Fractional CO_2 Laser of the Vagina for Genitourinary Syndrome of Menopause: Is the Out-of-Pocket Cost Worth the Outcome of Treatment?

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Objectives: The purpose of this study is to assess patient's satisfaction treatment outcomes and out-of-pocket expense for the fractional CO_2 laser (SmartXide) in the treatment of genitourinary symptoms of menopause (GSM).
Materials and Methods: A multicenter retrospective cohort study of patients who completed a course of three vaginal treatments with the SmartXide[11] Fractional CO_2 laser. Patients contacted *via* telephone and asked to participate in questionnaires to evaluate for adverse outcomes since last treatment, symptom severity before and after treatment, patient satisfaction with treatment, patient satisfaction with out-of-pocket expense, and sexual function.
Results: Of the 368 patients contacted, 122 agreed to be interviewed. No patients reported seeking emergent medical treatment. Patient reported vaginal dryness significantly improved following treatment ($P < 0.05$). The frequency of intercourse increased from "once a month" to "few times a month" ($P < 0.001$). The vast majority of patients reported being satisfied with their treatment results (86%) and with the cost of treatment (78%). Satisfaction with the out-of-pocket expense did not correlate with household income ($P = 0.07$).
Conclusion: The SmartXide Fractional CO_2 laser is a safe and efficacious treatment for GSM. This treatment is associated with a high level of patient satisfaction with both treatment results and out-of-pocket expense. Lasers Surg. Med. 9999:1–4, 2017. © 2017 Wiley Periodicals, Inc.

Key words: vulvovaginal atrophy; Genuine syndrome of menopause; vaginal burning; dysuria; dyspareunia; CO_2 laser; vaginal laser treatment

INTRODUCTION

Up to 50% of postmenopausal patients suffer from symptoms of vulvovaginal atrophy [1]. This condition, more recently termed Genitourinary Syndrome of Menopause (GSM), results from the loss of circulating estrogens. Over a period of time, the vaginal skin becomes thin and sensitive which leads to the various symptoms of GSM which include vaginal burning, itching, irritation, dysuria, and dyspareunia [2–4].

Multiple treatment modalities exist for treating GSM, ranging from vaginal hormone replacement, selective estrogen receptor modulators, and over-the-counter lubricants [5]. The North American Menopause Society recommends vaginal moisturizers and lubricants as first-line therapy with the goal of alleviating symptoms, but not correcting the underline cause. While local estrogen therapy and selective estrogen receptor modulators have been shown to be effective, they have certain drawbacks in that they are contraindicated in women with a history of a hormone dependent tumor or other contraindications to estrogen. Also they require continuous therapy to maintain efficacy, making compliance a significant problem [6].

Recently fractional CO_2 laser treatment of the vaginal canal has been shown to be very effective in alleviating the symptoms of GSM [7–10]. Vaginal laser therapy has the benefit of the ability to treat patients who cannot or prefer not to use estrogen therapy. To date, there is no CPT code for the procedure and it is not covered by insurance requiring patients to pay out of pocket. To measure overall patient satisfaction and to determine if patients felt that their treatment outcomes were worth the out-of-pocket expense, we performed a phone-based survey and contacted patients who had completed a course of three vaginal laser treatments.

This article was modified on 13 September 2017 after initial publication to correct the conflict of interest statement.
Conflict of Interest Disclosures: Dr. Karram is a consultant and speaker for Cynosure.
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Accepted 15 August 2017
Published online in Wiley Online Library (wileyonlinelibrary.com).
DOI 10.1002/lsm.22713

