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Women harmed by vaginal laser for treatment of GSM—the latest casualties of fear and confusion surrounding hormone therapy

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Abstract

Genitourinary syndrome of menopause (GSM) represents a highly prevalent condition in menopausal women which impairs quality of life. Unless treated, GSM is chronic and progressive.

New therapies needed

Treating vaginal atrophy and relieving dyspareunia, decreasing urinary incontinence, and improving pelvic floor tissues are worthy endeavors to improve the lives of postmenopausal women who are often underdiagnosed and undertreated. Minimally invasive energy based therapies, whether ablative or nonablative, offer a nonhormone option for (GSM) and there is some published data showing improved vascularization and connective tissue in the vaginal canal. Devices available include fractional lasers (carbon dioxide, erbium, YAG and hybrid technologies), and monopolar radiofrequency devices. These devices work via heat on the vulva or vaginal mucosa leading to re-epithelialization and neovascularization. The goal is remodeling of the vaginal tissue from atrophy to a thickened, glycogen-rich and well-vascularized state. A concern of NAMS[1] is the lack of adequate data on the long-term safety, efficacy, clinical outcomes, and short- and long-term adverse events of vaginal lasers and radiofrequency therapies being used.

On July 30, 2018, the US Food and Drug Administration (FDA) released an FDA Safety Communication[2] as an alert about "serious adverse events of vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain from the use of energy-based devices (radiofrequency or laser) which were approved to treat gynecologic conditions but being used for vaginal procedures such as vaginal "rejuvenation," vaginal cosmetic procedures,

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and procedures intended to treat vaginal conditions and symptoms related to menopause, as well as for urinary incontinence or sexual function." The FDA also stated "the safety and effectiveness of energy-based devices for treatment of these conditions has not been established" and that it "has not cleared or approved for marketing any energy-based devices to treat the symptoms or conditions, or any symptoms related to menopause, urinary incontinence, or sexual function including procedures for vaginal laxity, vaginal atrophy, dryness, or itching, pain during sexual intercourse, pain during urination or decreased sexual sensation." [2]

Current tested and effective therapies

Over the counter lubricants and moisturizers should be used as first line approaches to address vaginal dryness and sexual discomfort associated with GSM. [3] When symptoms of GSM, including vaginal dryness and pain with intercourse, persist, FDA-approved prescription treatments— low-dose vaginal estrogen, vaginal dehydroepiandrosterone (DHEA) and oral ospemifene—represent safe, effective therapies.[4–6] Two recently-published reports, one from the large Women's Health Initiative – Observational Study (based on 3,003 vaginal estrogen users aged 50–79 with an intact uterus (n=3,003 followed during the years 1993–2005 in the WHI Observational Study with median duration of vaginal estrogen use of two years)[7] and one from the large Nurses' Health Study (nearly 900 postmenopausal vaginal estrogen users compared to approximately 53,000 non-users between 1982 and 2012, based on 18 years of follow-up with mean duration of vaginal estrogen use of almost three years) [8], provide reassurance that vaginal estrogen does not elevate risk of cardiovascular disease, breast cancer, endometrial cancer, or all-cause mortality.

However, given the confusion and fear that surround menopausal hormone therapy (HT), prescription treatments for GSM are underused. [9,10] Against this backdrop, the C02 and other lasers are being marketed to women for the treatment of GSM. The July 2018 FDA advisory described 14 women harmed by vaginal laser treatment. [2,11] In this issue of Menopause, Gordon and colleagues describe four additional menopausal women who suffered vaginal pain, scarring and sexual dysfunction following vaginal laser treatments. One of these women had a history of ductal carcinoma and situ and had previously experienced headaches with use of vaginal estrogen cream. The other three women had no history of breast or endometrial neoplasia, had apparently never used FDA-approved prescription treatments for GSM, and were not offered these treatments prior to proceeding with vaginal laser vaginal therapy. [12]

Clinical Trials

Available laser therapies on the market are FDA-approved for general gynecologic use, but have not undergone the larger, longer-term sham controlled clinical trials the FDA requires for approval for specific medical indications. Current use and extensive marketing prior to the FDA warning letter have exceeded safety and effectiveness data. A review of published studies shows primarily small trials without sham controls, varying from 12 weeks to 12 months, with findings of effectiveness of multiple different devices on vulvovaginal atrophy,

sexual satisfaction, dyspareunia, incontinence, and pelvic floor laxity. What is lacking are prospective, randomized, case-control or sham-controlled trials of longer duration and with an adequate control arm to account for the placebo effect and using validated measures.[1] Recent randomized sham-controlled trials have been published using radiofrequency [13] and a YAG laser.[14]

As the case series [12] and a recent review [15] point out, uncontrolled studies suggest the CO2 vaginal laser may be helpful for some women with GSM; however, no large sham-controlled trial data are available. As Gordon and colleagues indicate, controlled trials in Italy and Brazil are underway. In the US, a multicenter trial randomizing women with GSM to fractionated CO2 vaginal laser therapy or vaginal estrogen has been initiated. However, as of January 11, 2019, Clintrials.gov listed this trial (VeLVET,) as 'suspended"- which means the study was stopped early but may start again.[16] Clintrials.gov lists five additional vaginal laser and energy device trials as recruiting, but provides no recent updates.

Society Concerns and Recommendations

In addition to the FDA, both the American College of Obstetricians and Gynecologists, the North American Menopause Society, International Urogynecological Association, the International Society for the Study of Vulvovaginal Disease (ISSVD) and the International Continence Society (ICS), support the use of evidence-based therapies for treatment of GSM. Accordingly, these organizations have recommended against using vaginal laser therapy until there is more rigorous and robust clinical trial information to assess long term safety and efficacy. [1,2, 17–19]

The current status of vaginal laser for women with GSM parallels that of compounded hormone therapy. Both of these treatments, although not evidence-based, are aggressively marketed to menopausal women, marketing that takes advantage of fears surrounding the safety of HT whether systemic or vaginal. The boxed warning on vaginal estrogen frightens many women and their partners needlessly as there is no evidence that low dose vaginal estrogen is associated with cardiovascular disease, breast cancer, dementia, stroke or blood clots.[10,20–22]

The pain, scarring and sexual dysfunction suffered by the four women described in this case series, along with the cases reported earlier by the FDA, raise troubling concerns regarding the safety of vaginal laser for GSM and the need to identify best candidates for these therapies and be able to counsel accurately about hoped for benefits and potential risks.

Summary

The new energy-based therapies, including vaginal lasers, seem promising and may eventually become an appropriate best choice for many women with GSM, particularly those concerned about using any type of hormone therapy. However, until more robust data allows identification of women most likely to have a favorable benefit-to-risk ratio, we suggest discussing the benefits and risks of available treatment options for vaginal symptoms, including over-the-counter lubricants, vaginal moisturizers; FDA-approved vaginal therapies of vaginal estrogen and intravaginal dehydroepiandrosterone; and systemic therapies such as

hormone therapy and ospemifene. Informed discussion can include information about vaginal energy devices but should also include the information that although they are FDA cleared devises, they have not yet received FDA approval as procedures for the treatment of GSM, sexual function, incontinence, or pelvic laxity.

Conclusion

Providers should provide patients accurate, evidence-based information about tested standard and less well –tested new approaches. Vaginal laser technology seems promising. However, as these case reports remind us, more robust, sham-controlled, and longer-term data are needed before recommending these devices as first line therapy. Discussion of vaginal energy-based therapies should include the disclosure that more studies are needed and these devices have not been approved for specific gynecologic indications.

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