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TREATMENT OF SUI IN WOMEN USING ROBOTIC ERBIUM LASER PROBE

Hypothesis / aims of study

Stress urinary incontinence (SUI) is a very common symptom of pelvic floor dysfunction that affects women of various ages and strongly impacts their quality of life. The purpose of this clinical study was to evaluate the use of new robotic probe for the non-invasive erbium:yttrium-aluminum-garnet (Er:YAG) laser treatment for stress urinary incontinence in women. The main objectives of our study were to assess the efficacy and safety of this laser thermo therapy when robotic probe is used.

Study design, materials and methods

Our study is a single arm prospective study performed in one medical centre from December 2015 to March 2016. Patients with stress urinary incontinence were treated with 3 sessions of non-ablative Er:YAG laser fitted with new robotic probe, once a month. Therapy efficacy was measured with ICIQ-UI questionnaire and 1 hour pad test. Incontinence severity was calculated using ICIQ-UI score and Incontinence Severity Index (ISI) was defined according to Klovning proposal [1]. No anaesthesia was used for this therapy. Repeated ICIQ measurements were performed before and at 1, 2 and 3 months after the first laser session, while 1 hour pad test was measured before and at last follow-up at 3 months after the first laser session. After every treatment session as well as at every follow-up patients were interviewed about adverse effects and also vaginal canals were visually inspected.

Results

40 patients having SUI of average age of 54.9 years (range 38-75), average BMI of 28.3 (range 24-41) and parity of 2.5 (range 0-8) were treated with 3 sessions of ErYAG laser using robotic probe. Average ICIQ-UI score before the treatment was 11.7 points and on subsequent measurements after 1, 2 and 3 months was 8.8, 5.8 and 3.4, respectively. All patients improved their ICIQ-UI score at 3 months follow-up. According to ISI calculated from ICIQ-UI score most of the patients, 60% had moderate SUI, 35% severe and 5 % very severe SUI before the treatment. At 3 months follow-up 17.5% of patients was dry, 70% of all patients improved to mild SUI, 7.5% remained with moderate and 5% with severe SUI. There were no patients with very severe SUI at 3 months follow-up. Average weight of urine loss measured with 1 hour pad test before the treatment was 9,6 gr and at 3 months follow-up 4,2 gr. 83% of patients improved their 1 hour pad test result at 3 months follow-up. According to ICS classification before the treatment 55% of the patients had slight to moderate SUI (2-10 gr of leaked urine), 42.5% had severe SUI (11-50 gr) and 2.5% was dry (less than 2 gr). At 3 months follow-up 27.5% of patients was dry, 62.5% had slight to moderate and 10% severe SUI. Patients tolerated the treatment very well and were not reporting any discomfort with treatment. No adverse effects were reported by patients or observed by physicians.

Interpretation of results

The results of this study have shown that Er:YAG laser treatment with new robotic probe is efficacious in reducing stress urinary incontinence in women. Both measurement tools, ICIQ-UI and 1 hour pad test showed significant incontinence reduction at 3 months after the beginning of the therapy. Patients' didn't report any discomfort during the treatment and their satisfaction with results was very high.

Concluding message

In spite of limitation of this study due to a small number of patients and short follow-up, the use of robotic probe in non-ablative Er:YAG laser procedure seems to be a safe and efficacious as well as minimally invasive and patients' friendly method for treatment of female SUI. Nevertheless more controlled studies should be performed to confirm this data and to evaluate the long term effects of this novel procedure.

References

1. Klovning A, Avery K, Sandvik H, Hunskaar S. Comparison of two questionnaires for assessing the severity of urinary incontinence: The ICIQ-UI SF versus the incontinence severity index. Neurourol Urodyn. 2009;28: 411–415

Disclosures

Funding: Fotona, the manufacturer of robotic laser probe had landed this device to Dr. Sandra Maestri and Dr.Adrian Gaspar to perform this clinical study, but they didn't received any other funding or grant. Zdenko Vizintin is employee of Fotona. **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics not Req'd:** Non-invasive ErYAG laser treatments for female SUI was already very well clinically evaluated and quite some studies were published in professional international journals. The procedure is CE approved from 2012. **Helsinki:** Yes **Informed Consent:** Yes