Quality of Life and Morbidity After Permanent Sacral Nerve Stimulation for Fecal Incontinence

Franc H. Hetzer, MD; Dieter Hahnloser, MD; Pierre-Alain Clavien, MD, PhD; Nicolas Demartines, MD

Hypothesis: Permanent sacral nerve stimulation (SNS) is a promising emerging treatment for fecal incontinence. However, there is little data on morbidity and quality of life (QOL) during long-term stimulation.

Design: Prospective trial to assess morbidity and QOL in patients treated with SNS. Median follow-up was 13 months (range, 1-42 months).

Setting: University hospital providing primary, secondary, and tertiary care.

Patients: Between December 2001 and July 2005, SNS was tested in 44 patients (30 women), with a median age of 65 years (range, 15-88 years).

Interventions: Percutaneous nerve evaluation and permanent insertion of an implantable pulse generator.

Main Outcome Measures: Morbidity, stool diary, and Wexner Score for fecal incontinence; Hanley Score for urinary incontinence; and Gastrointestinal Quality of Life Index, the 36-item short form health survey, and the Royal London Hospital questionnaire for QOL.

Results: A permanent stimulator was implanted in 37 patients (84%). Eight patients (22%) experienced complications that required surgical intervention. (A successful restimulation was possible for 5 of those patients.) Adverse effects of SNS were remedied in 5 patients by reprogramming the stimulator. Wexner Scores decreased from a median of 16 points preoperatively (range, 6-20), to a median of 5 points postoperatively (range, 0-13; P<.001). The median number of involuntary stool losses and for urge defecations also decreased significantly. Significant improvement in QOL was found in both generic and incontinence-specific questionnaires (P<.05). The success rate of SNS was 77% (34 of 44 patients) and 92% (34 of 37) in patients with permanent implantation.

Conclusions: The minimally invasive technique of SNS is safe and effective. Most adverse effects can be easily remedied. Our data demonstrate that SNS significantly improves patients’ QOL, including their physical and psychological well-being.

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Fecal incontinence affects approximately 2% of the population,1 with a prevalence of up to 15% in elderly people.2 The inability to control the passage of stool or flatus can produce embarrassment, and fear of such episodes may dramatically limit a person’s activity. Treatment of fecal incontinence is primarily conservative, including dietary advice, antidiarrheal medication, physical therapy (biofeedback), and supportive measures such as the use of pads or anal plugs.3 Conservative treatment, however, is disappointing, and therefore, novel therapeutic options are needed. Overlapping sphincter repair in patients with anal sphincter defects may improve continence from 47% to 100%.4 Although the procedure has some advantages, such as low costs, good availability, and the use of autologous tissue, the initial good results decline with time and become disappointing.5 Additionally, in patients with primary degeneration and weakness of the anal sphincters and pelvic floor, but with no structural defects of the anal sphincters, success rates for sphincter repair or plication are considerably lower, from 10% to 63%.4 Neosphincter therapies, such as dynamic graciloplasty or use of an artificial bowel sphincter, also improve or restore continence, but these operations are demanding and have high morbidity rates.6,7 Long-term results of dynamic graciloplasty have been disappointing and the procedure has not been performed in the United States since 1999. Artificial sphincter implantation is still available in the United States, and the procedure’s cost is reimbursed by insurance carriers. However, the complication rate is very high and up to one third of the implanted devices have to be removed.7 The emerging technique of sacral nerve stimulation (SNS) is minimally invasive and has a low morbidity rate.8

