Spinal Cord (2014) 52, 241–245

www.nature.com/sc

ORIGINAL ARTICLE

Sacral neuromodulation for neurogenic non-obstructive urinary retention in incomplete spinal cord patients: a ten-year follow-up single-centre experience

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Objective: To determine the success rate of percutaneous first stage of sacral neuromodulation (SNM) and the efficacy and safety of permanent SNM for incomplete spinal cord lesion (SCL) patients suffering from chronic neurogenic non-obstructive urinary retention (N-NOR).

Method: From January 2003 to December 2012, 85 individuals underwent the percutaneous first stage of SNM. Subsequently, only responders who reached a concomitant reduction by at least 50% of volume per catheterization and in the number of catheterizations per day comparing their 7-day voiding diaries at baseline underwent permanent SNM. Final follow-up was conducted by April 2013.

Results: Thirty-six individuals responded to percutaneous first stage of SNM. Post-surgery urodynamics documented all patients experiencing first sensation of bladder filling. A statistically significant increase in Qmax ml per sec and decrease in post-voiding residual urine per ml were documented. ($P<0.01$). First sensation of bladder filling at baseline represented a statistically significant parameter for the success of the first stage SNM ($P<0.05$). Eleven out of 34 patients at follow-ups were 'inconstant responders' because they returned to similar baseline voiding symptoms, but responded again with an implant on the controlateral S3 sacral root. Two failed twice and responded once again after an S4 sacral root implant. All but one failure occurred more than 3 years after the previous implant. Other drawbacks were resolved telemetrically.

Conclusions: Research is needed to increase the success rate of the first stage SNM on incomplete SCL patients with N-NOR. Permanent SNM is highly efficacious in the medium follow-up.

Spinal Cord (2014) **52,** 241–245; doi:10.1038/sc.2013.155; published online 7 January 2014

Keywords: neurogenic non-obstructive urinary retention; sacral neuromodulation; aseptic intermittent catheterizations; urodynamics

INTRODUCTION

Neurogenic non-obstructive urinary retention (N-NOR) due to spinal cord lesion (SCL) may be treated with pelvic floor reeducation, or drugs such as alpha-blockers and parasympathomimetics, though these therapies are commonly unsuccessful.[1,2]

Moreover, literature reports that with intravesical electrostimulation patients regained detrusor activity and increased awareness of bladder filling.[3,4] However, other authors show negative findings.[5,6]

A recent review on the use of sacral neuromodulation (SNM) for neurogenic lower urinary tract dysfunction reports that no definitive conclusions can be drawn from the available evidence regarding this procedure for neurogenic lower urinary tract dysfunction.[7]

The aim of this retrospective study is to address the success rate percentage of first stage SNM in individuals with an incomplete SCL. Moreover, medium- and long-term efficacy associated with the safety of permanent SNM on SCL subjects suffering from N-NOR were evaluated.

MATERIALS AND METHODS

This is a retrospective study. Data were retrieved from our neuro-urology database via a computerized search using the keywords: 'N-NOR and SNM'. Only individuals with an incomplete SCL according to the American Spinal Injury Association Impairment Scale suffering from objective evidence of chronic N-NOR were selected[8] (see Table 1).

This way we were able to access patients demographic information, diagnostic investigations as well as their 7-day voiding diaries completed at various stages.

First, the subjects who had undergone percutaneous first stage of SNM (Medronic Inc., Minneapolis, MN, USA) at our neuro-urology department were identified.[9] Responders were those categorized as having at least a 50% reduction in volume per catheterization per ml as well as a 50% reduction in the number of catheterizations per day, determined through the comparison of the 7-day voiding diaries at baseline and the end of SNM first stage. Video-urodynamic data were provided at baseline and at the end of the first stage of SNM for all subjects with incomplete SCL. Only responders underwent permanent SNM.

Subsequently, at each office visit, their voiding diary data and the values of the Q max ml per sec were pulled from the database as well as volume urine pre- and post-voiding residual (PVR) urine per ml was documented through a suprapubic ultrasound scan of the bladder.

At each follow-up, stimulus parameters such as amplitude in volts, pulse width (μs) and rate, mode (cycling versus continuous) and possible battery depletion were checked as well.

