Opposing Views

CO_2 Laser Treatment is Effective for Symptoms of Vaginal Atrophy

GENITOURINARY syndrome of menopause (GSM), previously known as vulvovaginal atrophy (VVA), is a condition affecting postmenopausal women, often characterized by vaginal dryness, burning, itching, irritation, dysuria and dyspareunia.[1] Therapies range from vaginal moisturizers to low dose topical estrogen, and selective estrogen receptor modulators. Cost, inconvenience, method of application and safety concerns are just a few common reasons for poor patient compliance. Topical estrogen is currently considered the gold standard therapy for GSM. However, many patients and providers are actively seeking more affordable, convenient and durable, yet effective, nonhormonal management options.

YES

For years the CO_2 laser has been used broadly in the field of dermatology for the treatment of skin lesions.[2] Vaginal rejuvenation performed with fractional micro-ablative technology regenerates the mucosa and improves symptoms of GSM. The 5-minute procedure is performed in the office setting and is painless when topical anesthetic is adequately applied. A complete treatment course consists of 3 procedures 6 weeks apart. This therapy provides new options for women with a history of estrogen receptor positive breast cancer, for those at risk for a thromboembolic event or for women who have another contraindication to hormone therapy.[3] Many women have no such contraindication yet prefer not to use vaginal estrogen as the application can be cumbersome.

Literature now exists demonstrating the efficacy of the CO_2 laser in treating GSM. In a large case series by Filippini et al 386 menopausal women with VVA were treated with 3 sessions of fractional micro-ablative CO_2 laser.[2] After the third treatment patients reported complete resolution of several symptoms. There was resolution of dryness in 60%, vaginal burning in 56%, dyspareunia in 49%, itching in 56%, soreness in 73% and vaginal introital pain in 49%. These effects were reported after the first session and continued for 1 year after the final session.

There is also emerging level I evidence supporting the use of the CO_2 laser for GSM. Cruz et al randomized 45 women to placebo, or CO_2 laser therapy and/or local estrogen therapy.[4] Assessments at baseline and at 8 and 20 weeks were conducted using validated measures. The laser and laser + estrogen groups showed a significant improvement in dyspareunia, burning and dryness vs placebo ($p < 0.001$). Although the estrogen only group had the greatest impact in vaginal dryness, Female Sexual Function Index total scores were comparable in all treatment arms at week 20. This study shows the promise of the CO_2 laser in treating GSM.

Unlike vaginal estrogen, the CO_2 laser has additional benefits such as treating lichen sclerosus in women as well as in men, potentially obviating the need for chronic topical steroids.[5] For lichen sclerosus more treatment sessions than the standard 3 are often needed (some suggest 5 to 7 treatments). In addition, the CO_2 laser has shown promise in the treatment of overactive bladder symptoms[6] and stress urinary incontinence,[3] although larger randomized trials are needed to determine the true effect on continence outcomes.

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NO

FRACTIONAL CO_2 laser technology for the management of GSM seems promising. However, the evidence to support its widespread use is lacking. The transition from cosmetic dermatologic use to GSM therapy began after Salvatore et al performed ex vivo studies using CO_2 laser technology on 10 postmenopausal vaginal tissue specimens obtained during prolapse surgery.[7] The study demonstrated

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connective tissue remodeling with the production of new collagen and elastic fibers without tissue damage.

Based on these findings they conducted a 12-week pilot study in 50 symptomatic postmenopausal women in whom local vaginal estrogen therapy had failed.[8] Three treatments during the course of 12 weeks improved VVA symptoms, Vaginal Health Index scores and quality of life, with an 84% satisfaction score. The authors concluded that the CO_2 laser for GSM is well tolerated, safe and effective. However, patient followup was short (12 weeks) and the study lacked randomization or a control group, raising concerns of the placebo effect and selection bias. Additionally, long-term safety and efficacy were neither addressed nor discussed.

Since this initial cohort study several noncontrolled observational studies have published similar findings while raising similar concerns regarding the quality of evidence. Nevertheless, in 2014 Food and Drug Administration approval for CO_2 laser therapy was granted under the 510(k) process for a wide range of indications, including gynecology and genitourinary surgery without specific mention of VVA.[9,10] Rigorous premarket approval studies required for other GSM therapies, such as topical estrogen, were not required. However, a small (sample size 45), 3-arm, randomized, double-blind, placebo controlled clinical trial was recently published with positive results.[4] This is certainly a step in the right direction, but larger randomized studies with longer followup are still needed to confirm previously published findings and demonstrate long-term durability and safety.

Finally, the high out-of-pocket cost is prohibitive for most patients for a therapy supported by low quality evidence.[11,12] Typically, 1 session costs $1,000 and most offices provide a package price for 3 treatments at $2,500. Thus, it would be a mistake for clinicians to widely adopt a therapy without demanding evidence of long-term durability, safety, efficacy and cost-effectiveness.

Although larger randomized studies are needed to elucidate the efficacy of the CO_2 laser for GSM compared to vaginal estrogen, studies to date show promise. In addition to placebo controlled studies, other studies will be needed to demonstrate cost-effectiveness which, in turn, will help support future insurance coverage and provide access to alternative therapy for the women who most need it.

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