Front. Biol. 2018, 13(2): 145–148
https://doi.org/10.1007/s11515-018-1486-2

RESEARCH ARTICLE

Effectiveness of fractional CO_2 laser in women with stress urinary incontinence

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BACKGROUND: Stress urinary incontinence (SUI) is a relatively common disorder that significantly affects the quality of life. Many conservative and surgical treatment methods have been recommended for SUI, but they have major limitations.
AIMS: To assess the use of the CO_2 fractional laser in the treatment of SUI.
METHODS: This clinical trial included 55 patients with confirmed SUI. Patients underwent fractional CO_2 laser treatment 3 times at 30-day intervals. Data on age, smoking history, sexual activity, menopause, and history of hormone replacement therapy (HRT) were collected. Response to treatment was assessed by SUI severity and the level of sexual satisfaction was assessed using the visual analog scale (VAS). Patients were evaluated at 3 different time points: before treatment, and 45 days and 6 months after the last laser treatment.
RESULTS: The mean patient age was 44.4 ± 11.4 years (range: 28 to 68 years). Smoking history was positive in 6 patients (9.1%); 19 (54.3%) were menopausal on HRT. The SUI severity score at baseline (before treatment) was 8.56 ± 0.62 and decreased to 2.28 6 months after treatment ($p < 0.0001$). The sexual satisfaction score was 3 ± 0.94 at baseline and increased to 7.87 ± 0.93 6 months after treatment (day 180) ($p < 0.0001$, slope = + 2.2)
CONCLUSION: Our findings are in line with a previous study that showed the value of transvaginal CO_2 fractional laser treatment for alleviation of SUI symptoms and its potential as an alternative treatment. We also observed improved sexual satisfaction in SUI patients.

Keywords stress urinary incontinence, CO_2 fractional laser, sexual function

Introduction

Stress urinary incontinence (SUI) is defined by the International Continence Society as a disorder of unintentional urine outflow during work, exercise, sneezing, or coughing (Nygaard and Heit, 2004). The exact prevalence of SUI has been difficult to estimate due to the absence of a universal definition. However, recent epidemiological analysis reported that 4% to 14% of younger women and 12% to 35% of older women have SUI. In addition, some risk factors have been reported as predisposing factors for developing SUI, including old age, obesity, and a history of smoking (Luber, 2004). A group of nerves, muscles, and connective tissues are arranged solely to control the bladder to avoid incontinence. These permit bladder emptying at appropriate times and even prevent incontinence during noticeable increases in abdominal pressure. The lower urinary tract, i.e., the bladder and urethra, plays a major role in regulating urination (Ulmsten and Falconer, 1999). Although there is no specific etiologic factor common to all SUI patients, at least some degree of weakness is required in the proximal and distal urethral sphincters and/or pelvic floor muscles (Zhou et al., 2016).

There are several treatment approaches to the management of SUI. The first-line treatment recommended in SUI patients with mild symptoms is conservative, nonsurgical therapy, including improvement of lifestyle behavior, bladder training, pelvic floor muscle exercises, and pelvic muscle electrical stimulation and biofeedback (Park and Kang, 2014). However, invasive treatment with surgical intervention provides the only known curative approach in cases with more severe symptoms (van Kerrebroeck et al., 2003). There are many types of surgical treatments for patients with SUI. Although surgical treatment has a greater success rate, the invasive nature also results in a high rate of complications, thereby presenting limitations to some of these treatments (Kavanagh et al., 2017). Therefore, some investigators have evaluated the efficacy of newly emerging UI therapeutic approaches. The

Received February 22, 2018; accepted April 2, 2018
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efficacy of photothermal laser therapy in treatment of genitourinary disease has been established (Pitsouni et al., 2016). Two major technologies for clinical use include the microablative fractional CO_2 laser and the non-ablative photothermal erbium: YAG-laser (Pitsouni et al., 2017). The CO_2 fractional laser induces collagen synthesis thorough delivery of laser energy at small spots called pixels. Thermal tissue damage at the pixels promotes collagen regeneration. Regeneration of collagen, as an important element of structures that support the pelvic floor, may be useful in treating complications related to weakness of pelvic floor supportive structure such as SUI (Pardo et al., 2016).

Some studies have evaluated the efficacy of microablative and non-ablative laser therapy in the management of patients with SUI. The current study aimed to assess the utility of the fractional CO_2 laser in treating women with SUI.

Material and methods

Study design

This interventional study was performed in patients suspected of having SUI admitted to a hospital urogynecology department. The patients were examined by an expert gynecologist. Inclusion criteria were a positive urodynamic test, negative urine culture, and absence of vaginal lesions. Patients with rectovaginal prolapse, urge incontinence, high-grade neurological disorders (such as multiple sclerosis, Parkinson's disease, spinal cord injury, and stroke), and neurogenic bladder were excluded from the study. The study was approved by the Ahvaz Jundishapour University of Medical Sciences ethics committee, and was submitted to the Iranian Registry of Clinical Trials. All patients provided signed informed consent before participating in the study.

