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ER:YAG LASER TREATMENT FOR STRESS URINARY INCONTINENCE (SUI) IN WOMEN

Hypothesis / aims of study

The technical advantages of medical laser technology have been amply justified and proven through its medical effects: biochemical, ablative and photo-thermal, are well established facts. Laser-generated thermal energy breaks up intermolecular cross-links and stabilizes the collagen triple-helix structure, thus resulting in the shortening of collagen fibres. In order to achieve a shrinking of the collagen protein without destroying its fibrilar structure and stimulation of neocollagenogenesis, the temperature must vary between 60ºC and 65ºC[1].

Clinical studies in dermatology, aesthetic medicine and orthopedics have reported significant successes in the treatment of various disorders and conditions based on collagen damage.

Inconvenience and fear of social stigma are the main reasons for not reporting stress urinary incontinence symptoms, leading to a 53% prevalence of undiagnosed SUI[2].

Recent review showed that the menopause has little if any impact on the risk of urinary incontinence (UI). At the same time, up to 76% postmenopausal women reported symptoms of SUI and deteriorating QoL[3].

Less or non-invasive intervention in premenopausal period may reduce incidence of postmenopausal SUI and promote QoL in postmenopausal years.

Main objectives of study were comparison of the efficacy of two methods (Er:YAG Laser versus pelvic floor muscle training) for the treatment of stress urinary incontinence (SUI) and pelvic floor distension syndrome.

Study design, materials and methods

After all the exclusions, this single-centre pilot study recruited 33 female patients suffering from SUI, 22 of them underwent treatment with Er:YAG (2940 nm) laser, while 11 were scheduled for pelvic floor muscle training (PMFT). Recruitment period was between January and June 2013. Number of the participants per group was calculated by Power analysis (80% power at a 2-sided α level of 0.01 and limit of tolerance of ±5.0%).

The degree of incontinence and its impact on quality of life (QoL) was assessed with the International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI SF), where a maximum score of 21 represents permanent incontinence. Quality of life in the area of sexuality was examined with the validated Pelvic organ prolapse / urinary Incontinence / Sexual Questionnaire (PISQ-12), with a maximum score of 48 points in terms of excellent sexual gratification.

The Q-tip test evaluates the mobility/instability of the urethra and bladder neck. Urethral hypermobility was defined as being present when the Q-tip angle was >30º, while a Q-tip movement of ≤30º was presumed as normal.

For the measurement of muscle strength of the pelvic diaphragm, an Apimedis perineometer (EXTT-101, Korea) was used to determine the maximum clamping pressure (mm Hg), the average contraction pressure (mm Hg) and mean duration of contractions (seconds).

Residual urine volume was measured immediately after the patient returned from the washroom. Measurements were performed with a DC-8 ultrasound unit (Mindray, China).

All statistical analyses were made using Statistica for Windows (StatSoft, Inc., Tulsa, USA) and the difference between the groups by Mann-Whitney-U test. Statistical significance in all calculations was set to $P < 0.05$.

The procedure was performed with a 2940 nm Er:YAG laser (XS Dynamis, Fotona, Slovenia), using a special modality, SMOOTH mode, which delivers laser energy in a non-ablative, thermal-only technique based on the manufacturer's proprietary pulsing sequence designed to achieve heating up of vaginal mucosa to around 60°C, achieving depth to 500-700 microns. The patients were placed in lithotomy position and laser probes, consisting of laser speculum and specially designed laser delivery system were introduced into vaginal canal. In three steps protocol the laser irradiation was applied to anterior vaginal wall, the whole circumference of vaginal canal and vestibule area. To each area several passes was applied until 2500 – 3000 J, depending on the length of canal. Cumulative laser energy was deposited in approximately 10 minutes time. No anaesthesia was used before or during the session. During the initial post-operative period of 14 days after intervention patients were instructed to avoid increased intra-abdominal pressure as well as sexual intercourse.

Results

Laser treatment was significantly ($p<0.05$) more effective than PFMT in all the domains tested: ICIQ-UI score reduced for more than 6 points at all follow ups ($p<0.01$). PISQ-12 scores increase after 6 months was 5.5 points ($p<0.03$). All three perineometric parameters (max. pressure, average pressure and duration of contraction) showed significant increase ($p<0.02$). Q-tip angle significantly decreased for 4.8˚ in restful and for 14.1˚in strain position at 6 months and residual urine volume (RUV) was significantly ($p<0.03$) reduced as well. Laser treatment had no adverse effects.

Interpretation of results

This study showed statistically significant improvements in all outcome measures. Our data revealed that reduction of incontinence achieved with laser therapy was also associated with significant improvements in sexual gratification.

Concluding message

Er:YAG laser is another possible minimally invasive method for treating premenopausal and postmenopausal women with SUI symptoms.

References
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Disclosures
Funding: None **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** The Ethics committee of the University of Rijeka School of Medicine in Rijeka, Croatia. The approval of the ethics committee was obtained according to the principles of the Nurnberg Codex and the latest version of the Helsinki declaration. A detailed written informed consent, with an attached Institutional Ethics Committee approval, as obligatory inclusion criteria was obtained from all participants. **Helsinki:** Yes **Informed Consent:** Yes