A modified approach to patient's selection with improved clinical outcomes in sacral nerve modulation

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Abstract

Introduction: Since the marketing of the percutaneous permanent tined leads (PPTL), many centres rely solely on these instead of the percutaneous nerve evaluation (PNE) as a screening tool. At our centre, we routinely perform PNE. Moreover, with our limited hospital resources, we have adopted a stricter definition of success in the patient selection process using an improvement of more than 60% as a cut-off point. This study presents our experience with sacral nerve stimulation using PPTL as an adjunct to PNE to improve the outcome of the screening method for patients suffering from refractory voiding dysfunction.

Methods: We reviewed the charts of 106 patients who underwent a PNE between 2001 and 2008. The outcome of the procedures, the complication rates and its long-term effect were reviewed.

Results: Overall, 116 PNE were performed and it was successful in 54%. Forty-five out of the 62 patients with a successful PNE underwent the stage I procedure. Of these, 93% had a successful stage I and were later implanted with the implantable pulse generator (IPG). The remaining 12 patients underwent the simultaneous implantation of the PPTL and IPG using the open procedure and it was successful in 10 of them.

Conclusion: The PNE is a good adjunct to the staged procedure to select the appropriate candidates for sacral nerve stimulation, especially with limited resources.

Introduction

Sacral nerve stimulation (SNS) was originally developed by Tanagho and Schmidt.[1] It is done in a stepwise fashion. The 2-stage procedure was first described by Janknegt and colleagues.[2] In this procedure, patients were first implanted with a temporary lead in the sacral foramina (percutaneous nerve evaluation-PNE) followed by the simultaneous implantation of permanent lead and subcutaneous implantable pulse generator (IPG) after a successful first step. The procedure was then modified by Spinelli and colleagues.[3] In this modified procedure, patients were implanted with a percutaneous permanent tined lead (PPTL) connected to an external pulse generator (stage I) followed by the implantation of the IPG (stage II) after a successful stage I. A stage success, arbitrarily defined as at least a 50% improvement in symptoms, meant that the patient would be offered the next step.

Since the marketing of the PPTL, many centres rely solely on the PPTL as a screening tool. Unfortunately, they are more expensive and more invasive than the PNE. To lower the cost and to improve the outcome of SNS at our centre, we perform a 3-stage technique where a PNE is done before the other permanent steps, serving as a screening tool. We have also adopted a stricter definition of success - improvement of more than 60% as a cut-off point. We present a retrospective long-term evaluation of our experience with SNS.

Methods

After obtaining the approval of our institutional review board, we performed a retrospective study to evaluate the outcome and the long-term efficacy of SNS. We reviewed all patients who underwent a PNE for refractory voiding dysfunction between 2001 and 2008 at our center. All patients underwent a preoperative assessment which included a history and physical examination, urine culture and a 7-day voiding diary. Parameters studied in the diaries included voiding frequency, voided volume, number of incontinence per day, number of protection or catheterization needed per day, urine volume per catheterization and quantification of pain on visual analog scale. Data were collected based on bladder diaries.

Candidates underwent a PNE for a period of 5 to 7 days. The procedure was performed based on the description by Thon and colleagues.[4] The procedures were done under local

anesthesia to determine the proper position of the electrode based on motor and sensitive responses and the lead was inserted unilaterally in one of the sacral foramina (usually S3). Patients were then given general precaution measures to avoid displacement of the electrode. Patients who showed an improvement of more than 60% of their symptoms on one of the voiding diary parameters were offered the next step. Patients who showed a suboptimal improvement (i.e., <60%) were either suggested an alternative treatment, a second PNE or a stage progression based on their preference. Patients with a suspected lead migration based on the clinical evolution (i.e., temporary initial improvement, disappearance or change in the stimulation responses) were offered a second PNE trial or a phase progression. Patients who showed no improvement, while having the adequate stimulation or motor and sensory responses, and those who did not like the stimulation sensation were offered an alternative treatment.

Candidates who underwent a successful PNE before 2003 were operated on using the open procedure as described by Janknegt and colleagues,[2] where the permanent lead and the IPG were implanted at the same time (PPTL were not yet available at that time). Candidates operated on after 2003 were implanted with the PPTL under local anesthesia. Details about both procedures are documented.[1-4] Patients who sustained an improvement of more than 60% after the evaluation period were proposed the stage II procedure, where an IPG is implanted in the buttock's region over the iliac crest. The lead was removed in the others. A treatment algorithm was developed (Fig. 1).

