

TREATMENT OF URINARY INCONTINENCE AFTER RADICAL PROSTATECTOMY WITH RADIOFREQUENCY: NEW CONCEPT

Hypothesis / aims of study

Radiofrequency (RF) with its high frequency waves, and when used at a temperature above 41°C, increases the production of collagen (neocollagenesis) and improves vascularization (1). Objectives of the study: To describe and assess the clinical effect and safety of radiofrequency for the treatment of urinary incontinence after radical prostatectomy.

Study design, materials and methods

This is a pilot study conducted from January to March 2017, in eight volunteers with urinary incontinence (UI) after radical prostatectomy. Included were men up to 65 years of age, with clinical complaints of UI after radical prostatectomy. Patients with less than 45 postoperative days, urge urinary incontinence (UUI), poor understanding of the used instruments, chronic degenerative neurological diseases, implantable cardioverter defibrillator and iatrogenic metals in the pelvic region, were excluded. The data collection was carried out by means of a basic anamnestic questionnaire with sociodemographic information (age, marital status, education, occupation, among others) and clinical information (e.g., information on radical prostatectomy, urinary symptoms, diagnosis of hemorrhoids and previous pathologies such as diabetes and hypertension, among others). In addition, evaluation of the pelvic floor muscle strength was rated by using the Modified Oxford Scale. To evaluate the clinical response the following actions were carried out before and after the treatment: a) the 1 hour Pad Test (incontinent with weight \geq 1g), b) ultrasound (US) to assess the presence of post-void residual (PVR), and c) self-administered questionnaires: International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF: the higher the value found, the greater the impairment of quality of life), International Consultation on Incontinence Questionnaire Overactive Bladder (ICIQ-OAB: the higher the score, the greater the impact on the quality of life), the International Index of Erectile Function (IIEF: the lower the score, the worse the quality of sexual life), and the Medical Outcomes Study 36-item short form health survey (SF36: the higher the score, the better the state of health). And ultimately, the Likert scale was used to measure the degree of satisfaction with treatment (1 - Very Dissatisfied, 2 – Dissatisfied, 3 – Unchanged, 4 - Satisfied, 5 - Very Satisfied). Participants underwent five sessions of non-ablative anorectal radiofrequency (RF). The RF application protocol was used in the form of a capacitive electric transfer, bipolar configuration, and a CAPENERGY device (figure 1). This equipment has two electrodes: an active one, which is inserted the anal region, using a condom and a gel for the emission of the wave, and a dispersive one, which is attached to the patient's hips and acts as grounding electrode (figure 2). The temperature used during the treatment was 41°C and when the desired temperature was reached, it was maintained for 2 minutes, with the therapist making slow rotational movements (figure 3). Safety has been assessed by patients reported outcomes, determining the presence of adverse effects such as hemochezia or hematuria, pain or burning and through US. The results were examined by descriptive analysis and the Wilcoxon nonparametric test.



Figure 1 – Radiofrequency device (Capenergy)
(Source: Image courtesy of researcher in charge)



Figure 2 - Active and dispersive RF electrode
(Source: Image courtesy of researcher in charge)



Figure 3 - Application with rotational movements
(Source: Image courtesy of researcher in charge)

Results

The mean age of participants was 58 ± 2.9 years. None of the patients reported hemorrhoids. The median muscle strength was 3 (3-3.8) and the initial pad test showed 6g (1.3-39.3) and the final 2g (0-15) ($p = 0.017$). The pad test indicated that 87.5% presented a decrease and 37.5% a complete resolution of urinary loss. The SF-36 test indicated an improvement of the General Health Status (55.6 ± 11.6 to 71.9 ± 13.1 , $p = 0.005$) and the pain section did not change ($p = 0.743$). ICIQ-OAB indicated a decrease of impairment in quality of life (QoL) from 6 (4.3-10.25) to 5 (0.75-8.3) ($p = 0.034$). The ICIQ-SF and IIEF showed no difference. The US showed no change in PVR after treatment, from 0.1 ml (0-3.8) to 0 ml (0-0.6) ($p = 0.715$). Regarding the degree of satisfaction, no patient indicated to be dissatisfied, only one remained unchanged and the others were satisfied. Four participants reported pain at the beginning, while the anal electrode was inserted, the pain ceased during the treatment.

Interpretation of results

In an innovative way, the results showed that RF is a treatment with a low adverse effect. Considering the outcomes of the Pad Test, the ICIQ-OAB and the SF-36 General Health Status domain, the clinical response was statistically significant and demonstrated that the technique is promising. Therefore, the need for a randomized clinical trial has been demonstrated. The mechanism of non-ablative RF action with the aim of restructuring the internal and external urethral sphincter, bladder neck, urethra and cavernous nerves after radical prostatectomy, is still unknown. However, it is known that the thermal effect produced by RF stimulates an increase in angiogenesis⁽²⁾ and local vascularization, with consequent denaturation and remodeling 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 RF treatment has led to a significant decrease in the pad test, hence the degree of patient satisfaction.

Concluding message

RF has shown to be a safe technique for the treatment of UI after radical prostatectomy, with positive results in both clinical response and quality of life, promoting patient satisfaction.

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

Disclosures

Funding: Research Foundation of the State of Bahia **Clinical Trial:** Yes **Registration Number:** NCT03048799 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Ethics Review Board from Bahiana School of Medicine and Public Health, Salvador-Bahia (Brazil), in December 2016 (protocol: CAAE - 58851916.9.0000.5544) **Helsinki:** Yes **Informed Consent:** Yes