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MATERIALS AND METHODS

Procedure

The patients who were surveyed received treatment performed at four US centers including: The Christ Hospital Pelvic Floor Center, Cincinnati, OH (MK); Roxbury Surgical Center, Beverly Hills, CA (PW); Institute for Female Pelvic Medicine, Knoxville, TN (JD), Fairfax OB/GYN Associates, Fairfax, VA (LR). IRB approval was obtained from each site. The names and phone numbers of all consecutive patients who completed a series of three vaginal treatments with the SmartXid [11] Fractional CO_2 laser from each of the four centers was provided to investigators. All patients were then contacted from a centralized location, at The Christ Hospital, by medical students who had undergone researcher training *via* the Collaborative Institutional Training Initiative (CITI). Patients were consecutively contacted between June and August 2016. After obtaining informed consent, patients were asked to participate in several questionnaires to evaluate for adverse outcomes since last treatment, patient satisfaction, and sexual function. The phone survey lasted ~10 minutes. Patients were asked their age, number of weeks from last laser treatment, menopausal status, and whether or not they had a personal history of breast cancer. She was asked what prior treatments she had received. She was asked to identify her primary and secondary symptoms of GSM (vaginal dryness/pain/irritation, dyspareunia/postcoital spotting, bladder irritation/cystitis/recurrent UTI or other) and reason for seeking laser treatment. Patients were then asked to quantify their vaginal dryness before and after treatment on a 10-point Likert scale. Patients were asked to quantify the discomfort of the laser session and discomfort after the laser session on a 10-point Likert scale. The type of pain felt immediately after each laser session and after completing the course of three laser sessions and 4 weeks after completing the course was indicated using this scale: nothing, vaginal burning/pain, vaginal yeast infection, UTI symptoms, vaginal laxity/decreased sexual sensation, dyspareunia, or other. Patients were asked if they sought medical attention for any reason related to their vaginal laser treatment and if they were able to tolerate all three treatments. Sexual function prior to treatment and at the time of the survey was also recorded using the following scale: not active, couple times per year, once a month, few times a month, at least once per week. Patient global impression of improvement (PGI) was recorded on a 5-point Likert scale. Patients' level of satisfaction with treatment results and with the cost of the laser treatment was recorded on a 5-point Likert scale. Patients were asked whether they would recommend the treatment to a friend or family. Patients were also asked whether the treatment was worth the out-of-pocket expense and to report a range of their average annual household income.

For statistical analysis, continuous variables will be analyzed by using the paired *t*-test and the signed rank test accordingly to data distribution. It was planned to enroll 300 patients. We hypothesized an efficacy of treatment of 60% (95%CI 49.26–70.74%).

RESULTS

Characteristics of the Study Population

Total of 368 patients were identified as completing a series of three vaginal laser treatments, 40–50 days apart, for GSM. The mean age was 62 ± 8 years. The mean age was significantly lower in patients from the California and Virginia centers (52.9 and 54.3 years, respectively, $P < 0.001$). Patients were contacted at a mean of 31.7 ± 21 weeks following their final treatment. Overall, 90% of patients reported that they were postmenopausal and 10% reported a personal history of breast cancer (Table 1). Prior treatments were utilized in 81.8% of patients (Fig. 1). Forty-four percent reported that they used more than one treatment modality and 43.8% had used a form of estrogen replacement prior to vaginal laser treatment.

All patients paid out-of-pocket for the procedure with an average of $2,009 for a course of three vaginal laser treatments. At the Christ hospital in Ohio and the Institute for Female Pelvic Medicine in Tennessee, patients were charged $1,800 for a series of three treatments. Patients at the Roxbury Surgical Center in California were charged $3,000 for a complete series and at Fairfax OB/GYN Associates in Virginia were charged patients $1,950.

Of the 368 patients contacted, 122 agreed to be interviewed for a response rate of 33.2%. Of the 246 patients who were unable to be contacted, 187 were never reached after three tries (76%), 26 patients were contacted and requested to be called back at a later date, but were then unable to be reached (10.5%), 20 patients were not interested in completing the survey (8.1%), and 13 were found to have incorrect contact information (5.2%).

