

NEW CONCEPT FOR TREATMENT OF ANAL INCONTINENCE WITH RADIOFREQUENCY

Hypothesis / aims of study

Anal incontinence (AI) may have its etiology in the incompetence of the internal anal sphincter. This structure is composed mainly of smooth muscles, rich in collagen. Radiofrequency (RF) with its high frequency waves, and when used at a temperature of approximately 41°C, increases the production of collagen (neocollagenesis) and improves vascularization (1). The objective of this innovative study is to describe and assess the clinical effect and safety of radiofrequency for treatment of anal incontinence in women.

Study design, materials and methods

This is a pilot study, conducted from June 2016 to March 2017, in 10 women who communicated the clinical complaint of anal incontinence. Included were adult patients under 65 years of age. Excluded were those who presented difficulties in understanding the used instruments, patients with chronic neurological degenerative diseases, those with an implantable cardioverter defibrillator and iatrogenic metals in the pelvic region. The data collection was carried out by means of a basic anamnestic questionnaire with socio-demographic and clinical information. Safety has been assessed by patient reported outcomes as well as the observation of a presence of adverse effects such as hematochezia, mucosal lesion, moisture around the anus, pain, burning sensation and sand sensation in the anal region.

The clinical response was measured in a subjective way by means of the Likert scale to measure the degree of satisfaction with treatment (1 - Very Dissatisfied, 2 - Dissatisfied, 3 - Unchanged, 4 - Satisfied, 5 - Very Satisfied). An objective evaluation was performed using questionnaires: the Fecal Incontinence Quality of Life scale (FIQL) and Fecal Incontinence Severity Index (FISI), applied before the first session and after the last radiofrequency treatment.

All underwent five sessions of non-ablative radiofrequency (RF) in the perianal region, with a seven-day interval. The RF treatment was performed by a physiotherapist trained in the radiofrequency technique using the Spectra G2 Tonederm® device, using an active electrode in the anal area and a grounding electrode positioned on the participant's hip. For the treatment, each patient used a sterile electrode, connected to a hand device protected by plastic film. Circular movements (figure 1) were made after reaching the temperature of 41 degrees, and maintained for 2 minutes. Liquid glycerin was used and the participants were in lateral decubitus position. The results were examined by a descriptive analysis and the nonparametric Wilcoxon test.

Results

The mean age of participants was 51.90 ± 11.49 years. Six patients reported some kind of side effect (such as burning, pruritus, wet sensation and sand sensation in the anal region). No patient discontinued treatment. Evaluating the clinical response by degree of satisfaction, 9 out of the 10 women were satisfied or very satisfied, only one reported to be unchanged. The severity was reduced by 23.5 points by the AI severity questionnaire (p <0.05). There was no significant change in quality of life.

Interpretation of results

The results showed that RF is a treatment with low adverse effect with a low abandonment of treatment. The clinical response was satisfactory according to the patients' reports, also demonstrated by the decrease in severity of AI. Although the results were positive, there is a need for a randomized clinical trial to assess the efficacy of the technique. The mechanism of action of non-ablative RF in the restructuring of the internal and external anal sphincter is still unknown. Nevertheless, it is known that the thermal effect produced by RF stimulates an increase in angiogenesis (2) and local vascularization, with consequent denaturation and remodelling of the collagen fibers. In addition, it also leads to a greater activation of the fibroblasts, leading to the formation of new collagen proteins (neocollagenesis) (1,3). Thus, it is believed that the restructuring of the tissue provided by the RF has led to a decrease of the fecal losses, hence the degree of patient satisfaction.

Concluding message

RF demonstrated to be a technique with low adverse effects for the treatment of AI in women, with positive results, in the clinical response as well as in the Fecal Incontinence Severity Index, with an increase in patient satisfaction.



Figure 1 - Demonstration of non-ablative radiofrequency treatment in the anal area.

References

1. Herman RM, Berho M, Murawski M, Nowakowski M, Rys J, Schwarz T, Wojtysiak D, Wexner SD., Defining the histopathological changes induced by nonablative radiofrequency treatment of faecal incontinence--a blinded assessment in an animal model. *Colorectal Dis.* 2015 May;17(5):433-40.
2. 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.
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

Disclosures

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Subjects: HUMAN **Ethics Committee:** Ethics Review Board from Bahiana School of Medicine and Public Health, Salvador-Bahia (Brazil) - (CAAE: 43462915.8.0000.554 4) **Helsinki:** Yes **Informed Consent:** Yes