

Factors Associated with Percutaneous Nerve Evaluation and Permanent Sacral Nerve Modulation Outcome in Patients with Fecal Incontinence

B. Govaert, M.D.¹ • J. Melenhorst, M.D.¹ • F. H. M. Nieman, Ph.D.² • E. M. J. Bols³
W. G. van Gemert, Ph.D.¹ • C. G. Baeten, Ph.D.¹

¹ Department of Surgery, Maastricht University Medical Center, Maastricht, The Netherlands

² Department of Clinical Epidemiology and Medical Technology Assessment, Maastricht University Medical Center, Maastricht, The Netherlands

³ Department of Epidemiology, University Maastricht, Maastricht, The Netherlands

PURPOSE: Sacral nerve modulation is an established treatment for fecal incontinence. Little is known about predictive factors for successful percutaneous nerve evaluation (or test stimulation) and permanent sacral nerve modulation outcome. The purpose of this retrospective study was to discover predictive factors associated with temporary and permanent stimulation.

METHODS: We analyzed data from test stimulations performed in patients with fecal incontinence from March 2000 until May 2007. Successful outcome was defined as >50% improvement of incontinence episodes in three weeks. Patients with a successful test stimulation were eligible for permanent sacral nerve modulation implantation. All patients who subsequently had permanent sacral nerve modulation were analyzed. Logistic regression was used to determine the predictive power of baseline demographics and diagnostic variables.

RESULTS: Test stimulations were performed in 245 patients (226 females; mean age, 56.6 (standard deviation, 12.8) years). Our analysis showed that older age ($P = 0.014$), external anal sphincter defects ($P = 0.005$), and repeated procedures after initial failure ($P =$

0.001) were significantly related to failure. One hundred seventy-three patients (70.6%) were eligible for permanent sacral nerve modulation implantation. The analysis showed no significant predictive factors related to permanent sacral nerve modulation.

CONCLUSION: Three predictive factors were negatively associated with the outcome of test stimulation: older age, repeated procedures, and a defect in the external anal sphincter. These factors may indicate lower chances of success for test stimulation but do not exclude patients from sacral nerve modulation treatment. Although assessed in a selected patient group, no factors were predictive of the outcome of permanent stimulation.

KEY WORDS: Fecal incontinence; Sacral nerve modulation; Predictive factors; Neuromodulation; Outcome.

Sacral nerve modulation (SNM) is an established and successful treatment for fecal incontinence (FI).¹ Since Matzel *et al.*¹ reported the first patients in 1995, more studies have shown positive results of SNM treatment.^{2–7} Initially the indications for SNM treatment were an intact anal sphincter with or without a previous anal sphincter repair.⁸ Today indications are expanding as evidence has been provided that SNM may have good results in patients with external anal sphincter defects.^{9–11}

A unique advantage of SNM treatment is the possibility to assess the feasibility of permanent stimulation by a temporary percutaneous nerve evaluation (PNE). Reported PNE success rates vary, ranging from 26.7% to 100% in a recently performed review.¹² Earlier published results showed a success rate of 74.6% in 134 patients.²

Several factors predictive of successful PNE have been reported. One study demonstrated a negative relation be-

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Address of correspondence: Professor Cor G. Baeten, Maastricht University Medical Center, Department of Surgery, Postal Box 5800, 6202 AZ Maastricht, The Netherlands. E-mail: c.baeten@mumc.nl

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tween age and PNE outcome.¹³ A recent study found that previous PNE failures was predictive of poor outcome.¹⁴

For this study, all patients who underwent one or more PNEs were of interest. The purpose of this study was to determine which factors can predict PNE outcome and whether possible factors may exclude patients from this treatment. Another purpose of this study was to determine which factors can predict outcome of permanent SNM.

