New concept for treating stress incontinence urinary: Preliminary results of a phase study

Patrícia Lordelo1, Cristina Brasil2, Danieliel Valverde2, Danielle Sodré4, Andrea Vilas Boas 5

ABSTRACT

Urinary loss is the main complaint of stress urinary incontinence (SUI), and has a prevalence of 25% to 30% in adult women. Intra-urethral, non-ablative radiofrequency (RF) is used as a form of treatment, and considered a successful procedure in the office, but comes with the need for antibiotic prophylaxis, oral sedation, and local anesthesia, increasing the risk of urinary tract infections and costs (1,2,3). Aim of study: To describe the safety and to evaluate the therapeutic response of RF treatment on the external urethral meatus.

MATERIALS AND METHODS

Phase II study, the description of a prospective number of cases, in 10 women with SUI and aged 18 to 65 years. We excluded pregnant women, users of copper intrauterine devices, patients suffering from cognitive disorders, sensory deficit in the genital area and carrying pacemakers. The RF treatment was performed by trained physiotherapists, using a Tonederm® G2 Spectra model with non-ablative transfer method with a frequency of 1.5 MHz, monopolar handle with active regional electrodes for use on the urethral meatus, and an external coupled passive electrode placed on the participant’s back. (Figure 1).

For treatment, the participant was in lying position. The protocol consisted of five sessions, with one session per week. RF was applied on the external urethral meatus (Figure 2) for two minutes, after reaching 39 to 41 °C. The temperature was measured with an infrared thermometer (figure 2). The evaluation criteria for the therapeutic response were: 1hr Pad test to quantify the urine loss, and to assess the degree of treatment satisfaction, using a 5-point Likert scale: 1) dissatisfied, 2) little satisfied; 3) unchanged; 4) satisfied; 5) very satisfied. Safety consisted of the observation of adverse effects such as mucosal injury, pain, fear, dysuria or burning. The pad test was evaluated at the end of treatment and one month after treatment. All participants signed an informed consent form. This pilot study was registered in clinicaltrial.gov.com (NCT02623842)

Keywords: Radiofrequency, women, Urinary Incontinence

RESULTS

The average age of participants was 51.9 ± 8.63 years. Of the 10 participants, 4 had an initial test pad with light losses, 50% (5) moderate and 10% (1) severe. In the evaluation of the final Pad test 70% (7) showed a reduction of urinary loss, and 20% (2) showed no further loss and 30% (3) a worsening of urinary loss. With the Pad test after a month there was a reduction of loss in all patients. The degree of satisfaction was 90%, as 9 participants were satisfied with the treatment and experienced no side effects. Only one patient reported a light burning sensation during treatment. Conclusion: The non-ablative radiofrequency on the external urethral meatus proved to be a safe technique with a therapeutic response, especially after a month of treatment, and with a high degree of satisfaction among users.

REFERENCES