Patients were seen 4 weeks after the final step, then every 6 to 12 months as needed. During these visits, the patient's response was evaluated and the neurostimulation parameters were checked and adjusted for optimal symptoms relief.

SPSS version 17.0 statistical analysis software (SPSS Inc, Chicago, IL) was used to analyze and compare the different data. Data were summarized using the adequate descriptive statistics.

Results

The mean age of the population was 56 ± 11 years old. There were 70 women (66%) and 36 men (34%). Patient indications for PNE are summarized (Table 1). Of the 106 patients, the PNE was repeated in 10 of them. The reasons for the repeated procedure were a suspicion of lead migration in 8 patients and a trial at bilateral lead stimulation in the others. Overall, 116 PNE were performed with a success rate of 53% (62/116). The outcome of procedures were recorded (Table 2).

Thirteen failures (11%) were suspected to be due to electrode's migration (11 after first PNE, 2 after second attempt). Of these, 8 underwent another PNE while the remaining 5 (3 after first attempt, 2 after second attempt) underwent the installation of the PPTL after having showed a temporary initial improvement. Stage I was successful in 4. The others showed the appropriate clinical sensation, but lacked symptom relief and were thus deemed failures.

Of the 62 patients with a successful PNE, 45 (73%) underwent the implantation of the PPTL, while 12 patients (19%)

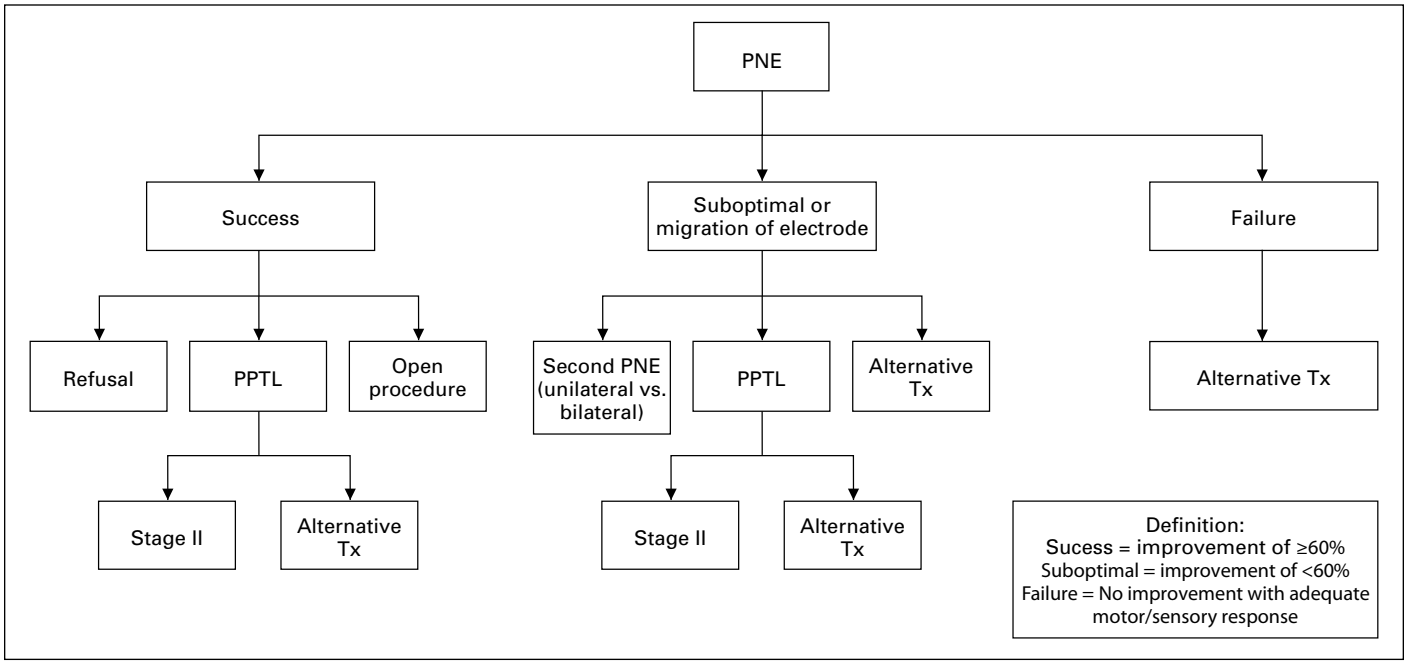

Fig. 1. Treatment algorithm.

