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ORIGINAL ARTICLE

Intravesical electrostimulation versus sacral neuromodulation for incomplete spinal cord patients suffering from neurogenic non-obstructive urinary retention

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Objectives: To compare the efficacy of intravesical electrostimulation (IVES) versus sacral neuromodulation (SNM) in patients with incomplete spinal cord lesions (SCL) and neurogenic non-obstructive urinary retention (N-NOR).
Methods: In this retrospective study, 77 N-NOR patients underwent IVES (minimum 28 sessions), then after returning to voiding baseline symptoms, percutaneous first stage of SNM (lasting for minimum 4 weeks). After the two neuromodulation treatments, responders were categorized as patients experiencing both a 50% reduction of volume per catheterization per ml and a 50% reduction in number of catheterizations per day when comparing the 7-day voiding diaries at the end of both procedures to baselines. New urodynamics were performed subsequently. Responders to first stage of SNM underwent permanent SNM.
Results: Forty-eight patients responded to neither of the treatments, whereas 29 responded to both IVES and first-stage SNM. No significant statistical differences ($P > 0.05$) were detected in the voiding diaries. Following the two procedures, the first sensation of bladder filling was either maintained or recovered by all responders, whereas the same 11 patients reached a bladder contractility index of >100. The 29 IVES responders lost their clinical benefits in a mean follow-up of 9.6 months. Only 10 out of the 29 patients became nonresponsive to permanent SNM, in a mean follow-up of 54 months.
Conclusion: A strict correlation in terms of clinical and urodynamic patterns was demonstrated in patients with incomplete SCL and N-NOR, following IVES and first stage of SNM. However, voiding improvement through IVES was short-term when compared with the effects of permanent SNM.
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Keywords: intravesical electrostimulation; sacral neuromodulation; neurogenic non-obstructive urinary retention; intermittent catheterizations

INTRODUCTION

Neurogenic non-obstructive urinary retention (N-NOR) due to spinal cord lesion (SCL) may generate therapeutic problems for the urologist because pelvic floor re-education or medical therapies, such as alpha-blockers and parasympathomimetics, are commonly unsuccessful, and for the latter, drug literature has reported serious possible drawbacks.[1–3] Intravesical electrostimulation (IVES) represents another conservative treatment for individuals with N-NOR. However, IVES has not been widely accepted as standard treatment for patients suffering from N-NOR because several groups have reported, regained detrusor activity and increased awareness of bladder filling after IVES, while negative findings have been reported by other authors.[4–7]

Only recently a few studies, including a small number of patients with incomplete SCL suffering from N-NOR, have reported results with permanent sacral neuromodulation (SNM).[8,9] At this time, it is not known whether these neuromodulation therapies are complementary or alternative for patients affected by incomplete SCL and N-NOR. The aim of this study is to address the clinical and urodynamic patterns of IVES versus SNM for patients afflicted with incomplete SCL and N-NOR.

MATERIALS AND METHODS

After receiving approval from our internal ethical committee, we conducted a retrospective review of patients with incomplete SCL (C or D), according to the American Spinal Injury Association Impairment Scale, with objective evidence of N-NOR treated with a round of IVES and subsequently submitted to the percutaneous first stage of SNM because each patient had returned to pre-IVES baseline voiding symptoms[10,11] (see Table 1). Additional inclusion criteria for our study are reported in Table 1.

Data were retrieved from our neuro-urology admissions database via a computerized search using the keywords: neurogenic non-obstructive urinary retention, IVES and SNM. Inpatient data were available over a 10-year period (January 2003–October 2012).

We were thus able to access patients' demographic information, diagnostic investigations and their voiding diaries, completed at various stages. From our database, we identified the number of patients who had responded to both IVES and first stage of SNM. Patients subsequently submitted to permanent SNM surgery were selected as well. Responders were defined as patients who had reached a minimum of 50% reduction of volume per catheterization per ml as well as a 50% reduction in the number of catheterizations per day, comparing the 7-day voiding diaries at the end of the two neuromodulation procedures to the 7-day voiding diaries at baselines. Through urodynamics concluded at the end of both IVES and first stage of SNM, we compared the following urodynamic patterns: number of patients referencing bladder

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Table 1 Inclusion criteria of the study

