Effects after use of laser therapy for vulvovaginal atrophy in a patient with lichen sclerosus: a case report

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Abstract

Objective: *Use of laser therapy has most recently been introduced as a non-invasive option for the treatment of genitourinary syndrome of menopause (GSM). Recent literature has shown promise in providing benefit for patients with symptoms of vulvovaginal atrophy (VVA) and stress urinary incontinence with minimal adverse effects. Despite this, the United States Food and Drug Administration has not cleared laser therapy for these specific indications given the lack of sufficient evidence to support safety and efficacy.*

A case is presented of a patient with GSM in the setting of lichen sclerosus who was referred to a tertiary vulvovaginal disease clinic after worsening of symptoms after three laser therapy treatments. Patient data is protected by the Health Insurance Portability and Accountability Act of 1996.

The case presented demonstrates initial worsening of symptoms after treatment with laser therapy, with initial exam findings showing atrophic vaginitis, marked introital narrowing, partial phimosis of the clitoral hood, and fusion of the labia minor and majora. The patient ultimately had complete resolution of post-laser therapy symptoms by one year after initial presentation. The case findings and follow-up are presented.

Conclusions: *Despite case series and studies in the literature showing promise of the use of laser therapy for GSM and urinary incontinence, laser therapy is not currently FDA-approved for these indications. Large scale, long-term prospective randomized controlled data is necessary to provide data on the safety, efficacy, indications, and appropriate candidates for laser therapy.*

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Introduction

With an aging population in the United States, the genitourinary syndrome of menopause (GSM) is becoming more prevalent, with up to 40-80% of postmenopausal women affected[1]. GSM symptoms include decreased vaginal canal and introital caliber, decreased quality and elasticity of vaginal tissues, associated vaginal dryness, dyspareunia, and voiding dysfunction[2]. These symptoms describe a progressive condition related to a hypoestrogenic state of genitourinary tissues seen after menopause, during lactation, or associated with treatment for hormone-dependent cancers. Current first-line therapies include vaginal moisturizers, topical or systemic estrogens, and Kegel exercises. Although estrogen therapy has proven benefit for GSM and vulvar vaginal atrophy (VVA), some patient populations may not be candidates[3]. Salvatore et al. demonstrated benefit of VVA symptoms with use of a fractional CO_2 laser through connective tissue remodeling. The study showed improvements of vaginal burning, itching, and dyspareunia at a 12-week follow-up with subsequent improvements in sexual health and quality of life[4].

In addition to VVA, many postmenopausal females also suffer from lichen sclerosus, a benign, progressive dermatologic condition that affects the anogenital skin in the majority of cases. Vulvar lichen sclerosus (VLS) has a mean age of onset in the mid- to late-50s. Lichen sclerosus is marked by inflammation and epithelial thinning, leading to scarring and introital stenosis with subsequent impacts on quality of life. Additionally, VLS is a risk factor for vulvar intraepithelial neoplasia and squamous cell carcinoma, with lifetime risk estimated 2-6%[5]. Topical corticosteroids are the first-line therapy for VLS, although other topical immunosuppressive agents, including tacrolimus, and rarely systemic immunomodulating therapies have been described.

Laser therapies are reported to be a minimally invasive treatment option, and their proposed mechanism includes the creation of small epithelial and lamina propria wounds via laser-generated heat for the supposed regeneration of tissues[6]. Studies have demonstrated that the new dermal collagen regeneration lasts at least 6 months after treatment[7]. In the treatment of GSM, two types of laser therapy are currently used: fractional micro-ablative infrared CO2 and non-ablative infrared lasers with an erbium-doped yttrium aluminum garnet medium (Er:YAG) lasers[8]. Histologic and gross examination of laser-treated vulvovaginal tissues has been shown to improve lubrication and tissue architecture, including rugae and superficial epithelium, resulting in tissue with qualities similar to estrogenized tissue[9].

