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Original Article

Patient Satisfaction and Complications Following Sacral Nerve Stimulation for Urinary Retention, Urge Incontinence and Perineal Pain: a Multicenter Evaluation

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Abstract: The aim of the study was to determine the success rate, the complications, the failures and the solutions found in troublesome cases. A retrospective study was performed in three university centers in Belgium. Between March 1994 and April 1998, a quadripolar electrode and a pulse generator were implanted in 53 patients (8 men, 45 women, 43 ± 12 years, mean follow-up 24 ± 8 months, range 13–39 months). During the first few months, 45 (85%) of the 53 patients had an objective response. Eight late failures occurred, with a mean failure delay of 9 ± 5 months. We performed 15 revisions in 12 patients. Major complications were pain and current-related troubles. The outcome was significantly better ($P = 0.001$) in post-stress incontinence surgery patients. Device-related pain was found more frequently in patients with dysuria and/or retention or perineal pain, and the test stimulation was less reliable ($P = 0.025$) in patients with a psychiatric history. Sacral nerve stimulation is efficient in treating patients with refractory lower urinary tract symptoms and/or perineal pain.

Keywords: Incontinence; Neuromodulation; Neurostimulation; Pain; Retention; Voiding dysfunction

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Introduction

Sacral nerve stimulation is a fairly new treatment for refractory urgency and/or urge incontinence, dysuria and/or retention, and perineal pain syndromes. Although the action mechanism is unknown, the presence of pelvic floor dysfunction seems to play an important role in the success of patient selection [1–6]. The main effect of the therapy is probably inhibition of the bladder and/or pelvic floor.

The advantage of this treatment is that the patient can be selected beforehand with test stimulation and a temporary external stimulator. However, failure rates up to 27% after implantation of the neuroprosthesis have been reported [7]. Objectification of the effect of the test stimulation is obviously necessary, as well as longer test stimulations [2,8]. However, very few data are available on long-term results, patient satisfaction, complications and failures and their treatment [9,10]. The aim of our retrospective multicenter study was to determine the response rate, patient satisfaction, complications, failures and solutions found in troublesome cases.

Patients and Methods

A retrospective study was performed in three university centers in Belgium. All patients presenting with therapy-resistant symptoms of urgency, urge incontinence, dysuria, urine retention and/or perineal pain seeking treatment were included in this study. Only pregnant women and prepubertal children were excluded.

We evaluated 177 patients following a subchronic test stimulation with a temporary lead and an external

