Fecal incontinence treated by sacral neuromodulation

Citation for published version (APA):

Janssen, P. T. J., Kuiper, S. Z., Stassen, L. P. S., Bouvy, N. D., Breukink, S. O., & Melenhorst, J. (2017). Fecal incontinence treated by sacral neuromodulation: Long-term follow-up of 325 patients. *Surgery*, 161(4), 1040-1048. <https://doi.org/10.1016/j.surg.2016.10.038>

Document status and date:

Published: 01/04/2017

DOI:

[10.1016/j.surg.2016.10.038](https://doi.org/10.1016/j.surg.2016.10.038)

Document Version:

Publisher's PDF, also known as Version of record

Document license:

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Fecal incontinence treated by sacral neuromodulation: Long-term follow-up of 325 patients

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Background. Long-term results of large patient cohorts with fecal incontinence treated by sacral neuromodulation are limited. This study shows the long-term results after a mean follow-up of 7.1 years in 325 patients with fecal incontinence treated by continuous sacral neuromodulation.

Methods. All patients with fecal incontinence and eligible for sacral neuromodulation between 2000 and 2015 were evaluated retrospectively. Primary outcome was a decrease in episodes of fecal incontinence, which was defined as involuntary fecal loss at least once per week and documented by a 3 week bowel habit diary. Quality of life was assessed using the Short-Form 36 and the Fecal Incontinence Quality of Life Score.

Results. In the study, 374 patients were included for sacral neuromodulation screening and 325 patients (32 male, 9.7%) received permanent, continuous sacral neuromodulation. Mean age was 56.5 years (17–82 years) and mean follow-up was 7.1 years (3.0–183.4 months). In the 325 patients with permanent sacral neuromodulation, fecal incontinence episodes decreased from a mean of 16.1 ± 14.5 to 3.0 ± 3.7 per 3-week period after sacral neuromodulation ($P < .001$) according to the bowel habit diary. Sacral neuromodulation was removed due to unsatisfactory results in 81 patients. Quality of life (both Short-Form 36 and Fecal Incontinence Quality of Life Score) showed no significant difference compared with the Dutch population during follow-up.

Conclusion. Long-term efficacy of sacral neuromodulation can be maintained in about half (52.7%) of all patients screened with sacral neuromodulation for fecal incontinence after a mean follow-up of 7.1 years. Importantly, the quality of life of patients with sacral neuromodulation for fecal incontinence did not differ from the general population. (Surgery 2017;161:1040-8.)

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FECAL INCONTINENCE (FI) is an embarrassing condition that can lead to social isolation.¹ Reports on the prevalence vary greatly between 7.1% in the general population² and $\geq 60\%$ in nursing

homes.³ Throughout the past decade, continuous sacral neuromodulation (SNM) has become an established treatment option for FI unresponsive to conservative treatment. Several large, prospective series have demonstrated a success rate of 74–86% in patients with intractable FI treated with SNM.⁴⁻⁹ Importantly, SNM improves the quality of life of patients with FI and is cost effective in the treatment of FI compared with other sphincter-restoring treatments and lifelong incontinence material, but data regarding long-term follow-up of large patient-cohorts remain limited.^{10,11} Previous studies have reported a long-term follow-up ranging from 22–96 months including cohorts of 25–200 patients.^{4,6,9} We report the long-term results of 374 patients with FI treated with SNM after a median follow-up of 7.1 years. This is a follow-up report of previously published articles.^{4,12}

METHODS

FI was defined as at least 1 episode of involuntary fecal loss per week documented by a 3-week

Drs Janssen, Breukink, and Melenhorst received an unrestricted research grant from Medtronic. The other authors have no financial support to declare.