Inclusion criteria
Pre-intravesical electrostimulation (IVES)
Absence of mechanical-anatomical bladder outlet obstruction (BOO) evaluated through urological examination, abdominal ultrasonography, urethrocystoscopy, radiological investigation, pressure/flow studies in patients able to void, and urethral pressure profilometry
Creatinine serum level between 0.6 and 1.2 mg/dl
Patients without symptoms and/or signs of urinary tract infection
Patients whose kidney and bladder ultrasounds did not detect morphological alterations, solid tumors, kidney and/or bladder stones and hydronephrosis
Patients who properly completed all bladder diary entries for 7 days, reporting volume per catheterization per ml and number of aseptic intermittent catheterization per day
During IVES treatment
Patients who properly completed all bladder entries 7 days before the end of IVES
Patients submitted to urodynamic investigations at the end of IVES
Follow-up post-IVES
Patients attended all programmable follow-up visits at 1, 3 and 6 months and then every 6 months, and upon patient request owing to worsening symptoms or loss of voiding symptoms
Patients properly completed their voiding diaries 7 days before each follow-up visit
Pre-first stage of sacral neuromodulation (SNM)
Patients were required to respect the same pre-IVES criteria
Each patient had to return to similar clinical voiding conditions before IVES: for each patient the same number of catheterizations per day and a maximum variation of ± 5% of post-void residual urine per ml comparing the 7-day voiding diary pre-IVES versus pre-first stage of SNM
First stage of SNM
Patients who properly completed all bladder entries 7 days before the end of the first stage of SNM
Patients submitted to urodynamic investigations at the end of the first stage of SNM
Permanent SNM
Only patients responding to first stage of SNM underwent permanent SNM, according to our criteria (see text)
Patients attended all programmable follow-up visits at 1, 3 and 6 months and then every 6 months, and upon patient request owing to worsening symptoms or loss of voiding symptoms

sensation, number of patients with bladder contractility index (BCI) > 100, and post-void residual urine per ml. BCI was calculated using the formula: PdetQmax + 5 Qmax. According to the BCI, detrusor contractility was categorized as weak (< 100), normal (100–150) and strong (> 150).[12]

In the end, all drawbacks correlated to IVES, first stage of SNM and the follow-ups post-permanent SNM, were extracted from our database.

All neuromodulation procedures were to be performed exclusively at our neuro-urology department.

Urodynamic studies had been performed according to 'good urodynamic practice', recommended by the International Continence Society.[13]

Description of the IVES technique

The IVES procedure was performed using either the Uroplus A 20 device or the Urotrain micropulse (mP)-controlled type biofeedback (BF), both from SI. EM (Società; Italiana Elettro-Medicali) Milan, Italy. These devices were programmed with the same stimulation parameters.

A monopolar active electrode was inserted into a catheter (10–12 Ch) and placed in the bladder, while one neutral electrode was applied to skin with preserved sensitivity. Sterile saline solution instillation measuring onethird of their bladder capacity was used. Continuous cystomanometry was performed during each IVES session. Each session took 90 min.

IVES parameter settings

Parameter settings specific to each patient were researched during the cystomanometry study in order to increase or recover bladder sensation, reduce residual urine and improve detrusor contraction. The intensity varied from 2–25 mA, frequency from 10 to 70 Hz, duration of pulse between 2 and 5 ms, interval between pulse trans from 3 to 6 s, and finally the rise to maximum intensity of stimulation in the range from 2 to 6 s.

SNM surgery

During the first stage of SNM, a permanent electrode was inserted percutaneously into the monolateral third S3 sacral foramina, and was then stimulated by using an external pulse generator (Medtronic Interstim model 3625, Medtronic Inc., Minneapolis, MN, USA).[11] Subsequently, responders to first stage of SNM had an implantable pulse generator positioned in the buttock. Continuous stimulation was always used. The neuromodulation device settings had a frequency between 14 and 25 Hz and pulse width of 210 ms.

Statistical tests

Descriptive analyses were presented as a percentage and mean, and describe both patient characteristics and urodynamic findings before neuromodulation treatments.

For patients responding to IVES as opposed to the first stage of SNM, we used the following statistical tests: the Wilcoxon-paired test to compare the mean values of each diary entry and post-void residual urine per ml during urodynamics.