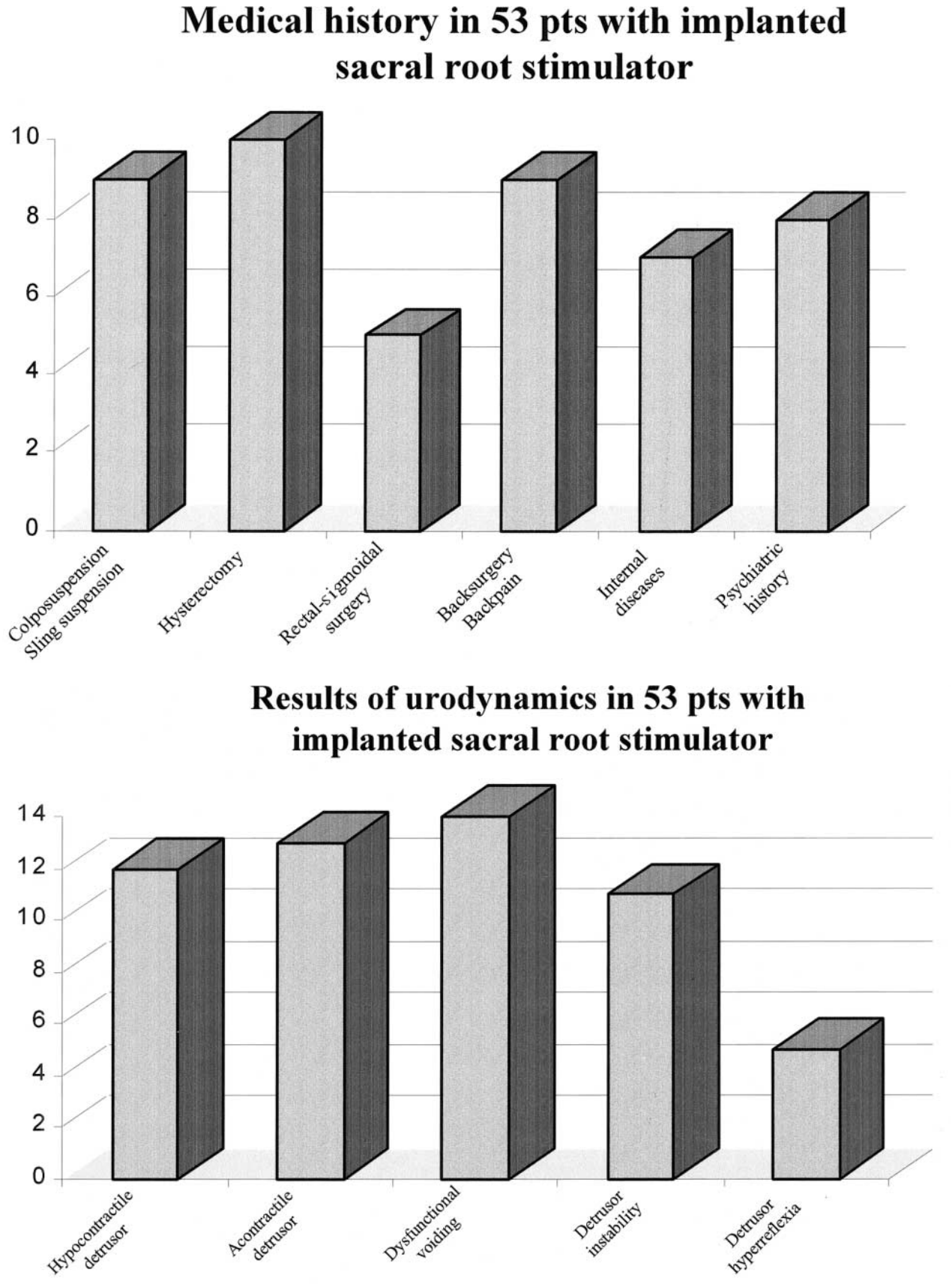

Fig. 1. A sacral root stimulator (S3) was implanted in 53 patients with urge and/or urge incontinence, dysuria and/or retention, or perineal pain.

stimulator (Screener, model 3625, Medtronic Interstim) lasting at least 4 days [1]. The outcome of these test stimulations was evaluated with micturition and/or incontinence diaries in patients with urgency and/or urge incontinence (n = 107), visual analog scales in patients with perineal pain (n = 24), or uroflowmetry and residual urine measurements in patients with dysuria or retention (n = 92).

From March 1994 to April 1998, 53 patients (8 men, 45 women, 43 ± 12 years) were implanted with a quadripolar electrode in the S3 foramen (Medtronic Interstim, model 3886 in 6 patients, model 3080 in 47 patients) and a subcutaneous pulse generator in the abdominal site (Medtronic Interstim: Itrel 2 [n = 8], IPG 3 [n = 45]). Initially we implanted 49 patients with a unilateral lead and 4 with bilateral leads as a result of the test stimulation results (when a bilateral test stimulation was needed to relieve the symptoms). All but 7 patients paid for their implants themselves. Only patients with a follow-up of 12 months were included in the study. The follow-up after implantation was 24 ± 8 months (range 13–49 months).

Patients had symptoms of dysuria and/or retention (n = 38), urgency and/or urge incontinence (n = 22), or perineal pain (n = 19). The medical histories and urodynamics of these patients are summarized in Fig. 1. Patients having previously had surgery for stress incontinence or hysterectomy were implanted with an interval of 6 months to 31 years. Internal diseases were diabetes (n = 2), thyroid disease (n = 1), lung disease (n = 3), hepatitis (n = 1), and cardiac disease (n =1). Psychiatric diagnoses were hysteria (n = 2) and severe depression necessitating hospitalization and/or prolonged drug treatment (n = 6).

Success (before and during the test stimulation, 1 month postoperatively, and at the end of the study) was considered to be a more than 50% decrease in the number of leakages or micturitions in the diaries of patients with urgency and/or urge incontinence, a more than 50% increase on the visual analog scale in patients with perineal pain, and of a normalization (disappearance of staccato voiding or a straining pattern) of the uroflow patterns and/or decrease of residual urine below 50 ml in patients with dysuria and/or retention. Patient satisfaction was recorded at a recent patient visit. Information on complications and revisions was compiled from the patient files. In conclusion, the outcome measures were objective success criteria, patient satisfaction, complications and revisions.