P.T.J.J., L.P.S.S., N.D.B., S.O.B., and J.M. designed the study; P.T.J.J. and S.Z.K. performed the research; P.T.J.J., S.Z.K., S.O.B., and J.M. analyzed and interpreted the data; P.T.J.J., L.P.S.S., N.D.B., S.O.B., and J.M. drafted the manuscript; L.P.S.S., N.D.B., S.O.B., and J.M. supervised the study. All authors gave final approval of the final version.

Presented as an oral poster presentation during the European Society for Coloproctology, September 28–30, 2016, Milan, Italy. Accepted for publication October 19, 2016.

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0039-6060/\$ - see front matter

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<http://dx.doi.org/10.1016/j.surg.2016.10.038>

bowel habit diary. The inclusion criteria were broadened during follow-up due to new insights regarding the effect of SNM on different forms of FI. Patients with FI from March 2000 until July 2015 were included in a retrospectively reviewed, prospective database. All patients failed conservative treatment prior to evaluation.

Exclusion criteria. Patients were excluded if they had chronic skin conditions, inflammatory bowel disease (Crohn's disease, ulcerative colitis), chronic diarrhea refractory to drugs or diet, neurologic pathology (spinal cord transection, multiple sclerosis, Parkinson's disease), psychiatric or psychologic comorbidity, having a stoma in situ, or if they were pregnant. Patients with spina bifida who were able to walk were not excluded.

Assessment. All patients referred to our center underwent a baseline assessment that consisted of a 3-week bowel habit diary completed by the patient, a defecography, an endo-anal ultrasonography (Hitachi Aloka Medical, model ASU-67, Wallingford, CT) and anorectal manometry using a catheter-based system (Konigsberg Instrument Inc, Pasadena, CA; MUI Scientific, Anorectal 4ch Catheter, Mississauga, Canada) connected to a polygraph (Synectics Medical, Stockholm, Sweden; Medtronic, Polygram NET, Minneapolis, MN). Patients eligible for SNM who consented to the operative procedure were included in this study.

Operative procedure. The operative procedures were conducted under local or general anesthesia. Local anesthesia was preferred, because the patients were usually able to describe the location of sensation intraoperatively.¹³ The operative technique for sacral neuromodulation was described previously.¹⁴ In brief, a testing needle was used intraoperative to identify the correct sacral foramen and to assess the integrity of the neurologic pathway. After identification of the correct foramen, a percutaneous nerve evaluation (PNE)-lead (Medtronic Interstim model 3057) or a tunneled, quadripolar tined lead (tined lead procedure [TLP]; Interstim model 3093/3889) was inserted in the identified foramen and connected to an external stimulator (Medtronic model 3625/3531), which was attached to the patient's belt. Between 2000 and 2007, the PNE-lead was used in all patients. A tined lead was used in all patients from 2008 onward.

Implantation of the PNE-lead or tined-lead was followed by a 3-week screening period. During this period, the patients completed the same 3-week bowel habit diary to evaluate the clinical response of the test stimulation. Stimulation during the screening period was applied continuously at low amplitude using standard settings (amplitude

0.1–10V; pulse width 210 μ s; frequency 16 Hz). After the screening period, the PNE-lead was removed, whereas the tined lead was left in situ in case the screening period showed positive results. To be eligible for permanent stimulation, patients had to have both subjective and objective improvement of symptoms as documented in the 3-week bowel habit diary. In case of a positive PNE screening, an electrode was inserted in the identical foramen as the PNE-lead, fixated to the sacrum with sutures, and connected to a permanent implantable pulse generator (IPG) which was implanted under general anesthesia. In case of a positive, tined-lead screening, the electrode was left in situ and connected to the IPG that usually was implanted under local anesthesia. The IPG was implanted in a subcutaneous gluteal pocket with perioperative antibiotic cover. Two types of stimulators were used, depending on the patient age, amount of subcutaneous tissue, and applied current. The larger neurostimulator (Medtronic Interstim Model 3023) was connected to the definitive electrode lead via a short connecting cable (Interstim model 3095). The smaller type (Interstim Model 3058) was connected directly to the definitive lead.