χ^2 test was consistently applied to the responders at the end of the two treatments to compare the number of patients experiencing first sensation of bladder filling with baselines.

The χ^2 test was used to compare the following variables at baseline for responders and non-responders: demographics, voiding symptoms and urodynamic patterns, so as to detect statistically significant parameters for the success of the two neuromodulation procedures.

In the statistical study of the data, $P < 0.05$ was considered significant.

RESULTS

From our database, 82 patients with incomplete SCL and suffering from N-NOR for at least 6 months underwent IVES, followed by the first stage of SNM. Overall, five patients were excluded from our study: two who responded to the IVES cycle and then to the first stage of SNM were excluded because of missing urodynamics data after procedures. Seventy-seven patients were included in this retrospective study (see Table 1).

Analyzing the results, two groups were identified: responders and non-responders to both neuromodulation treatments (see Figure 1).

The group of non-responders comprised the same 48 individuals. Their voiding symptoms did not improve clinically according to our criteria; neither following the IVES cycle nor after the first stage of SNM.

Twenty-nine patients responded to IVES treatment, but all of them returned to similar voiding symptoms during follow-ups before undergoing the first stage of SNM. Following the first stage of SNM, all of them qualified as 'responders'. Table 2 reports the characteristics of the SCL patients in both groups.

Patients with complete N-NOR utilized 4–5 catheterizations per day, whereas individuals who demonstrated incomplete

