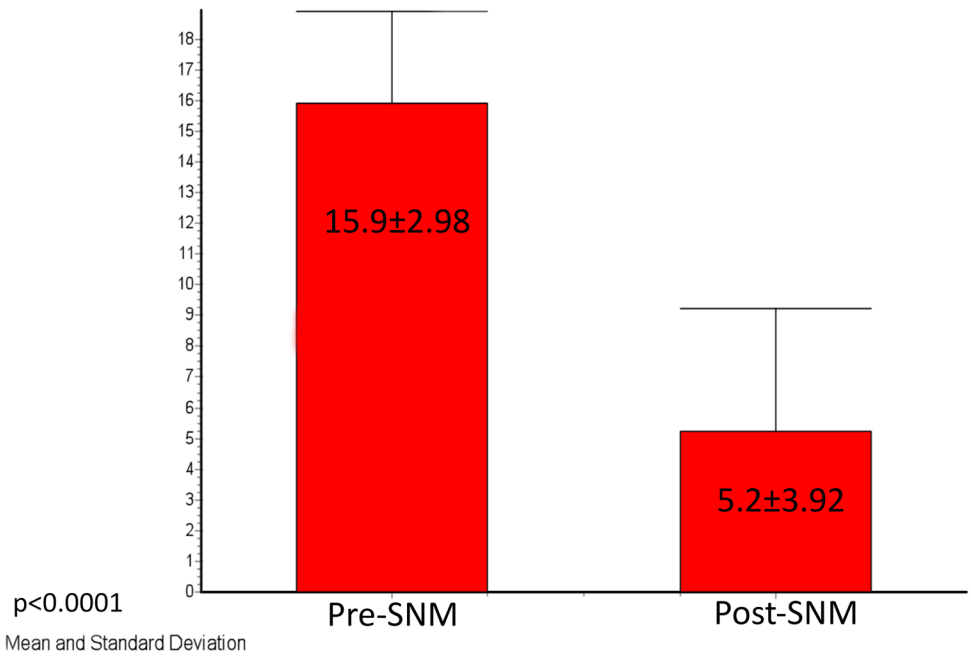

Fig. 1 Improvement in Cleveland Clinic Florida–Fecal Incontinence score (CCF-FIS), pre- and post-sacral neuromodulation (SNM)

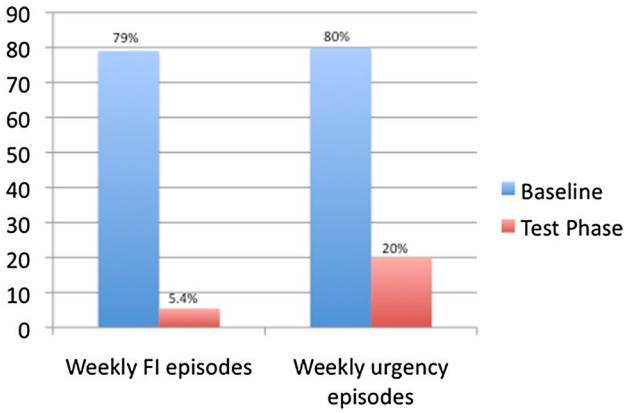

Fig. 2 Number of patients with improvement in frequency of incontinent episodes and urgency at baseline and after the test phase

(battery depletion) patients, respectively. The device was explanted in 2 patients (2.2%), one due to pain and the other due to infection, both at the site of the generator.

Discussion

In this first Latin American series of patients undergoing SNM for FI, the overall results are very satisfactory with a significant improvement of symptoms in 90% of patients. These results compare favorably with the results from the USA, Canada, Australia, the UK and Western Europe [15–20]. The infection rate in our study of 3.8% is similar to multicenter SNM studies in the literature [15–20]. In addition, the relatively low device explantation rate of 2.2% may indicate good patient selection and treatment. The relatively high success rate may be due to patient selection and meticulous technique. In addition, some patients may have had to share in the cost of the SNM and, therefore, could have been highly motivated.

Cost effective management compares the cost and health effects of an intervention to obtain the best results with expenditure of the least healthcare resources. In the case of SNM, variables that may impact this goal include the incidence and severity of morbidity and appropriate patient selection to ensure optimal efficacy. Limited appropriate preoperative investigation is an important first step. Since the best predictor of successful SNM is a successful test period, extensive physiologic investigations can potentially be avoided. In Latin America, the decision to offer SNM is often based on the surgeon's clinical judgement and quality of life evaluation of the patient. To minimize morbidity, appropriate administration of perioperative antibiotics combined with meticulous operative technique may be associated with limited occurrence of infection, as seen in this series. Optimal lead placement was our goal in prolonging pulse generator life, limiting the need for lead replacement and allowing for future reprogramming, as needed.

The limitations of this study are its retrospective and non-randomized nature. However, the reproducibility of patient selection by all centers and utilization of the same validated incontinence score (CCF-FIS) allowed similar evaluation and analysis of the results. In addition, all surgeons were trained following the same principles: cadaver lab and

surgical procedures under proctored monitoring. Adequate surgical training is important to ensure correct electrode implantation and optimal stimulation results. Another limitation of this study is the lack of post-implantation quality of life assessment in all patients.

Randomized trials that include cost analyses and comparisons with other therapies are needed in Latin America. Furthermore, it would be important to compare costs associated with SNM to other treatment modalities. Although SNM can be prohibitively costly for most, the advantages of this procedure such as improvement in lifestyle and quality of life, should be measured against the actual costs for a demonstrable model to prove the true benefits of this procedure.

Conclusions

Sacral neuromodulation is safe and efficient treatment for FI, even in less wealthy less developed countries.

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Author contributions All authors: Final approval of the version to be published; Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Compliance with ethical standards

Conflict of interest Wexner: Paid consultant for Medtronic. Oliveira, Hagerman, Torres, Lumi, Marzan: Paid consultant for Medtronic. Carrera Siachoque, Reyes, Perez-Aguirre, Sanchez-Robles, Guerrero, Regadas, Gaburgio Filho, Rosato, Vieira, Lima, Londoño-Schimmer: None.

Human and animal rights All procedures were in accordance with the ethical standards of the institution and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Ethics approval This study was exempt from Ethics approval from the participating institutions.

Informed consent All patients gave signed informed consents prior to their surgery.

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