Commentary

Laser devices for vaginal rejuvenation: effectiveness, regulation and marketing

Blayne Welk MD MSc, Erin Kelly MD

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In the mid-2010s, vaginal energy devices (such as fractional CO_2 lasers, erbium-doped yttrium aluminium garnet lasers [Er:YAG], diode lasers or radiofrequency ablation) emerged as a new potential treatment for genitourinary sydrome of menopause (GSM). A clinical diagnosis of GSM requires the presence of vaginal symptoms (irritation, decreased lubrication, burning, dyspareunia or discharge) and signs (labial or clitoral atrophy, vaginal dryness, introital stenosis or friable vaginal tissue).[1] It is associated with health complications (e.g., urinary tract infections, vaginal bleeding, lower urinary tract symptoms), can impair sexual function and can negatively affect quality of life. About 40%–80% of postmenopausal people have GSM, and only about half discuss their symptoms with a physician.[2] About one-third of postmenopausal people with GSM use over-the-counter vaginal lubricants,[1] and about one-tenth use vaginal prescription therapies (most often estrogen-based therapies).[2] Where do the evolving laser rejuvenation therapies fit in the spectrum of treatments available to treat GSM?

The North American Menopause Society guideline makes a strong recommendation for over-the-counter products as the first-line treatment of GSM, and for vaginal estrogen as the second-line treatment for patients with moderate-to-severe GSM.[1] In randomized controlled trials of patients with GSM, vaginal estrogen therapies (such as vaginal rings, tablets or creams) are 4–12 times more likely to result in symptom improvement than placebo, and no differences in efficacy between these estrogen formulations have been observed.[3]

Vaginal lasers heat the vaginal epithelium and cause thermal necrosis, which induces collagen remodelling and synthesis, neovascularization and elastin formation. This may lead to improved vaginal elasticity and restoration of premenopausal epithelial function.[4] The first vaginal energy device was issued a medical device licence from Health Canada in 2015 for the treatment of GSM, meaning that it was deemed to have met basic safety, effectiveness and device quality metrics. Unlike medications, controlled studies are not required for the regulatory approval of many new medical devices. After licensing, marketing of the devices discussed regulator "endorsement" in their direct-to-consumer advertising,[5] and the device indication was rebranded by some providers from the medical condition of GSM to providing "vaginal rejuvenation." Vaginal rejuvenation procedures with energy devices are purported to tighten the vagina and treat stress urinary incontinence — indications separate from the treatment of GSM.[1,5]

Few high-quality studies support the use of vaginal energy devices for GSM, the most common indication, or for incontinence.

Key points

- Genitourinary syndrome of menopause (GSM) is common and can be treated with over-the-counter vaginal lubricants or supplementation with vaginal estrogen.
- Vaginal energy devices (such as CO_2 lasers) have been licensed in Canada to treat symptoms of GSM; however, these devices are often marketed for "vaginal rejuvenation," with claims that they will tighten the vagina, improve sexual function and treat urinary incontinence.
- Unlike medications, controlled studies are not required for the regulatory approval of many new medical devices, and although several case series have suggested that vaginal energy devices may be effective for GSM or incontinence, recent randomized controlled studies have not shown benefit.
- Marketing these devices for vaginal rejuvenation and urinary incontinence may not be serving patients' best interests.

For GSM, a systematic review published in 2021 identified 26 studies with 2678 participants who had GSM and were treated with a vaginal laser or energy device.[6] Most studies (23 of 26) were prospective or retrospective case series that reported positive outcomes — most commonly an improvement in the female sexual function index score — with the use of a vaginal CO_2 laser; however, the quality of evidence was low, with a high risk of bias. Three randomized controlled trials with 179 patients did not show a significant difference between vaginal laser treatment and vaginal hormone therapy.[6] However, a high-quality, sham-controlled randomized trial with 85 patients found that CO_2 laser treatment did not significantly improve GSM symptoms, quality of life or sexual function at 12 months, compared with the sham treatment. Both groups showed no significant difference in beneficial histologic changes on vaginal biopsy.[7] The systematic review and randomized trial did not identify a risk of serious adverse events with laser therapy, compared with sham or standard care.[6,7] However, the United States Food and Drug Administration has reported that "vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain" can occur with energy-based vaginal rejuvenation.[5]

A systematic review on the treatment of urinary incontinence with vaginal energy devices (most commonly Er:YAG lasers) predominantly identified case series with a high or very high risk of bias.[8] Identified studies showed a small reduction in stress incontinence;

however, the outcome measures were generally subjective and follow-up periods were short. A randomized, multicentred, sham-controlled clinical trial (n = 101) of a CO_2 laser device for the treatment of stress incontinence did not show any subjective or objective improvement in stress incontinence, or difference in adverse events.[9] In contrast, numerous randomized controlled trials of pelvic floor therapy or surgery have shown benefit for women with stress incontinence.[10]

Vaginal laser therapies are offered across Canada, and the 10 most populous cities all have at least 1 provider who offers energy-based vaginal rejuvenation procedures. The number of patients who pay for these procedures cannot be tracked, nor can the exact number of vaginal laser systems that are active in Canada. Direct-to-patient marketing with vaginal lasers is readily found online, and the diverse benefits of vaginal rejuvenation are listed on providers' websites. Patients can self-refer for this service, and providers' publicly quoted costs are thousands of dollars for treatment and maintenance sessions.