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Sacral nerve stimulation was used initially in patients with urinary incontinence or retention by Tanagho et al in 1989. The first 3 patients treated successfully for fecal incontinence with SNS were documented in 1995. Sacral nerve stimulation treatment for fecal incontinence was approved by the European Community Council in 1995 and its use started in 1999. Since then, the number of patients treated successfully has increased continually. By 2004, 500 permanent stimulators had been implanted in patients in 13 different European countries. During this time, several studies demonstrated the success of SNS in the treatment of fecal incontinence, based on continence scores and stool diaries. A high response rate was observed in patients with neurological incontinence, idiopathic incontinence, and even in patients with sphincter defects. Despite some suggestions that stimulation of the sacral root stimulates afferent sensory nerves, as well as efferent voluntary somatic and autonomic motor nerves, the exact mechanism of SNS remains unclear. Currently, the success of SNS is mainly measured by continence diaries and scores and is defined as a reduction of symptoms or incontinence episodes by more than 50%. Little information is available on medium-term outcome and quality of life (QOL) in patients after SNS for fecal incontinence. Therefore, the aim of this study was to prospectively assess the medium-term outcome and QOL of a consecutive series of incontinent patients treated with SNS.

ETIOLOGY OF INCONTINENCE

Between December 2001 and July 2005, after informed consent, SNS was tested in 44 patients (30 women) with a median age of 65 years (range, 15-88 years). All patients were referred after unsuccessful conservative treatment, which included stool-regulating medications and biofeedback. In 17 patients, the etiology of fecal incontinence was a sphincter defect. In this case, the sphincter, measured by endoanal ultrasound in all patients, was less than 90° in circumference. Three patients had previous sphincter repairs. Idiopathic incontinence was found in 13 patients, and neurogenic incontinence (caused by spinal cord trauma, multiple sclerosis, or residual Guillain-Barré polyneuritis) was found in 7 patients. Six patients experienced incontinence after pelvic surgery (low anterior resection, rectal prolapse surgery), and 1 patient had a congenital sphincter malformation.

OPERATIVE TECHNIQUE

After informed consent, SNS was performed in 2 phases. First, a percutaneous nerve evaluation was conducted and an electrode was implanted, followed by a 2- to 3-week screening phase. Second, if the screening test showed a reduction in the number of incontinence episodes per week of more than 50% (as evidenced by a stool diary), a permanent insertion of the implantable pulse generator was performed. A prophylactic single dose of antibiotics (intravenous cefuroxime and metronidazole) was used for all procedures and in all patients. The technique was described in detail previously. Both steps were performed using local anesthesia, except for patients who requested a general anesthesia for personal convenience. The principal surgeon (F.H.H.) was involved in all procedures and was trained in SNS at the St Marks Hospital in 2000.

At the beginning of this series, the conventional test electrode (model 30576SC; Medtronic, Inc, Minneapolis, Minn) was used in 5 patients for the screening phase. This electrode, however, dislocates easily and before definitive stimulation has to be removed and exchanged for the permanent electrode (model 3080; Medtronic, Inc). For this reason, the strategy was changed after 5 patients in favor of the immediate implantation of the newly designed, permanent-tined lead electrode (model 3889; Medtronic, Inc). Moreover, better screening results have been reported with this new electrode. The last step of the operation, usually performed after 2 to 3 weeks of screening, was the placement and connection of the permanent stimulator (InterStim model 3023; Medtronic, Inc) in a gluteal subcutaneous pocket created on the opposite side of the implanted electrode. The stimulation parameters were identical for all patients: pulse width, 210 µs; frequency, 15 Hz; amplitude was adaptable by the patients (limited range, 0-10 V).

FOLLOW-UP AND QOL

Patients were followed-up at 1, 3, 6, and 12 months after insertion of the implantable pulse generator. Incontinence diaries and QOL questionnaires were self-administered and checked by our clinical nurse. A physician evaluated incontinence scores based on Wexner and Hanley scores during the clinical control period. Quality of life was evaluated prior to therapy and 6 months after the permanent implantation with the use of 3 different questionnaires: the Gastrointestinal Quality of Life Index (SF-36), the 36-item short form health survey, and a bowel-specific questionnaire from the Royal London Hospital. Although not yet validated, the Royal London Hospital questionnaire has shown its value in assessing incontinent patients and is comparable to the subsequently developed American Society of Colon and Rectal Surgeons QOL score. The severity of fecal and urinary incontinence was graded with the Wexner Score and the Hanley Score, respectively.

STATISTICS

Results were documented by their median values and range. To compare the preoperative and postoperative incontinence and QOL scores, the Wilcoxon signed rank test was used. P values less than .05 were considered significant.