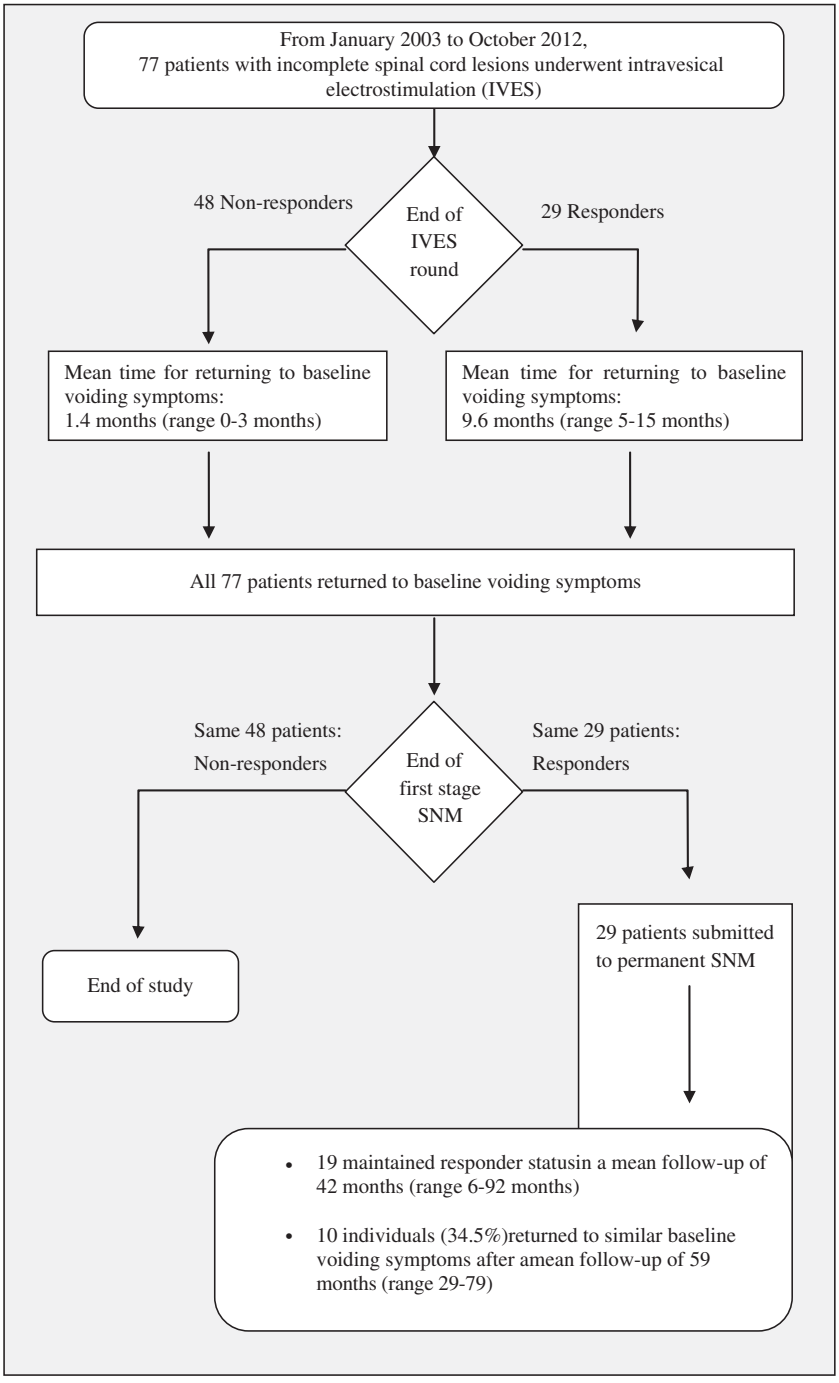

Figure 1 The study protocol of the patients who completed the study.

N-NOR, in that they were able to void (>50 ml per void) with high post-void residual urine volume per ml >200 ml, required 2–4 catheterizations per day.

Table 2 The characteristics of patients who completed the study

	Non-responders 48 patients (%)	*Responders 29 patients (%)*
Number of males	32 (66.6)	18 (62.1)
Mean age at the time of IVES (range)	41.7 (26–65)	40.1 (26–58)
Level of lesion (thoracic 11–lumbar L5)	48 (100)	29 (100)
ASIA/AIS scale		
C	34 (70.8)	19 (65.1)
D	14 (29.2)	10 (34.9)
Etiology of SCL		
Traumatic	34 (70.8)	20 (69.0)
Myelitis	8 (16.7)	7 (24.1)
Vascular	4 (8.3)	2 (6.9)
Others	2 (4.2)	/
Previous therapies		
Use of oral alfa-blocker drugs	48 (100)	29 (100)
Pelvic floor rehabilitation	7 (14.6)	3 (10.3)
Patients with complete urinary retention	30 (62.5)	15 (51.8)
Mean duration of IVES cycle per days (range)	31 (28–35)	31 (28–42)
Mean duration of first stage of SNM (range)	32 (28–42)	32 (28–42)

Abbreviations: ASIA/AIS, American Spinal Injury Association/ASIA Impairment Scale; IVES, intravesical electrostimulation; SCL, spinal cord lesions; SNM, sacral neuromodulation.

Non-responders group

Spontaneous micturition with voiding volume per ml per void and range (60–90 ml) was recovered by six patients, following IVES, and by the same six patients plus one after first stage of SNM. The mean values of each bladder entry recorded during the last week of the two neuromodulation treatments are reported in Figure 2. Urodynamics data are described in Table 3.

Pressure/flow studies for all spontaneous voiders at baselines and at the end of the two neuromodulation procedures showed bladder emptying via the Valsalva maneuver. No patient revealed detrusor sphincter dyssynergia.

All patients returned to similar baseline voiding symptoms with a mean follow-up of 1.4 months (range 0–3 months) (see Figure 3).

Responders group

Twenty-nine patients who responded at the end of IVES returned to similar baseline voiding symptoms, with a mean follow-up of 9.6 months (range 5–15 months). Only at 3 months did each patient maintain analogous improvement in their voiding symptoms compared with results at the end of IVES (see Figure 3).

A worsening of their neurological status, such as the onset of new neurological pathologies or the presence of mechanical–anatomical bladder outlet obstruction, was not detected. All of these patients maintained the same ASIA/AIS class before undergoing the first stage of SNM.