METHODS

This is a retrospective cohort analysis of patients who underwent a PNE between 2000 and 2007 in the Maastricht University Medical Center and were diagnosed with FI. Patients with anal pain or constipation were excluded from this study, as were patients with FI caused by rectal resection, congenital disorders, or spinal lesions. A strict procedure of data acquisition was followed before PNE. Patients were evaluated by anal manometry using a solid-state Konigsberg catheter (Konigsberg Instruments, Inc., Pasadena, CA) connected to a polygraph (Synectics Medical, Stockholm, Sweden). The highest basal pressure and the constriction pressure were measured with a standardized stationary pull-through technique. With the repeated inflation of a balloon, intrarectal sensitivity and capacity were assessed in milliliters.¹⁵ Endoanal ultrasound (SDD 2000 (7.5-MHz endoanal transducer), Multiview, Aloka, Japan) was used to visualize the anatomy of the anal sphincter. An internal or external anal sphincter defect was measured in degrees of the circumference and percentage of the circumference.¹⁶ Defecography was performed according to established methods.¹⁷ Incontinence was confirmed on defecography by contrast medium loss at rest or during a Valsalva maneuver. Pudendal nerve investigation (pudendal nerve terminal motor latency) was performed according to previously described techniques.¹⁸ Before the PNE procedure, a baseline three-week bowel habit diary was completed.

All PNEs were performed according to the procedure described by Schmidt *et al.*¹⁹ Correct placement of the needle was confirmed by observing the typical S-3 sensory and/or motor responses. Sensation of the stimulation in the anal, perineal, or vaginal region was considered a good position. Typical muscle responses are levator ani muscle contraction (Bellows' sign) and great toe flexion. Once a patient had a good response, the temporary lead was inserted, and an external stimulator was attached to the lead. Lead placement was checked by a plain sacral x-ray film, obtained directly after the procedure. Afterward, a three-week subchronic test stimulation was done and a bowel habit diary was kept to assess incontinence episodes. A >50% decrease in the number of incontinence episodes in three weeks during the test stimulation was considered a successful PNE test, and permanent stimulation was then the final step. When the test stimulation was not successful

because of technical reasons or suspected technical reasons (electrode dislocation or lead fracture, test stimulator malfunctioning, ground pad dislocation), the PNE was repeated.

In cases of successful PNE outcome, patients were eligible for permanent stimulation. This means that the analysis for permanent SNM outcome is performed in a selected group. Successful permanent SNM outcome was defined as a >50% decrease at last follow-up in the number of incontinence episodes over the three weeks of the test stimulation as compared with baseline. Failure of permanent SNM is defined as a <50% decrease at last follow-up in the number of incontinence episodes over three weeks as compared with baseline or explantation because of no reduction in symptoms. Explantations performed because of infections were excluded from this analysis.

Statistical Analysis

Continuous metric variables were tested for normality of distribution by the Kolmogorov-Smirnov test. For normally distributed data, means and standard deviations are presented; otherwise, medians and ranges are provided. Categorical data are given as frequencies and percentages. Principal outcomes of the study were PNE outcome (0 = failure, 1 = success) and SNM outcome (0 = failure, 1 = success). Univariate statistics for outcome with dichotomous risk factors were first done by cross-tabulations with log-likelihood chi-squared tests and its *P* values and odds ratios (ORs) with 95% confidence intervals (CIs). For polytomous factors, a univariate logistic regression was done to present multiple ORs and their 95% CIs; for continuous risk factors, this same procedure was followed, resulting in one OR and its 95% CI. Multiple logistic regression analysis was done with backward elimination changes in a log-likelihood chi-squared analysis. At first, all factors or variables relevant according to the univariate analysis (*P* < 0.20) for PNE and permanent SNM success (with the exception of age and gender, which were retained in each tested model regardless of their statistical significance) were introduced into the model. After elimination of non-significant ORs, a model was found where each risk or protective factor or variable showed a statistically significant direct effect on PNE and permanent SNM outcome. A *P* value of <0.05 was considered to be statistically significant. All data analysis was done with SPSS® version 15.0 (SPSS Inc., Chicago, IL).

RESULTS

Percutaneous Nerve Evaluation

From March 2000 through May 2007, a total of 260 patients underwent a PNE for FI. Fifteen patients were not analyzed in this study because of the etiology of their FI: low anterior resection (five), incomplete cauda syndrome

