Sacral nerve stimulation in the treatment of fecal incontinence – the experience of a pelvic floor center : short term results

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Abbreviations: SNS, sacral nerve stimulation; FDA, Food and Drug Administration

Objectives: The aim of this paper is to present the data pertinent to the experiences of our Pelvic Floor Center on the utilisation of SNS in the treatment of fecal incontinence and compare these data to the data of current literature.

Methods: All patients who had had SNS treatment for fecal incontinence between the dates of 1st April 2008 and 1st April 2011 were enrolled in the study. We considered a 50% reduction of fecal incontinence episodes as a success of the test phase. The score used for assessment was the Cleveland Clinic Florida-Fecal Incontinence score (CCF-FI).

Results: The 21 patients treated for fecal incontinence (19 ♀ and 2 ♂, average age 59.7 [26-73] years) were sub-divided on the basis of the presence or absence of sphincter damage (group A1 had damage while group A2 did not). A patient (group A1) was excluded from the study as the result of the external connector breaking during the test phase. Of the 20 remaining patients (9 from group A1 and 11 from A2), 14 (70%) felt benefit and subsequently underwent definitive stimulator implantation. The variation between the pre-operative CCF-FI and the value at 6 months was statistically significant both in group A1 ($p=0.009$) and in group A2 ($p=0.003$). The only complication reported was one case (7.1%) of infection of the definitive stimulator.

Conclusion: SNS represents an effective treatment for patients with fecal incontinence. The results have been encouraging, and in line with current literature.

Introduction

The concept of sacral nerve stimulation (SNS) was developed at the University of California in San Francisco in 1979 by Schmidt et al.¹ In 1994, this therapy was awarded the mark of recognition of European Conformity and in 1997 received the approval of the Food and Drug Administration (FDA) for urological disorders.

The first evidence that this approach could possibly be used in the treatment of fecal incontinence was reported by Matzel and Erlangen² in 1995. Although the action mechanism is not yet clear,³ this therapeutic approach has gained wide consensus both in urinary and colon-proctology spheres, demonstrating success percentages, relative to the pathology, which are clearly interesting.

The aim of this paper is to present the data pertinent to the experiences of our Pelvic Floor Center, in the Sassuolo Civil Hospital, on the utilisation of SNS in the treatment of fecal incontinence and compare these data to the data of current literature.

Materials and method

All consecutive patients who had had SNS treatment for fecal incontinence in our Pelvic Floor Centre between the dates of 1st April 2008 and 1st April 2011 were enrolled in the study. The data, which were retrospectively analysed, were extracted from a prospectively-maintained database.

Inclusion criteria included chronic fecal incontinence with or without sphincter damage, of duration greater than 6 months. Exclusion criteria included spina bifida or sacral malformation, sphincter damage > 180°, pregnancy, untreated pilonidal sinus, immune deficiency, multiple sclerosis for the necessity of MRI surveillance and major psychological instability.

All the patients, who had received accurate clinical assessment, by means of rectal examination and anoscopy, underwent the following examinations: Colonoscopy; Endoanal Ultrasonography, Ano-rectal manometry and, in selected cases (of suspected internal rectal prolapse), a defecography.

Moreover, the patients had initially been treated with medical therapy and subsequent rehabilitation (biofeedback and/or Neotonus™ system). Those patients who had not responded

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positively to these therapies were offered SNS.

The symptoms during the first phase of stimulation were monitored by the patients themselves, by means of a diary. We considered a 50% reduction of fecal incontinence episodes referred by the patient as a success of the test phase.

The first phase of SNS was carried out in all cases under local anesthetic, without sedation and in day-surgery. Tined lead was used (3093 Medtronic) with the dedicated kit to aid insertion in S3 foramen (right foramen or, if there wasn't a good response at the intraoperative stimulation, in left foramen). After a 4-week trial period, the patient was re-assessed and then a decision was taken as to whether to implant a definitive Interstim™II (Model 3058; Medtronic) stimulator or remove the electrode.