Statistical analysis was done with a χ^2 test.

Results

During the first few months after the implantation, 45 (85%) of the 53 patients had an objective response. Of these, 30 (57%) were considered cured and 15 (28%) improved. Another 8 patients (3 initially cured, 5 improved) were considered late failures, with a mean failure delay of 9 ± 5 months, which reduced the success rate to 70%. No significant differences in outcome were found between patients with symptoms of dysuria and/or retention, urgency and/or urge incontinence, or perineal pain. Patients with a history of incontinence surgery were more likely to be treated efficiently with the implant (P = 0.001). A Kaplan–Meier survival diagram is shown in Fig. 2.

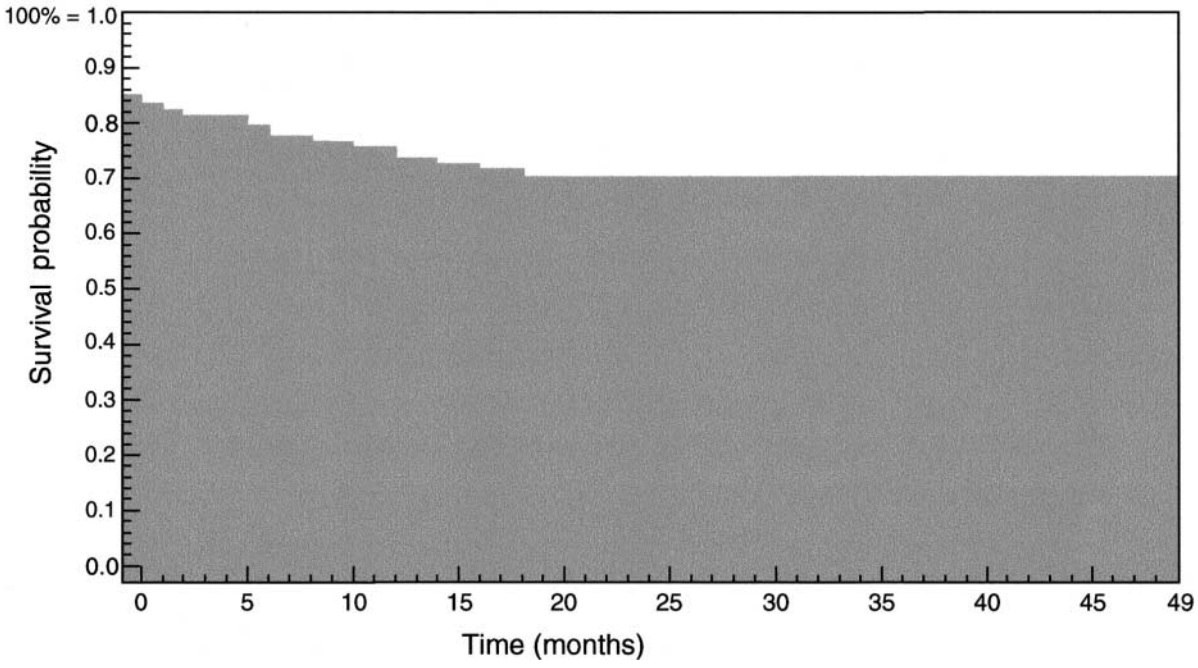

Fig. 2. A Kaplan–Meier survival diagram of 53 patients in whom a sacral root stimulator was implanted.

Patient satisfaction was 68%, and 66% would repeat the procedure if necessary. Nevertheless, 81% were still using the prosthesis. The dissatisfaction with long-term success was explained by the occurrence of complications in all patients. The therapeutic effect of the implant was considered equal to the test stimulation in 34 (64%), poorer in 18 (34%), and better in 1 (2%) patient. The difference in outcome between the test stimulation and the implant did not depend on 'complications' or 'incomplete response', but was significantly related to psychiatric disease in the history ($P = 0.025$).