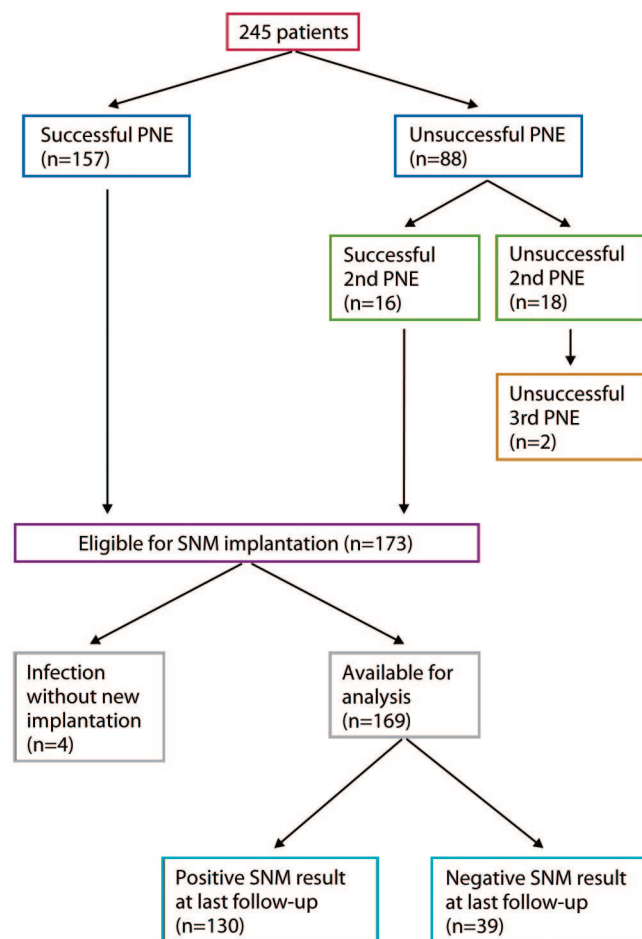


FIGURE 1. Study flow chart. PNE = percutaneous nerve evaluation; SNM = sacral nerve modulation.

(three), incomplete spinal lesion (two), and anal atresia (five). Two hundred forty-five patients were analyzed in this study. Figure 1 shows a study flow chart of the number of patients available for follow-up. The population consisted of 226 females and 19 males with a mean age of 56.6 (standard deviation, 12.8; range, 17.2–83.3) years. The median length of symptoms was 5.0 (range, 0.1–60.0) years. All patients had failed previous conservative therapy. Table 1 shows the different etiologies and previous proce-

dures in the study group. PNE was successful in the first test in 157 patients (64.1%). A second PNE was attempted in cases of insufficient reduction of symptoms caused by a proven or suspected technical failure. Thirty-four patients (13.9%) had a second PNE, which was successful in 16 of these patients (47%). Furthermore, two patients had a third PNE with unsuccessful results. Ultimately, a total of 173 (70.6%) patients had a successful PNE and were suitable for permanent SNM implantation.

Univariate statistics of baseline demographics and anorectal examination outcome within the success and failure groups for PNE outcome are shown in Table 2. Three factors showed significant differences in PNE outcome and were identified as negative predictive factors: higher age, previous failure of PNE, and presence of external anal defect. First, the percentages of successful outcomes were 71.8%, 71.2%, and 74.6% among patients aged <50 years, 50 to 60 years, and 60 to 70 years, respectively, compared with 44.7% among those aged >70 years (OR, 0.97; 95% CI, 0.95–0.99; $P = 0.014$). Second, the success rate for first PNE procedures was 64.1%, compared with 47.1% for second PNEs (OR, 0.31; 95% CI, 0.15–0.62; $P = 0.001$). A third procedure was performed in two patients but was a failure in both. The percentages of success in the intact external anal sphincter group and the external anal sphincter defect group were 76.2% and 57.4%, respectively (OR, 0.42; 95% CI, 0.23–0.76; $P = 0.005$). The lower success rate among patients with an external anal sphincter defect was not related to the size of the defect, because the mean size of the external sphincter defect did not differ between the success group and failure group (65° vs. 52°, or 18.2% vs. 14.5%, respectively; $P = 0.12$).

After introduction of all variables considered to be relevant in the univariate logistic regression analysis, two predictors remained in the regression model with ORs demonstrating statistical significance, the number of previous PNE procedures and external anal sphincter defect. When PNE was performed on older patients (either once or twice), the chances of success at the final procedure turned out to be much lower (OR, 0.31; 95% CI, 0.14–0.69; $P = 0.004$). When defects of the external sphincter were found on ultrasound, chances were higher that a PNE test would fail (OR, = 0.47; 95% CI, 0.24–0.92; $P = 0.028$). Table 3 shows the results of the final model for PNE outcome.

TABLE 1. Etiology of fecal incontinence

Cause of fecal incontinence	n
Idiopathic ^a	88
Obstetric trauma	151
Perineal surgery	6
Previous procedures	
Anal repair	39
Hemorrhoidectomy	4
Fistula surgery	2
Episiotomy	73
Hysterectomy	61

^aWeak but anatomically intact sphincters confirmed by endoanal ultrasound.