Despite the touted benefits of laser therapy, at present, vulvovaginal CO2 laser therapy is not approved by the United States Food and Drug Administration (FDA) for GSM, urinary incontinence, or lichen sclerosus indications. According to the FDA position statement, no guidelines exist regarding which patients should be

considered appropriate for this therapy[10]. In fact, in July 2018 the FDA warned against the use of these energy-based devices for GSM and other vaginal rejuvenation/cosmetic purposes, citing adverse events including vaginal burns, scarring, and chronic pelvic pain [11]. The North American Menopause Society (NAMS) affirms, and states that while a promising emerging therapy, they call for more "randomized, prospective, sham-controlled trials of adequate size and scope"[12]. Additionally, the American College of Obstetricians and Gynecologists (ACOG) recommends that regarding vaginal cosmetic procedures, women must be informed that high-quality data about the safety, efficacy, and potential complications is lacking[13].

Here we present the case of a patient with GSM in the setting of chronic lichen sclerosus who sought care with CO2 vaginal laser therapy.

Case Presentation

The case presented is a 65-year-old postmenopausal Caucasian female presenting to the vulvovaginal disease clinic at a tertiary care center for evaluation of dyspareunia, lower urinary tract symptoms, pelvic pain, and atrophic vaginitis. These symptoms developed three months after she received vaginal laser therapy with a fractional CO2 laser. Approximately 6 years prior, in 2012, the patient had experienced a tragic personal loss and subsequently developed pelvic pain, difficulty voiding, and dyspareunia in the setting of existing lichen sclerosus. After receiving pelvic floor physical therapy, vaginal dilator therapy, and biofeedback therapy for several months, her symptoms became more manageable. Under the guidance of her gynecologist, she underwent laser therapy for vaginal dryness and dyspareunia in an effort to improve "vaginal tissue health" with a local urologist. She received three treatments in total from 12/1/2017 through 3/28/2018, with her last treatment approximately three months prior to presentation for care. The patient noted that during the three treatments, she had worsening symptoms, including urge incontinence symptoms, voiding 20-25 times per day, nocturia 3-4 times nightly, and significant mid-void dysuria beginning after the first treatment. She also reported frequent vaginal itching and severe sharp pains during intercourse, which were not present prior to the laser treatments. She underwent cystoscopy with hydrodistension without improvement in symptoms. She also tried medical therapy with oxybutynin for urge incontinence without improvement. For her vaginal symptoms, she tried vaginal estrogen cream although opted to discontinue use secondary to external irritation before seeking subsequent evaluation.

At her initial visit with the vulvovaginal disease clinic, her initial physical exam was remarkable for profound atrophic vaginitis with partial phimosis of the clitoral hood, and fusion of the anterior labia minora and majora. Her exam was notable for uniform hypopigmentation in a horseshoe distribution around the clitoris with associated loss of hair. There was severe introital narrowing, with ability to accommodate only one finger in diameter for examination. The levator ani muscles were tender to

palpation with high resting tone bilaterally, and the patient had significant discomfort on bimanual exam. Findings consistent with lichen sclerosus were identified as well (Image 1).

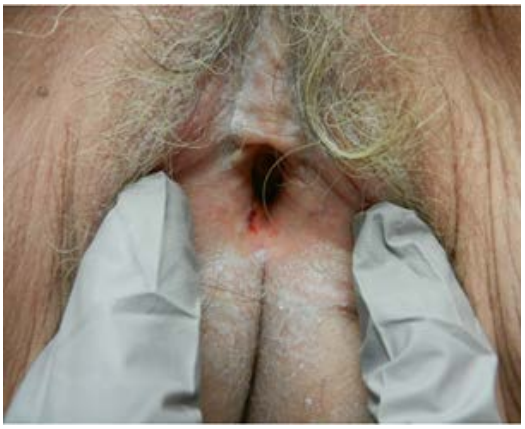

Image 1: Examination findings on initial presentation to vulvovaginal disease clinic

Additionally, she did have a vaginal yeast culture positive for *Candida albicans* which was treated with fluconazole in addition to initial treatment including estradiol cream and hydrocortisone butyrate ointment. She had negative urine analysis findings. Similarly, to prior trials of topical estrogen, the patient was unable to tolerate either topical medication due to irritation, and she subsequently discontinued use of both estradiol and hydrocortisone ointments. She was ultimately started on a compounded vaginal estrogen cream that she tolerated. The patient was counseled on vulvovaginal skincare guidelines to minimize irritation and it was recommended that she also resume pelvic floor physical therapy, with the goal to increase vulvar comfort and to resume sexual activity. The patient was seen by the urology team at the tertiary hospital, who recommended mirabegron for her urge urinary incontinence.