Loss of efficacy. SNM failure was defined as a decrease in the effect of SNM after permanent implantation. Loss of efficacy was treated according to a standardized protocol, which is comparable with the algorithm of Dudding et al.¹⁵ First, the electrode and pulse generator were checked for technical failure. If there was no technical failure, the electrode polarity was changed to a different bipolar stimulation setting without changing pulse width and/or stimulation frequency. Ideally, the patient would report a perianal sensation; however, a vaginal/perineal sensation also was accepted. If changing polarity did not improve treatment efficacy, the second option was increasing the stimulation frequency to 21 or 31 Hz. A stimulation frequency of 31 Hz only has been used recently.^{16,17} The new settings for both changing polarity and changing stimulation frequency were tested for at least 1 month. Changing polarity or stimulation frequency always was accompanied with a plain radiography of the sacrum to exclude displacement of the electrode. If efficacy was restored by changing electrode polarity only, displacement of the electrode was assumed to have occurred. In case the new settings did not improve SNM efficacy or if ≥ 3 electrodes were subject to technical failure, patients were eligible for implantation of a new electrode. A contralateral electrode was placed in patients with loss of efficacy without technical failure. Patients with loss

Fig 1. Details of SNM screening. PNE 2 and TLP 2 are a second test period with a contralateral electrode after failure of the initial test period.

of efficacy due to technical failure received an electrode in the same sacral foramen.

Complaints of pain related to the position of the pulse generator early after implantation were observed for a minimum of 3 months. If the pain remained, patients were eligible for a revision of the pocket. In the early period of SNM, pain was treated by a relocation of the pulse generator to the lower abdominal wall; during later years, relocation of the pulse generator more caudal or cranial within the buttocks was preferred over relocation to the abdominal wall.

Outcomes and follow-up. The primary outcome was defined as a decrease in the number of episodes of involuntary fecal loss. Secondary outcomes were an increase in time postponing defecation from the time of the sensation of urge and a decrease in defecation frequency. These outcomes were evaluated by comparing the 3-week bowel habit diary at baseline with the different follow-up evaluations. Follow-up was scheduled at 1, 3, 6, and 12 months after implantation of SNM and yearly thereafter.

Finally, all patients were asked to fill out 2 questionnaires for a cross-sectional evaluation of the quality of life at various follow-up moments after definitive SNM implantation. Questionnaires consisted of the Short-Form 36 (SF-36)¹⁸ and the Fecal Incontinence Quality of Life Scale (FIQL) of the American Society of Colon and Rectal Surgery.¹⁹ SF-36 was used to assess overall quality of life (QoL). This questionnaire comprises 8 subdomains: bodily pain, general health, social functioning, physical functioning, mental health, vitality, functioning physical role, and functioning emotional role. All scales range from 0–100, with a greater score indicating better QoL. The FIQL

score was used to assess the impact of FI on the QoL. The FIQL consists of 4 scales: lifestyle, coping/behavior, depression/self-perception, and embarrassment. Total scores range from 29–119, with a lesser score indicating a better QoL.

To evaluate the QoL at different times during follow-up, questionnaires were sent to the patients with an effective SNM implant in situ. If the questionnaires were not returned after 6 weeks, the patients were contacted by telephone, and the questionnaires were sent again.

Statistical analysis. For all outcomes in this study, each patient served as his or her own control. In this way, outcome of each follow-up evaluation was compared with baseline data. Data are presented as mean (SD) for continuous variables, and count (percentage) for categorical variables. Long-term efficacy was evaluated as the proportion of successfully implanted patients after SNM screening compared with the total number of patients undergoing SNM screening. Primary and secondary outcomes were evaluated as the proportion of the number of patients who actually received a permanent implant. Statistical testing was based on the paired *t* test for paired samples. The χ^2 test was used for nonpaired samples. Statistical significance was defined at $p < 0.05$. Data were analyzed using SPSS (version 23 for Windows, IBM, Armonk, New York). Continuous data are presented as mean $\pm$ standard deviation.