The patients who had 'failed' post-permanent SNM were identified. 'Failure' was defined as less than 50% reduction in volume per catheterization per ml and number of catheterizations per day comparing the 7-day diary post-permanent SNM with baseline. The causes for failure were identified from our database.

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Received 13 June 2013; revised 26 August 2013; accepted 6 November 2013; published online 7 January 2014

Patients who underwent another first stage of SNM were included if they had respected the same inclusion criteria (see Table 1).

Video-urodynamic study

The video-urodynamic study included continuous filling cystometry with maximum filling of 500 ml. During cystometry, patients were asked to report all sensations related to bladder filling: initial sensation, first desire to void and strong desire to void.

Urodynamic studies were performed according to 'Good Urodynamic Practice' recommended by the International Continence Society.[10] Pressure/flow studies were reported for patients able to void with concomitant assessment of detrusor sphincter dyssynergia through a needle electromyography located at the perineum.

SNM surgery

In the first stage of SNM the permanent electrode was inserted percutaneously into the monolateral third S3 sacral foramina and was then stimulated by using an external pulse generator (Medtronic InterstimTM model 3625, Minneapolis, MN, USA). The proper positioning of the needle was confirmed by fluoroscopy. Subsequently, those responding to the first stage of SNM underwent permanent SNM where an implantable pulse generator was placed.

Statistical analysis

Descriptive analyses were performed to describe the patients characteristics.

The students *t*-test and paired *t*-test were used to compare quantitative values of the urodynamic patterns at baseline versus the end of first stage of SNM. Instead χ^2 test was applied to compare qualitative values of the urodynamic patterns. The χ^2 test was also used to detect possible statistically significant predictable parameters for the success of the first stage of SNM, comparing the following variables for both responders and non-responders at baseline—demographics, voiding symptoms and urodynamic patterns. In the statistical study of the data only those values with $P<0.05$ were considered significant.

All patients admitted to our neuro-urological department provided written informed consent before each treatment and also signed a proper form of informed consent, accepted by our internal ethical committee, allowing the collection of personal data for further research.

RESULTS

Patient population

A total of 87 incomplete SCL subjects from our database underwent the first stage of SNM from January 2003 to December 2012 in our neuro-urology department because objective evidence indicated N-NOR. Two patients were excluded from our study because their 7-day voiding diaries and/or videourodynamics data were incomplete, though they were non-responders at the end of the first stage of SNM. Eighty-five individuals were included during the first stage of SNM.

The main characteristics of the patients are reported in Table 2. They are stratified into two groups: 49 non-responders to the first stage of SNM (57.5%) and 36 responders (42.5%).

Patients with complete N-NOR performed 4–5 catheterizations per day, whereas those who demonstrated incomplete N-NOR, in that they were able to void (more than 50 ml per void), performed 2–4 catheterizations per day due to high PVR urine per ml greater than 200 ml.

First stage of SNM non-responders

At the end of the first stage of SNM, seven patients recovered spontaneous micturition with voiding volume per ml per void

Table 1 Inclusion criteria of the study

Pre-first stage of SNM
Incomplete SCL patients, C or D, according to ASIA/AIS scale.
Patients with complete or partial urinary retention for at least 6 months with high-residual urine due to detrusor acontractility or hypocontractility were included.
Absence of mechanical–anatomical bladder outlet obstruction evaluated through urological examination, abdominal ultrasonography, urethrocystoscopy, radiological investigation and pressure/flow studies in patients able to void.
Creatinine serum level between 0.6–1.2 mg dl^{-1}.
Patients without symptoms and/or signs of urinary tract infection.
Patients in which kidneys and bladder ultrasound did not detect morphological alterations, solid tumors, kidney and bladder stones and hydronephrosis.
Patients who completely filled in all the bladder entries for 7 days reporting volume per catheterization per ml and number of aseptic intermittent catheterization per day.
Patients without psychiatric disorders according to the MMPI-2 questionnaire.
During first stage of SNM
Patients who completely filled in all bladder entries 7 day before the end of first stage of SNM.
Patients submitted to video-urodynamics investigations at the end of the first stage of SNM.
Permanent SNM
Patients who completely filled in their voiding diaries during the 7 days prior to each programmable visit at 1 month, 6 months and then every 6 months.
Completely filled in 7-day voiding diary was mandatory also for 'on demand' visits in case their voiding symptoms worsened.
Free flowmetry and post-voiding residual urine per ml collected at each office visit.

