

## COMPARISON OF INTRAVAGINAL NEUROMUSCULAR ELECTRICAL STIMULATION AND PERCUTANEOUS TIBIAL NERVE STIMULATION IN THE TREATMENT OF LOWER URINARY TRACT SYMPTOMS IN WOMEN WITH MULTIPLE SCLEROSIS.

### Hypothesis / aims of study:

Up to 90% of the patients with multiple sclerosis (MS) present lower urinary tract symptoms (LUTS) at some time in the course of their disease. Invasive treatments and anticholinergic drugs are not always well tolerated or curative. Pelvic floor muscle training (PFMT) is a conservative treatment that has been reported to be effective for LUTS in patients with MS, improving symptoms and suppressing detrusor overactivity (1). Neuromuscular electrical stimulation (NMES), most commonly applied intravaginally stimulating the pudendal nerve, is another conservative treatment that assists with the management of LUTS (2). An alternative to intravaginal NMES treatment is posterior tibial nerve stimulation (PTNS) (3). Both NMES and PTNS appear to be beneficial in the treatment of LUTS in patients with MS, however no study has directly compared both treatments. This preliminary, blind, randomised and prospective trial aimed at investigating the impact of intravaginal NMES and PTNS on lower urinary tract function in women with MS.

### Study design, materials and methods:

Twenty five women with MS and LUTS were randomized into one of the three treatment groups: Group I: PFMT and sham NMES (GI, n= 8); Group II: PFMT and intravaginal NMES (GII, n= 8) and Group III: PFMT and PTNS (GIII, n= 9). Evaluation consisted of 24-hour Pad testing; 3 day bladder diary; pelvic floor muscle evaluation according to Perfect scheme, and post void residual volume, maximum cystometric capacity, detrusor overactivity, maximum flow rate (Qmax) and detrusor pressure (p det) at Qmax were recorded by urodynamic study. All patients were assessed before and after treatment by a research assistant blinded to participant group assignment. The intervention was performed by a physiotherapist for a period of 12 weeks in both groups with participants attending twice a week. Group I received sham NMES treatment by placing a pair of surface electrodes over the sacrum with no physiological effect parameters (2). Group II underwent vaginal NMES with a pulse width of 200 µs at a frequency of 10 Hz. Group III underwent PTNS with a pulse width of 200 µs at a frequency of 10 Hz. All groups received electrostimulation treatment over a period of 30 minutes. After the electrotherapy session, all groups performed 30 slow pelvic floor muscle contractions and 3 minutes of fast contractions in supine position with the assistance of an electromyographic biofeedback (Miotool - Porto Alegre, Brazil). Repeated-measures ANOVA were used to compare measures according to time and groups. For all statistical tests, the significance was  $P < 0.05$ .

### Results:

There were no significant differences between groups at baseline. By the week 12, all groups demonstrated significant reduction in pad weight ( $p < 0.001$ ) (Figure 1). In the 3 day - bladder diary assessment GII showed reduction in day time urinary frequency ( $p = 0.019$ ). Feeling of incomplete bladder emptying and hesitancy were reduced in GII ( $p < 0.001$ ) and GIII ( $p < 0.001$ ). Episodes of nocturia, urgency and urge-incontinence were reduced in GI ( $p < 0.001$ ), GII ( $p < 0.001$ ) and GIII ( $p < 0.001$ ) (Figure 2). In the end of the treatment all groups showed improvements of all parameters of the PERFECT scheme with a  $p < 0.001$  in all domains. Significant increase in Qmax was found in GII ( $p < 0.001$ ) and GIII ( $p < 0.001$ ), significant reduction of Pdet Qmax was found in GI ( $p = 0.004$ ) and GII ( $p = 0.004$ ) and significant reduction of post void residual volume in GII ( $p < 0.001$ ) and GIII ( $p < 0.001$ ). No statistical significant differences were found between groups in all assessments.

