

RANDOMIZED TRIAL OF TIBIAL NERVE STIMULATION (TNS) IN MOTOR AND SENSORY THRESHOLDS FOR TREATING OVERACTIVE BLADDER (OAB) IN OLDER WOMEN – PILOT STUDY

Hypothesis / aims of study

TNS is a minimally invasive peripheral neuromodulation technique suggested as effective line treatment for patients with overactive bladder. The direct stimulation of the tibial nerve is supposed to elicit a motor and/or sensory response in the foot, specially in the hallux. Motor response includes flexion of the hallux and the other toes. Sensory response includes a radiating sensation under the sole of the foot and/or in the toes. Some authors suggested starting conventional treatment only if a motor response is elicited during the testing phase, however returns to the sensory response. In the sensory response, only the superficial cutaneous nerve fibers with larger diameter are activated. The probable mechanism of pain modulation is a peripheral block direct transmission or activation of central inhibition of pain transmission by stimulating the fiber larger diameter. In the motor response the contraction non-painful is induced and the stimulation can simply make pain relief in the same way that sensory stimulation level (blocking activation of the peripheral or central inhibition). Induction of rhythmic contraction can also activate endogenous opioid mechanisms of analgesia. How these mechanisms of detrusor inhibition occurred is still not known. We conducted a pilot study to assess the effect of TNS in urinary habits and the impact of symptoms on QoL in older women with OAB and to compare the two intensity thresholds, sensory and motor.

Study design, materials and methods

It's a pilot study with randomization of two groups, with blind assessment and comparison between groups. The eligibility criteria were female, aged equal to or higher than 60 years, and likely urinary dysfunction, that was identified by a score equal to or greater than 8 points in OAB-V8 questionnaire. Were excluded women with urinary infection, identified by urine test, history of treatment for OAB and hormone replacement therapy in the last six months, prior surgery to treat UI, neurological diseases base, genital-urinary cancer history, complaints of pain in the lower abdomen for more than six months, prior pelvic irradiation, genital prolapse above third degree of Baden and Walker scale, use of cardiac pacemakers, metal implants in foot and right ankle region, inability to respond questionnaires properly and abstentions to treatment. The assessment instruments were ICIQ-OAB (International Consultation on Incontinence Questionnaire Overactive Bladder) and three days of voiding diary. The treatment consisted of eight sessions - 2x/week in groups 1 TNS (sensory threshold) and 2 (motor threshold) with fixed parameters F=10 Hz, T=200 μ s, t=30 minutes. The normality distribution was performed using Shapiro Wilk with non-normal distribution for all dependent variables (urinary and QoL habit). The homogeneity between the groups was analyzed using the Mann-Whitney U test and t-student for independent samples. For the analysis before and after in each group, we used the Wilcoxon test and the comparison of delta's improvement between the two groups was performed using the Mann-Whitney U test. The significance level (α) of 0.05 was considered.

Results and Interpretation of results

Were selected by convenience, 41 older women who met the eligibility criteria, but 13 were excluded: neurological disease (3), previous surgery (2), did spare two or more sessions (2) greater prolapse and/or equal to grade 3 of Baden Walker (2), urinary tract infection (4). Were randomized 28 patients, 15 in G1 (sensory threshold), 13 in group 2 (motor threshold). The two groups were homogeneous for socio-demographic and clinical characteristics, as well as the scores on assessment instruments (Table I). Both groups, showed significant improvement after treatment for all variables except the bother of urge incontinence for G2. Regarding the delta's improvement between G1 and G2, was also not observed significant difference for all variables, except for the total score of ICIQ-OAB (Table II).

Table I. Comparison of QoL and urinary habit inter- and intra-group study

Variable	G1 (n=15)	G2 (n=13)	P ^a
ICIQ-OAB			
Before†	11.00±2.72	9.15±2.07	0.057
After†	4.46±2.66	4.53±3.07	
P ^b	0,001*	0,002*	
Bother of Daytime Frequency			
Before†	7.66±2.31	7.23±2.16	0.529
After†	3.20±2.59	3.38±3.17	
P ^b	0.001*	0.007*	
Bother of Nocturia			
Before†	7.73±2.18	5.84±3.53	0.178
After†	3.40±3.26	1.84±2.51	
P ^b	0.002*	0.015*	
Bother of Urgency			
Before†	8.46±1.99	7.61±1.93	0.268
After†	4.00±2.59	3.53±3.59	
P ^b	0.002*	0.003*	
Bother of Urge incontinence			
Before†	7.66±2.52	7.38±3.20	0.933
After†	2.73±3.65	4.38±4.29	
P ^b	0.003*	0.076*	
Urinary frequency 24 hours (VD)			
Before†	13.15±3.07	11.22±2.32	0.077
After†	8.33±2.52	7.89±2.64	
P ^b	0.001*	0.006*	
Nocturia (VD)			
Before†	2.53±1.79	2.35±1.19	0.922
After†	1.26±1.21	1.05±1.01	
P ^b	0.001*	0.008*	
Urgency episodes (VD)			
Before†	2.75±2.22	2.40±1.89	0.657
After†	0.79±0.96	0.58±0.65	
P ^b	0.003*	0.008*	
Urge incontinence episodes (VD)			
Before†	1.53±1.29	2.73±1.69	0.043
After†	0.33±0.57	0.84±1.39	
P ^b	0.006*	0.008*	

P^a † Student test P^b Wilcoxon test (before and after) * p<0,05 VD voiding diary † x±dp mean ± standard deviation

Table II. Comparison among delta's improvement between G1 and G2

Variable	G1 (n=15) Mean ± SD	G2(n=13) Mean ± SD	P
ICIQ-OAB	-6.53±1.99	-4.61±2.59	0.033
Bother of Daytime Frequency	-4.46±3.50	-3.84±3.65	0.639
Bother of Nocturia	-4.33±3.45	-4.00±4.43	0.918
Bother of Urgency	-4.46±3.50	-4.07±3.22	0.706
Bother of Urge incontinence	-4.93±4.04	-3.00±5.33	0.416
Urinary frequency 24 hours (VD)	-4.82±3.45	-3.33±2.86	0.344
Nocturia (VD)	-1.26±1.13	1.30±1.39	0.829
Urgency episodes (VD)	-1.95±2.12	-1.81±2.02	0.973
Urge incontinence episodes (VD)	-1.19±1.21	-1.89±1.92	0.277

Mann-Whitney U test VD: voiding diary x±dp mean ± standard deviation

Concluding message

This pilot study showed that the TNS using the sensitive and motor threshold significantly improved QoL and urinary habit, when analyzed before and after treatment variables in older women with OAB. However, there was no difference between the two techniques, except for the total score of ICIQ-OAB, which showed a greater improvement in G1.

References

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Disclosures

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