Vaginal rejuvenation procedures are being used for the treatment of urinary incontinence and GSM, as well as for less clear indications (e.g., vaginal tightening for better sexual satisfaction), without good evidence that it helps any of these conditions. For many vaginal energy devices, this represents a difference between the licensing of a medical device by Health Canada, and the way that these devices are used and marketed. A procedure with limited high-quality evidence supporting its efficacy and a potential financial conflict of interest for providers may not be serving the best interests of people in Canada, even if the risk of adverse events is low.

Health Canada has identified a need to better address medical device regulation. Mandatory reporting of serious incidents with the use of medical devices, and the ability to compel information on medical device safety and effectiveness from manufacturers, represent important progress in this regard.[11] However, limitations with the approval process persist, such as the lack of a requirement for peer-reviewed, controlled studies.[12] The College of Physicians and Surgeons of Ontario has policies on advertising such that it must be accurate and supported by evidence. However, it is not clear if or how advertising by medical providers is actively monitored by regulatory authorities. Better standards of clinical evidence for new devices are needed, and regulatory bodies should monitor how new medical devices are portrayed to the public.

Patients who undergo energy-based vaginal rejuvenation therapy may be seeking treatment for GSM or urinary incontinence; their symptoms may not have been properly evaluated and they may not have been offered standard evidence-based treatments. Although vaginal energy devices may be a reasonable low-risk intervention in certain situations (e.g., patients for whom estrogen therapy has been ineffective or contraindicated), first-line, evidence-based therapies should be attemped for most patients with GSM or incontinence before substantial out-of-pocket expenditure on interventions with limited high-quality evidence. Providers who offer laser energy therapy should carefully consider how the procedure is portrayed in advertisements, and consent discussions for vaginal energy devices should reflect the limitations of the evidence, standard care alternatives and the limited effectiveness of treatment with these devices compared with standard therapies.

References

1. The NAMS 2020 GSM Position Statement Editorial Panel. The 2020 genitourinary syndrome of menopause position statement of The North American Menopause Society. *Menopause* 2020;27:976-92.
2. Kingsberg SA, Wysocki S, Magnus L, et al. Vulvar and vaginal atrophy in postmenopausal women: findings from the REVIVE (REal Women's VIews of Treatment Options for Menopausal Vaginal ChangEs) survey. *J Sex Med* 2013;10:1790-9.
3. Lethaby A, Ayeleke RO, Roberts H. Local oestrogen for vaginal atrophy in postmenopausal women. *Cochrane Database Syst Rev* 2016;2016:CD001500.
4. Tadir Y, Gaspar A, Lev-Sagie A, et al. Light and energy based therapeutics for genitourinary syndrome of menopause: consensus and controversies. *Lasers Surg Med* 2017;49:137-59.
5. Kaunitz AM, Pinkerton JV, Manson JE. Women harmed by vaginal laser for treatment of GSM: the latest casualties of fear and confusion surrounding hormone therapy. *Menopause* 2019;26:338-40.
6. Li F, Picard-Fortin V, Maheux-Lacroix S, et al. The efficacy of vaginal laser and other energy-based treatments on genital symptoms in post-menopausal women: a systematic review and meta-analysis. *J Minim Invasive Gynecol* 2021;28:668-83.
7. 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. *JAMA* 2021;326:1381-9.
8. Alsulihem A, Corcos J. The use of vaginal lasers in the treatment of urinary incontinence and overactive bladder, systematic review. *Int Urogynecol J* 2021;32:553-72.
9. Alexander JW, Karjalainen P, Ow LL, et al. CO_2 surgical laser for treatment of stress urinary incontinence in women: a randomized controlled trial. *Am J Obstet Gynecol* 2022;227:473.e1-12.
10. Imamura M, Hudson J, Wallace SA, et al. Surgical interventions for women with stress urinary incontinence: systematic review and network meta-analysis of randomised controlled trials. *BMJ* 2019;365:l1842.
11. Health Canada's action plan on medical devices: continuously improving safety, effectiveness and quality — informing Canadians about medical device treatment options [news release]. Ottawa: Health Canada; 2019 Jan. 31, modified 2021 Mar. 16. Available: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/notice-pre-market-transparency-initiative-medical-devices.html (accessed 2022 Oct. 17).
12. Re: Guidance document: Guidance on supporting evidence to be provided for new and amended licence applications for Class III and Class IV medical devices, not including In Vitro Diagnostic Devices (IVDDs) [notice]. Ottawa: Health Canada; 2012 July 5. Available: https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/md-im/applic-demande/guide-ld/md_gd_data_im_ld_donnees_ciii_civ-eng.pdf (accessed 2022 Oct. 17).

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Affiliations: Department of Surgery and Epidemiology and Biostatistics (Welk), Western University, London, Ont.; Department of Obstetrics and Gynecology (Kelly), University of Alberta, Edmonton, Alta.

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Correspondence to: Blayne Welk, blayne.welk@sjhc.london.on.ca