Abbreviations: ASIA/AIS, American Spinal Injury Association (ASIA) Impairment Scale (AIS); MMPI, Minnesota Multiphasic Personality Inventory; SCL, spinal cord lesion; SNM, sacral neuromodulation.

Table 2 Reports the characteristics of patients participating in the study

	First stage of SNM non responders	*First stage of SNM responders*
Number of patients	49	36
Number of Males (%)	31 (63.3)	21 (58.3)
Mean age in years at time of the first stage of SNM (range)	39.3 (24–67)	38.2 (27–54)
Patients with complete N-NOR (%)	33 (67.3)	20 (55.5)
Time lapse from SCL to first stage of SNM in months (range)	44 (12–78)	38.3 (15–67)
ASIA/AIS scale		
C (%)	34 (69.4)	27 (75)
D (%)	15 (30.6)	7 (25)
Etiology of SCL		
Traumatic (%)	35 (71.4)	27 (75)
Vascular (%)	2 (4.1)	1 (2.8)
Myelitis (%)	12 (24.5)	9 (22.2)
Previous treatment for N-NOR		
Use of alpha-blockers (%)	49 (100)	34 (100)
IVES (%)	32 (65.3)	28 (77.7)
Pelvic rehabilitation (%)	14 (28.6)	13 (36.1)
Mean duration in days of first stage of SNM (range)	33 (28–42)	34 (28–42)

Abbreviations: ASIA/AIS, According to the American Spinal Injury Association (ASIA) Impairment Scale (AIS); IVES, intravesical electrostimulation; N-NOR, neurogenic non-obstructive urinary retention; SCL, spinal cord lesions; SNM, sacral neuromodulation.

between 60–100 ml, using three catheterization per day due to high PVR urine per ml of around 300 ml per catheterization. The others showed voiding symptoms similar to baseline (see Figure 1). At the end of the first stage of SNM, only two more patients referenced first sensation of bladder filling during cystometric filling compared with baseline (see Table 3).

First stage of SNM responders

Sixteen out of 36 patients (44.4%), five of them women, reported PVR urine per ml of less than 80 ml (range 20–70 ml) in their 7-day voiding diaries. Sixteen (44.4%) carried out one catheterization per day with PVR per ml between 120 and 150 ml, whereas four individuals (11.2%) with complete N-NOR at baseline performed two catheterizations per day with PVR per ml of around 200 ml (see Figure 2). Table 4 describes the principal urodynamics findings.

Predictive parameters for the success of the first stage of SNM

The higher number of responding patients with first sensation of bladder filling at the video urodynamics at baselines represented the only statistically significant parameters for the success of the first stage of SNM, compared with non-responders (see Table 5).

Patients submitted to permanent SNM

From our database we noted that final visits were performed for all patients between November 2012 and April 2013. Of the 36 subjects who underwent permanent SNM, two patients (one male, one female) with complete N-NOR at baseline were excluded because they were lost during the follow-up at 2 years and 3 years, respectively post-permanent SNM, though at their final follow-up they were still responders.

The individuals were divided into two groups. The first was composed of 23 subjects, 10 of them females, called 'constant responders' because they consistently maintained their voiding improvement according to our criteria in the mean post-permanent SNM follow-ups of 50 months (range 6–95 months). Overall, 204 free-flowmetry (range 2–17) had been performed. Bladder volume pre-free flowmetry varied from 200–500 ml. Mean Q max ml per sec was 14.1 ml per sec (range 9.2–21.4).