Both the second phase of therapy and the removal of the electrode, in the event of non-efficacy, were carried out under local anesthetic and in day-surgery. Antibiotic treatment, Cefazolin 2 g, was used in all processes of the procedure and then prolonged at home with Cefibuten 400 mg/per day for 5 days. In the event of allergy to Penicillin, Clindamycin was prescribed.

The stimulation parameters set on the definitive stimulator are strictly co-related to the values set during trial stimulation and therefore vary from patient to patient. In general terms, the initial impulse width was 210 µs, with an amplitude of 2 V and a frequency which, for fecal incontinence, was maintained around 15 Hz.

The score used for initial assessment and a minimum follow-up period of 6 months was the Cleveland Clinic Florida-Faecal Incontinence score (CCF-FI). We have data after one year only for a group of implanted patients.

Statistical analysis

The significance of the variation of non-parametric data from pre- to post- operation was assessed by means of the Mann-Whitney U test. A value of $p < 0.05$ was considered statistically significant.

The parametric data were presented with the mean value (range) and the non-parametric data were presented with the median value (range).

Results

In our centre, in the period between 1st April 2008 and 1st April 2011, a total of 27 patients were treated with SNS. Of these, 21 for fecal incontinence (77.8%), 3 for constipation (11.1%), 2 for pelvic pain (7.4%) and 1 for urinary incontinence (3.7%) after radical post-prostatectomy.

The 21 patients treated for fecal incontinence (19 ♀ and 2 ♂, average age 59.7 [26-73] years) were sub-divided on the basis of the presence or absence of sphincter damage (group A1 had damage while group A2 did not), this was assessed by means of a 3D endoanal ultrasonography.

Group A1 ($n=10$ ♀ [47.6%]; average age 63.8 [57-73] years) had average damage of 90.1° (40-130) to the external sphincter. In 5 patients (50%) there was also damage to the internal sphincter, on average 70.8° (40-95). The cause of sphincter damage was of obstetric origin in 9 patients (90%) and post-surgical origin in 1 patient (10%). Anorectal manometry showed an average resting

pressure of 39.5 (30.1-72.6) mmHg while the average squeeze pressure was 66.3 (36.9-133) mmHg.

The CCF-FI median of the group at pre-operative assessment was 12 (9-14).

Group A2 ($n=11$ [9♀ e 2♂] 52.4%; average age 56 [26-71] years) presented idiopathic aetiology in 10 patients (90.9%) and post anterior resection of the rectum in 1 patient (9.1%). Anorectal manometry showed an average resting pressure of 41.1 (20-88.4) mmHg and an average squeeze pressure of 79.2 (44-133.8) mmHg.

The CCF-FI median at pre-operative assessment was 14.1 (6-20).

A patient (group A1) was excluded from the study as the result of the external connector breaking during the test phase and the desire, on the part of the patient, to have the implant removed immediately.

Of the 20 remaining patients (9 from group A1 and 11 from A2), 14 (70%) felt benefit and subsequently underwent definitive stimulator implantation.

By analysing the individual groups, in group A1, 6 out of 9 patients (66%) underwent definitive implantation while in group A2, the numbers were 8 out of 11 (72.7%).

During the first month after the definitive implant, another patient (group A1) left the study as the result of infection of the stimulator and the subsequent need to completely remove the implant (1 out of 14 [7.1%]).

The median preoperative CCF-FI of patients who underwent definitive implant in group A1 was 12.9 (9-14) and in group A2 was 13.5 (6-20).

At the six-month follow-up the CCF-FI median of group A1 was 1 (1-4) while for group A2, it was 3.5 (1-13).

The variation between the CCF-FI at the baseline and the value at 6 months was statistically significant both in group A1 ($p=0.009$) and in group A2 ($p=0.003$) (**Fig. 1, Fig. 2**)

We have data of 8 patients (3 group A1 and 5 group A2) at an annual follow-up that shows stable results. CCF-FI median of group A1 was 1 (1-3) while for group A2, it was 3 (1-13).