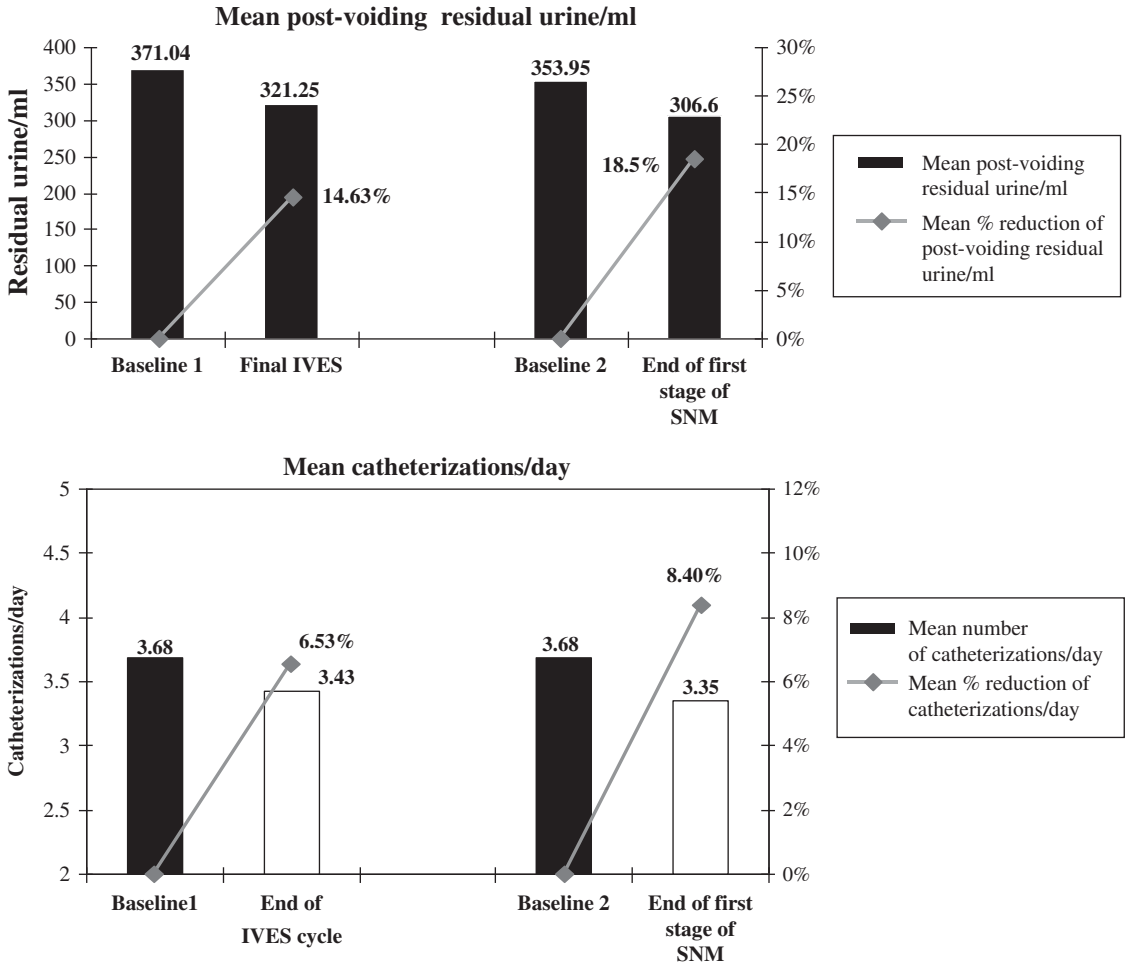

Figure 2 For the non-responders, the mean percentage improvement is shown for each voiding entry at the end of IVES versus the end of first stage of SNM compared with baselines.