Safety

No patients reported seeking emergent medical treatment. Of the 122 patients contacted only 7% reported that they sought medical attention during the course of their

TABLE 1. Demographic Data

	Ohio	California	Virginia	Tennessee	Overall
Age in years (Mean ± CI)	61.7 ± 6.3	52.9 ± 5.2	54.3 ± 8.0	64 ± 8.1	62 ± 8
Weeks from completion (Mean ± CI)	23.5 ± 14.2	52	29 ± 4.8	35.0 ± 22.5	31.7 ± 21
Menopausal status	100%	61%	83%	95%	90%
H/o breast cancer	6.00%	11%	17%	11%	10%

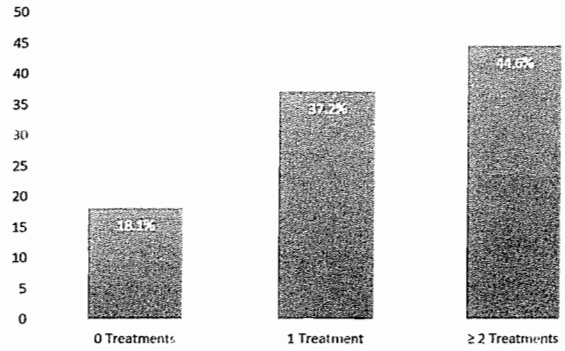

Fig. 1. Percentage of patients treated prior to vaginal laser therapy.

treatment. Reasons for seeking medical attention included: five patients (4%) reporting urinary tract symptoms, two patients (1.6%) reporting vaginal pain/burning, one patient (0.1%) reporting vaginal itching, and one patient (0.1%) reporting dyspareunia.

Overall Satisfaction

Patients were asked to quantify their vaginal dryness on a 10-point Likert scale with 0 being "Less Dry" and 10 being the "More Dry." Vaginal dryness significantly improved from 8.1 before treatment to four after treatment ($P < 0.05$). Subjects were asked to quantify their frequency of intercourse using a scale that ranged from "none," "couple times per year," "once a month," few times a month," and "at least once per week." Prior to treatment, 20% of patients reported they were not sexually active, 20% reported they were sexually active a "couple times per year," 23% reported sexual activity "once a month," 15% reported sexual activity "few times a month," and 23% reported "at least once per week." When asked about frequency of sexual intercourse since laser therapy, 16% reported they were not sexually active, 12% reported frequency of sexual activity of "couple times per year," 16% reported sexual activity "once a month," 20% reported sexual activity "few times a month," and 35% reported "at least once per week." Overall, we found that the frequency of intercourse increased from "once a month" to "few times a month" ($P < 0.001$). Patients were also asked to report satisfaction of overall improvement *via* PGI score. Eighty-six percent reported being satisfied with their treatment results, with 49% reporting they were "Very Satisfied." Additionally, 84% of patients reported that they would recommend the treatment to a friend or family member.

Financial Satisfaction

When asked about the cost of treatment, 78% of patients reported that they were satisfied with the cost and 21% reported being "Very Satisfied." When asked about having to pay out-of-pocket for the laser treatment, 66% felt that the out-of-pocket expense was acceptable. Satisfaction with the out-of-pocket expense did not correlate with household income ($P = 0.07$). Additionally, patients were more likely to be satisfied with the out-of-pocket cost if their pre-treatment symptoms were more severe ($P = 0.005$). Patient's average household income was collected with 38.7% reporting an income between \$30,000 and 100,000, 37.9% reporting an income >\$100,000 (Table 2). The difference in reported household income was not significantly different between institutions ($P = 0.22$).

There was no statistical difference in patient satisfaction with symptoms following treatment or in overall treatment satisfaction between the four institutions ($P = 0.068$–0.8). Though the overall satisfaction with the cost of treatment was positive, there was a statistically significant difference between institutions. Patients of the Institute for Female Pelvic Medicine, Knoxville, TN were found to be significantly more satisfied ($P = 0.0001$) with the cost of treatment (Table 3).

DISCUSSION

Unlike other menopausal symptoms, GSM symptoms are likely to worsen over time and are unlikely to resolve without treatment. Treatment of this issue is multimodal and includes various over-the-counter and prescribed treatments. Many women try and discontinue numerous treatments due to either minimal improvement or unwanted side effects. Studies have found that the fractional CO_2 laser is an effective non-hormonal treatment for GSM [7–10].

