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# RESULTS OF SACRAL NERVE MODULATION FOR THE TREATMENT OF BLADDER DYSFUNCTIONS IN MULTIPLE SCLEROSIS PATIENTS

#### Hypothesis / aims of study

Sacral nerve modulation (SNM) has been used in some cases of neurogenic bladder caused by multiple sclerosis (MS) but the few references available usually regard a small number of patients (pts) or with a short follow-up (1, 2). We reviewed data of MS pts treated with SNM in order to evaluate the effectiveness of the therapy.

# Study design, materials and methods

In July 2008 this survey was proposed to all the centres in North-East of Italy. Only 3 centres have been performing SNM in MS pts and a questionnaire has been filled for each included subject. The questionnaire enquired about demoscopic data, MS features, perceived changes in micturition symptoms and changes coming from micturition-diaries. A visual analogic scale was used to assess the improvement in both Quality of Life (QoL) and symptom urgency.

#### Results

Sixteen pts (12 females and 4 males, mean age  $50 \pm 11$  years) were analysed. MS was mainly the intermittent-remittent type (56%) and had been lasting for 4 to 40 years (mean  $13 \pm 10$ ) before implant. Indications to SNM were voiding symptoms (VOID) in 4 pts (25%), storage symptoms (STOR) in 7 (44%) and mixed symptoms (MIX) in 5 cases (31%). Six pts reported simultaneous constipation. Twelve subjects (75%) were paraparetic, and 3 (19%) tetraparetic.

The mean follow-up was  $45 \pm 28$  months (range 7-84). The electrical parameters have been individually programmed and the number of reprogrammations ranged from an average of 0.9 in STOR to 2.4 in MIX. In 4/5 cases of MIX the stimulation has been interrupted after a mean time of 66 months (range 24-84) for disease progression in 1 patient and for loss of efficacy in 3. The Expanded Disability Status Scale (EDSS) for all pts doesn't change significantly between the basal evaluation and the last follow-up visit ( $5.8 \pm 1.8$  pre-SNM,  $6.2 \pm 2.1$  post-SNM) but pts complaining of MIX presented a quicker progressive MS (from  $6.5 \pm 0.0$  to  $8.0 \pm 1.0$ ). To the question "After SNM did you detect any significant and lasting change in your bladder symptoms?" totally 80% of pts replied positively (100% of STOR pts, 75% of VOID pts and 50% of MIX pts). Pictures show the changes, all statistically significant, observed between the basal and the last follow-up evaluation - number of micturitions/die (Fig.1), voided volumes (Fig.2), number of pads/die (Fig.3) and urgency level (Fig.7) of the STOR and MIX pts; number of catheterisations/die (Fig.4) and residual volumes (Fig.5) of VOID and MIX pts and QoL of all pts (Fig. 6) -. We had also found a relationship between improvement of bladder function and disease status (p= 0.044)

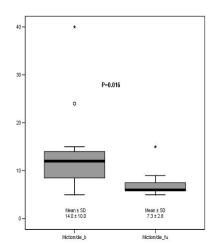


Fig. 1 – **Nr of miction/die.** (from 14.0±10 to 7.3±2.8, p=0.016) \* Strong Outlier values;

° Outlier value;

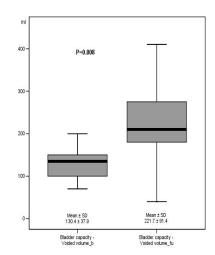


Fig. 2 – **Voided volume (ml).** (from 130.4±37.9 to 221.7±91.4, p=0.008)

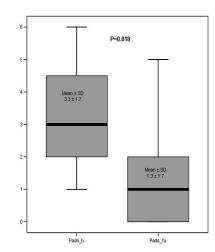


Fig. 3 – **Nr of pads/die.** (from 3.33±1.66 to 1.33±1.67, p=0.018)

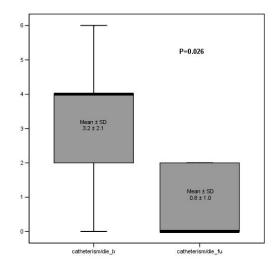


Fig. 4 - Number of catheterisations/die.

Fig. 5 – Residual volume (ml).

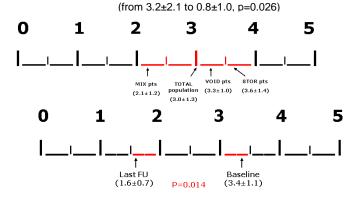


Fig. 6 – "How much has changed your quality of life?" The score ranges from 0 (nothing at all) to 5 (very much)

Fig. 7 – **Urgency level.**The score ranges from 0 (no urgency at all) to 5 (severe)

# Interpretation of results

The improvement of bladder symptoms with SNM is significant in MS pts and it regards all the items and subsequently the QoL. The best results have been observed in STOR and the worst in MIX, where SNM has obtained the poorer results. It is worthwhile that pts complaining of MIX presented a more aggressive disease and this could explain the decrease of efficacy of SNM with time observed in 4 pts.

# Concluding message

SNM is a good therapeutic option in selected and refractory bladder dysfunctions caused by MS. Overall we observed objective and subjective improvement both in symptoms and in QoL, especially in STOR and then in VOID. In MIX SNM should be well-pondered considering the poorer and shorter results obtained.

## References

- Chartier-Kastler EJ, Bosch JLH, Perrigot M, Chancellor MB, Richard F, Denys P. Long-term results of sacral nerve stimulation (S3) for the treatment of neurogenic refractory urge incontinence related to detrusor hyperreflexia, J Urol 2000 164:1476-80
- Wallace PA, Lane FL; Noblett KL Sacral nerve neuromodulation in pts with underlying neurologic disease, Am J Obstet Gynecol 2007 197:96e1-96e5

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Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	No
This study did not require eithics committee approval because	Clinical review
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	No