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A randomized clinical trial comparing vaginal laser therapy to vaginal estrogen therapy in women with genitourinary syndrome of menopause: The VeLVET Trial

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Abstract

Objective

The aim of the study was to compare 6-month efficacy and safety for treatment of vaginal dryness/genitourinary syndrome of menopause in women undergoing fractionated CO_2 vaginal laser therapy to women using estrogen vaginal cream.

Methods

This multicenter, randomized trial compared fractionated CO_2 laser to estrogen cream at 6 institutions. We included menopausal women with significant vaginal atrophy symptoms and we excluded women with prolapse below stage 2, recent pelvic surgery, prior mesh surgery, active genital infection, history of estrogen sensitive malignancy, and other autoimmune conditions. The primary outcome was the visual analog scale vaginal dryness score. Secondary outcomes included evaluation of vaginal atrophy, quality of life symptoms, assessment of sexual function, and urinary symptoms. Adverse events (AEs) and patient global impression of improvement (PGI-I) and satisfaction were also assessed.

Results

Sixty-nine women were enrolled in this trial before enrollment was closed due to the Federal Drug Administration requiring the sponsor to obtain and maintain an Investigational Device Exemption. Of the 69 participants enrolled, 62 completed the 6-month protocol; 30 women were randomized to the laser and 32 to estrogen cream from June 2016 to September 2017. Demographics did not differ between groups except the laser group was less parous (0 [range 0-4] vs 2 [0-6], P = 0.04). On patient global impression, 85.8% of laser participants rated their improvement as "better or much better" and 78.5% reported being either "satisfied or very satisfied" compared to 70% and 73.3% in the estrogen group; this was not statistically different between groups. On linear regression, mean difference in female sexual function index scores was no longer statistically significant; and, vaginal maturation index scores remained higher in the estrogen group (adj P value 0.02); although, baseline and 6-month follow-up vaginal maturation index data were only available for 34 participants (16 laser, 18 estrogen).

Conclusions

At 6 months, fractionated CO_2 vaginal laser and vaginal estrogen treatment resulted in similar improvement in genitourinary syndrome of menopause symptoms as well as urinary and sexual function. Overall, 70% to 80% of participants were satisfied or very satisfied with either treatment and there were no serious adverse events.