

# 305 - RANDOMIZED CONTROL TRIAL OF TRANSCUTANEOUS ELECTRICAL TIBIAL NERVE STIMULATION AS A TREATMENT OF OVERACTIVE BLADDER IN OLDER WOMEN – PILOT STUDY



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## Introduction

Transcutaneous electrical tibial nerve stimulation (TTNS) is a non-invasive technique that has been shown to be effective in the treatment of symptoms of the Overactive bladder syndrome (OAB), demonstrating positive results in urinary habits, urodynamic values and quality of life (QoL), especially in patients resistant to drug therapy (1).

TTNS is a peripheral neuromodulation, where the access to the sacral plexus is indirectly done by means of intermittent electrical stimulation of this nerve, which aims to stimulate the sacral plexus through the afferent fibers of the tibial nerve, mixed nerve containing L5-S3 fibers. The stimulation of the afferent nerve can therefore lead to the activation of sympathetic inhibitory neurons and suppression of detrusor contraction through a direct sacral pathway (2).

The first-line therapy for OAB suggested by the Guidelines is a behavioral therapy (BT) that includes changes in lifestyle, bladder reeducation, pelvic floor muscle training and biofeedback training (3). Considering the high prevalence of OAB in older women, the negative impact on QoL, the high use of medications, older women to opt for non-invasive, painless treatments and that do not include vaginal manipulation, and also because it is an effective conservative treatment, we opted for the use of transcutaneous electrical nerve stimulation in peripheral pathway. We conducted a pilot study to evaluate the effects of TTNS associated with BT in the treatment of OAB in older women, comparing with the effects of exclusive BT recommended treatment as Guidelines in adults.

## Methods

This is a pilot study with randomization of two groups: G1 (behavioral therapy) and G2 (transcutaneous electrical tibial nerve stimulation associated with behavioral therapy), with blind evaluator and comparison between groups. The inclusion criteria were female gender, age between 60 and 80 years, with the presence of urinary dysfunction identified by the score greater than or equal to 8 points in OAB-V8 (Overactive Bladder Awareness Tool) questionnaire. Were excluded women with lower urinary tract infection, identified by urine test, history of treatment for OAB in the last 6 months, baseline neurological diseases, history of genitourinary neoplasia, previous pelvic irradiation, genital prolapse that exceeds the vaginal ostium, cardiac pacemaker or use of medicine for OAB.

The analyzed variables of the study were urinary habit, through the bladder diary (BD) of three days, symptoms and degree of discomfort of the OAB through the ICIQ-OAB (International Consultation on Incontinence Questionnaire Overactive Bladder). The treatment of the G1 consisted of 2 sessions of BT, were passed orientations in relation to the proper positioning for urination, always seated, with legs apart, trunk forward, elbows supported on the knees and use of a foot support in order to maintain greater hip flexion; programmed urination, patients should try to postpone the urination to the maximum, trying to reach an interval of 2 hours; avoid the ingestion of liquid 2 hours before bedtime in order to avoid episodes of nocturia and avoid the consumption of irritants food and beverages to the bladder. The G2 performed 8 sessions (2x per week) of TTNS associated with 2 sessions of BT. The following parameters were fixed for electrical nerve stimulation F = 10 Hz, T = 200 µs, t = 30 min and maximum intensity tolerated by the patient.

For the normality analysis, Shapiro Wilk was used with non-normal distribution for all dependent variables. The Mann-Whitney U test was used to analyze homogeneity between groups and for analysis before and after intergroup. The Wilcoxon Test evaluated the intra-group comparison analysis. A significance level of 0.05 was considered. To evaluate the power of the test used in the study was applied the post hoc analysis which demonstrated a power of 0.89 with an effect size of 2.29.

## Results

Were selected by convenience, 37 older women with OAB, who were considered eligible for the study, but 7 patients were excluded by: neurological disease (2), severe genital prolapse (2), history of physiotherapeutic treatment for OAB (2) and drug treatment for OAB (1). Were randomized 30 patients, 13 in G1 and 17 in G2. However, at the end of the treatment, after dropouts and incomplete data on the evaluation forms in both groups, 19 patients were composed of the final sample (G1= 8 and G2= 11).

