# 153 - RANDOMIZED CONTROL TRIAL OF PARASACRAL TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION FOR OVERACTIVE BLADDER IN OLDER WOMEN – PILOT STUDY

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## INTRODUCTION

Inherent modifications to the aging process might be related to an increase in the prevalence of overactive bladder (OAB) in older women (1). As a treatment proposal, it is found in literature, the behavioral therapy (BT), the medicines and the electrical stimulation (2). The transcutaneous parasacral electrical stimulation (TPS), which is used as a non-invasive alternative for the treatment of OAB, emphasizes positive results on the clinical condition and on the urodynamics variables studied, especially on children (3), and has the potential to produce similar effects on the elderly population. We conducted a pilot study with the aim of evaluating the effects of transcutaneous parasacral electrical stimulation on the urinary habits and quality of life (QoL) in older women with the OAB.

## METHODS

This is a pilot study randomized control trial in two groups, and a blind one. There were included on the study women with the age of 60 or more and with the OAB, which was identified using the score of 8 or more through the Overactive Bladder - version 8 questionnaire (OAB-V8). There were excluded the women who presented an inferior urinary tract infection, a history of medical or physiotherapeutic treatment for OAB in the last 6 months, base neurological diseases, a history of genitourinary neoplasia, previous pelvic irradiation, severe genital prolapse evaluated by the Baden-Walker scale and a cardiac pacemaker. The urinary habits evaluation instruments and quality of life were: bladder diary (BD) of three days, the ICIQ-OAB (International Consultation on Incontinence Questionnaire Overactive Bladder) and the ICIQ-SF (International Consultation on Incontinence Questionnaire-Short Form). The treatment of group G1 consisted of two BT sessions, in which they received, through a lecture, an orientation regarding urinary habits. In the end, an educational booklet was given to fix the content. The patients were oriented regarding the sanitary positioning, programmed urination, programmed water intake and the avoidance of intaking irritative drinks and food. The G2 group received the same protocol of G1, added to the parasacral electrical stimulation, which was done in 8 sessions, twice a week, with a duration of 30 minutes. The parameters used for stimulation were: F= 10 Hz, T= 700 µs with the maximum intensity sustained by the patient.

## Statistical Analysis

For the normality analysis, it was used the Shapiro-Wilk test. The Mann-Whitney U test was used to analyze the homogeneity between groups and the before and after intergroup analysis. The Wilcoxon test evaluated the intergroup comparing analysis. It was considered a significance level of 0,05. To evaluate the testing power used on the study, it was applied a post hoc analysis which demonstrated the power of 0.80 with an effect size of 0.66.

## RESULTS

Results 37 eligible patients were selected for the study. However, 16 participants were excluded with a total of 21 patients (G1= 11 and G2= 10). During the intervention period, 3 participants of G1 and 2 of G2 groups withdrew the treatment (Figure 1).