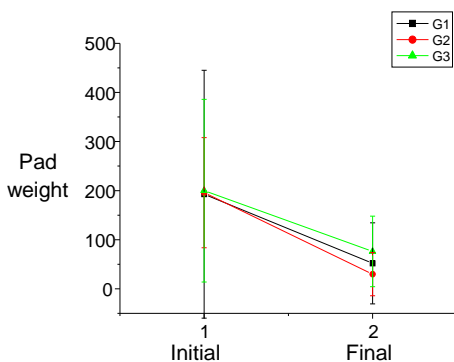


Figure 1 – Mean and standard deviation of pad weight before and after intervention in GI,GII and GIII.

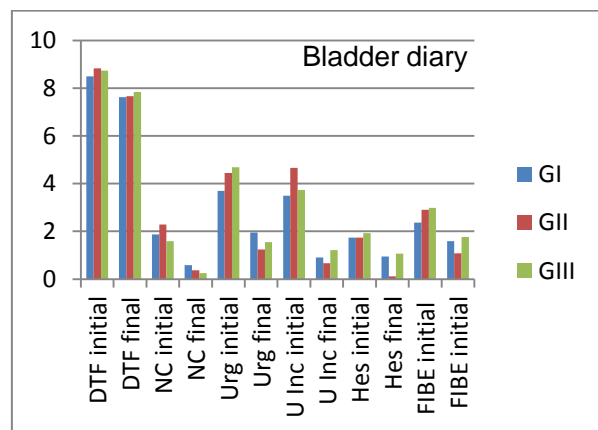


Figure 2 – Mean values of 3 day - bladder diary assessment. DTF (day time frequency), NC (nocturia), Urg (urgency), U Inc (urge-incontinence), Hes (hesitancy), FIBE (feeling of incomplete emptying).

### Interpretation of results:

Although pelvic floor muscles may be impaired in MS, PFMT has been reported to be effective in the treatment of LUTS in these patients. Different electrical stimulation techniques have been proposed to assist this treatment. The effect of intravaginal NMES has proved to be useful to reduce incontinence episodes and the amount of leakage (3). PTNS appears to have similar success with the potential advantage of being more acceptable to patients; both treatments seem to have a great contribution in the treatment of LUTS in MS population, but no RCTs have never directly compared both.

Our study corroborates with the findings in literature where all groups showed improvements in the reduction of the amount of leakage, nocturia, urgency and urge urinary incontinence episodes. In the end of the treatment, the groups receiving electrostimulation techniques showed statistically significant differences in a larger number of variables assessed than the group that practiced only PFMT. Comparing the groups that received electrotherapy treatment, GII contributed to the reduction in daytime frequency, increase in Qmax and reduction in post void volume and GIII didn't show differences in these variables. No differences were found between groups, probably because of the sample size.

### Concluding message

Findings from the current study suggest that PFMT alone or in combination with vaginal NMES or PTNS is effective to reduce the amount of leakage, nocturia, urgency and urge urinary incontinence episodes. The association of PFMT with vaginal NMES helps to reduce daytime frequency, increase Qmax and reduce in post void volume. Due to the small number of subjects, no differences were found between the three groups.

### References

1. Lucio AC, Campos RM, Perissinotto MC et al. Pelvic Floor Muscle Training in the Treatment of Lower Urinary Tract Dysfunction in women with Multiple Sclerosis. *Neurourol Urodyn* 29:1410–1413 (2010)
2. McClurg D, Ashe RG, Lowe-Strong AS. Neuromuscular electrical stimulation and the treatment of lower urinary tract dysfunction in multiple sclerosis – A double blind, placebo controlled randomised clinical trial. *Neurourol Urodyn* 2008;27:231-237
3. Kabay S, Kabay SC, Yucel M, Ozden H, Yilmaz Z, Aras O, Aras B. The Clinical and Urodynamic Results of a 3-Month Percutaneous Posterior Tibial Nerve Stimulation Treatment in Patients With Multiple Sclerosis-Related Neurogenic Bladder Dysfunction. *Neurourol Urodyn*. 2009;28(8):964-8

### Disclosures

**Funding:** Funding: FAPESP **Clinical Trial:** Yes **Registration Number:** National Information System on Ethics in Research involving Human Subjects - SISNEP. registration number 1151/2009. **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Institutional Ethical Committee at the Faculty of Health Sciences of Universidade Estadual de Campinas (UNICAMP) **Helsinki:** Yes **Informed Consent:** Yes