## Results

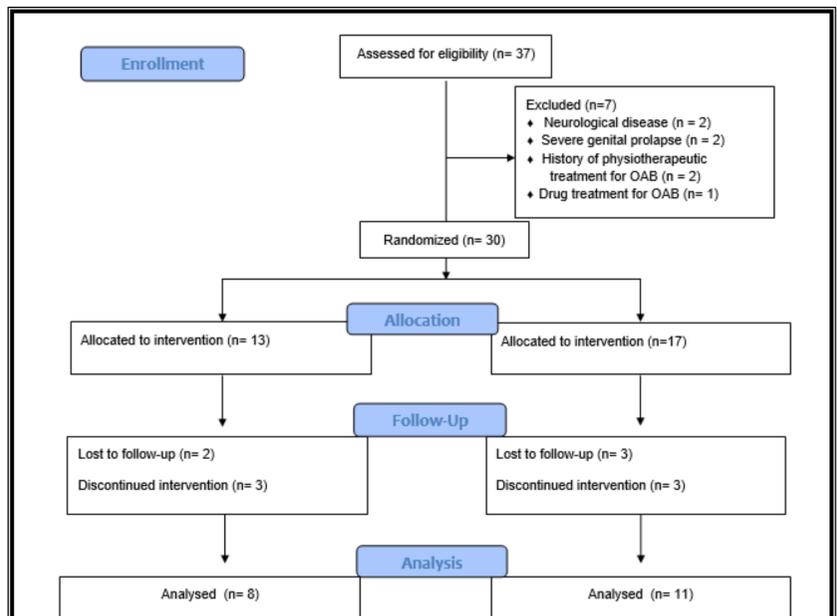


Figure 1 – Consort 2010 Flow Diagram

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

Variable	G1 (n = 8)	G2 (n = 11)	p <sup>a</sup>	P
<b>ICIQ-OAB</b>			0,480	0,067
Before	10,25±4,37	9,09±3,67		
After	8,00±5,90	3,18±2,96		
p <sup>b</sup>	0,114	0,005		
% improvement	21,95	65,02		
<b>Bother of Daytime Frequency</b>			0,475	0,405
Before	5,00±4,63	7,00±2,93		
After	4,38±4,96	2,64±3,85		
p <sup>b</sup>	0,317	0,028		
% improvement	12,40	62,29		
<b>Bother of Nocturia</b>			0,782	0,758
Before	8,13±3,48	7,64±3,91		
After	4,50±4,99	3,82±4,17		
p <sup>b</sup>	0,066	0,018		
% improvement	44,65	50,00		
<b>Bother of Urgency</b>			0,195	0,012
Before	9,38±1,19	7,82±3,06		
After	7,25±4,53	2,36±3,35		
p <sup>b</sup>	0,285	0,014		
% improvement	22,71	69,82		
<b>Bother of Urgency urinary incontinence</b>			0,782	0,120
Before	8,88±1,81	8,73±2,00		
After	6,25±5,18	3,18±3,84		
p <sup>b</sup>	0,102	0,012		
% improvement	29,62	63,57		
<b>Urinary frequency 24 hours (BD)</b>			0,321	0,772
Before	7,02±4,27	10,95±8,72		
After	6,86±4,27	6,98±2,75		
p <sup>b</sup>	0,833	0,075		
% improvement	2,28	36,26		
<b>Nocturia (BD)</b>			0,709	0,736
Before	2,08±1,99	2,35±1,71		
After	2,00±1,13	1,56±1,38		
p <sup>b</sup>	0,889	0,028		
% improvement	3,85	33,62		
<b>Urgency episodes (BD)</b>			0,600	0,434
Before	2,25±3,52	1,72±2,21		
After	1,79±3,09	0,85±1,41		
p <sup>b</sup>	1,00	0,069		
% improvement	20,44	50,58		
<b>Urgency urinary incontinence episodes(BD)</b>			0,799	0,490
Before	2,37±3,59	2,42±2,70		
After	1,33±2,15	0,64±1,27		
p <sup>b</sup>	0,345	0,036		
% improvement	43,88	73,55		

p<sup>a</sup> Mann-Whitney U test for analyze homogeneity between groups P Mann Whitney U test for intergroup comparison; p<sup>b</sup> Wilcoxon test for intragroup comparison; ICIQ-OAB International Consultation on Incontinence Questionnaire Overactive Bladder; G1 behavioral therapy; G2 transcutaneous electrical tibial nerve stimulation and behavioral therapy; BD bladder diary; % percent; x±SD mean ± standard deviation.

## Conclusions

TTNS associated BT showed significant improvement in the reduction of symptoms of OAB and the degree of discomfort of symptoms, assessed by the ICIQ-OAB and in episodes of urgency urinary incontinence and nocturia evaluated by BD, when compared to isolated BT in older women in the community with OAB.

## References

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