The complications are listed in Table 1. Device-related pain was the most frequent and occurred equally in all implantation sites (sacral, flank or abdominal). Pain was more frequently reported ($P = 0.001$) by patients with dysuria and/or retention or perineal pain. Device-related pain was treated successfully with physiotherapy in 8 patients. No explantations were performed for this reason. Pain not related to the device was reported by 9 patients: in 2, thoracic radicular pain was diagnosed and treated with physiotherapy; in 1 patient alcoholization of the nerve was performed; 1 patient with a hysterical personality had unbearable pain in the sacral region, which was resolved with psychological support. Gastroenterological disease was found to be responsible for abdominal pain in 2 patients, and so causal treatment wad instituted. No diagnosis was found in the other patients. Current-related problems occurred in 6 patients and were inversely related to the follow-up ($P = 0.001$). Leakage of current along the stimulator ($n = 1$) was handled by changing from unipolar to bipolar stimulation. Difficulties in balancing complications, painful stimulation or effect occurred in 5 patients, of whom 2 had an Itrell 2 with a magnet patient control. Thus far, no revisions have been necessary for amplitudes higher than 3.7 V. High amplitudes (3–3.5 V) were found in 7 patients. Diarrhea occurred in 3 patients, of whom 2 complained of disturbing toe flexion. Both of these patients had an acontractile detrusor. Technical problems with the device were difficulty in controlling the pulse generator (Itrell 2) with a magnet patient control ($n = 2$). Other complications (Table 1) were stimulation-related symptoms such as difficulty in swallowing, heavy sweating and fatigue. Six months after implantation, 1 patient developed generalized fasciculation for which no etiology could be found.

Table 1. Complications after implantation of a sacral nerve stimulator for voiding dysfunction and perineal pain

Complications	*n* (%)
Device-related pain	18 (34)
Other causes	9 (17)
Late failures	8 (15)
Current-related problems	6 (11)
Disturbing toe flexion	4 (8)
Diarrhea	3 (6)
Technical problems with device	3 (6)
Lead migration (model 3886)	2 (4)
Infection	1 (2)
Operation-related problems	1 (2)
Other	4 (8)

We performed 15 revisions in 12 patients. Revisions were made more frequently ($P = 0.004$) in those with a history of internal disease. Revisions for prosthesis-related pain ($n = 3$) were not successful. If a correct S3 muscle response was found, revisions for late failures were useless ($n = 6$). Among these 6 patients, a temporary clinical response occurred in 2 after placement (following a test stimulation) of a new lead in the contralateral S3 foramen, but the ultimate result was failure. Also, placement of bilateral leads as a salvage maneuver in 4 patients was not helpful. Revisions for lead migration ($n = 2$), in which 3886 leads were replaced by 3080 (with fixed anchor) and for an accidental insertion of the lead in an S4 foramen ($n = 1$) succeeded.

Discussion

An 85% early objective effect and an ultimate 70% success rate is a fairly good result in a population with a therapy-resistant condition and with a 15% history of psychiatric illness. A success rate of 70% correlates with a patient satisfaction of 68%. These results are comparable to what has been reported in the literature [11–13]. Although we assumed that patients with an incomplete response after implantation are likely to focus on the residual symptoms, and consequently will not be satisfied in the long term, this was not confirmed by our data. On the contrary, non-satisfaction was explained only by complications, of which the most important was pain. In spite of the 70% long-term success rate, 81% continued using the implant, which indicates some remaining effect. The Kaplan–Meier survival diagram shows that no further failures were seen 18 months after implantation (41 patients had a follow-up of 18 months or more). Long-terms results (53% success rate) in patients with urine retention [14] and on spinal cord stimulation for chronic pain [15,16] suggests that a further decline in our results is to be expected.

We implanted only 30% of the patients evaluated with a test stimulation, as patients had to pay for the implant themselves and therefore only decided to go ahead if the response to the test stimulation was spectacular, and if their symptoms were incapacitating. The percutaneous test stimulation was representative for the early outcome after surgery in 66% of the patients, but 34% found the implanted system less effective. These findings were significantly related to a psychiatric history, but not to incomplete responses or complications. Dysfunctional voiding, perineal pain and urgency, and/or urge incontinence frequently coincide with psychological and emotional lability, even when patients without a psychiatric history are considered [17]. A multidisciplinary approach involving a psychiatrist or a psychologist is advisable.