Intervention

Patients underwent fractional CO_2 laser treatment 3 times at 30-day intervals. The laser probe was set at low energy and was positioned from the vaginal fundus to the introitus and was rotated between 0, 3, 6, and 12 o' clock positions after each pulse and then between 1 and 2, 4 and 5, 7 and 8, and 10 and 11 o' clock positions. Thereafter, the probe was withdrawn by 1 cm and rotated again. The cycle was repeated 3 times. The duration and intensity of laser pulses was increased until the patients reported no discomfort. The CO_2 fractional laser (IDS company, South Korea) was set at a power of 40 W, with pulsed mode a 1 Hz and energy delivery of 50 mJ/pixel. Patients were advised to avoid sexual activity for 7 days after laser therapy.

Evaluation

Data on age, smoking history, sexual activity, menopause, and history of hormone replacement therapy (HRT) was recorded. Response to treatment was assessed by change in SUI severity and the level of sexual satisfaction. The visual analog scale (VAS) was used to determine the level of SUI severity and sexual satisfaction. Patients were evaluated before treatment, 45 days after phase 2 of treatment (75 days after treatment), and finally 6 months after treatment.

Statistical analysis

To achieve 71% power and a correlation as small as 0.25 with 0.05 type I error, the sample size was calculated as 55 patients. The data were initially analyzed using descriptive statistics and Kolmogorov–Smirnov analysis was performed to assess data normality. Repeated measures analysis of variance and multiple comparisons were used to assess the means of variables. All statistical analyses were performed using GraphPad Prism software. A p value less than 0.05 was considered significant.

Results

The study included 55 patients with confirmed SUI. The mean patient age was 44.4±11.4 years (range: 28 to 68 years). Smoking history was positive in 6 patients (9.1%); 19 (54.3%) were menopausal on HRT (Table 1).

Table 1 Patient characteristics

Variables		Frequency
Age (mean±s.d)	44.4±11.40 (28–68)	
Smoking	Yes	6(10.9%)
	No	49(89.1%)
Hormone replacement therapy	Yes	19(34.5%)
	No	36(65.5%)
Menopause	Yes	19(34.5%)
	No	36(65.5%)

The SUI severity score at baseline (before treatment) was 8.56±0.62 and decreased to 2.28 6 months after treatment. The decrease was statistically significant ($p < 0.0001$) (Table 2) (Fig. 1). Moreover, the multiple comparison analysis showed a significant decrease from baseline to day 45 and from day 45 to day 180 (Fig. 2).

The sexual satisfaction score was 3±0.94 at baseline and increased to 7.87±0.93 6 months after treatment (day 180). The increment was statistically significant ($p < 0.0001$, slope = + 2.2) (Fig. 3).

Discussion

Weakness of pelvic floor supportive structures is the most common etiological factor in SUI. Therefore, most conservative and surgical treatments focus on strengthening the pelvic

Table 2 Treatment effects

Variables	Prior treatment	After treatment (day 45)	After treatment (day 180)	*p*-value
Stress urinary incontinence	8.56±0.62	3.02±0.8	2.28±0.66	$p < 0.0001$
Sexual satisfaction	3±0.94	4.2±1.57	7.87±0.93	$p < 0.0001$

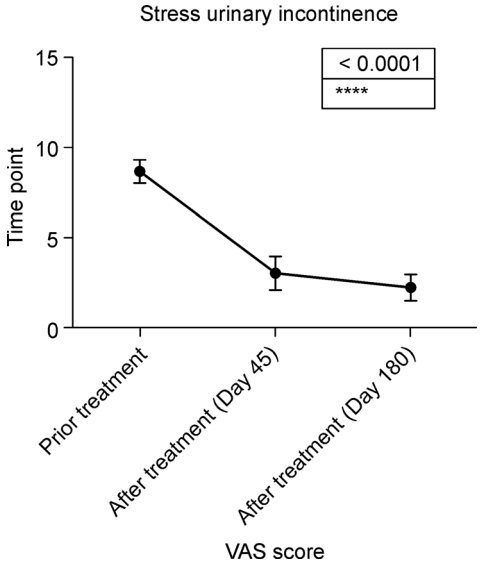


Figure 1 Changes in SUI severity during study follow-up.