RESULTS

The number of patients and percutaneous nerve evaluations are presented in Figure 1. In 6 patients, the screening test—even after a second test, and in 1 case after a third test with a newly placed electrode—did not reduce symptoms. Therefore, these patients were not given permanent implantations. In 22 of 44 patients, the first stage, percutaneous nerve evaluations and the implantation of the electrode, was performed in an outpatient setting (<12 hours). In the remaining 22 patients the median hospital stay was 1 day (range, 1-2 days). Insertion of the implantable pulse generator was achieved in all 37 patients (26 women), median age of 66 years (range, 15-88 years) with no intraoperative complications.

SHORT-TERM COMPLICATIONS

Postoperative complications after permanent implantation occurred in 3 patients (postoperative morbidity of
8%). One patient developed a subcutaneous seroma around the stimulator and needed surgical revision, which was achieved without removing the device. Another 2 patients developed a wound infection after 2 and 4 weeks, and the stimulator had to be removed (Figure 2).

MEDIUM-TERM COMPLICATIONS

Adverse effects of the chronic stimulation were observed in 6 patients. Two patients complained about sleeping disturbance and 4 patients complained about perineal pain or leg pain. Quality of sleep was restored by switching off the stimulator overnight without negative effect on continence. Painful sensations disappeared in all but 1 patient after modification of the stimulation parameters, also without a decrease in the quality of continence. After an unsuccessful replacement of the electrode, the remaining patient with increasing pain in the left leg after 12 months requested a removal of the device and a permanent colostomy (Figure 2).

A loss of SNS efficiency was noted in 2 patients after 8 and 12 months. This was corrected by a new placement of the electrode in 1 patient. The other patient, who had reduced rectum compliance, wanted a colostomy. One woman fell on her hip and broke her arm, and the SNS electrode was dislocated (Figure 3). We could successfully place a new lead and she became continent again.

FUNCTIONAL OUTCOME

The median follow-up of the 37 patients after permanent implantation was 13 months (range, 1-42 months). All data and questionnaires were available for 30 patients at 6-month follow-up. Functional outcome after SNS significantly improved for all patients, from a median preoperative Wexner score of 14 (range, 6-20) to a median score of 5 (range, 0-13) at 6 months (P < .001). Hanley urine incontinence scores also decreased from 0.5 (range, 0-8) to 0 (range, 0-4; P = .12). The median number for involuntary stool losses and the number for urge defections in 14 days are given at baseline, during test stimulation, and at 1, 3, and 6 months after implantation in Figure 4.

Regarding an intention-to-treat analysis, SNS was successful in 34 of 44 patients (77%). However, the successful permanent stimulation after a positive screening phase was 92% (34 of 37 patients).

QUALITY OF LIFE

Significant improvement of QOL was found in patients’ lifestyles (including socializing and relationships), coping and behavior, and depression/self-perception, according to the Royal London Hospital score (Table 1). Analysis of the SF-36 questionnaire showed considerable improvements in subscales; however, a few of the results did not reach statistical significance (Table 2). In the Gastrointestinal Quality of Life Index score (0-
144), significant differences in QOL could be found, from a preoperative median score of 96 (range, 47-128) to a postoperative median score of 107 (range, 36-128; \( P = .02 \)).

In this single-center series including 44 patients, the medium-term success rate of SNS as treatment for fecal incontinence was 77%. Once permanently stimulated, the success rate was 92% at a median follow-up of 13 months. For those patients, the number of involuntary stool losses decreased and continence improved significantly. More importantly, the patients’ QOL increased dramatically and their social life also improved.