Table 3 Urodynamic findings of the non-responders at baseline and at the end of first stage of sacral neuromodulation

Urodynamic patterns	*Non responders 49 patients*		
	Baseline	*End of first stage of SNM*	*Statistical tests* (P)
Filling phase			
Number of patients experiencing first sensation of bladder filling	6	8	Chi square (0.773)
Mean volume per ml ± s.d. of first sensation of bladder filling	431.7 ± 31.9	440 ± 34.3	T paired (0.363)
Mean bladder capacity (ml) ± s.d.	493.6 ± 31.8	486.7 ± 37.9	T paired (0.088)
Mean compliance (cmH20) ± s.d.	78 ± 17	76.8 ± 17.4	T paired (0.116)
Voiding phase			
Number of patients able to void	14	21	Chi square (0.206)
Mean maximum flow rate (ml per s) ± s.d.	5.3 ± 0.4	5.6 ± 0.6	Student's *t* (0.137)
Mean PdetQmax (cmH20) ± s.d.	6.8 ± 0.5	7.1 ± 0.9	Student's *t* (0.376)
Mean PVR urine (ml) ± s.d.	435 ± 32.7	420 ± 24.1	Student's *t* (0.128)
Mean maximum urethral closure pressure (cmH20) ± s.d.	68.2 ± 7.2	67.7 ± 6.9	T paired (0.130)

Abbreviations: PVR, post-voiding residual; s.d., standard deviation; SNM, sacral neuromodulation.

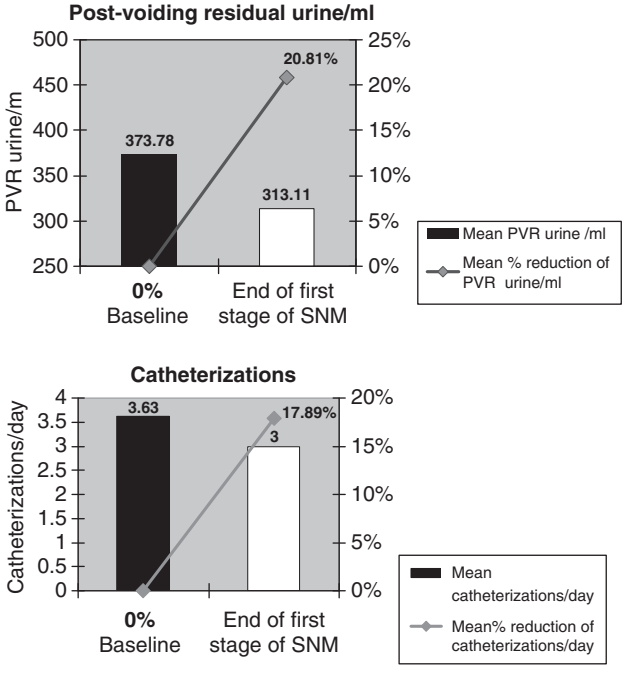

Figure 1 Depicts the main clinical data on non-responders before sacral neuromodulation and at the end of first stage.

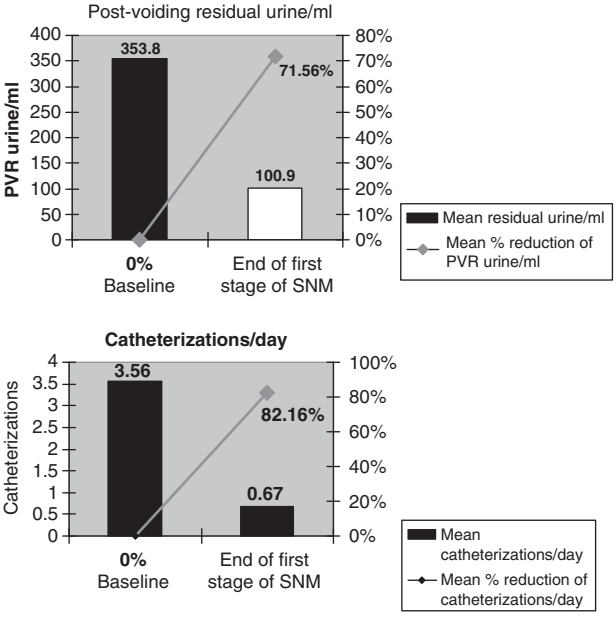

Figure 2 Shows the main clinical data on responders before sacral neuromodulation and at the end of first stage.

