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LASER THERMOTHERAPY IN PELVIC FLOOR DYSFUNCTION, RANDOMISED PLACEBO CONTROLED STUDY

Hypothesis / aims of study

The aim of this study was to evaluate the efficacy and safety of newly proposed laser thermo-therapy for female stress urinary incontinence (SUI) and sexual dysfunction in women.

In spite of many therapeutic approaches to SUI and sexual dysfunction in women, there is still need for efficacious, safe and minimally invasive therapy.

Recently developed, novel thermal laser therapy appeared on the market a few years ago, declaring to have the features of safety, efficacy and minimal invasiveness, so we performed a study to assess this new method and to see if it could become a new therapy for many women suffering from SUI and sexual dysfunction.

Study design, materials and methods

This is a randomized control trial performed in one medical centre from October 2012 to October 2013. 120 women, being diagnosed with SUI, older than 18 years, with premenopausal status, having at least one vaginal delivery with signed informed consent were included in this study. Patients were randomly divided into two groups of 60 women, laser intervention group (A) and control (placebo) group (B). There were no statistically significant differences in demographic data among the groups.

Prior to treatment all patients were clinically inspected, and following measurements were performed: SUI severity evaluation by ICIQ-UI, sexual dysfunction assessment by PISQ-12 and FSFI and perineometric measurement.

All patients were submitted to single laser session with Er:YAG laser (SP Spectro, Fotona, Slovenia), laser intervention group (A) was treated according to manufacturer's protocol, receiving therapeutic laser irradiation dosage, while the control group (B) was treated with the same laser, but with zero intensity settings, without adequate laser irradiation. No anaesthesia was used.

Three months after the therapy all patients were assessed again with the full set of measuring tools (ICIQ-UI, PISQ12, FSFI; perineometry) and after measurements the control group was treated again, this time with active therapeutic laser dosage.

Results

Overall 118 patients of the mean age of 41.0 ± 6.1 years (A group: 40.0 ± 6.4 , B group 42.0 ± 5.7) concluded the study (one patient dropped out from each group). Average ICIQ-UI score, before the treatment was 11.4 points in A group and 11.8 points in B group. At three months follow-up ICIQ-UI score in A group dropped to 7.7 (32.5% reduction) while in control group dropped to 11.0 (-6.8%). Although both groups improved, laser group improvement was significantly larger (p<0.001). PISQ12 scores before the treatment were 33.04 (A) and 33.85 (B) and at three months follow-up were 36.21 (A) and 34.84 (B). Laser group achieved significantly better improvement in comparison with placebo group (p=0.009). The scores of FSFI also improved in both groups, in group A from 25.14 to 28.42 and in group B from 24.65 to 27.26. Both improvements were statistically significant (p<0.001), but the difference between groups was not significant (p=0.512). All three values measured with perineometer: maximal and average contraction pressure as well as the duration of the contraction showed significant improvements in both groups (p=0.006 for max. pressure, p=0.002 for average pressure and p<0.001 for duration). Although the improvements in all three values were better in laser than placebo group there were no significant differences between the groups (p=0.166 for max pressure, p=0.128for average pressure, p=0.071 for duration). Average values of maximal pressure were: for A group: 34.9 hPa before and 40.0 hPa after (+14.6%), for B group 31.4 hPa before and 33.2 hPa after (+5.7%); average pressures were for A group: 21.6 before and 25.5 after (+18.1%), for B group 18.7 hPa before and 20.4 hPa after (+9.1%) and finally duration of contractions were for A group 8.0 sec before and 9.2 sec after (14.4%) and for B group 7.2 sec before and 7.6 sec after (+6.0%). Treatment discomfort was minimal and there were no adverse effects reported.

Interpretation of results

Results of this study showed significant improvement in both groups and in both observed indications: stress urinary incontinence and sexual dysfunction. In all measured values the laser group achieved better results than control group and in two most important assessment tools (ICIQ-UI for incontinence and PISQ12 for sexual dysfunction) the improvements of laser group were significantly better than in control group. The improvements achieved in control group were expected and at 3 months follow-up the placebo effect hadn't faded yet, what would probably happen if we would have a chance to perform longer follow-ups (like at 6 and 12 months).

Concluding message

We found this new thermal Er:YAG laser treatment efficacious for treatment of stress urinary incontinence and sexually dysfunction in women. The therapy proved to be well tolerated by patients and safe – there were no adverse effects noted.

Disclosures

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