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SACRAL NEUROMODULATION FOR THE TREATMENT OF REFRACTORY LOWER URINARY TRACT DYSFUNCTION: RESULTS FROM A MULTICENTER STUDY

Hypothesis / aims of study
Sacral neuromodulation (SNM) has been used as a safe, effective treatment option for patients with lower urinary tract dysfunction (LUTD). Several clinical studies demonstrated its positive effects on refractory urge incontinence, non-obstructive urinary retention, urgency frequency syndrome, as well as on other non urological disorders, such as faecal incontinence and chronic constipation. The aim of this research project was to evaluate the efficacy and safety of sacral neuromodulation on the management of LUTD refractory to the standardised first line treatment options.

Study design, materials and methods
We retrospectively collected and evaluated data from patients undergoing SNM between September 2001 and November 2010 in 4 Urological Centres of Northeast Italy. The patients were affected by Overactive Bladder Syndrome (OAB) and non-obstructive Urinary Retention (UR). All the patients were evaluated with voiding diaries, before and after implantation.

Patients included in the present evaluation were followed in a network of 4 Italian urological centres which participate to the Italian Clinical Service project - a national urological database and medical care project aiming at describing and improving the use of implantable urological devices in the Italian clinical practice. To evaluate the patient reported outcome (PRO) of the impact of SNM on refractory OAB, we retrospective revised files from all implanted patients who completed pre and post-operatively the King's Health Questionnaire (KHQ). KHQ is a specific assessment instrument of the heath related quality of life (HRQoL) for patients with OAB, and incontinence symptoms. It consists of 21 items distributed in nine dimensions: general health (GH), incontinence impact (II), role limitations (RLs), personal limitations (PLs), social limitations (SLs), personal relationship (PR), emotions (Em), sleep/energy (Slp/En), and severity measures (SMs). The score of each dimension ranges from 0 (lower OAB symptoms impact; better HRQoL) to 100 (higher OAB symptoms impact; worse HRQoL).

Continuous normally distributed variables were reported as the mean value ± standard deviation (SD). Continuous non-normally distributed variables were presented as the median values and an interquartile range (IQR). The t-test, the Mann-Whitney and Wilcoxon tests were used to compare continuous variables, as appropriate. A two-sided $p < 0.05$ was considered statistically significant.

Results
Overall, 135 patients underwent implantation of SNM during the period under review. Eighty-three out of 135 (61.5%) patients complained of OAB, and 52 (38.5%) of UR. In patients treated for OAB, we documented a statistically significant reduction in the mean number of: incontinence episodes/die, pads/die, daily micturitions, nocturnal micturitions and global micturitions (see table I). In patients treated for UR, we observed a statistically significant reduction in the mean post voiding residual volume and in the number of self catheterization (see table II).

Concerning the impact of SNM on HRQOL from patients complaining of refractory OAB, only nineteen patients (17 female and 2 male), from a single centre, filled-in the KHQ pre- and/or postoperatively The median patients' age was 70 years (range 65-74) with a median follow-up of 42 months (range 17.5-48). Median and range of quality of life KHQ of general health and personal relationship pre- and post-operatively were reported in table III.

Table I. SNM clinical outcomes in patients with refractory OAB

Variable	N	Baseline	FU	P-value
Incontinence episode/die, mean±SD	48	4.1±2.7	1.5±2.1	<0.001°
Pads/die, mean±SD	44	3.4±2.4	1.3±1.4	<0.001°
Voided volume, mean±SD	45	143.6±69.9	206.7±88.5	<0.001*
Daily micturition, mean±SD	48	10.4±4.2	7.4±2.5	<0.001°
Nightly micturition, mean±SD	48	2.6±1.8	0.8±0.9	<0.001°
Global micturition, mean±SD	48	13.0±5.3	8.1±2.7	<0.001°

**T-Test; ° Wilcoxon test*

Table II. SNM clinical outcomes in patients with non-obstructive urinary retention

Variabile	N	Baseline	FU	P-value
Post void reisdual urine, mean±SD	30	321.4±153.5	87.2±96.9	<0.001°
Catheterism/die, mean±SD	30	3.8±1.4	1.3±1.3	<0.001°
Daily micturition, mean±SD	29	4.7±3.8	5.4±2.0	0.159°
Nightly micturition, mean±SD	29	0.7±1.3	0.7±1.1	0.886°
Global micturition, ,mean±SD	29	5.4±4.6	6.1±2.5	0.328°

**T-Test; ° Wilcoxon test*

Table III. Median and range of HRQoL assessed pre- and postoperatively by King's Health Questionnaire* of general health and personal relationship of patients underwent SNM for refractory OAB.

Dimension	pre-SNM median (rance)	post-SNM median (range)	p-Value Wilcoxon matched pairs test
GH	50 (37.5-50)	50 (25-62.5)	1
II	100 (100-100)	100 (50-100)	0.063
RLs	83.3 (50-100)	50 (33.3-100)	0.102
PLs	83.3 (66.7-100)	33.3 (16.7-83.3)	0.026
SLs	77.8 (50-94.4)	0 (0-50)	0.017
PR	0 (0-25)	0 (0-33.3)	0.785
Em	77.8 (22.2-88.9)	33.3 (11.1-44.4)	0.14
Slp/En	50 (33.3-75)	50 (16.7-66.7)	0.109
SMs	58.3 (33.3-79.2)	66.7 (25-75)	0.671

**The score ranges from 0 (lower OAB symptoms, better HRQoL) to 100 (higher OAB symptoms, worse HRQoL).*

In comparison of the preoperative setting, patients after the implant showed a better scores in many KHQ dimensions. In particular for personal limitations (p=0.026), and social limitations (p=0.017). The length of follow-up did not significantly impact on HRQoL scores.

Interpretation of results

SNM offers objective benefits for people with refractory OAB and for those with urinary retention without structural obstruction. Concerning the PRO, because OAB symptoms in general may have a serious impact on a person's daily activities and social life, the effect of treatment on disease-specific HRQoL also reflects its efficacy. In our series we observe a significant improvement of HRQoL for the following KHQ items: personal limitations and social limitations. We observe a better, although not significant, HRQoL also for the following items: Incontinence Impact, Role Limitations, and Emotions. We did not found any correlation between the follow-up length and HRQoL. We should take great caution in interpreting these results because all the measures of the impact of SNM on the HRQOL comes from a small number of patients' perspective.

Concluding message

This multicenter research project confirmed the midterm safety and effectiveness of sacral neuromodulation in the treatment of refractory overactive bladder syndrome and non-obstructive urinary retention, showing high cure rates and low complication rates.

Disclosures

Funding: no source of funding nor grant **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics not Req'd:** It is a retrospective study and it needs only a notification letter without approval **Helsinki:** Yes **Informed Consent:** Yes