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Usefulness of sacral nerve modulation in a series of multiple sclerosis patients with bladder dysfunction

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ABSTRACT

Objective: Bladder dysfunctions are common in multiple sclerosis (MS) often causing the most distressing symptoms. The aim of this paper was to evaluate the effectiveness of sacral nerve modulation (SNM) in this disease.
Methods: We conducted an observational retrospective survey in 17 patients treated with SNM in the north-east of Italy, all complaining of bladder symptoms (storage in 41%, voiding in 24%, mixed in 35%) unresponsive to conventional therapies, with a mean follow-up of 52 ± 26 months and mean Expanded Disability Status Scale score of 5.8 ± 1.8.
Results: 75% of patients reported significant and lasting improvement in bladder symptoms and in quality of life. We observed a statistically significant improvement in frequency, urgency, number of pads, residual volumes, number of catheterizations and in the voided volumes.
In 5 out of 6 cases with mixed symptoms the stimulation was discontinued (device totally explanted or turned off) after a mean time of 66 months (range 10–84 months) after the implant, for disease progression or loss of efficacy.
Conclusion: SNM could be an option in very selected cases of storage and voiding symptoms refractory to conservative treatments caused by a stable or slowly progressive MS considering its minimal invasiveness and reversibility. The poor results observed suggest avoiding this therapy in mixed symptoms and in cases of advanced disability.

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1. Introduction

Multiple sclerosis (MS) is a chronic inflammatory, demyelinating, neurodegenerative disorder affecting the central nervous system (CNS) with unknown etiology [1] and it represents the commonest progressive neurological disease affecting young people.

Bladder dysfunctions are common in people with MS, occurring in up to 75% of patients during the course of the disease; they can cause some of the most distressing symptoms, with a great impact on the quality of life (QoL), and are often associated with significant morbidity [2]. Urinary symptomatology is polymorphic and, like its incidence, subject to change over time, but it tends to increase with disease progression and it is mainly the result of spinal cord involvement. The most frequent are storage symptoms (urinary frequency, urgency, and urge incontinence) while voiding symptoms (hesitancy, incomplete voiding and urinary retention) exist to a lesser degree [3]. Therapeutic options for storage symptoms vary and they include, with or without associated clean intermittent self-catheterization, conservative treatments such as anticholinergic drugs — although the published data provide limited evidence for their efficacy in MS [4,5]. In patients with severe bladder overactivity unresponsive to anticholinergics there is evidence for the use of bladder injections of botulinum toxin A [6,7] and also emerging evidence on the use of cannabinoids [8] and tibial nerve stimulation [9]. Surgical procedures, which have been advocated with varying success [10], are a last resort being irreversible, with a risk of major operative morbidity and long-term consequences; they include augmentation cystoplasty [11], in which the bladder is transected and repaired with a patch of ileum isolated from the small intestine, and urinary diversion [12].

Sacral nerve modulation (SNM) is a safe and minimally invasive treatment and it has become an option in refractory low urinary tract symptoms (LUTS) from different underlying diseases [13–16]; a number of prospective trials and numerous case series have provided an evidence base that has confirmed the efficacy and durability of SNM [17]. Despite the documented clinical benefit, the exact underlying neurophysiological mechanism of action of SNM is complex and not fully

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understood. However, evidence supports an emerging consensus that it exerts its effect through afferent pathways that modulate the activity in other neural pathways within the spinal cord and higher centers [18]. Some studies have just investigated the effects of SNM on the higher centers. Braun et al. [19] performed serial electroencephalograms (EEG) in 10 patients with both neurogenic and idiopathic bladder dysfunction who had permanent implants of SNM in S3, using an on–off paradigm with 1.5 s with stimulation "on" followed by a 10 second stimulation "off". They demonstrated in all patients a cortical potential complex following stimulation with an early electronegative component at 50 ms followed by a late potential component with a mean latency of 253 ms, both with a maximum in the post-central gyrus. These findings occurred irrespective of patients' reports of actually feeling the SNM being switched on and off, whereby the authors concluded that, although these potentials are similar to cognitively mediated "event-related potentials", they are clearly distinct from any subjective sensory or even painful response and support the potential role of suprasacral centers in SMN, most probably in the sensory cortex areas [19].

Blok et al. [20] used positron emission tomography (PET) to study the brain effects of SNM in patients with urge incontinence comparing chronic (in whom SNM was switched on for >6 months) and acute patients (neurostimulator activated for the first time in PET scanner). They observed different modifications in cerebral blood flow in different areas during the chronic and acute stimulations. On the basis of these findings, the authors suggested that chronic SNM influences, presumably via the spinal cord, brain areas previously implicated in bladder overactivity, awareness of bladder filling, the urge to void and the timing of micturition and, furthermore, areas involved in alertness and awareness. On the other hand acute SNM modulates predominantly areas involved in sensorimotor learning, which might become less active during the course of chronic SNM [20].

Since few data are available about this treatment for LUTS in MS [21–23], in the present retrospective evaluation we wanted to determine whether SNM benefits patients with LUTS caused by this disease and unresponsive to first line conservative treatment and to assess if there is any difference in the responsiveness degree of different symptoms.