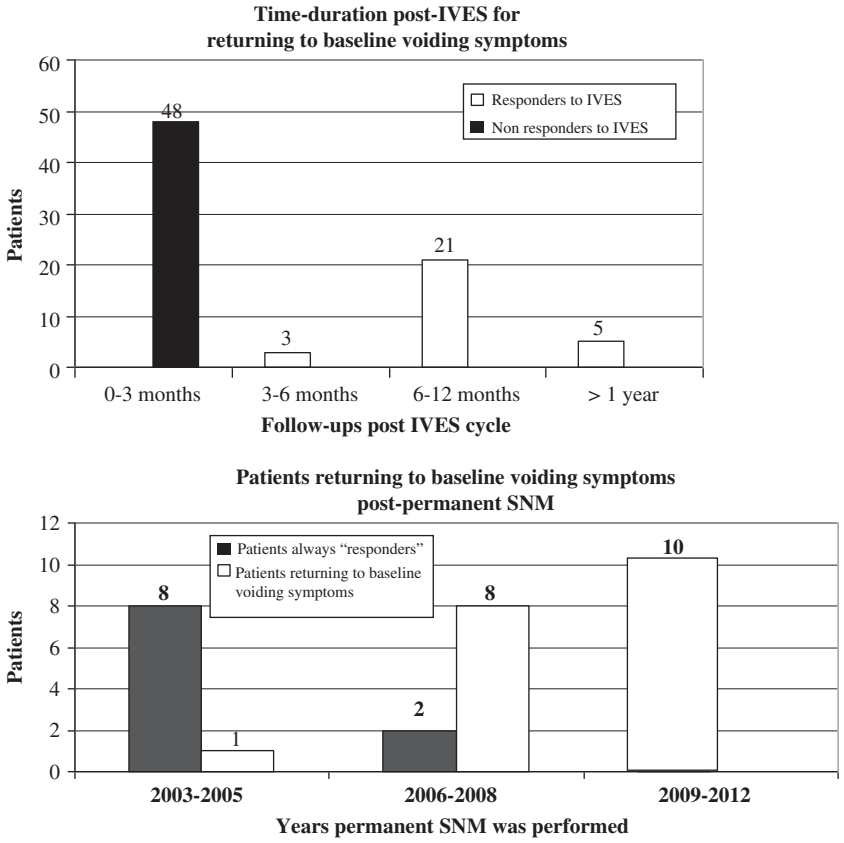

Figure 3 The follow-up results after IVES and permanent SNM.

Table 3 The main urodynamic findings at baselines and at the end of IVES and first stage of SNM for non-responders

Urodynamic patterns	*Non-responders 48 patients*			
	Baseline pre-IVES	*End of IVES cycle*	*Baseline 2 pre-first stage of SNM*	*End of first stage of SNM*
Cystometric phase				
Patients experiencing first sensation of bladder filling (%)	8 (16.66)	13 (27.08)	8 (16.66)	12 (25)
Voiding phase				
Number of patients able to void (%)	18 (37.50)	24 (50)	18 (37.50)	25 (52.08)
Mean residual urine per ml (range)	393.33 (280–420)	372.10 (270–420)	384.44 (270–420)	368.20 (280–420)

Abbreviations: IVES, intravesical electrostimulation; SNM, sacral neuromodulation.

Comparing 7-day diary entries from the end of IVES with those from the first stage of SNM, each patient reported similar clinical results. In particular, the same 16 'best responders' reported comparable post-void residual urine per ml, with a maximum of 80 ml (range 20–80 ml). The mean values of each bladder entry recorded during the last week of the two neuromodulation treatments were statistically matching (see Figure 4).

During filling cystometry, all patients experienced first sensation of bladder filling at the end of the two neuromodulation rounds. Moreover, during the cystometric phase, no detrusor overactivity was detected in any patients (see Table 4).

Only the same 11 out of 29 patients (31%) reached a BCI of >100 at the end of the two neuromodulation treatments (see Table 4). The others used assisted bladder emptying through the Valsalva maneuver, with vesical pressure between 72 and 95 cm H20. No detrusor sphincter dyssynergia was documented for any patient.

Predictive parameters for the success of the two neuromodulation treatments

A higher number of patients experiencing first sensation of bladder filling at baselines represented the only statistically significant