Most centers define success of SNS as improvement of an incontinence score of at least 50% and report suc-

**Table 1. Functional Outcome Assessed by the Royal London Hospital Quality of Life Score**

<table>
<thead>
<tr>
<th>Scale</th>
<th>Before Stimulation (n = 37)</th>
<th>6-Month Follow-up (n = 30)</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lifestyle</td>
<td>18 (0-90)</td>
<td>4 (0-54)</td>
<td>.02</td>
</tr>
<tr>
<td>Coping and behavior</td>
<td>35 (0-100)</td>
<td>11 (0-60)</td>
<td>.000</td>
</tr>
<tr>
<td>Depression and self-perception</td>
<td>27 (0-72)</td>
<td>13 (0-43)</td>
<td>.003</td>
</tr>
<tr>
<td>Embarrassment</td>
<td>35 (3-78)</td>
<td>14 (0-54)</td>
<td>.001</td>
</tr>
</tbody>
</table>

*Values are median (range). The score range is between 0 and 100, with low scores indicating better health status.

**Table 2. Functional Outcome Assessed by SF-36 Quality of Life Questionnaire**

<table>
<thead>
<tr>
<th>Category</th>
<th>Before Stimulation (n = 37)</th>
<th>6-Month Follow-up (n = 30)</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>55 (0-100)</td>
<td>85 (10-100)</td>
<td>.03</td>
</tr>
<tr>
<td>Role, physical</td>
<td>50 (0-100)</td>
<td>75 (0-100)</td>
<td>.09</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>58 (10-100)</td>
<td>68 (20-100)</td>
<td>.06</td>
</tr>
<tr>
<td>General health</td>
<td>50 (0-100)</td>
<td>60 (10-95)</td>
<td>.21</td>
</tr>
<tr>
<td>Social function</td>
<td>63 (0-94)</td>
<td>75 (13-100)</td>
<td>.02</td>
</tr>
<tr>
<td>Role, emotional</td>
<td>74 (0-99)</td>
<td>78 (17-99)</td>
<td>.10</td>
</tr>
<tr>
<td>Mental health</td>
<td>60 (0-95)</td>
<td>73 (40-100)</td>
<td>.007</td>
</tr>
<tr>
<td>Vitality</td>
<td>63 (0-94)</td>
<td>66 (25-100)</td>
<td>.007</td>
</tr>
</tbody>
</table>

*Values are median (range). The score range is between 0 and 100, with high scores indicating better health status. SF-36 is the 36-item short form health survey.23
cess rates between 67% to 96%. These success rates are at least equal to, and in many cases superior to, the success of sphincter repair alone or neosphincter procedures. This statement is limited by the studies’ lack of long-term results for SNS. The previous analyses of sphincter repair or neosphincter procedures have a follow-up of 5 years or more, whereas for SNS, only data of up to 3 years are available.

The success of SNS, however, is not only measured by changes of involuntary stool loss or urgency, but also by analyzing QOL. Incontinence affects patients in many different ways, for instance, by matters of leakage, hygiene, and also social embarrassment. As a consequence, new incontinence scores had to be developed to include an assessment of QOL. For incontinent patients (mostly elderly patients), to have to reach a toilet in time is a limiting factor in their ability to socialize. A little improvement in deferring defecation can dramatically increase the patient’s mobility. Our preliminary results, published in a Swiss medical journal, already showed a significant reduction of the Wexner score and a tendency toward QOL improvement. The changes did not reach statistical significance, probably owing to the small number of patients (n=16). However, in the present study, one of the largest single-center studies on SNS, the frequency of involuntary stool loss and urge defecation were significantly reduced in all patients, resulting in significant improvement of QOL. The improvement in QOL scores measured in the present study was also observed in a subanalysis of our patients. Our results also suggest that less specific QOL scores, like the Gastrointestinal Quality of Life Index (developed to assess QOL after laparoscopic cholecystectomy) or the SF-36 questionnaire, adequately assess incontinence after SNS. Although the questions are oriented toward gastrointestinal disorders in general and do not focus primarily on specific changes in lifestyle and mental health for patients with severe fecal incontinence, the improvement in QOL in our patients was so dramatic that with an increasing number of patients, the augmentation in those generic instruments became significant, too.

