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NEW CONCEPT FOR TREATING STRESS INCONTINENCE URINARY: PRELIMINARY RESULTS OF A PHASE ONE STUDY

Hypothesis / aims of study

Urinary incontinence (SUI) is the main complaint of urinary loss with a prevalence of 25% to 30% in adult women. Radiofrequency intra-urethral non-ablative is used as a form of treatment being successfully used via urethral intra allowing the procedure in the office, but in need of antibiotic prophylaxis, oral sedation, local anesthesia, increasing the risk of urinary tract infections and increased costs. (1,2,3) Aim of study: Describing the safety and to evaluate the effect of non-ablative transfer of RF application with external urethral meatus for the treatment of urinary incontinence.

Study design, materials and methods

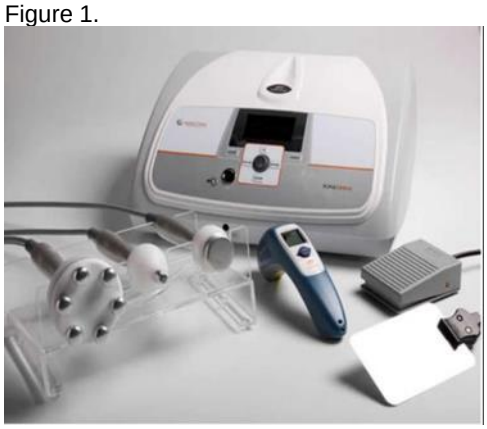
Phase II study, the description of a prospective number of cases, on 10 women with SUI and aged 18 to 65anos. We excluded pregnant women, IUD users of copper, suffering from cognitive disorders, sensory deficit in the genital area and carrying pacemaker. The application of the RF was performed by trained physiotherapists by means of Tonederm® G2 Spectra (figure 1) 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 2) 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. The evaluation criteria for therapeutic response were: Pad test 1hr to quantify the urine loss, and to assess the degree of satisfaction of the treatment was applied to Likert scale: 1) dissatisfied, 2) unchanged; 3) little satisfied; 4) satisfied; 5) very satisfied. Security was the account or observation of side effects or 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 recorded in clinicaltrial.gov.com (NCT02623842)

Results

Table 1. Results of pad test 1hour (quantify the urine loss)

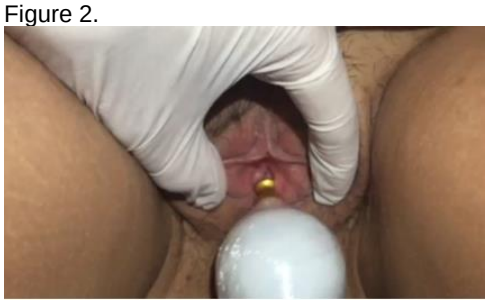
Patients	Initial Pad Test (grams)	End Pad Test (grams)	After 1 month Pad test (grams)
1	2	1	0
2	6	2	0
3	13	23	10
4	16	21	10
5	7	2	5
6	6	3	5
7	11	10	4
8	25	27	20
9	70	5	22
10	16	0	-

Figure 1.



Radiofrequency Tonederm® G2 Spectra

Figure 2.



Applying Radiofrequency Tonederm® G2 Spectra to the external urethral meatus

Interpretation of 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 test pad the final 70% (7) decreased loss, and 20% (2) showed no further loss and 30% (3) had worsening. With the Pad test after a month there was a reduction in all patients. The degree of satisfaction was 90% (9) satisfied with the treatment and no side effects. Only one patient reported burning sensation during application.

Concluding message

The non-ablative radiofrequency in external urethral meatus proved to be a safe technique with a therapeutic response, especially after a month of application and with a good degree of satisfaction among users.

References

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Disclosures

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