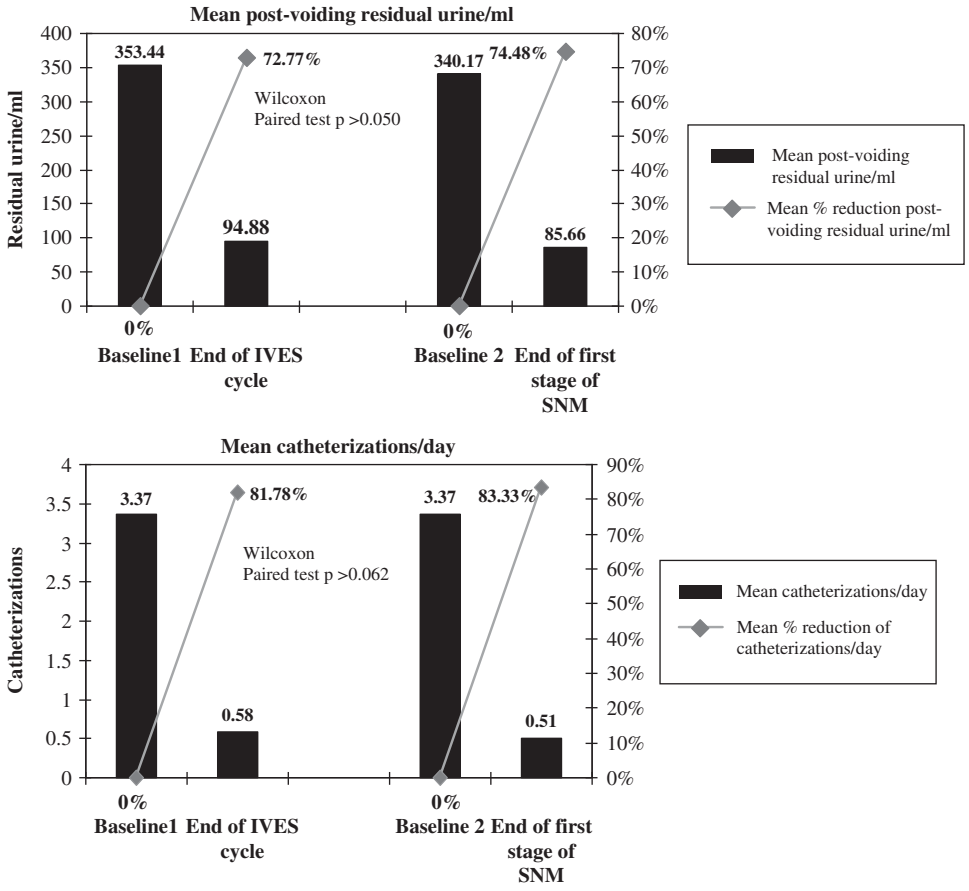

Figure 4 For responders, the mean percentage reduction is shown for each voiding entry at the end of IVES versus the end of first stage of SNM compared with baselines.

parameters for the success of the neuromodulation procedures (see Table 5).

Permanent SNM

All 29 responders to first stage of SNM underwent permanent SNM. Mean follow-up after SNM up to the final checkup (performed from June to October 2012) was 55 months (range 6–107 months). Ten individuals (34.5%) returned to similar baseline voiding symptoms after a mean follow-up of 59 months (range 29–78), whereas 19 patients were still responsive at a mean follow-up of 42 months (range 6–92 months); see Figure 3). The reason for returning to baseline voiding symptoms was determined in only one case: displacement of the sacral electrocatheter. A worsening of neurological status, such as the onset of new neurological pathologies or the presence of mechanical–anatomical bladder outlet obstruction, was not detected. Moreover, modification of the parameter settings (at least three attempts) did not improve voiding symptoms. In all cases, patients responded once again with a new implant in the controlateral S3 sacral root.

DISCUSSION

IVES and SNM are not standard treatments for neurogenic voiding dysfunction caused by incomplete SCL; in fact, there are no randomized trials showing the efficacy of these treatments for patients with incomplete SCL and N-NOR.

In a recent review on the use of SNM for neurogenic lower urinary tract dysfunction, the authors reported that at this time no definitive conclusions can be drawn from the available evidence regarding the general use of SNM for neurogenic lower urinary tract dysfunction.[14]

In the last 10 years, our center has proposed IVES as the first option for patients with incomplete SCL and N-NOR, refractory to other conservative therapies. The percutaneous first stage of SNM is suggested when patients do not respond to IVES or have short-term benefits. The rationale for this retrospective study is based on the fact that these patients had undergone unsuccessful conservative treatments for N-NOR, and these neuromodulation therapies represented the only other two possible options: conservative IVES and the mini-invasive surgery of SNM.

A strict correlation in terms of clinical and urodynamic patterns emerged from our study between IVES and first stage of SNM. These results seem to indicate that these two neuromodulation treatments are not absolutely complementary to each other, in that no patient responded or did not respond to only one of these therapies. The high clinical cut-off (50% clinical improvement in voiding symptoms) could be one of the reasons the two different treatments gave reproducible clinical results.