Morbidity and invasiveness of a procedure are not measured with QOL scores, but are important factors for the comfort of patients and should also be taken into account in the global evaluation of a new surgical technique. We have shown in a subanalysis of our patients that this minimally invasive technique, first described by Spinelli and colleagues, has a low morbidity rate and can be performed easily under local anesthesia and in a 1-day setting. Initially, SNS was performed in 3 stages: (1) percutaneous nerve evaluation (acute stimulation), (2) implantation of a test electrode and screening (subchronic stimulation), and (3) removal of the test electrode and implantation of the permanent electrode and implantable pulse generator (long-term stimulation). Today most centers favor a 2-stage procedure: a combination of percutaneous nerve evaluation with primary implantation of a permanent electrode (model 3080 or 3889; Medtronic, Inc), followed by implantation of the permanent stimulator after 2 weeks. The evolution of this technique may explain the lower implantation rates found in older studies. For example, Uludag et al reported an implantation rate of 71% (27 of 38 patients); and Ganio et al reported a success rate of 26% (5 of 19 patients). In the present study, a permanent implantation was achieved in 34 of 37 tested patients (implantation success rate of 92%).

Complications requiring surgical intervention (grade III or higher, according to Dindo et al) occurred in 8 patients (removal of the stimulator or replacement of the electrode, 22%). However, a successful restimulation is still possible, and was also the case for 5 of the 8 patients. Infection at the site of the electrode during the screening phase or at the site of implantation of the permanent stimulator is the most frequent complication, occurring in up to 20% of patients. Treatment is usually conservative. In the present study, infection occurred in 3 patients (8%), requiring permanent removal of the stimulator in only 1 patient (3%), similar to the results of others (4%). Compared with alternative procedures that have morbidity rates of up to 40%, like artificial bowel sphincter implantation or dynamic graciloplasty, SNS is certainly less invasive and has a significantly lower morbidity.

Although SNS is a reproducible and safe technique from a surgical point of view, the programming aspects of the stimulator still remain demanding and patients need to be observed closely. The electrode can be stimulated at different levels along the sacral root with different frequencies and amplitudes. Changing the stimulation parameters, for instance, increasing amplitude or frequency, can treat a loss of response during permanent stimulation. Adverse effects of the stimulation, like pain in the perineum or gluteal region, can be corrected by modifying stimulation settings. These modifications were successful in alleviating adverse effects in 5 of 6 patients in the present study. More importantly perhaps, for the patients, the handling of stimulation is very easy with a simple remote control. The patient can increase or decrease the stimulation intensity and switch the implantable pulse generator on or off, for example, during the night, which would also serve to save the electrode’s battery (life expectancy of 6-8 years).

Concerns may occur because of the costs for SNS. The device is about $10 000. However, the minimal invasiveness of the technique, the low rate of severe complications, and the high success rate after the positive screening phase may compensate for these costs. A comparison study analyzing costs of alternative procedures, like dynamic graciloplasty or the implantation of an artificial sphincter or permanent soma, remains to be performed. In the United States there is an ongoing study to evaluate SNS for FDA approval, including 14 academic centers (Mayo Clinic, Jacksonville, Fla; Lahey Clinic, Burlington, Mass; Washington Hospital Center, Washington, DC; Norman F. Gant Research Foundation, Fort Worth, Tex; Cleveland Clinic, Cleveland, Ohio; University of Southern California, Los Angeles; Colon and Rectal Surgery Associates, Minneapolis, Minn; Ochsner Clinic, New Orleans, La; University of Kansas Medical Center, Kansas City; Rush University Medical Center, Chicago, III; University of Oklahoma, Oklahoma City; California Pacific Medical Center, San Francisco; Cleveland Clinic Florida, Westin...
and Switzerland. Currently, in Switzerland, the costs of SNS are covered by insurance on an individual basis; rigorous follow-up to evaluate cost-effectiveness is required by the National Department of Health.

In conclusion, the minimally invasive technique of SNS is a safe and effective treatment for patients with fecal incontinence. Due to the possibility of modifying the stimulation parameters at any time, adverse effects of permanent stimulation are easily corrected and treated. Most importantly, our data demonstrate that SNS significantly improves patients’ general and incontinence-specific QOL. This was shown in incontinence-specific questionnaires, as well as generic ones.

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