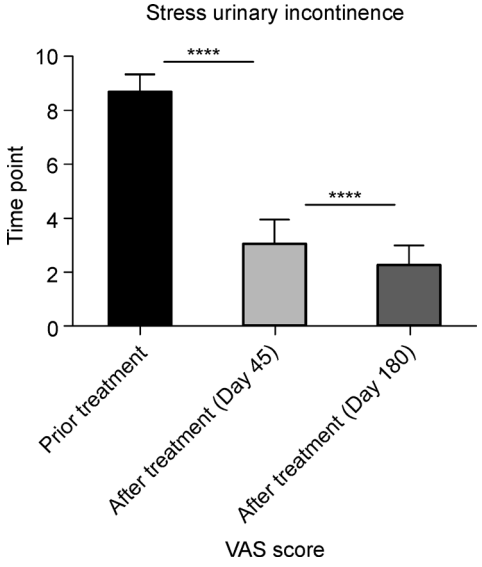
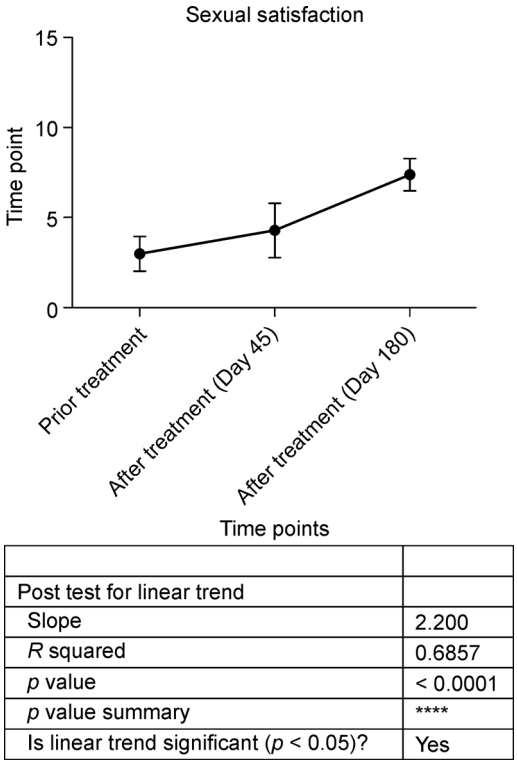


Figure 2 Multiple comparisons of SUI severity at different time points

floor supportive structures. Conservative treatment has many advantages, but can be very difficult for patients and outcomes are controversial. On the other hand, surgical methods are



Post test for linear trend	
Slope	2.200
R squared	0.6857
p value	< 0.0001
p value summary	****
Is linear trend significant ($p < 0.05$)?	Yes

Figure 3 Changes in sexual satisfaction score during study follow-up.

usually associated with complications (Kociszewski et al., 2017). In the current study, we evaluated the short-term efficacy of CO_2 fractional laser therapy in 55 patients with confirmed SUI. The severity of SUI and sexual satisfaction were compared before and 6 months after treatment.

Our findings indicated that SUI severity based on the VAS score decreased from 8.56 before treatment to 2.28 6 months after treatment. The decrease was statistically significant. Moreover, multiple comparisons at different time points showed that SUI severity not only significantly decreased 45 days after treatment but showed significant differences between the second (45 days) and third (180 days) measurements. The later results actually compared the short- and long-term effects of transvaginal CO_2 fractional laser (TCO2L) treatment. Our findings are in line with previous studies. Isaac et al. in a recent study showed the efficacy of TCO2L as an alternative treatment in patents with SUI. They showed that TCO2L significantly improved SUI at 12, 24, and 36 months after treatment (Isaza et al., 2017). Compared with our study, they followed the patients for a longer time. In another trial, Menechem et al. evaluated the ability of TCO2L to alleviate SUI symptoms. The authors assessed treatment outcomes by counting pads used and episodes of urge incontinence and showed that pad use decreased by 80% and 97% in patients with urge incontinence (Menachem et al., 2016). Owing to differences in methodology, their study results cannot be directly compared with our

findings. Moreover, studies on Er:YAG laser therapy showed similar findings, Fistonic et al. treated 31 SUI patients with the Er:YAG laser and found significant improvement in SUI symptoms (Fistonic et al., 2016). Thus, based on the hypothesis that laser therapy promotes collagen synthesis, SUI symptoms can be significantly improved.

The negative effects of SUI on sexual function have been reported. A recent study investigated the effects of SUI on sexual function and reported a negative association in both partners. Our results showed that TCO2L therapy could improve patient sexual satisfaction. Previous reports also supported these findings, Salvatore et al., (2015) showed that fractional microablative CO_2 laser treatment could significantly improve overall sexual function as well as satisfaction in postmenopausal patients. More studies are needed to determine the exact role of TCO2L on sexual function (psychological or physiologic effects) in SUI patients.

Collectively, our findings are in line with previous studies that showed the efficacy of TCO2L in the treatment of SUI symptoms and its potential as an alternative therapy. We also demonstrated improvement in sexual satisfaction in SUI patients. The small sample size and relatively short follow-up are among the major limitations of our study.

Acknowledgments

We wish to thank all our colleagues in Golestan Hospital, Ahvaz, Iran

Compliance with ethics guidelines

The authors declare that they have no conflict of interest. This paper does not involve any studies with human or animal subjects performed by any of the authors.

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