However, similar findings through urodynamic patterns following IVES and the first stage of SNM were recorded for the responders. In fact, the first sensation of bladder filling was recovered by all patients, and the same 11 patients recovered a normal BCI during the two neuromodulation treatments. In addition, a common significant

Table 4 The urodynamic findings of the responders at both baselines and following both neuromodulation treatments: statistical tests are included

Urodynamics	*Baseline 1*	*Baseline 2*	*End of IVES*	*End of first stage SNM*	*Wilcoxon-paired tests* (P)
Cystometric phase					
Patients experiencing first sensation of bladder filling	12	14	29	29	–
Voiding phase					
Number of patients able to void	14	14	29	29	–
Mean post-PVR urine per ml (range)	333.57 (280–420)	329.88 (270–420)	104.31 (60–210)	101.83 (60–220)	($P>0.05$)
BCI >100	0	0	11	11	–

Abbreviations: BCI, bladder contractility index; IVES, intravesical electrostimulation; SNM, sacral neuromodulation; PVR, post-voiding residual.

Table 5 Possible predictable factors for the success of the two neuromodulation treatments

	Non-responders	*Responders*	χ^2 *test* (P)
Demographics			
Male/female	32/16	18/11	(0.870)
Complete/incomplete urinary retention	30/18	15/14	(0.490)
Age (<40) at the end of the two treatments	19/29	16/13	(0.274)
Presence/absence of anal contraction pretreatments	36/12	22/7	(0.851)
AIS C/D	34/14	19/10	(0.815)
Etiology of SCL (traumatic/non-traumatic)	34/14	20/9	(0.934)
Presence/absence of first sensation of bladder filling pre-IVES	8/40	12/17	(0.033)
Presence/absence of first sensation of bladder filling pre-first stage of SNM	10/38	14/15	(0.023)

Abbreviations: AIS, ASIA Impairment Scale; IVES, intravesical electrostimulation; SCL, spinal cord lesion; SNM, sacral neuromodulation.

parameter for both procedures indicating success emerged through urodynamics at baselines; both responding groups had a higher percentage of patients experiencing first sensation of bladder filling. Therefore, although the exact mechanisms of IVES and SNM are not yet fully understood, urodynamic findings give a hint that the principle mechanism of these neuromodulation procedures is to induce/improve bladder sensation.

Our findings seem to support, for the first time, the thesis of limiting or bypassing IVES treatment for patients with incomplete SCL and N-NOR. Not only did IVES appear to be a possible alternative in selecting responders compared with first stage of SNM, but patients responding to IVES also maintained their voiding clinical benefits for a shorter time compared with permanent SNM. The continuous stimulation with permanent SNM versus IVES may explain the short-time efficacy of IVES, and the need for new IVES cycles to recuperate lost voiding improvement.[15]

IVES treatment seems then to be a primary indication for patients with a recent incomplete SCL, as permanent SNM might be disproportionate because the patient may recover detrusor function spontaneously, as affirmed by Madershacher *et al.*[16] who explained the high success of IVES for patients who underwent the procedure a few weeks after SCL. Moreover, ideal IVES candidates are patients with 'low compliance' for SNM surgery, mainly because this surgery does not assure the resolution of voiding disturbances. This way, patients could evaluate possible voiding improvement before SNM surgery.

We are conscious that the retrospective nature of our study poses possible limitations. However, objective data in the form of voiding diaries and urodynamics were recorded. The duration in days of both treatments were analogous for the two groups. Moreover, no neurological modifications were noted in any patient, and so we believe that any potential biases were avoided.

Finally, considering that patients are otherwise forced into performing life-long intermittent catheterizations, an overall success rate of around 40% with these neuromodulation treatments is more than just a benefit. However, ongoing investigation, improving our knowledge of the mechanisms of action assessed by urodynamic studies, neurophysiological investigations, stimulation parameters, functional brain imaging and measuring biomarkers are needed to increase their success rate.[17,18]

In particular, the percentage of SCL patients with N-NOR, responding to SNM, is low compared with other categories of patients with NOR, such as idiopathic patients and those with Fowler's syndrome.[19,20] Continuing studies should focus on what factors may favor the time-duration efficacy of these treatments, mainly for IVES, leading to a cost-effective treatment, with positive impact on these patients' quality of life. Such new information on these two neuromodulation procedures would afford neuro-urologists the opportunity to pursue a more appropriate, individual treatment course for patients suffering from incomplete SCL and N-NOR.

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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