Table 1. Indications for PNE implantation

	N (%)
Overactive bladder ± urgency urinary incontinence	45 (42.5)
Urinary frequency	11 (10.4)
Non obstructive urinary retention	24 (22.6)
Painful bladder syndrome/interstitial cystitis	26 (24.5)
Total	106 (100)

PNE: percutaneous nerve evaluation.

underwent the open procedure. Five patients (8%) refused to go on with the procedures because of the potential nuisance that could result from the treatment. Of the patients with a successful PNE and who underwent the stage I procedure (PPTL), 93% (42/45) had a successful trial and the improvement was sustained after the stage II in all of them. Ten patients (83%) had a successful outcome when the open procedure was used.

Seventeen patients (16%) had a suboptimal improvement during PNE including 6 who had an improvement of more than 50% but less than 60%. Of these, 2 underwent a bilateral PNE trial which failed in both of them and after discussion with the patients, procedures were stopped. Seven chose to continue with the procedures. Stage I was successful in 4 of them (including 3 who showed an improvement of more than 50% but less than 60% during the PNE). They were later implanted with the IPG. All the other patients chose to stop the procedures. One patient, even though he showed no improvement after the PNE despite having the adequate motor and sensitive response, was implanted with the PPTL. He showed no benefit from the latter and the lead was removed (Table 3).

Overall, 91% (52/57) of the patients with a successful PNE and who completed the staged procedures had a successful outcome, and 58% (61/106) of those who underwent the PNE evaluation completed the staged procedures (Fig. 2).

After a mean follow-up of 53.1 months (range: 9-109), 75% of the patients (46/61) implanted with the IPG reported a subjective improvement of more than 60% from their initial complaint (median subjective improvement of 80% (range: 65-100). This information was unavailable for 8 patients.

In all, 16 adverse events (26.2%) were reported during the follow-up period (Table 4). Thirteen surgeries were needed in 9 patients (14.8%) after the implantation of the IPG and 5 devices (8.2%) needed to be explanted, including the 2 patients who failed the open procedure (Table 5). Five patients had their battery replaced after an average of 85 months (range: 81-96).

Discussion

Many centres prefer PPTL as a screening tool because it is thought to be a better predictor of progression to IPG than the PNE. The PPTL allows for a longer screening period, has a lower migration rate and if successful the lead is already in place. Our 53% PNE success rate is comparable to the rates in the literature, which vary between 35% and 70%.[5-10] A reason for this low result was the high rate of lead migration. According to Weil and colleagues,[11] this rate is at least 20%. However, we found that by properly securing the electrode and by giving precaution measures, this rate could be lowered (11%). We believe that to improve its efficacy, it is primordial to do the procedure under local anesthesia to locate the adequate stimulation site guided by the patient's feedback. The test should be repeated when a lead migration is suspected. In our opinion, patients who lacked clinical response while feeling the adequate stimulation or contraction should be considered for alternative treatment.

A recent study by Borawski and colleagues[12] stated that PPTL was a better predictor of progression to IPG then the PNE (88% vs. 46%) among patients suffering from refractory urge incontinence. Other studies in favour of the PPTL reported similar rates (67%-80%).[3,7,10,13] We reported a 56% progression rate to IPG when the PNEs were used. However, when only successful tests were considered, 91% of patients were subsequently implanted with the IPG. This value is higher than those reported previously with failure rates varying between 21% and 51% after a successful PNE.[14,15] We do not dispute the fact that stage I seems to be a better predictor of progression to IPG than the PNE. However, even though it is not perfect, the PNE still has its place as a screening instrument mainly because it is less expensive (about $2150 vs. 295$) and less morbid than the PPTL while providing acceptable results. It is also useful to weed out patients who

