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# SACRAL NERVE STIMULATION IN FEMALE NON-OBSTRUCTIVE URINARY RETENTION: LONG-TERM OUTCOMES IN A RETROSPECTIVE MULTICENTRIC EVALUATION.

Hypothesis / aims of study

Sacral neuromodulation (SNM) has been used as a safe and effective treatment option for patients with lower urinary tract dysfunctions as refractory urge incontinence, non-obstructive urinary retention (UR) and urgency frequency syndrome [1]. Besides SNM, there was no effective treatment for functional UR, except clean intermittent self-catheterization. The long-term results (84.2 - 60 months) of SNM as a treatment for non-obstructive UR has been reported from few studies, showing efficacy ranging from 56.8 to 87.5%. [2], [3]. The aim of this retrospective analysis is to report a multicenter experience on the efficacy and safety of SNM on a large population of female with non-obstructive UR, with a median follow-up (F-up) of 57 months (IQR 33-97 months) and a maximum F-up of 152 months.

Study design, materials and methods

From July 1999 to January 2011 data of 76 female patients candidate to SNM for non-obstructive UR, from 4 Urological Departments, have been retrospectively considered. All the patients were evaluated with voiding diaries at baseline, during test phase (percutaneous nerve evaluation -PNE- or first stage with tined lead) and during chronic therapy. After PNE and/or first stage, patients with a functional recovery ≥ 50% underwent to a definitive implant. Continuous normally distributed variables were reported as mean value ± standard deviation. Continuous non-normally distributed variables were presented as median values and interquartile range (IQR). The t-test and Wilcoxon test were used to compare continuous variables, as appropriate. A two-sided $p < 0.05$ was considered statistically significant.

Results

Clinical characteristics and parameters at baseline are shown in Table 1 and 2.

Tab.1 - Patients characteristics at accrual

| Variable | |
|---|---|
| **Age** at 1° stage, average±SD | 49.0±16.5 |
| **Symptom duration**, years, median (IQR) | 3 (2-11) |
| **UR Etiology**, n (%) | |
| Idiopathic | 28 (37%) |
| Iatrogenic | 38 (50%) |
| Neurologic | 10 (13%) |
| **Secondary Diagnose**, pts n (%) | 43 (57%) |
| Overactive Bladder (OAB) | 7 ( 9%) |
| Chronic Pelvic Pain (CPP) | 7 ( 9%) |
| Fecal Incontinence (FI) | 1 ( 2%) |
| Constipation (Co) | 38 (50%) |

Tab. 2 - Clinical parameters at baseline

| Parameter | |
|---|---|
| Medium micturition volume, ml, average±SD | 185.8±79.6 |
| Medium post voiding residual, ml, average±SD | 334.8±120.6 |
| N catheterism/die, average±SD | 4.0±2.5 |

Medium age of the patients at SNM test was of 49.0±16.5 years (range 21-82). The etiologies of UR were: 50% iatrogenic, 37% idiopathic and 13% neurologic. Median symptom duration was 3 years (range 1-48 years, IQR 2-11 years). The medium post voiding residual (PVR) was 334.8±120.6 ml and the patients performed intermittent self-catheterization 4.0±2.5 times/die. The 57% (43 pts) of the patients suffered from at least one comorbidity, 13% (10 pts) have two comorbidities. The 50% (38 pts) of the patients has constipation (5 as secondary comorbidity), 9% (7 pts) pelvic pain syndrome (2 pts as secondary) and 9% (7 pts) urinary incontinence/urgency (3 pts as secondary), one patient has faecal incontinence. After the test phase 79% of the patients (60/76) received the definitive SNM implant. 54/60 (90%) patients had at least one follow-up visit with a median follow-up of 57 months (IQR 33-97 years).

The table 3 shows the differences between baseline and last follow-up in the medium micturition volume, post voiding residual and number of CI/die for the implanted patients. The improvements obtained, micturition volume more than doubled and PVR decreased to 30%, are confirmed at statistical analysis.

Tab.3 - Results SNM at last Follow-up (implanted patients)

| | Baseline | Follow-up | P |
|---|---|---|---|
| Medium micturition volume, ml, average±SD | 110.6 ± 77.5 | 247.7 ± 94.0 | <0.001 |

| | | | |
|---|---|---|---|
| Medium post voiding residual, ml, average±SD | 340 ± 124.9 | 118.6 ±144.7 | <0.001 |
| N catheterism/die, average±SD | 4.2 ± 2.8 | 1.3 ± 1.8 | <0.001 |

At last follow-up, 7 patients were lost at follow-up (2 patients died for causes neither connected to the dysfunction nor to the treatment). The IPG was replaced due to battery depletion in 12 patients, in 3 patients the stimulator was repositioned due to dislocations and 6 patients were explanted (for loss of efficacy/worsening of the underling neurological disease).

Interpretation of results

The comparative evaluation between the group with more than 5 years of F-up and all the implanted patients does not evidence significant difference in the results, we can state that the results obtained within 24 months remain unchanged over the time.
In our analysis we documented a statistically significant reduction in the post-voiding residual volume, micturition volume and in the self-catheterization number in the patients treated for UR, demonstrating that sacral NMS is an effective treatment. Due to the retrospective evaluation, we do not have data about the impact of NMS on the health-related quality of life domains.

Concluding message

This multicentric research project demonstrated that sacral neuromodulation is an effective treatment for non-obstructive UR in women, durable over time, without significant reduction of efficacy and without important complications, even at long term.

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