On follow-up three months later, the patient had much improved vulvar atrophy symptoms and improvement on exam with ability to tolerate small (circumference 2 inches) and medium-sized (circumference 3.5 inches) dilators. On exam, the areas of hypopigmentation present initially were improved and although levator ani muscle tone remained elevated, the patient did not experience pain on palpation. Additionally, physical exam demonstrated decreased irritation at the posterior fourchette that was initially present on the first evaluation. Although the patient discontinued mirabegron, she continued working with her urologist and with pelvic floor physical therapy for treatment of urinary urgency (Image 2).

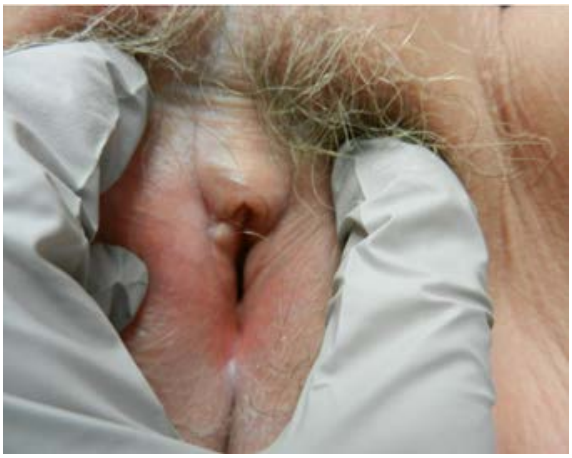

Image 2: Examination findings at three-month follow-up

By five months after initial presentation, the patient was able to tolerate the largest dilator size (circumference 4 inches) without discomfort. At her five-month follow-up visit, she also reported much improved day-to-day symptoms, with decreased pain, irritation, and urinary symptoms overall (Image 3).

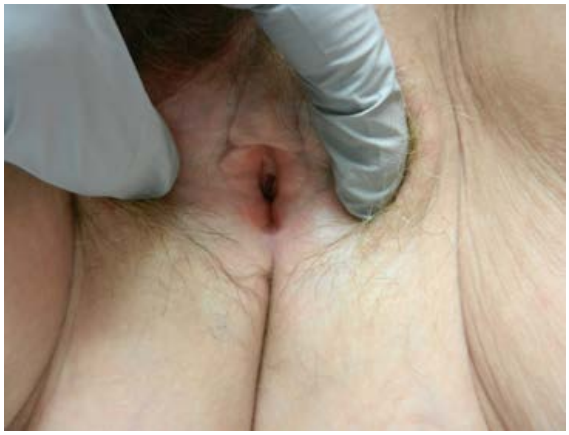

Image 3: Examination findings at five-month follow-up

By one year after initial presentation she reported resumption of sexual activity with improvement of pain symptoms. She had intermittent cultures positive for vaginal yeast infection with *Candida parapsilosis*, for which she took fluconazole for treatment as needed. She additionally reported improvement of her urinary symptoms overall. The patient continued to be followed every 6 months in the vulvovaginal disease clinic for monitoring of lichen sclerosus, given the 2-6% risk of vulvar cancer to develop in the setting of VLS. She was followed for atrophic vaginitis and history of yeast vulvovaginitis as well.