Table 2. Outcome of procedures after successful PNE trial according to diagnosis

Diagnosis (n)	Successful PNE (%)	Refusal after successful PNE or PPTL (%)	Successful PPTL (%)	Failure of PPTL (%)	Successful 2-stage procedure (%)	Failure 2-stage procedure (%)
OAB ± UUI (45)	30 (67)	1 (3)	20 (67)	1 (3)	7 (23)	1 (3)
Frequency (11)	7 (64)	1 (14)	3 (43)	0 (0)	3 (43)	0 (0)
NOUR (24)	6 (25)	1 (17)	5 (83)	0 (0)	0 (0)	0 (0)
PBS/IC (26)	19 (73)	2 (11)	14 (74)	2 (11)	0 (0)	1 (5)
Total (106)	62 (59)	5 (5)	42 (38)	3 (3)	10 (9)	2 (2)

OAB: overactive bladder; UUI: urgency urinary incontinence; NOUR: non-obstructive urinary retention; PBS: painful bladder syndrome; IC: interstitial cystitis; PNE: percutaneous nerve evaluation; PPTL : percutaneous permanent tined lead.

Table 3. Outcome of the permanent implant stage according to the results of the PNE

	Success (%)	Failure (%)
After successful PNE		
– PPTL trial (n=45)	42 (93)	3 (7)
– Open procedure (n=12)	10 (83)	2 (17)
After suboptimal PNE		
– Bilateral PNE (n=2)	0 (0)	2 (100)
– PPTL trial (n=7)	4 (57)	3 (43)

PNE: percutaneous nerve evaluation; PPTL: percutaneous permanent tined lead.

Table 4. Adverse events

	N (%)
Permanent lead problems	3 (4.9)
– Migration	2
– Fracture	1
Infection	2 (3.3)
– Superficial wound infection	1
– Abscess	1
Cease using SNS	4(6.6)
– Refractory painful stimulation	1
– Lack/loss of efficacy	3
Pain IPG site	4 (6.6)
IPG malfunction	2 (3.3)
Hematoma	1 (1.6)

SNS: sacral nerve stimulation; IPG: implantable pulse generator.

cannot tolerate the stimulation or find it too cumbersome. Furthermore, it can be performed under local anesthesia in an office setting, unlike PPTL which usually requires at least some anesthesia supervision.

We believe that the 3-staged procedure, although more time consuming, is the best compromise between cost and adequate patient selection. Furthermore, 4 patients were successfully treated with the SNS although they initially showed a suboptimal improvement rate during the PNE trial. It is important to inform patients with suboptimal results during the PNE trial of the higher failure probability. Nevertheless, because the SNS treatment is last resort, the stage progression is still to be considered and offered as it may still successfully relief a patient's symptoms.

Although, the success rates of the procedures were arbitrarily defined as an improvement of more than 50%, we used a stricter criterion (improvement of more than 60%).