RESULTS

Three hundred and seventy-four patients, 37 male (9.9%), were included for a 3-week SNM screening period. The first 148 patients underwent screening using a PNE-lead. The other patients

Table I. Patient characteristics of permanent SNM implant ($n = 325$)

Patient characteristics	
	Number of patients (%) (total $n = 325$)
Age (y)	57 (17–82)
Follow-up (mo)	85.1 (3.0–183.4)
Electrode position	
S3R	173 (53.2)
S3L	118 (36.3)
S4R	23 (7.1)
S4L	11 (3.4)
Infection	24 (7.4)
Diseased	15 (4.6)

Table II. Permanent SNM characteristics (total, $n = 325$)

Permanent SNM characteristics					
	PNE-lead	Fixed-lead	Tined-lead	Interstim I	Interstim II
Type anesthesia					
General (n)	0	136	125		
Local (n)	136	0	64		
IPG type implanted				290	35
IPG location					
Buttocks (n)				288	35
Abdominal wall (n)				2	0
End of stimulation					
Number (n)				69	1
Duration (y)				8.3	6.2

received a tined lead. Details of the SNM screening are presented in Fig 1.

In total, 325 patients (32 male, 9.7%) received a permanent SNM implant. In the study, 427 SNM screening periods were conducted resulting in a SNM screening success rate of 76.1%. Patient and definitive IPG characteristics are displayed in Tables I and II. Of the 325 patients (86.9% of all screened patients) who received permanent SNM, 47 patients were lost to follow-up (12.6% of all screened patients; 14.5% of all patients who received a permanent implant), and the SNM was removed in 81 patients (21.7% of all screened patients; 24.9% of all patients who received a permanent implant). This resulted in a total of 197 patients with a successful SNM still

in follow-up (52.7% of all screened patients; 60.1% of all patients who received a permanent implant; Fig 2).

Outcomes. The number of incontinence episodes per 3 weeks decreased from 16.1 ± 14.5 at baseline to 3.0 ± 3.7 after the SNM testing period ($P < .001$) in patients who received permanent SNM. This decrease appeared to be stable during 15 years of follow-up with a mean of 1.6 ± 2.3 incontinence episode per 3 weeks ($P < .001$; Fig 3).

The time patients could postpone defecation from the time of sensation of urge increased from 1.5 ± 3.1 minutes at baseline compared with 7.5 ± 10.5 minutes after the SNM screening period ($P < .001$). The time period to postpone defecation remained greater compared with baseline during 8 years follow-up with mean 6.7 ± 9.1 minutes ($P < .001$). Defecation frequency decreased from 2.70 ± 1.6 to 1.9 ± 1.0 defecations per day after the SNM screening period ($P < .001$). This decrease in defecation frequency remained less during 6-year follow-up with mean 1.8 ± 1.2 defecations per day ($P = .008$).

QoL. In total, 130 of the 197 patients with successful SNM returned the questionnaires concluding a response rate of 66.0%. Results of the SF-36 were compared with the Dutch population.²⁰ No significant differences were found between patients with SNM and the Dutch population (Fig 4). The FIQL score of SNM patients was compared with the general population¹⁹ and showed no difference between the 2 groups (Fig 5).

Loss of efficacy. Some patients experienced a decline in the effect of SNM during follow-up; 123 patients experienced loss of efficacy, which was treated operatively (32.9% of all screened patients; 37.8% of all patients who received a permanent implant). Loss of efficacy occurred in 62 of the 136 fixed leads (45.6%) and in 61 of the 189 tined leads (32.3%). Loss of efficacy occurred more in patients with a fixed lead compared with a tined lead ($P < .001$). Patients who received a tined lead under general anesthesia (36.3%) experienced more loss of efficacy compared with patients who received a tined lead under local anesthesia (24.6%; $P = .008$).