Table 4 Urodynamic findings of responders at baseline and at the end of first stage of sacral neuromodulation

Urodynamic patterns	*Responders 36 patients*		
	Baseline	*End of first stage of SNM*	*Statistical tests (P-value)*
Filling phase			
Patients experiencing first sensation of bladder filling	16	36	Chi square (<0.01)
Mean volume of first sensation of bladder filling per ml ± s.d.	421.30 ± 57	361.20 ± 51.10	Student's *t* (0.04)
Mean bladder capacity per ml ± s.d.	495 ± 34.8	480.90 ± 50.6	T paired (0.075)
Mean compliance cm/H20 ± s.d.	81.9 ± 20.9	79.7 ± 22.4	T paired (0.090)
Voiding phase			
Number of patients able to void	14	36	Chi square (<0.01)
Mean PdetQmax (cmH20) ± s.d.	7.2 ± 0.9	16.5 ± 2.2	Student's *t* (<0.01)
Mean maximum flow rate ml per sec ± s.d.	5.5 ± 0.4	13.9 ± 3.7	Student's *t* (<0.01)
Mean PVR urine per ml ± s.d.	433.6 ± 31	114.1 ± 39.1	Student's *t* (<0.01)
Mean maximum urethral closure pressure (cmH20) ± s.d.	67.1 ± 7.7	65.9 ± 6.4	T paired (0.103)

Abbreviations: PVR, post-voiding residual; s.d., standard deviation; SNM, sacral neuromodulation.

Table 5 Predictive parameters for the success of first stage of SNM

Predictive parameters for success	*Responders 34 patients*	*Non responders 45 patients*	*Chi square test (p)*
Reported first sensation of bladder filling during cystometric filling at baseline	16	6	0.02
Complete N-NOR	20	31	0.491
Less than 3 years from N-NOR to first stage of SNM	13	8	0.075
Number of patients 40 years or older	10	16	0.739
Number of females	16	14	0.226
Number of patients with ASIA/AIS D	7	14	0.429
Number of patients with traumatic etiology of SCL	30	37	0.674

Abbreviations: ASIA/AIS, American Spinal Injury Association (ASIA) Impairment Scale (AIS); N-NOR, neurogenic non-obstructive urinary retention; SCL, spinal cord lesion.

A group of 11 'inconstant responders' including four females, documented at least one failure during the post-permanent SNM follow-ups. Overall 11 patients suffered 13 failures because two male subjects presented two failures and needed two new permanent SNM implants. At the first failure, a new implant on the S3 controlateral root was introduced, whereas at the second failure, a sacral S4 root implant was carried out on the two subjects. Thirty out of the 34 patients (88.2%) with permanent SNM responded for up to five years post-permanent SNM. In fact, one failure occurred within 3 years of the previous permanent SNM (28 months), five between 3 and 5 years for three patients and the other seven in a follow-up longer than 5 years with a maximum of 77 months.

For all patients with failures, prior to the new first stage of SNM, the 7-day voiding diary detected PVR of more than 300 ml (range 320–380) with range of catheterizations from three to four per day. Their Q max varied from 3 to 5 ml per sec and during failure they emptied less than 1/4 of their urine volume. During cystometric filling, six patients who did not experience bladder sensation at baselines recovered it at the end of the new first stage of SNM. In the emptying phase, mean PVR urine ml was 120 ml (range 60–180 ml). These patients continued to respond according to our criteria up to the final check-up with a mean follow-up of 23 months for the nine patients with one failure (range 6–42 months), whereas the two males with double failures responded up to their final follow-ups of 12 months and 18 months, respectively.

Only in two cases (15.3%) were the reasons for failure revealed and attributable to the displacement of the sacral electrocatheter. The causes were unidentified for the other 11.

The following were not detected: worsening of neurological status, the onset of a new neurological pathology, manifesting psychiatric disorders according to the Minnesota Multiphasic Personality Inventory questionnaire or the presence of mechanical–anatomical bladder outlet obstruction.[11] Moreover, modifying the patients parameter settings (at least 3–5 attempts) did not improve their voiding symptoms.