Permanent Sacral Nerve Stimulation

Ultimately, 173 patients had permanent stimulator implantation. Four patients were excluded from the analysis for predictive factors for permanent SNM outcome because of an infection that necessitated explantation of the device. The remaining 169 patients were analyzed for predictive factors for success of permanent SNM outcome. Mean follow-up after implantation was 34.7 (standard deviation, 25.6; range, 0.9–99.3) months. One hundred

TABLE 2. Univariate statistics showing the relationship between successful percutaneous nerve evaluation and relevant (clinical) parameters (n = 245)

	<i>n</i>	<i>PNE success (%)</i>	<i>Log-likelihood^a</i>	<i>P value</i>	<i>OR</i>	<i>95% CI</i>	<i>Missing data</i>
Baseline demographics							
Gender			0.047	0.828	1.12	0.81–3.10	0
Male	19	68.4					
Female	226	70.8					
Age (yr)	245		6.40	0.014 ^b	0.97	0.95–0.99	0
Incontinence episodes	159		1.95	0.186	1.01	0.995–1.02	86 (35%)
Years of incontinence	225		0.41	0.531	1.01	0.98–1.04	20 (8%)
Procedure							
No. of PNE procedures	245		11.30	0.001 ^b	0.31	0.15–0.62	0
Anorectal examinations							
Resting pressure (mmHg)	216		1.07	0.307	1.01	0.99–1.02	29 (12%)
Squeeze pressure	216		1.59	0.220	1.004	0.997–1.012	29 (12%)
Rectal sensation thresholds							
Sensitivity volume (ml)	213		1.82	0.200	1.01	0.996–1.018	32 (13%)
Urge volume	213		2.66	0.121	1.01	0.999–1.012	32 (13%)
Maximum tolerable volume	213		1.28	0.267	1.00	0.998–1.007	32 (13%)
PNTML			0.40	0.530	1.21	0.67–2.16	27 (11%)
Normal	119	70.1					
Prolonged	109	74.3					
Incontinence confirmed by defecography			0.08	0.776	1.11	0.54–1.96	6 (2%)
Yes	196	71.9					
No	43	69.8					
Ultrasound							
IAS			0.91	0.340	0.68	0.31–1.48	9 (4%)
Normal	203	71.9					
Defect	33	63.6					
EAS			8.00	0.005 ^b	0.42	0.23–0.76	9 (4%)
Normal	168	76.2					
Defect	68	57.4					

CI = confidence interval; EAS = external anal sphincter; IAS = internal anal sphincter; OR = odds ratio; PNE = percutaneous nerve evaluation; PNTML = pudendal nerve terminal motor latency.

^aChi-squared test.

^bStatistically significant.

thirty patients (76.9%) had a successful permanent SNM outcome, defined as >50% decrease in incontinence episode over three weeks, as compared with baseline, at last follow-up. Thirty-nine patients had a <50% decrease, which was considered as an unsuccessful outcome. Because of an insufficient response during permanent SNM, 15 patients in this group required interventions: 6 had a stoma, 4 had an explantation of the SNM without further

action, 3 had a dynamic graciloplasty, and 2 had an artificial bowel sphincter. The remaining 24 patients did not require interventions. Univariate statistics of baseline demographics and anorectal examination outcomes within the success group and failure group for permanent SNM outcome are shown in Table 4. No factors showed significant differences in permanent SNM outcome; as a result, the logistic regression analysis replicated these findings.

TABLE 3. Results of final multivariate logistic regression model for percutaneous nerve evaluation outcome

<i>Predictor</i>	β	<i>SE for β</i>	<i>Wald statistic</i>	<i>df</i>	<i>P value</i>	<i>OR</i>	<i>95% CI for OR</i>
Age	−0.19	0.013	2.045	1	0.153	0.98	0.96–1.01
Gender	0.23	0.60	0.15	1	0.699	1.26	0.39–4.09
Number of PNE procedures	−1.17	0.40	8.39	1	0.004 ^a	0.31	0.14–0.69
EAS defect ^b	−0.75	0.34	4.80	1	0.028 ^a	0.47	0.24–0.92
Sensitivity volume	−0.001	0.011	0.003	1	0.954	1.00	0.98–1.02
Urge volume	0.004	0.007	0.383	1	0.536	1.00	0.99–1.02
Constant ^c	3.07	1.08	8.07	1	0.004	21.60	

CI = confidence interval; *df* = degrees of freedom; EAS = external anal sphincter; OR = odds ratio; PNE = percutaneous nerve evaluation; SE = standard error of β ; β = logistic regression coefficient.