Symptoms of GSM can also affect premenopausal women who have undergone surgical- or medical-menopause while being treated for breast cancer. For these patients, hormonal treatments may be contraindicated due to risk of disease recurrence. Studies have shown that vaginal CO_2 laser was associated with significant improvement in GSM symptoms in breast cancer survivors [7,8].

TABLE 2. Annual Household Income

	Ohio (%)	California (%)	Virginia (%)	Tennessee (%)	Overall (%)
<\$30,000	3.0	6.7	0.0	3.2	2.6
\$30,000–75,000	9.1	13.3	33.3	25.8	20.7
\$75,000–100,000	12.1	6.7	33.3	24.2	18.1
>\$100,000	54.5	40.0	16.6	30.6	37.9
Declined to answer	21.2	33.3	16.6	16.1	19.8

TABLE 3. Patient Satisfaction Between Institutions

	Ohio	California	Virginia	Tennessee	*P*-value
Mean PGI of symptoms after treatment (0–5) with SD	4.0 ± 1.0	4.0 ± 0.8	4.3 ± 1.0	4.1 ± 1.1	0.08
Mean PGI of satisfaction with treatment (0–5) with SD	3.6 ± 1.6	4.2 ± 1.1	4.2 ± 1.0	3.9 ± 1.3	0.65
Mean PGI of satisfaction with cost (0–5) with SD	3.2 ± 1.4	2.9 ± 1.4	2.3 ± 1.5	3.8 ± 1.0	0.0001

Our study confirms previous findings that fractional CO_2 laser therapy is not only a safe and effective treatment for GSM symptoms [7–10], but also confirms that patients are willing to pay out-of-pocket for this treatment. While the amount of money patients pay for vaginal fractional CO_2 laser treatment varies by provider ($1,800–3,000), we found that a significant number of patients were satisfied with the cost (78%) and analysis found that the level of satisfaction with both treatment outcome and cost did not necessarily correlate with household income ($P = 0.23$–0.85). While several studies have validated the safety and efficacy of vaginal CO_2 laser for treatment of GSM symptoms, some physicians have been hesitant to adopt this treatment modality, as it is not covered by insurance, forcing patients to pay out-of-pocket. Physicians are also weary of adding CO_2 laser to their treatment armamentarium due to high start-up cost, compared with prescribing medications or physical therapy. This study signals to providers that women are seeking alternatives to hormonal therapy and are willing to pay out-of-pocket. Most importantly, we found that patients are satisfied with the treatment effects achieved with vaginal CO_2 laser and that the effects are worth the cost. Armed with this information, providers can more confidently adopt this treatment modality.

This is the only study, to date, that assesses the cost of CO_2 vaginal laser treatment and evaluates patients who have paid out of pocket. A consistent problem with performing a phone survey is that response rates are expected to be low. According to a 2012 report from the Pew research center, the response rate to a phone survey in which patients received monetary compensation was 16% [12]. While patients in our study did not receive monetary compensation for completing the phone-based survey, our response rate (33.2%) was significantly higher than expected. An additional strength of our study is the regional diversity, in that women from four distinct parts of the country were included.

Deficiencies from our study include the fact that no validated questionnaires were used to assess quality of life, symptom severity or pelvic floor dysfunction. This study asked patients to quantify their symptoms prior to treatment thus the severity reported for pre-treatment symptoms could be influenced by recall bias. Ninety percent of our study patients reported that they were menopausal, but this is self-reported menopausal status, which is not always consistent with actual menopausal status. There are numerous ways for patients to become menopausal (i.e., surgical, drug induced, etc.) and after examination by the physician, it was determined that the patient's symptoms were consistent with GSM.

In conclusion, these study findings are consistent with previous findings confirming the safety and efficacy of the SmartXide Fractional CO_2 laser in addition to identifying a high level of patient satisfaction with both treatment results and out-of-pocket expense.

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