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# EFFICACY OF NEUROMODULATION OF UROLOGICAL DISEASE : A MULTICENTRIC RESEARCHE PROJECT

Hypothesis / aims of study: Sacral neuromodulation has been used as a safe, effective treatment option for patients with lower urinary tract dysfunction. Several clinical studies demonstrated its positive effects for refractory urge incontinence, nonosbtructive urinary retention and urgency frequency syndrome and, in addition to urological disorders, for fecal incontinence and chronic constipation. The aim of this research project is to evaluate the efficacy and safety of sacral neuromodulation on urological diseases

Study design, materials and methods: We retrospectively collected and evaluated data from patients undergoing sacral neuromodulations between September 2001 and November 2010 in 4 Urological Departments. The patients were affected by Overactive bladder syndrome (OAB), Urinary retenction (UR), Fecal incontinence (FI), Constipation (CO), Chronic pelvic pain (CPP). The patients were evaluated with voiding diaries, before and after the implantation.

Patients included in the present analysis 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 to describe and improve the use of implantable urological devices in the Italian clinical practice.

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 and Wilcoxon test were used to compare continuous variables, as appropriate. A two-sided $p < 0.05$ was considered statistically significant

Results: 157 patients underwent implant of sacral neuromodulator in the evaluation period. Patients characteristics were as follow: 122 (78%) female; mean age at symptoms presentation 51 years; mean age at implantation 58 years; 83 (53%) of patients suffered from overactive bladder (OAB); 52 (33%) of urinary retention (UR); 5 (3%) fecal incontinence; 4 (2%) stipsis; 12 (8%) chronic pelvic pain. The secundary diagnosis was OAB in 49 (31%) patients; UR in 6 (4%); FI in 7(5%); Co in 27 (17%) and CPP in 6 (4%).The etiology of the primary symptom was hydiopatic in 59 (44%) patients; neurogenic in 36 (27%) and surgery related in 39 (29%). 75 (58%) underwent previous surgery, with hysterectomy in 35 patients (27%) and cystopexy in 9 (7%) being the most frequent. About the 38 patients affected from a neurological disease (28%), 7 (5%) suffered from multiple sclerosis, 8 (5%) spinal lesion, 4 (3%) stroke, 3 (2%) Parkinson disease. Twenty – four complications were observed in 20 patients (13%), with lost of efficacy in 10 cases as the most frequent; . 78/157 (50%) of patients were eligible at follow up. The median follow up was 11 months (IQR 1 – 91 months).

***Tab.I OAB patients***

| 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 | 48 | 3.4±2.4 | 1.3±1.4 | **<0.001°** |
| **Micturition volume**, mean±SD | 48 | 143.6±69.9 | 206.7±88.5 | **<0.001*** |
| **Daytime frequency**, mean±SD | 48 | 10.4±4.2 | 7.4±2.5 | **<0.001°** |
| **Nighttime frequency**, mean±SD | 48 | 2.6±1.8 | 0.8±0.9 | **<0.001°** |
| **Micturition/die**, mean±SD | 48 | 13.0±5.3 | 8.1±2.7 | **<0.001°** |

** T-Test ; ° Wilcoxon test*

***Tab.II –UR patients***

| Variable | N | Baseline | FU | P-value |
|---|---|---|---|---|
| **Post voiding residual volume**, mean±SD | 30 | 321.4±153.5 | 87.2±96.9 | **<0.001°** |
| **Number of CIC/die**, mean±SD | 30 | 3.8±1.4 | 1.3±1.3 | **<0.001°** |
| **Daytime frequency**, mean±SD | 30 | 4.7±3.8 | 5.4±2.0 | 0.159° |
| **Nighttime frequency**, mean±SD | 30 | 0.7±1.3 | 0.7±1.1 | 0.886° |
| **Micturition/die,** mean±SD | 30 | 5.4±4.6 | 6.1±2.5 | 0.328° |

** T-Test; ° Wilcoxon test*

The results at the follow up are represented in the table I and II. With regards to the patients treated for OAB, we documented a statistically significant reduction in the mean number of incontinence episodes/die, number of pads used, number of daily micturition, of nocturnal micturition and global micturition. With regard to the patients treated for UR, we documented a statistically significant reduction of the post voiding residual volume and of the number of self catheterization. The reduction in the daily, nocturnal and global micturition was not statistically significant. 86% of the patients with complete retention achieve a voided volume > 120 cc. Only 6 (5%) patients interrupted the therapy under the permanent implantation, with a median time of 18 months (IQR: 7-30 months).

Interpretation of results: The physiological mechanisms underlying the mode of action of SNM on fecal and urinary incontinence are still barely understood. Patients that underwent sacral neuromodulation are complicated patients, suffering from multiple and often neurological disease, widely difficult to manage.

Nevertheless, it is difficult to translate into quantifiable data the subjective perception of improvement of the symptoms expressed by the patients, as they are frequently subjective perceptions, not always numeric data.

This subjective perception makes it difficult to the clinician to evaluate the real outcomes of this procedure and makes it difficult

to achieve a complete follow up.

Concluding message: This multicentric research project demonstrated that sacral neuromodulation is a safe, durable and efficacy treatment for refractory overactive bladder syndrome and urinary retention, with a high cure rate and a less invasive technique.

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| ***Specify source of funding or grant*** | **No** |
| ***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 ethics committee approval because*** | **because is part of routinely clinical setting** |
| ***Was the Declaration of Helsinki followed?*** | **Yes** |
| ***Was informed consent obtained from the patients?*** | **Yes** |