^aStatistically significant predictors.

^bAs observed on ultrasound.

^cIntercept term when all variables are zero.

TABLE 4. Univariate statistics showing the relationship between sacral nerve modulation successful outcome and relevant (clinical) parameters (n = 169)

	n	SNM success (%)	Log-likelihood ^a	P value	OR	95% CI	Missing data
Baseline demographics							
Gender			2.46	0.116	0.25	0.31–1.99	0
Male	13	92.3					
Female	156	75.0					
Age (yr)	169		0.045	0.832	1.00	0.98–1.03	0
Incontinence episodes	100		0.0	0.995	1.00	0.98–1.02	69 (41%)
Years of incontinence	162		0.41	0.514	0.99	0.96–1.02	7 (4%)
Procedure							
No. of PNE procedures	169		0.02	0.895	0.92	0.28–3.04	0
Anorectal examinations							
Resting pressure (mmHg)	151		1.31	0.426	1.01	0.98–1.05	22 (13%)
Squeeze pressure	151		1.22	0.621	1.03	0.96–1.02	22 (13%)
Rectal sensation thresholds							
Sensitivity volume (ml)	148		1.03	0.345	1.01	0.99–1.02	21 (12%)
Urge volume	148		0.01	0.928	1.00	0.99–1.01	21 (12%)
Maximum tolerable volume	148		2.00	0.153	1.00	0.991–1.001	21 (12%)
PNTML			0.62	0.431	0.75	0.36–1.55	8 (5%)
Normal	81	79.0					
Prolonged	80	73.8					
Incontinence confirmed by defecography			0.005	0.946	0.97	0.38–2.46	1 (1%)
Yes	138	76.1					
No	30	76.7					
Ultrasound							
IAS			0.66	0.418	0.64	0.23–1.83	6 (4%)
Normal	144	77.1					
Defect	19	68.4					
EAS			0.53	0.468	1.40	0.56–3.50	6 (4%)
Normal	127	74.8					
Defect	36	80.6					

CI = confidence interval; EAS = external anal sphincter; IAS = internal anal sphincter; OR = odds ratio; PNE = percutaneous nerve evaluation; PNTML = pudendal nerve terminal motor latency.

^aChi-squared test.

Table 5 shows the results of the final model for predicting success of permanent SNM outcome.

DISCUSSION

Since the first publication by Matzel *et al.*¹ concerning neurostimulation as treatment for FI, many centers have implemented this procedure. Follow-up studies have shown the effectiveness of SNM for FI.^{2,8} The first study had clear inclusion and exclusion criteria.⁸ More recently, several studies have shown that SNM can be a good treat-

ment option for patients with a structural defect in the anal sphincter.^{9,10}

A major advantage of SNM treatment is the ability to test the treatment outcome before permanent implantation of the stimulating device. PNE success rates vary in the literature. A review published by Jarret *et al.*¹² in 2004 showed PNE success rates ranging from 26.9% to 100% in several studies and an overall success rate of 56.0% among 266 PNEs performed. A recent study by Melenhorst *et al.*¹ showed a PNE success rate of 74.6% in 134 patients.

In this study, a total of 70.6% of all patients had a

TABLE 5. Results of final multivariate logistic regression model for permanent sacral nerve modulation outcome

Predictor	β	SE	Wald statistic	df	P value	OR	95% CI for OR
Age	−0.01	0.02	0.30	1	0.586	0.99	0.96–1.02
Gender	−1.42	1.08	1.72	1	0.190	0.24	0.03–2.02
Maximum tolerable volume	−0.01	0.003	2.77	1	0.096	0.995	0.990–1.001
Constant ^a	3.47	1.55	5.85	1	0.016	42.11	

CI = confidence interval; df = degrees of freedom; EAS = external anal sphincter; OR = odds ratio; PNE = percutaneous nerve evaluation; SE = standard error of β ; β = logistic regression coefficient.