There were no complications reported in patients who underwent removal of the electrode as the result of inefficacy after the first phase. Those patients returned to be treated with medical therapy.

Discussion

From 1995 to now, SNS for fecal incontinence has been increasingly used. This study aims to highlight the experience of a centre which is dedicated exclusively to anorectal and pelvic pathologies and compare their results with those of current literature.

In our experience, there was not a high number of patients with fecal incontinence candidate for SNS over three years of the centre's activity. This can probably be explained by the adoption, as a first treatment approach, of both medical therapy and rehabilitation of the pelvic floor, by means of classical techniques such as bio-feedback and by also adopting innovative techniques such as Neotonus™. These have resulted in an improvement of the overall clinical situation and a satisfactory symptom solution

Figure 1.

Figure 2.

for most of patients with fecal incontinence.

If we look at the aetiology of fecal incontinence in patients selected for SNS, the obstetric origin of the problem is confirmed as the predominant cause of sphincter lesion while incontinence is of an idiopathic nature in almost all those cases which did not have sphincter damage.

The percentage of patients who underwent definitive implant was around 70% and this data is similar to the current literature data. In effect, the success rate, considered as the 50% reduction of symptoms referred by the patient, which led to definitive stimulator implantation, varied between 49%⁴ and 96%⁵ with percentages which frequently range from 77%⁶ to 90%.⁵⁻⁷

This result, however, includes both patients with muscular damage and patients whose sphincters had no damage.

By analysing the individual groups of our cases who did not have sphincter damage, the percentage of patients who underwent definitive implant rose to 72.7% and this is in line with current literature results.

The presence of a lesion of the external sphincter was initially considered as a contraindication. But over time, we began to observe how this factor did not influence the therapy results in those cases of sphincter damage which was less than 180°. Melenhorst et al⁸ reported a success rate of 70%, even in cases with sphincter damage (inferior to 33% of the circumference). In our series, the patients presented an average damage to the external sphincter of 90.1° which represented approximately 25% of the circumference.

The percentage of definitive stimulator implant was 66.6%.

In order to assess the results obtained after definitive stimulator implant, we chose to use the CCF-FI score, because it was a validated test, it was easy to use and it also provided an assessment of quality of life.

In the 6-month follow-up after definitive implant a statistically significant reduction of the CCF-FI was observed in the two groups of patients examined ($p=0.009$ in group A1 and $p=0.003$ in group A2). The results remained stable, with the same value of CCF-FI, in the group of patients (3 group A1 and 5 group A2)

who had follow-up after a year.

The only complication reported was one case (7.1%) of infection of the definitive stimulator within a month of definitive implant with the subsequent need to remove the electrode. In literature, this kind of complication appears with a frequency varying from 1.6% to 10.8%^{5,8,9} and must not be underestimated because it impacts greatly on the patient, given the frequent need to have to completely remove the implant.

The retrospective nature, the incomplete assessment of quality of life as the result of a lack of specific scores and a short-term follow-up represent the principal limits of this study. The low number of patients is the result of a strict selection process. We maintain that SNS is a valid option for the treatment of faecal incontinence and is to be offered only when medical and rehabilitative therapies have not been beneficial. Its utilisation in the case of sphincter damage, however, is a separate issue. In our opinion, this procedure could be efficacious even before eventual sphincter repair occurs, as the literature would also suggest.¹⁰⁻¹²

Conclusion

In our experience SNS represents an effective treatment for patients with fecal incontinence. The results have been encouraging, and in line with current literature, on both patients with and without sphincter damage. But, in our opinion, it is fundamental to offer this therapy only when a standard medical-rehabilitative approach has not given satisfactory results. There are some key points that have to be still clarified as yet unclear action mechanism and the current absence of pre-operative tests which have a sound positive predictive value with regard to efficacy.

The research in this field with the implementation of random perspective studies are to be hoped for the future, with the aim of improving our understanding of these points and increasing the clinical evidence of results.

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