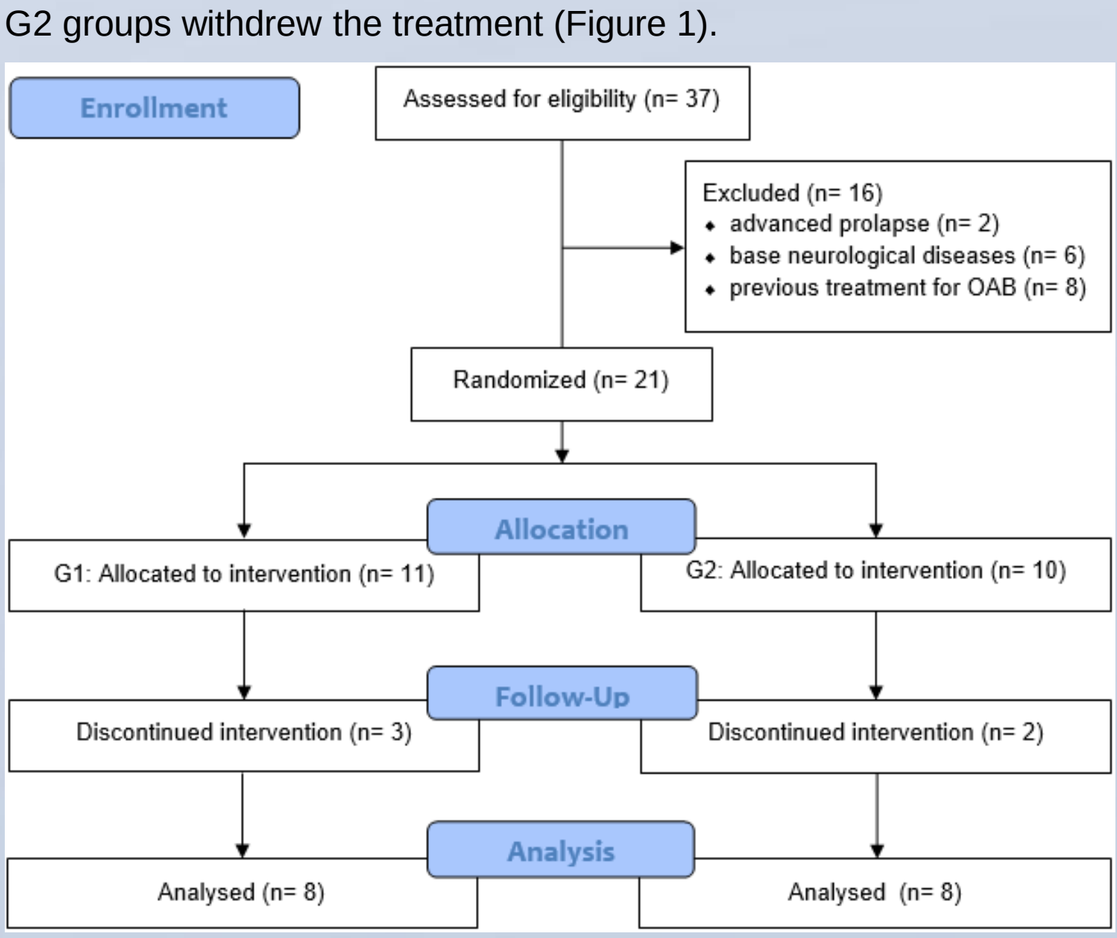


Figure 1. CONSORT Flow Diagram

Table 1. Comparison of urinary habits and QoL intra-and intergroup

| Variable | G1 (n = 8) | G2 (n = 8) | $p^a$ |
|---|---|---|---|
| **ICIQ-OAB** | | | |
| Before | 11 ± 3,07 | 8,87 ± 3,13 | 0,167 |
| After | 8 ± 5,90 | 4,5 ± 4,56 | 0,170 |
| $p^b$ | 0,062 | 0,018* | |
| **Bother of Daytime Frequency** | | | |
| Before | 5,5 ± 4,84 | 7,62 ± 3,70 | 0,282 |
| After | 4,37 ± 4,95 | 3,5 ± 4,86 | 0,637 |
| $p^b$ | 0,180 | 0,042* | |
| **Bother of Nocturia** | | | |
| Before | 8,5 ± 3,50 | 8,25 ± 3,45 | 0,653 |
| After | 4,5 ± 4,98 | 3,62 ± 4,10 | 0,692 |
| $p^b$ | 0,066 | 0,026* | |
| **Bother of Urgency** | | | |
| Before | 9,5 ± 0,92 | 8,62 ± 1,92 | 0,370 |
| After | 7,25 ± 4,52 | 3,12 ± 4,58 | 0,108 |
| $p^b$ | 0,180 | 0,026* | |
| **Bother of Urgency incontinence urinary** | | | |
| Before | 8,87 ± 1,80 | 9 ± 1,92 | 0,701 |
| After | 6,25 ± 5,17 | 4,37 ± 4,95 | 0,444 |
| $p^b$ | 0,102 | 0,039* | |
| **ICIQ-SF** | | | |
| Before | 15 ± 6,80 | 16,12 ± 3,27 | 1,00 |
| After | 11,65 ± 7,85 | 8,37 ± 8,01 | 0,392 |
| $p^b$ | 0,075 | 0,056 | |
| **Urinary Frequency 24 hours (BD)** | | | |
| Before | 6,98 ± 4,45 | 5,81 ± 3,09 | 0,674 |
| After | 6,95 ± 4,64 | 4,9 ± 3,06 | 0,400 |
| $p^b$ | 0,888 | 0,091 | |
| **Urgency Episodes (BD)** | | | |
| Before | 1,79 ± 3,08 | 1,49 ± 1,78 | 0,772 |
| After | 2,24 ± 3,52 | 1,75 ± 3,15 | 0,602 |
| $p^b$ | 1,000 | 1,000 | |
| **Urgency Urinary Incontinence episodes (BD)** | | | |
| Before | 2,41 ± 3,56 | 2,29 ± 2,53 | 0,957 |
| After | 1,49 ± 2,08 | 2,70 ± 4,70 | 0,779 |
| $p^b$ | 0,343 | 0,498 | |
| **Nocturia (BD)** | | | |
| Before | 2,08 ± 1,98 | 2,23 ± 1,53 | 0,721 |
| After | 2,03 ± 1,04 | 1,78 ± 1,46 | 0,596 |
| $p^b$ | 0,889 | 0,750 | |

$p^a$ value calculated by the Wilcoxon test, $p^b$ Mann-Whitney U test for analyze homogeneity between groups ICIQ-OAB International Consultation on Incontinence Questionnaire Overactive Bladder, BD bladder diary, ICIQ-SF International Consultation on Incontinence Questionnaire-Short Form, x±dp mean ± standard deviation, *p≤0,05

## CONCLUSIONS

The transcutaneous parasacral electrical stimulation presented a significant improvement for the variables related to the symptoms and to the degree of discomfort evaluated by ICIQ-OAB in older women with OAB.

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