^aIntercept term when all variables are zero.

successful PNE outcome. Unsuccessful outcome may indicate that patients have no clinical benefit from SNM. However, PNE outcome can be influenced by other factors. The outcome parameter for PNE is the number of incontinence episodes over three weeks. This can be influenced by factors other than neuromodulation alone. In our experience, changed stool consistency or illness during PNE may influence PNE outcome. The current study, conducted in a large group of patients, found several predictors of PNE outcome. In the univariate analysis, older patients had a slightly lower chance of successful test stimulation. Gourcerol *et al.*¹³ also described age as a significant predictive factor for test stimulation outcome. In their study, younger patients had a higher probability of successful test stimulation outcome. This may be due to differences in clinical characteristics. Younger women are more likely to have anal sphincter defects and may have had previous anal repair, whereas older women have a more multifactorial etiology with multiple childbirths and pudendal neuropathy.²⁰

Patients with a defect of the external anal sphincter had a significantly lower chance of successful PNE outcome, as found by Dudding *et al.*¹⁴ In our study, patients with a PNE and external sphincter defect had defects of $<120^\circ$ of the circumference. Several articles have recently been published describing successful SNM treatment in patients with defects of $<120^\circ$ of the circumference.^{9–11} Overlapping sphincteroplasty for late repair of sphincter defects has good initial results, but these deteriorate in the long term. Reported long-term success rates vary between 40% and 50% at six to ten years of follow-up.^{21,22} Initial results of SNM in patients with sphincter defects are good, as reported by Melenhorst *et al.*; however, long-term follow-up data are not yet available. The longest follow-up reported is 24 months.⁹

We found that a repeated PNE is associated with a lower probability of successful PNE outcome. The same relation was described by Dudding *et al.*¹⁴ Lead migration during the subchronic test stimulation is one cause of unsuccessful PNE. Patients with lead migration report displaced sensation of stimulation in the gluteal area. In cases of early migration or unclear results, a repeated procedure is justified. Some patients have a second (or third) PNE after unsuccessful initial test stimulation with normal sensation during the entire period. This group of patients has a lower chance of success in the new PNE and test stimulation. Simultaneous bilateral stimulation may be an option in these patients. There have been reports in urology describing bilateral stimulation. Results were not better than those achieved with unilateral stimulation, but the authors speculated that bilateral stimulation may be more effective.²³ In FI treatment there are few reports on bilateral stimulation. Melenhorst *et al.*² have described one patient with bilateral permanent stimulation after failure of unilateral stimulation and reported fair results.¹ One case

report showed that better results were achieved with bilateral stimulation than with unilateral in a patient with FI after low anterior resection.²⁴

In cases of successful PNE outcome, patients are eligible for permanent SNM implantation. However, despite prior successful results during PNE, relapse of symptoms can occur. Success rates for permanent SNM are influenced by a number of factors and vary in the literature from 79% to 95.6%. Infection necessitates explantation of implanted devices, and some patients do not want a new SNM implant after a cured infection. Technical failures, such as lead dislocation or lead dysfunction, can occur. These can be managed by stimulation reprogramming or lead revisions. However, failure can also occur over the long term with a technical properly functioning SNM.^{1,25–27} This may occur because of a different electrode location during PNE when temporary screening electrodes are used. But in our experience, similar failures occur in patients with tined lead PNE procedures, in which the electrode used during the test is not removed and is connected to the permanent stimulator. Failure in these patients may also be the result of a placebo effect during the screening period, which occurs over a relatively short period of three weeks.

A limitation of this study is the fact that predictive factors for SNM could be assessed only in patients with a previous positive PNE test confirming their eligibility for SNM treatment. This selection bias may have influenced the outcome of the analysis. In this study, 39 patients had insufficient results with permanent SNM at last follow-up. Some of these patients had other treatments, but 24 of them had no actions undertaken other than possible reprogramming of stimulation settings and parameters in some. This number of patients that did not require any other treatment may be explained by the definition of successful outcome used in this study, which was based on incontinence episodes recorded in a bowel habit diary. A number of patients may have had subjectively good results but also have had a period with more complaints during the three weeks they were supposed to fill in their diaries.

In our study, success rates for PNE were found to be lower in patients with a higher age, previous PNE failures, and/or external anal sphincter defects in an analysis comparing patients with successful and those with unsuccessful PNE outcomes. These factors may indicate lower chances for PNE success, but they do not exclude patients from SNM treatment. Although the predictive factors for SNM were assessed in this selected patient group, no predictive factors for permanent SNM outcome were discovered.

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