Sixty-seven patients received a new electrode due to the decrease in SNM. A tined lead was used in 60 of the 67 revisional operations. The interventions for loss of efficacy are summarized in Fig 6. The SNM was removed in 73 patients (19.5% of all screened patients; 22.5% of all patients who received a permanent implant) due to loss of efficacy.

Fig 2. Flow chart of long-term results regarding maintained efficacy.

Fig 3. Incontinence episodes per 3 weeks; values are represented as mean $\pm$ SD. Numbers represent number of patients at follow-up. *Statistically different compared with baseline.

Pain or discomfort. Pain or discomfort due to the position of the pulse generator required operative intervention occurred in 45 patients

(13.8% of all patients who received a permanent implant) and resulted in 52 operative procedures. We relocated the IPG 26 times within the gluteal

Fig 4. Results of the SF-36, values are presented as mean (SD). *PF*, Physical functioning; *RP*, role physical functioning; *BP*, bodily pain; *GH*, general health; *V*, vitality; *SF*, social functioning; *RE*, role emotional; *MH*, mental health.

Fig 5. Results of the Fecal Incontinence Quality of Life questionnaire. Values are presented as mean (SD). *L*, Lifestyle; *C/B*, coping/behavior; *D/SP*, depression/self perception; *E*, embarrassment.

region, 24 times from the gluteal region to the abdominal region, once from the abdominal region to the subpectoral space, and once from the gluteal region to the subpectoral space. It was necessary to change the type of pulse generator in 1 patient due to continuous discomfort of the Interstim I despite multiple relocations within the abdominal region. Three of the 35 Interstim II (8.6%) and 42 of the 290 Interstim I (14.5%) required operative revision for pain or discomfort ($P = .39$). Five patients (11.1%) had their SNM removed due to nonimproving pain the location of the IPG.

DISCUSSION

In 52.7% of the patients with fecal incontinence, long-term efficacy was achieved with SNM. The number of episodes of fecal incontinence remained significantly less compared to baseline

after a median follow-up of 7.1 years. Moreover, efficacy of SNM was maintained for 15 years of follow-up in the 10 patients followed for 15 years. Time to postpone defecation increased and defecation frequency decreased after implantation of SNM compared with baseline. These effects were maintained up to 6 to 8 and 6 years. Most studies describing outcome of FI after SNM including larger patient cohorts ($n = 100$ –142) reported only short- or medium-term outcomes.^{4,6,9,21} To our knowledge, only 4 studies have published long-term outcomes of SNM with a follow-up longer than 5 years; those studies, however, included only small patient populations ranging between 9–52 patients.^{5,21–23} These studies reported success rates ranging between 74–83%; ie, results were based on patients who received a permanent implant.⁵ There is an overall lack of studies reporting SNM efficacy based on an analysis of the entire cohort of patients including all SNM screenings.²⁴ Our long-term efficacy of SNM for FI is comparable with the results of Altomare et al²⁵ who reported long-term efficacy of 47.7% based on 228 patients who underwent SNM screening with a follow-up of 84 months. A previous review reported similar long-term efficacy of 54% of the patients based on 2 studies with a maximum follow-up of 5 years.²⁶

Because a baseline assessment of QoL was lacking in our study, we performed a cross-sectional assessment of QoL. This showed that the overall QoL (both SF-36 and FIQL) did not differ from the general Dutch population. To our knowledge, no studies are known that compare QoL after SNM in FI patients with healthy persons;

Fig 6. Operative intervention details for loss of efficacy.

previous studies reporting on QoL after SNM in FI patients showed an improved QoL after short and long-term follow-up in patients with SNM for FI.^{11,27}