2. Materials and methods

In July 2008, we proposed to the Departments of Urology in the north-east of Italy performing SNM a retrospective survey about the effectiveness of SNM in MS patients. Only in 3 departments was SMS used in MS patients and all the MS patients implanted in these centers were included in the survey. A questionnaire has been filled for each included subject, enquiring about general data, MS features, perceived changes in micturition symptoms after SNM and changes coming from micturition-diaries. The post-voiding residual volume was evaluated by the clean intermittent catheterization which is usually performed by patients with voiding and mixed symptoms.

A visual analogic scale (VAS) was used to assess the improvement of the QoL and the symptom urinary urgency. Outcome data were obtained from the periodic follow-up as usually conducted.

For statistical analysis the following tests were applied: Cramer's V test, Kruskal Wallis test, univariate ANOVA, true Fisher test.

The clinical practice followed with uniformity by all the Departments required that the candidates for surgical implantation were selected on the basis of informed consent, prolonged failure of the conservative treatments with severe impact on QoL, no abnormality of upper urinary tract and kidney function. The pre-operative assessment included a 5 day voiding diary, the post-void residual evaluation, serum creatinine determination, urine culture, kidney ultrasound and videourodynamics. In the voiding diaries were recorded also the leakage episodes, degree of urgency and the pad used. The SNM implant procedure was performed as previously described [24].

The test period lasted for at least 3 weeks and the stimulation parameters (pulse width, frequency and amplitude) were individually chosen for each patient on the basis of the best responses, with stimulation below threshold. Eligibility criteria for the definitive implant were represented by a positive neuroanatomical response to the stimulation with clinical improvement in the symptoms and no side effects.

3. Results

17 subjects agreed to complete the survey during a follow-up visit, 13 females and 4 males, mean age 49.8 ± 10.9 years. The disease duration before implant ranged from 4 to 40 years (mean 13.5 ± 9.2 years); 10 subjects (59%) had the relapsing remitting, 2 (12%) the secondary progressive and 5 (29%) the primary progressive forms of the disease, with a mean Expanded Disability Status Scale (EDSS) score of 5.8 ± 1.8 [25]. Thirteen subjects (77%) were paraparetic. Regarding LUTS, 4 patients (24%) had voiding symptoms, 7 (41%) storage symptoms and 6 (35%) mixed symptoms; 6 patients reported simultaneous constipation. No statistical differences were identified among these three groups in baseline characteristics except for the anal tone, which resulted hypertonic in 83% of patients with mixed symptoms ($p = 0.032$). The mean baseline EDSS score was worse in mixed and voiding LUTS than in the storage ones. The mean time from the implant was 52 ± 26 months (range 12–97 months). The electrical parameters have been individually programmed and the number of reprogramming during the period of observation ranged from an average of 0.9, in patients with storage symptoms, to 3.0, in those with mixed LUTS. In five out of 6 cases with mixed symptoms the stimulation has been discontinued after a mean time of 66 months (range 10–84 months) for disease progression in 2 cases and for loss of efficacy in 3. The mean EDSS score didn't change significantly from baseline to the last follow-up evaluation, but patients complaining of mixed symptoms presented a quicker progressive MS (Table 1).

Regarding the subjective improvements, 75% of the total population (100% of patients with storage, 75% with voiding and 40% with mixed symptoms) replied positively to the question "After SNM did you detect any significant and lasting improvement in your bladder symptoms?"

The change in QoL was evaluated by the VAS after the question "How much has your QoL changed?" with a score ranging from 0 (not at all) to 5 (very much). The average score reported was 2.9 ± 1.5 for the whole population, 1.8 ± 1.4, 3.3 ± 1.0 and 3.6 ± 1.4 for patients respectively with mixed, storage and voiding symptoms (Fig. 1). Furthermore, there was a statistically significant reduction in subjective urgency level evaluated by the VAS – ranging from 0 (no urgency at all) to 5 (severe urgency) – in patients with storage and mixed symptoms; they passed from an average score of 3.6 ± 1.1 before SNM to 2.0 ± 1.3 during SNM ($p = 0.014$) (Fig. 2).

Analyzing the subgroups, there was a statistically significant reduction in the number of micturitions/day (from 14.3 ± 9.6 to 8.1 ± 3.7; $p = 0.012$) and number of pads/day (from 3.5 ± 1.8 to 1.9 ± 2.4; $p = 0.033$) in patients with storage and mixed symptoms. In subjects with voiding and mixed symptoms was found a statistically significant reduction in number of catheterizations/day (from 3.1 ± 2.0 to 0.9 ± 1.0; $p = 0.017$) and residual volumes (from 195.0 ± 9.0 to 71.5 ± 63.3 ml; $p = 0.018$) and a statistically significant increase in

Table 1
EDSS score in different LUTS, at baseline and during SNM.

	N	Baseline EDSS	Follow-up EDSS
All patients, mean (SD)	17	5.8 (1.8)	6.3 (2.1)
Voiding symptom, mean (SD)	4	6.5 (1.8)	6.5 (1.9)
Storage symptoms, mean (SD)	7	5.1 (2.1)	5.4 (2.2)
Mixed symptoms, mean (SD)	6	6.8 (0.5)	7.9 (0.9)

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