Continuous stimulation was used on all the 34 subjects. The neuromodulation device settings were set at a frequency between 14 and 25 Hz, with a pulse width of 210 msec. Substitution due to battery expiration was required in 12 patients. The mean life span of the replaced implantable pulse generator was 62.4 months (range 45–77).

Side effects

No drawbacks were recorded during the first stage of SNM.

After permanent SNM, in addition to failure, our database revealed the following drawbacks with regard to eight more patients: four females showed new pain/undesirable change in stimulation, four males reported pain at the implantable pulse generator site (2) and adverse change in bowel function (2). All these side effects were resolved telemetrically.

CONCLUSIONS

The present study shows that about 40% of incomplete SCL patients suffering from N-NOR responded to first stage of SNM. It is important to be aware of the fact that our sample had previously undergone conservative treatments that failed. Therefore, the percutaneous first stage of SNM testing seems worthwhile for incomplete SCL subjects with N-NOR who find themselves in otherwise hopeless situations. That a higher percentage of patients in the responding group experienced first sensation of bladder filling, which was observed through urodynamics at baseline, representing a statistically significant predictable factor for the success of the first stage of SNM. The urodynamics study performed at the end of the first stage of SNM showed that the first sensation of bladder filling was recovered by all patients lacking it at baselines in the responding group versus non-responding.

Furthermore, a mean slight raise in detrusor contractility was documented at the end of first stage in the responder group; however, it is statistically significant compared with baseline. SNM may then favor the improvement and return of voiding ability for subjects with

incomplete SCL mainly by inducing/improving bladder sensation associated with a small increase in detrusor contractility.

Our success rate with permanent SNM is above 80% in this category of neurologic patients within a 5-year follow-up post-surgery. This percentage is similar to other studies including other categories of patients suffering from non-obstructive chronic urinary retention.[12–15] However, the reasons for failure were identified in only two cases, and at this time we are only able to speculate on the unknown causes. Our findings showed that the time-duration of permanent SNM increased the possibility of failure, and the group of constant responders had a much shorter mean follow-up post-permanent SNM compared with the inconstant responder. One possible explanation for the failure is that over time the continuative stimulation may have caused fatigue in the sacral root as this setting was always used on all patients.

The fact that the implant on a new 'virgin' sacral root restored voiding improvement for all patients seems to confirm the theory of nerve fatigue as the reason for unknown causes of failure. Unfortunately, it is impossible to know whether the old sacral root may have recovered the capacity to improve voiding symptoms because the old SNM implant was removed when the new permanent SNM was implanted.

The urodynamics of the 'inconstant responders' documented that those patients who had recovered bladder sensation with the first permanent SNM and then returned to similar voiding symptoms, did not report bladder sensation, but recovered it again after the new first stage of SNM. Therefore, whatever the motivation behind the failures, it leads to losing bladder sensation. This study is limited by its retrospective nature and the small number of patients included. However, objective data in the form of voiding diaries, flowmetry with PVR per ml and urodynamics were recorded.[16] Flowmetry with PVR urine per ml seems to have been a good method for determining responders from non-responders.

However, based on our objective data, it is necessary to better monitor patients submitted to SNM, to note in their voiding diaries whether there is the presence or absence of bladder sensation pre voiding, as well as prior to free flowmetry. This parameter could be useful to detect a praecox worsening of their voiding symptoms with the need for a urodynamic investigation, even if the patients maintained clinical voiding benefits of more than 50% compared with baseline.

Not assessing the impact of SNM on quality of life is another possible limit to our study. That said, all patients willingly agreed to undergo a new permanent SNM implantation to restore their previous voiding benefits if the first SNM failed. Though at this time SNM is not a standardized treatment for incomplete SCL subjects suffering from N-NOR, it does represent a possible therapeutic option considering that SNM is a mini-invasive surgery, no serious adverse effects have been reported, and it doesn't preclude any other treatments for N-NOR.[17] Ongoing investigations should focus on those factors increasing the success rate of first stage of SNM; for example, adopting bilateral SNM and the time/duration of efficacy after permanent SNM, thereby reducing the cost of this therapy and increasing the these patients' quality of life.[17–20]

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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