Our success rate of 76.1% of the SNM screening period was comparable with previous studies.²⁴ Both PNE and TLP were used as screening techniques; however, most patients underwent a TLP ($n = 189$). A tined lead has multiple advantages compared with the older, PNE technique. First, the use of a tined lead accounted for a smaller number of lead displacements during the screening period allowing a possible prolonged screening period and fewer PNE redo procedures.^{28,29} Second, direct implantation of the definitive quadripolar lead ensured effectivity of the position of the lead before an IPG was implanted. Other advantages of TLP compared with PNE are the greater positive response rate (respectively 67–88% vs 48–60%)^{29–34} and the advantage of bipolar stimulation (short range) with the quadripolar tined-lead compared with the unipolar stimulation (wide range) of the PNE-lead.^{14,29} Unfortunately, we could not perform a proper comparison between the success rates of PNE and TLP due to missing data. Our study demonstrated clinical superiority of the tined lead over the fixed lead for permanent SNM. Patients with a tined lead had less loss of

efficacy compared with patients with a fixed lead. Superiority of the tined lead over the fixed lead has also been reported previously.⁵

One-hundred-and-twenty-three patients (32.9% of all screened patients; 37.8% of all patients who received a permanent implant) reported loss of efficacy and received a new electrode. Patients who were treated successfully by reprogramming the stimulation parameters were not included in this study due to missing data. Therefore, the total number of patients with loss of efficacy in our population is expected to be greater than reported. Previous studies reported greater percentages of patients who had loss of efficacy, ranging from 74.8–88.1%.^{24,26,35} Maeda et al²⁴ reported that loss of efficacy is likely to occur within the first 2 years of the treatment. These findings were confirmed by urologists using SNM for urinary incontinence who reported a high correlation between a successful SNM at 1 year and maintained efficacy at 5-year follow-up.³⁶ Our results did not show a significant loss of efficacy within the first 2 years, which might be related to careful patient selection or to missing data related to the retrospective data collection.

Despite its high prevalence, the causes of loss of efficacy remain unknown. Whether the motor or sensory response is a better predictor for a successful SNM has been subject of debate since

the introduction of SNM. This study demonstrates more loss of efficacy in patients who underwent implantation of SNM using a tined lead under general anesthesia (only motor response) compared with patients whom received SNM under local anesthesia (sensory response). Superiority of the sensory response has been described previously.¹³ Other factors that may have contributed to the loss of efficacy are the pragmatic trial-and-error approach, the evolving inclusion criteria, the variation in the SNM screening period between 14–20 days,^{6,21} and the lack of understanding of the mechanism of action.^{4,21} A better understanding of the mechanism of action could lead to a better definition of the inclusion and exclusion criteria and to decrease the percentage of patients with loss of efficacy on the long-term.

The second most common cause for operative reintervention was pain or discomfort at the site of the IPG. In our study, 45 patients required a revision of the IPG pocket (13.8% of all patients who received a permanent implant). The overall incidence of pain and discomfort was comparable to previously reported results.^{24,36,37} In addition, we did not find any difference between the 2 pulse generators regarding pain and discomfort. Optimal positioning of the gluteal pocket during electrode implantation for the SNM screening period may help decrease the number of pocket revisions. We think the optimal position of the gluteal pocket is in the midline of the gluteal area, ± 5 cm caudal to the iliac crest at a minimum depth of ± 2 cm.

This study was limited by its retrospective design and the absence of baseline values of the quality of life. Due to the absence of baseline values, we choose the second best approach to assess quality of life by cross-sectional survey. Therefore results should be interpreted with some caution due to a possible selection bias. During the past 16 years, different diaries of bowel habit and FI questionnaires have been used in our center to assess the clinical improvement of patients treated with SNM for FI. This approach resulted in missing baseline data of secondary outcomes, such as time to postpone defecation and defecation frequency. These data therefore, could not be used for paired analysis.

Long-term efficacy of SNM can be maintained in about half of all patients screened with SNM for FI after a mean follow-up of 7.1 years. Quality of life of patients with SNM for fecal incontinence did not differ from the general population.

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