Interestingly, patients with a history of surgery for stress incontinence had a significantly better long-term result, whatever their symptoms were. Surgery for stress incontinence is complicated by urgency and/or urge incontinence in up to 30%, and dysuria and/or retention in up to 5% of the patients, according to the type of surgery [18]. Dysuria and/or retention symptoms after surgery for stress incontinence may be due to partial denervation of the external sphincter [19]; these patients are also considered ideal candidates for sacral nerve stimulation [5–6].

The complications in our series are comparable with those reported in the literature [11–13]. Device-related pain demanding frequent control visits and/or therapy occurred in 34% of the patients, and significantly more often in those with dysuria and/or retention or perineal pain. Both patients with dysuria and/or retention and those with perineal pain are more likely to be good responders to sacral nerve stimulation if dysfunctional-micturition is diagnosed [3,4]. In 70% of patients with chronic pain or dysfunctional micturition (urethral syndrome, prostatodynia, Fowler syndrome), psychological disturbances are found. Psychologically and emotionally labile patients are reported to have a lower pain threshold [20], which accounts hypothetically for why device-related pain may be reported more frequently by patients with dysuria and/or retention or pain than by those with urgency and/or urge incontinence.

Diarrhea occurred in patients with acontractile bladders, and concomitant disturbing toe flexion was found in these patients. However, only 3 patients had this complication, so that no conclusions can be drawn from it.

In 5 patients difficulty in finding a balance between disturbing stimulation and effect was encountered and was not related to the use of a magnet control or a patient programmer. These current-regulatory difficulties confirm the animal experiment observation that suboptimal stimulation is obtained with unilateral leads, and that bilateral leads may be the solution for these patients [21].

The revision rate was comparable to those reported in the literature [11–13]. Revisions performed in patients with late failures, unlike a correct motor response, failed even after implantation of a contralateral or bilateral lead. Therefore, we consider revisions for late failures with a good S3 muscle response (flexing big toe or several toes, deepening and flattening of buttock groove, circular and contraction) to be unnecessary.

Conclusion

Sacral nerve stimulation is efficient in treating patients with therapy-refractory symptoms of urgency and/or urge incontinence, dysuria and/or retention, or perineal pain. The test stimulation is less predictive of the outcome for patients with a psychiatric history. Device-related pain was the main complication, and was found predominantly in patients with dysuria and/or retention or perineal pain.

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EDITORIAL COMMENT: This is a very well executed study of a relatively good number of patients followed for a significant period of time, and it does confirm the observation of other investigators who have been applying the same technology and the same kind of patients being reported.

It is very clear that this new technology will mature, primarily in the proper selection of patients. It was noted in this manuscript that only 30% of the patients evaluated were implanted, but with the experience they are gaining their selection would probably be much higher than that, as they will be testing more a selective group of patients who have more potential to benefit from this technology. The authors should be commended on their excellent outcome and I am sure it will improve with time and greater experience.

Review of Current Literature

Primary Nocturnal Enuresis: A New Approach to Conditioning Treatment

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Urology 1999;53:405–409

An ordinary home alarm clock was used to treat 125 patients with nocturnal enuresis. In group I the children were awakened after 3 hours' sleep and, if wet, the interval was decreased by 15 minutes the next night. If dry, the interval was increased. A critical time was eventually identified so that the child got up dry, with a full bladder, and was able to void in the toilet. Group II was instructed to have a fixed time to void of 2–3 hours, and then was awakened to void whether wet or dry, and whether or not the bladder was full. All patients restricted fluids for 2 hours prior to bedtime, and voided 1 hour before bedtime and at bedtime. The number of wet nights was recorded and treatment continued for 4 months. Follow-up continued at 3 and 6 months after treatment completion. The mean age was 13 years and the mean wet nights per week was 5. Success for group I (70 patients) was observed in 54 (77%) initially, 46 (66%) at 3 months, and 41 (59%) at 6 months after completion of therapy. In group II (55 patients) there was initial success in 34 (62%), success at 3 months in 31 (56%) and success at 6 months in 29 (53%). The results were not significantly different at 6 months. The dropout rate was 34%. Compared to electronic alarms the initial cure rates were slightly less, but the relapse and dropout rates were similar.

Comment

The alarm clock method is cheap, safe and effective in controlling nocturnal enuresis. There is no concern regarding side effects from medication, and the device is readily available. Some patients are more resistant than others, and there will be a natural selection in terms of completing the therapy. A comparative study would seem to be the next step.