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Brasil C[1], Sodré D[1], Teles A[1], Mascarenhas I[1], Valverde D[1], Costa M[1], Ferreira J[1], Lordelo P[1]
1. *Pelvic Floor Care Center - Bahiana School of Medicine and Public Health, Salvador, Bahia, Brazil*

RADIOFREQUENCY FOR THE TREATMENT OF STRESS URINARY INCONTINENCE IN FEMALE: RANDOMIZED CLINICAL TRIAL (PRELIMINARY RESULTS)

Hypothesis / aims of study
Urinary stress incontinence (SUI) is defined as the complaint of involuntary urinary loss in the effort in which it affects about 25 to 30% of the female population. Radiofrequency (RF) is a new therapeutic possibility that may aid in one of the pathophysiological mechanisms of SUI that is the decrease of collagen in the urethral walls. (1) Therefore, the objective of this study was to verify the clinical response of radiofrequency in the treatment of stress urinary incontinence in women.

Study design, materials and methods
It is a randomized clinical trial. Women with stress urinary incontinence, aged 18 to 65 years, who presented pelvic floor muscles function on the OXFORD scale greater or equal to 3, result of 1-hour Pad Test greater 1gram and excluded those with sensory deficits in the genital region, with pacemakers and pregnant women. The initial evaluation consisted of anamnesis, then evaluation of the function of the pelvic floor muscles (Oxford Scale and Surface Electromyography) and the 1-hour Pad test. Randomization was performed by block 4 and stratified by age. The allocation concealment was ensured by a secretary who was not part of the research. The study was divided into two groups, the study group (SG) in which it consisted the application of the RF was performed by trained physiotherapists by means of Tonederm® G2 Spectra model with non-ablative transfer method with a frequency of 1.5 MHz, monopolar using handle with active electrode region of the urethral meatus and external coupling passive electrode placed on the participant's back. For application, the participant was in lying position. The protocol consisted of five sessions, with one session per week. RF was applied to the external urethral meatus (figure 1) for two minutes after reaching 39 ° C. The temperature was mentioned by an infrared thermometer. The protocol consisted of five sessions, with one session per week. In addition to RF, kinesiotherapy of the pelvic floor muscles (5 sessions) was performed. In the control group (CG) the protocol performed was the same (RF off + kinesiotherapy) as the study group, differing that the radiofrequency device was switched off and the gel used was heated to mask the thermal effect for the patient. The evaluation the clinical responde were: Pad test 1hr to quantify the urine loss one week after the last session RF, and to assess the degree of satisfaction of the treatment was applied to Likert scale: 1) very dissatisfied, 2) dissatisfied; 3) little dissatisfied 4)unchanged; 5) little satisfied; 6) satisfied 7) very satisfied. For the statistical analysis of intra-group urinary loss, the Wilcoxon test was used, and the mann-whitney test was used to compare the mean difference of inter-group urinary loss.

Results
The study group consisted of 9 women with a mean age of 48,5±10 and the control group with 7 women with a mean age of 49±7 (p=0,890). The groups were homogeneous on the oxford scale (Oxford 3 for all), the initial urinary loss Pad test in the SG was 7 (5,5-12) and the CG was 8 (3-15) (p=0,837) and the BMI was SG 25,6±5 and CG was 26,5±5 (p=0,760). In the analysis of intra-group urinary loss, the SG presented a modification in the median of the pad test of: 7(5,5-12) for 1(0-4) (p=0,007) and the CG initial median 8(3-15) for 1 (0-38) (p=0,865) . In the intergroup comparison of urinary loss the study group was a median 5 (3-7,5) and the control group was a median of 3 (23-7,5) (p=0,200). In the satisfaction of the treatment all the women in the study group reported being very satisfied or satisfied, however in the control group of the 7 women 5 reported they are very satisfied / satisfied but 2 reported they are not very satisfied with the treatment.

Interpretation of results
The results suggest that noninvasive radiofrequency has significant clinical effects in reducing urinary loss, but due to the sample size of the present study it was not possible to observe a difference between the groups. The reduction of urinary loss in the study group may be justified by the thermal effect in which it promotes a denaturation of the collagen fibers, remodeling of the fibers and a greater activation of the fibroblasts, causing the formation of new collagen proteins (neocolagenogenesis). (2,3)

Concluding message
It suggests that the RF presents positive clinical responses in the reduction of the urinary loss, but without presenting an intergroup difference.

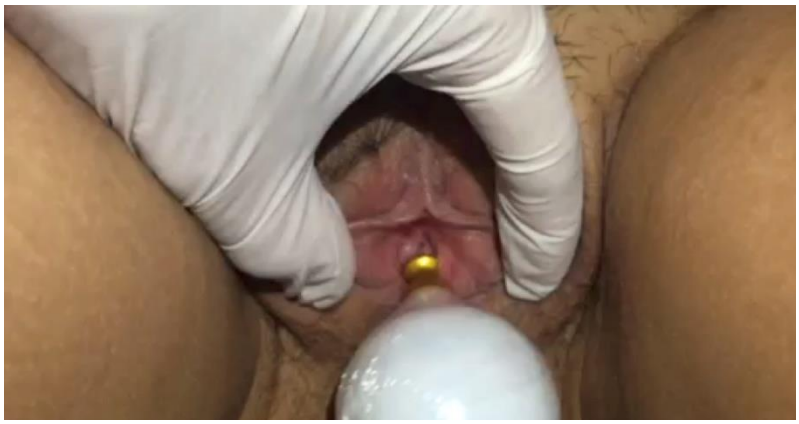

Figure 1 - Demonstration of application of non-ablative radiofrequency in external urethral meatus

References

1. Lukban JC. Transurethral Radiofrequency Collagen Denaturation for Treatment of Female Stress Urinary Incontinence: A Review of the Literature and Clinical Recommendations. Obstet Gynecol Int. Hindawi Publishing Corporation; 2011;2012:1–6
2. Smith WB, Melton W, Davies J. Midsubstance Tendinopathy, Percutaneous Techniques (Platelet-Rich Plasma, Extracorporeal Shock Wave Therapy, Prolotherapy, Radiofrequency Ablation). Clin Podiatr Med Surg Internet. Elsevier Inc; 2017;34(2):161–74
3. Lordelo P, Boas AV, Sodre D, Valverde D, Lemos A, Tozetto S, Brasil C. New Concept for Treating Female Stress Urinary Incontinence with Radiofrequency. International Braz J Urol. In press 2017.

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