Discussion

Since the introduction of laser therapy, many specialties have adopted its use for a wide variety of treatments. Studies performed to analyze the benefit of laser therapy for GSM and stress urinary incontinence treatment have shown promise in the treatment of GSM symptoms. In 2014, a study of 77 postmenopausal women with vulvovaginal atrophy used a 12-week (3 month) treatment program of vaginal laser. Prior to the study, 20 of the women avoided intercourse secondary to pain. Of those, 17 (85%) reported regaining a “normal sex life” after treatment[14]. Additionally, a 2016 study of 30 women showed that 25 (83%) of the participants gained an increase in comfortable dilator size at 3-month follow up. The study also demonstrated statistically significant improvements in pain, burning, itching, dryness, and dyspareunia[15]. Recent studies have demonstrated promise of lasers in treatment of stress urinary incontinence. In 2017, a study of 161 postmenopausal women with GSM evaluated the effect of an ablative fractional CO2 laser as alternative treatment for stress urinary incontinence. The laser treatment group showed significant improvement in International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) scores and in 1-hour pad weight test at 12 months, 24 months, and 36 months[16]. Most recently, researchers conducted the first randomized controlled trial of 52 post-menopausal patients with biopsy-proven lichen sclerosus. Patients were randomized to receive either fractional CO2 laser treatment or clobetasol propionate for 6

months. Findings of the study concluded that laser therapy for lichen sclerosus was “noninferior to steroid therapy six months” after assessment using various patient- and physician-based scores[17].

Despite these promising studies, however, laser therapy has not been cleared for these indications by the FDA, given the lack of large-scale and long-term evidence. Many of the studies currently in the literature have follow-up periods of 12 weeks, with few studies following patients to 12 months. Additionally, very little evidence exists on the indications, criteria for candidates, standardization of technique, or adverse event rate. Furthermore, the effects of laser therapy on surrounding pelvic organs, including the bladder, rectum, and pelvic nerves and vasculature, remain unknown. While there are case series and studies in the literature that provide evidence of the benefit for GSM and incontinence, many case reports also exist describing worsening symptoms related to scarring, fibrosis, and adhesions that result from laser therapy. Information on patient demographic variables, laser therapy technique and settings, and indications that are more likely to yield successful results remains scant.

In the case discussed here, we present a 65-year-old postmenopausal Caucasian female who sought care for worsening pelvic pain and atrophic vaginitis in the setting of lichen sclerosus following treatment with laser therapy. This patient had complete resolution of symptoms one year after initial presentation. The patient’s atrophic vaginitis was complicated by lichen sclerosus, and she ultimately had resolution of atrophic symptoms after starting compounded estrogen cream. While laser therapy is currently studied for treatment of atrophic vaginitis and urinary incontinence, it is not considered adequate therapy for lichen sclerosus. Although topical steroid use is typically used in the management of lichen sclerosus, the patient was unable to tolerate a mid-potency topical steroid due to burning and irritation several hours after application. The mechanism through which this patient ultimately achieved symptom resolution remains unclear. It is possible that vulvovaginal laser therapy requires an initial period of symptom worsening during initial tissue injury, after which healing is ultimately achieved. It may be possible that patients need counseling on expectations of new, worsening symptoms before the end result is achieved. It may also be possible that the patient’s symptoms improved through the compounded vaginal estrogen, and that her initial external irritation with other topical vaginal forms worsened her symptoms following tissue injury generated by laser therapy. This patient had previously been unable to tolerate several forms of topical estrogen before eventually working with an allergist to find a vaginal estrogen form that was non-irritating, likely due to fewer preservatives in the base of the estrogen cream. Similarly, the patient’s intolerance of mid-potency steroid cream may be due to preservatives or other chemical irritants in the base.

Conclusions

The patient presented in this case suffered initial worsening of her symptoms as well as the addition of new

urinary symptoms during and shortly after completing three vaginal laser therapy treatments. Laser therapy is currently not FDA-approved for GSM, incontinence, or lichen sclerosus, and no standardized guidelines exist to guide clinicians on which patients might benefit from therapy, rates of complications, or standardized techniques for laser therapy. The current first-line therapy for atrophic vaginitis is topical estrogen cream, which is a treatment that is expensive and poorly reimbursed for this age group of patients in the United States. Additionally, topical estrogen cream requires frequent use for benefit, which contributes further to potential compliance issues.

While the patient presented here had improvement, there are other case reports of patients harmed by laser treatments in recent years. Further large scale, prospective, randomized controlled trials are necessary to provide safety and efficacy data to guide use of this potentially promising treatment option.

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