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ER:YAG LASER TREATMENT OF SUI IS MORE EFFECTIVE IN YOUNGER AND NORMAL WEIGHT PATIENTS

Hypothesis / aims of study

Although the initial treatment for SUI should include nonsurgical therapies, surgical procedures are more likely implemented to cure SUI but are associated with more adverse events. Less invasive operative mesh techniques are relatively effective, but are not immune to complications such as bleeding, bladder perforation, urethral injury, infection, and the retention requiring mesh resection (1). In patients for whom the risks of anaesthesia and surgery are too high, a minimally invasive approach is recommended and further research is needed in terms of more compliant, less invasive and low-cost methods for the treatment of SUI and pelvic floor dysfunction (2).

Study design, materials and methods

In order to assess the effectiveness of minimally invasive Er:YAG laser technic a prospective cohort, single-center study at the Ob/Gyn Clinic, Zagreb, Croatia recruited a consecutive sample of 73 female patients suffering from stress urinary incontinence. The procedure was performed with a 2940 μm Er:YAG laser (XS Dynamis, Fotona, Slovenia) designed to achieve heating up of vaginal mucosa to around 60°C, 500 – 700 μm in depth. During the laser intervention, patient discomfort and treatment tolerability, as well as potential adverse events, were monitored. No anaesthesia was used before or during the session. During the initial postoperative period of 14 days after intervention, patients were instructed to avoid increased intra-abdominal pressure as well as sexual intercourse. The first follow-up appointments were at 1 month, and the second follow-up was at 2 – 6 months after the intervention.

The degree of incontinence and its impact on quality of life were assessed with the ICIQ-UI SF. Baseline comparabilities of those that remained in the study and those that were lost to follow-up were analysed with regard to age, parity, average, and the last birth weight, body mass index, percentage of menopausal patients, perineometry results, residual urine and PISQ-12 score (Pelvic Organ Prolapse/ Urinary Incontinence Sexual Function Questionnaire). For sensitivity analysis, missing values at follow-up were replaced by baseline values. Correlation of raw age data and ICIQ-UI SF score was analysed by Spearman rank correlation. Association of the four age groups with the ICIQ-UI SF score was assessed by the Jonckheere – Terpstra test. Data analysis used the R language.

Results

The score in the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form was reduced to a median of 46% (95% confidence interval 33 – 67%; $p<0.001$). The reduction was significantly higher in women with normal body mass index (67%) than in overweight women (25%), as well as in women younger than 39 years (100%) compared with those older than 60 years (8%) ($p < 0.001$). No major adverse events throughout the course of laser treatment and the follow-up period were noticed or reported. The patients eventually signalled sensation of warmth or pricking or irritation during treatment and seldom reported vaginal discharge in the next few days after the procedure. A visual analog scale (VAS) level of 2 was achieved by 5% of participants, and 95% had a score of 0. Slight vulvar oedema, which was infrequently noticed, disappeared within 48 h after the treatment. One case of *de novo* urgency was reported. The symptoms vanished spontaneously after 8 days.

Interpretation of results

Statistically significant differences between baseline and 2 – 6 months after the intervention were found. Sensitivity analysis, done under the worst case and the unrealistic assumption that all outcome values for those that were lost to follow-up would be the same throughout the study as at baseline, indicating no treatment effect, nevertheless revealed statistically significant and clinically relevant differences after the intervention. In a pre-specified *post-hoc* sub-group analysis, we noticed statistically significant differences between different BMI levels and a lowering of the ICIQ-UI SF score. The decrease in the normal BMI group was statistically significantly stronger (Mann – Whitney test, U =99.0; Z=- 2.65; p= 0.008). From baseline to the second follow-up, SUI changed from moderate, severe or very severe to mild in 38.3% of women in the normal BMI group, and in 12.5% of women in the overweight group. Age was associated with a relative decrease of ICIQ-UI SF score (Spearman rank correlation coefficient, p= -0.55; p< 0.001). The difference between age groups was statistically significant (Jonckheere – Terpstra test, standardized $J – T$ = -3.45; p<0.001).

Concluding message

The first assessment of efficacy and safety of the Er:YAG laser in the treatment of stress urinary incontinence has shown relevant improvement throughout a short-term period, with minimal adverse events of a transient nature. The improvement was more effective in younger and normal weight patients.

References

1. Olsson I, et al. Int Urogynecol J Pelvic Floor Dysfunct 2010;21:679 – 83
2. Imamura M, et al. Health Technol Assess 2010;14:1–188

Disclosures

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