Is vaginal laser therapy more efficacious in improving vaginal menopausal symptoms compared with sham therapy?

No. According to a randomized controlled trial in which 78 postmenopausal women with bothersome vaginal symptoms received either vaginal laser or sham therapy and completed the 12-month follow-up, no significant difference occurred between groups in change in symptom severity or in the most severe symptom.

Li FG, Maheux-Lacroix S, Deans R, et al. Effect of fractional carbon dioxide laser vs sham treatment on symptom severity in women with postmenopausal vaginal symptoms: a randomized clinical trial. JAMA. 2021;326:1381-1389. doi: 10.1001/jama.2021.14892.

EXPERT COMMENTARY

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FAST TRACK

In recent years, some physicians have been offering CO2 laser therapy as an alternative to vaginal estrogen in the treatment of GSM, but the efficacy of laser therapy in this setting has been uncertain

Symptomatic vaginal atrophy, also referred to as genitourinary syndrome of menopause (GSM), is common and tends to progress without treatment. When use of over-the-counter lubricants and/or moisturizers are not sufficient to address symptoms, vaginal estrogen has represented the mainstay of treatment for this condition and effectively addresses GSM symptoms.[1] In recent years, some physicians have been offering vaginal carbon dioxide (CO2) laser therapy as an alternative to vaginal estrogen in the treatment of GSM; however, the efficacy of laser therapy in this setting has been uncertain.

Li and colleagues conducted a double-blind randomized trial in postmenopausal women with bothersome vaginal symptoms to compare the efficacy of the fractional CO2 vaginal laser with that of sham treatment.

Details of the study

Investigators (who received no funding from any relevant commercial entity) at a teaching hospital in Sydney, Australia, randomly assigned 85 women with menopausal symptoms suggestive of GSM to laser (n = 43) or sham (n = 42) treatment. Participants underwent 3 treatments at monthly intervals. Laser treatments were performed with standard settings (40-watt power), while sham treatments were conducted with low settings that have no tissue effect. Local anesthesia cream was employed for all procedures, and a plume evacuator was used to remove visual and olfactory effects from laser smoke.

To maintain blinding, different clinicians performed assessments and treatments. Symptom severity assessments were based on a visual analog scale (VAS) and the Vulvovaginal Symptom Questionnaire (VSQ),

Dr. Kaunitz reports receiving royalties from UpToDate, Inc.

Dr. Iglesia reports being a contributor to UpToDate, Inc.

doi: 10.12788/obgm.0144

with a minimal clinically important difference specified as a 50% decrease in severity scores of both assessment tools. Change in severity of symptoms, including dyspareunia, dysuria, vaginal dryness, and burning and itching, was assessed at 12 months. Quality of life, the Vaginal Health Index (VHI) score, and vaginal histology were among the secondary outcomes. In addition, vaginal biopsies were performed at baseline and 6 months after study treatment.

Among the 78 women (91.7%) who completed the 12-month evaluations, the mean age was approximately 57, more than 95% were White, and approximately half were sexually active.

Results. For the laser and sham treatment groups, at 12 months no significant differences were noted for change in overall symptoms or in the most severe symptom. Many participants who received laser or sham treatment reported an improvement in vaginal symptoms 12 months following treatment.

The VAS score for a change in symptom severity in the laser-treated group compared with the sham-treated group was -17.2 versus -26.6, a difference of 9.4 (95% confidence interval [CI], -28.6 to 47.5), while the VAS score for the most severe symptom was -24.5 versus -20.4, a difference of -4.1 (95% CI, -32.5 to 24.3). The VSQ score was,

CONTINUED ON PAGE 49

WHAT THIS EVIDENCE MEANS FOR PRACTICE

We agree with editorialists that outside of clinical trials, we should not recommend laser for treatment of menopausal vaginal symptoms.[3] Currently, a US multisite randomized trial of fractionated laser versus sham for dyspareunia in menopausal women is planned.

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CONTINUED FROM PAGE 21

respectively, -3.1 versus -1.6 (difference, -1.5 [95% CI, -5.9 to 3.0]). The mean quality of life score showed no significant differences between the laser and the sham group (6.3 vs 1.4, a difference of 4.8 [95% CI, -3.9 to 13.5]). The VHI score was 0.9 in the laser group versus 1.3 in the sham group, for a difference of -0.4 (95% CI, -4.3 to 3.6). Likewise, the proportion of participants who noted a reduction of more than 50% in bother from their most severe symptoms was similar in the 2 groups. Similarly, changes in vaginal histology were similar in the laser and sham groups.

The proportion of participants who reported adverse events, including transient vaginal discomfort, discharge, or urinary tract symptoms, was similar in the 2 groups.

Study strengths and limitations

Although other randomized studies of fractionated laser therapy for GSM have been reported, this Australian trial is the largest and longest to date and also is the first to have used sham-treated controls.

Breast cancer survivors represent a group of patients for whom treatment of GSM can be a major conundrum—induced menopause that often results when combination chemotherapy is employed in premenopausal survivors can result in severe GSM; use of aromatase inhibitors likewise can cause bothersome GSM symptoms. Since the US Food and Drug Administration lists a personal history of breast cancer as a contraindication to use of any estrogen formulation, breast cancer survivors represent a population targeted by physicians offering vaginal laser treatment. Accordingly, that approximately 50% of trial participants were breast cancer survivors means the investigators were assessing the impact of laser therapy in a population of particular clinical relevance. Of note, as with participants overall, laser therapy when employed in breast cancer survivors did not result in outcomes distinct from sham treatments.[2] ●

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