TREATMENT OF FEMALE STRESS AND MIXED URINARY INCONTINENCE USING ERBIUM YAG LASER THERMO THERAPY – 1 YEAR FOLLOW-UP

Hypothesis / aims of study
Urinary incontinence (UI) is a common disorder that affects women of various ages and impacts all aspects of life. Therapeutic approaches range from conservative ones to different surgical procedures. Our aim was to evaluate the non-invasive erbium:yttrium-aluminum-garnet (Er:YAG) laser that exploits its thermal effect and has been used as a potential treatment strategy for stress UI (SUI) and mixed UI (MUI). There were two main objectives of our study: to assess the efficacy of this therapy and to evaluate its safety.

Study design, materials and methods
This is a single arm prospective study performed in one medical center from March 2012 to May 2013. Patients with stress and mixed urinary incontinence were treated with new Er:YAG laser treatment. Prior to treatment all patients were clinically inspected, and classified by incontinence types and grades using ICIQ-UI and forming Incontinence Severity Index (ISI) upon Klovning proposal. Patients received one to three treatment sessions with interval of 2 months in between the sessions. Treatment discomfort was measured at every session with 10 point numerical pain scale. Follow-ups with repeated measurements were performed at 2, 6 and 12 months.

Results
175 patients (average age 49.7 years, average BMI of 24.7 and parity of 2.0) were treated. Of all patients 66.0% were diagnosed SUI and 34% MUI. Average ISI score before the treatment was 5.7 points (moderate UI). Most of the patients, 51% had severe UI, 27% moderate, 17% mild and 5% very severe UI before the treatment. At 12 months follow-up 82% of patients with SUI and 37% with MUI were cured. 25% of all patients remained with mild UI, 12% with moderate and 2% with severe UI. There were no patients with very severe UI at 12 months follow-up. Treatment discomfort was very low (average grade 0.6 on 10 points scale).
There were no significant differences (p<0.001) in UI improvement among the age groups. However, there were statistically significant differences (p<0.001) in the UI improvement among the severity (ISI) groups. The largest ISI score decrease (of 8.4 points) was achieved in very severe group, followed by 5.7 points decrease in severe group, 3.6 points in moderate and 2.6 points in mild group. There were also no statistically significant differences (p<0.001) in the UI improvement at 6 and 12 months follow-up.
Adverse effects were mild and transient: negligible discomfort, mild erythema and edema. 11% of patients developed transient de-novo urge incontinence.

Interpretation of results
The results of our study have shown that new non-invasive Er:YAG laser could be regarded as a promising additional treatment strategy for SUI with at least one year lasting positive effects. On the other hand, it does not seem appropriate for treating MUI. Transient urge incontinence can appear as adverse effect. Patients’ discomfort during the treatment was minimal and satisfaction very high.

Concluding message
This clinical evaluation of a new non-invasive thermal Er:YAG laser treatment for stress and mixed urinary incontinence showed efficacy in improvement of UI with no major adverse effects noted.

Disclosures
Funding: NONE Clinical Trial: Yes Public Registry: No RCT: No Subjects: HUMAN Ethics not Req’d: The same technology was already clinically proven with at least two studies which had obtained ethics committee approvals - one performed by Prof. Lukancovic and his team (and presented on ICS 2014 in Rio) and the second performed by dr. Fistonic et al.(and also presented on ICS 2014 in Rio). Helsinki: Yes Informed Consent: Yes