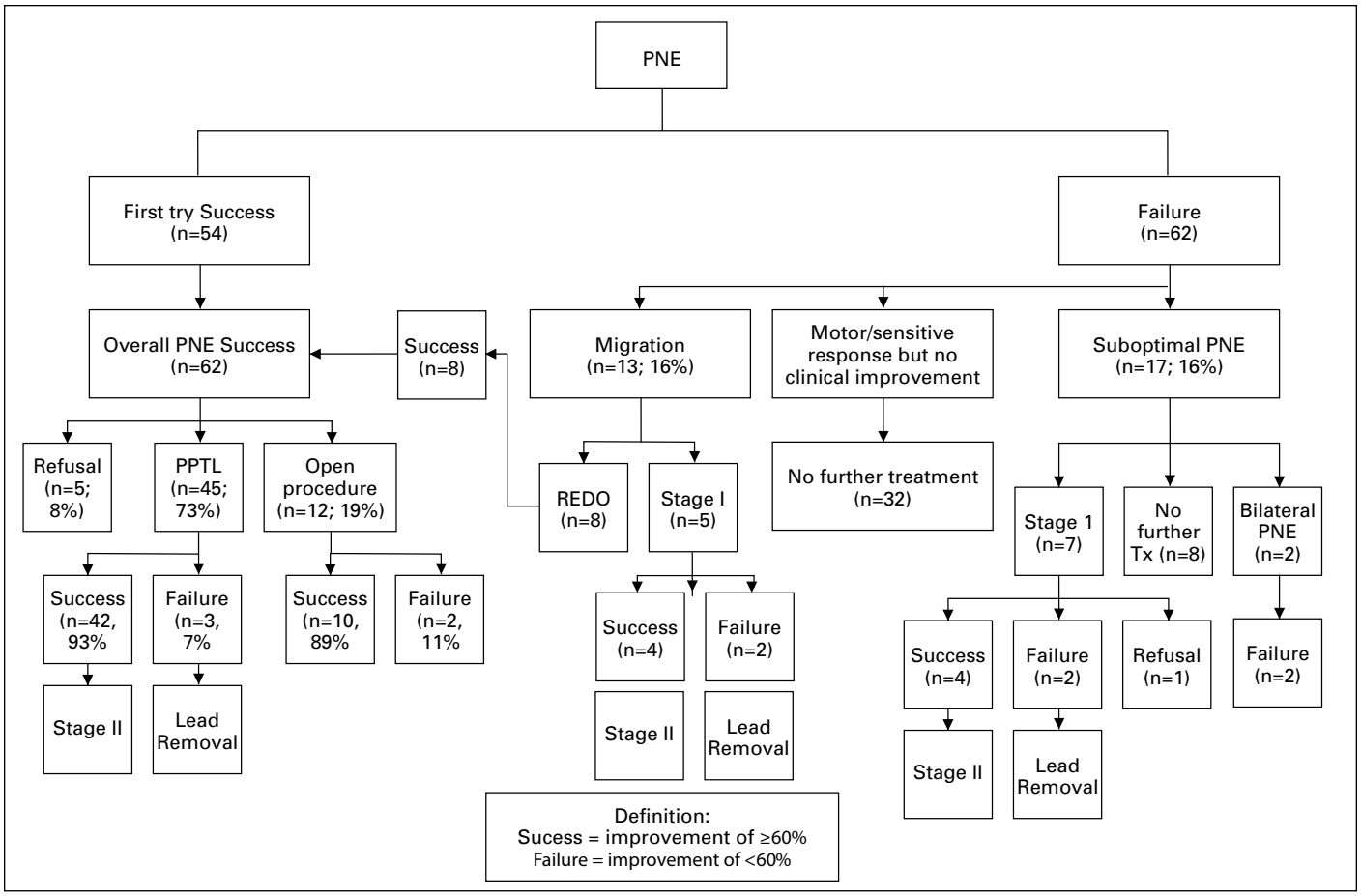

Fig. 2. Results algorithm.

Table 5. Reoperations

	N (%)
Revision	8 (13.1)
– Pain (IPG)	4
– Permanent lead migration	1
– Hematoma	1
– IPG malfunction	2
Explantation	5 (8.2)
– Loss of efficacy	3
– Pain (IPG)	1
– Abscess	1

IPG: implantable pulse generator

We based our decision on the fact that several studies have compared antimuscarinics agents to a placebo group and demonstrated a high placebo effect (up to 62%).[16-18] It has been stipulated that the voiding diaries themselves can be considered therapeutic because they resulted in a behavioural modification. Based on our experience, we have also found that most patients with an improvement of less than 60% were more likely to be dissatisfied with the outcome of SNS or to refuse to go on with procedure. Unfortunately, due to the retrospective nature of this study we have no data to support our claim.

Our post-implantation complication rate (26.2%) is lower than those described previously (53% to 67%),[19,21-23] although lower rates (15.5%) were reported by Spinelli and colleagues.[24] Moreover, our explantation (8.2%) and reoperation rates (14.8%) are also lower than in the other studies, with rates ranging from 9% to 15%[10,19-21,23] and 33% to 54%,[10,19,21,23] respectively. We also confirmed the durability of the effect provided by the SNS as most patients are still improved after a mean follow-up of 53 months. These numbers are better than those provided by van Voskuilen and colleagues,[25] who reported good results in 59.7% of patients, which is comparable to the 71% to 84% success rate at 5 years follow-up reported by Oerleman and van Kerrebroeck.[23]

The limitations of this study are its retrospective nature and our inability to accurately determine the proportion of patients defined as failures after the PNE that would have been improved following a stage I attempt. We assumed this rate was low because it is improbable that a patient with an adequate stimulation response and with no symptom relief would have shown an improvement after stage I. However, further studies will be necessary to confirm this hypothesis as this study was not designed to do so.

Conclusion

The PNE is a good adjunct to the staged procedure to improve the screening of the appropriate candidates, especially when the budget is limited. It is a good compromise between low cost and high prediction of long-term success. A good patient selection enhances clinical outcomes and reduces complication rates and the overall cost of the procedure.

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This paper has been peer-reviewed.

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