



Fractional CO₂ Laser for Treatment of Female Stress Urinary Incontinence

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Abstract: Background: Urinary incontinence (UI) is a common disorder that affects women of various ages and impacts all aspects of life. This condition negatively influences quality of life. Fractional CO₂ laser (10600nm) is the recent method for treatment of stress urinary incontinence in women. **Objectives:** The purpose of the study was to evaluate the efficacy and safety of fractional CO₂ laser (10600nm) in the treatment of female stress urinary incontinence. **Materials & Methods:** This study was done from July 2020 to February 2021 conducted at the laser institute for postgraduate studies university of Baghdad, patients collected from a private clinic and the Department of Obstetrics and Gynecology of Al-Kadhimiya private hospital, Baghdad, Iraq. Twenty women clinically diagnosed with SUI preferring non-surgical treatment were recruited to the study, their mean ages 43.6 ± 13.9 years. Response to treatment was assessed at baseline and at one month follow up after the third session using a pelvic Floor Questionnaire (PFQ-UI). The laser parameters used were CO₂ laser wavelength 10600 nm, power 35 watt, duration 1.0 ms, distance 1.0 mm, scan mode normal, scan times 4 and scan Rows 4, Interval 0.5s. **Results:** Most of the twenty women included in the study 80 % reported satisfaction and 20% not satisfied with treatment after 3 sessions of CO₂ laser four weeks apart. **Conclusion:** Fractional CO₂ laser treatment is an easy to use, minimally invasive and effective option for treatment of SUI.

Keywords: CO2 laser, and Urinary incontinence.

1.Introduction:

Stress Urinary Incontinence (SUI), defined as the complaint of involuntary urine leakage on effort or exertion, or on sneezing or coughing due to insufficient strength of bladder closure when urine leaks out with any sudden pressure on the bladder and urethra, causing the urethral sphincter muscles to open briefly. In mild SUI leaking may occur from any sudden activities, like exercise, coughing, laughing or sneezing, in more severe SUI, urine may leaks with fewer activities like standing up, bending over or walking. Urinary leakage can range from a few drops of urine to enough to soak through clothes (Aoki, et al;

1917). Stress urinary incontinence affects 15.7% of adult women and its prevalence increase with age particularly with menopause. (Nygaard I. et al. 2008).

An understanding of the path physiologic mechanisms that are related to be the cause SUI is substantial to accurate classification. Broadly two mechanisms are proposed: weakness in the supporting tissues of the urethra resulting in “urethral hyper mobility” or a defective urethral sphincter mechanism termed intrinsic sphincter deficiency (ISD), with many patients having features of both. (Kayigil O. et al 1999).

Management of uncomplicated SUI includes a variety of noninvasive interventions (Behavioral modification, Pelvic floor muscle training, Electrical Stimulation, Vaginal Cones, Occlusive Devices, Intravaginal Supportive Devices. If conservative measures fail then surgical treatments are considered. Although surgical treatments are widely used for, many women with SUI prefer a self-managed conservative option to avoid long-term recurrence or possible devastating complications of surgical interventions (Eric S Rovner et al 2004).

Laser therapy has a therapeutic role in various medical conditions and most recently has gained interest as a promising treatment for UI, particularly SUI, the most prevalent type of UI (Norton P BL. Urinary incontinence in women (Lancet 2006). Laser photo thermal energy can improve collagen structure and initiate neocollagenesis in the skin and pelvic floor with nearby tissue (Gambacciani M et al 2017). Elevation in temperature up to 63°C increases the contraction of collagen fibers in vaginal epithelium and provokes neocollagenesis, elastogenesis, neoangiogenesis, and increased fibroblast. In addition, histopathology showed an increase in the volume density of blood capillaries and the thickness of the epithelial layer that lead to restoration of most vaginal functions and also an increase in muscle tone that seems to be related to a clinical improvement in UI (Lapii G. A. et al; 2017). We aim to clinically evaluate the efficacy and safety of ablative fractional CO₂ laser in treatment of SUI.

2. Patients and Study Design

This was an interventional study conducted at the laser institute for postgraduate studies university of Baghdad. Patients collected from the private clinic and the Department of Obstetrics and Gynecology of Al-Kadhimiya private hospital, Baghdad, Iraq during a period of eight months from July 2020 to February 2021.

There was an interview with the study patients and detailed history was taken from them included questions about neurological and congenital abnormalities, previous obstetrics and gynecology history, including number of vaginal deliveries, mode of deliveries, symptoms of pelvic prolapse, micturition symptoms, the severity of

incontinence, degree of bother, previous surgery, urological diseases, bowel symptoms and symptoms of sexual dysfunction.

The physical examination of the patient with incontinence included: neurological exam, Pelvic organ prolapsed grading, Bimanual pelvic examination, assessment of pelvic floor musculature (tone and strength), cough stress test, Q-Tip test to document urethral hyper mobility: materials used for this test are Swab stick and Goniometer as shown in figure 1, one hour pad test, post voiding remnant.



Figure (1): Swab stick and Goniometer.

Patients included in this study are those with: mild to moderate SUI, no/unsatisfactory response to conservative treatments and they prefer non-surgical management of SUI symptoms, mild to moderate pelvic organ prolapse, negative urine examination, no injuries and bleeding in the (vaginal canal, introitus, and vestibule). Patients excluded are those with severe pelvic organ prolapse, genital tract infection, acute or recurrent urinary tract infections, pregnancy, any serious disease or chronic condition that could interfere with or cause treatment side effect, known cervical dysplasia, undiagnosed abnormal uterine bleeding, post void residual urine volume > 150 ml.

All participants were asked to complete bladder function questions of modified Pelvic Floor Questionnaire (PFQ-UI), (Table 1); at baseline then after one month following complete three CO₂ laser sessions to assess SUI symptoms changes and study results depend on the changes reported by the patients in this questionnaire.

Following laser parameters protocol used: Power 35, Pulse duration 1ms, spacing 1mm, scan rows 4, shoot times 4, Interval 0.5 sec.

designed with special wavelength and optical density for the CO₂ laser (10600 nm) to eliminate the risk of eye damage.

Table (1): Pelvic floor questionnaire-urinary incontinence.

PFQ-UI	Patient's name: Age:	Date of Birth Date Completed:
How many times do you pass urine per day? -Less than 5 -Between 5-10 -More than 10 -More than 15	Do you leak with coughing, laughing or sneezing? -Never - Less than once weekly -More than once weekly -Daily	Does urine leaking affect your daily activities? -Not at all -Slightly -Moderately -Greatly
Do you have to wear pads due to urinary incontinence? -No -As a precaution -During exercise -Daily	Do you have pain in your bladder or urethra during micturition? -Never - Less than once weekly -More than once weekly -Daily	Does urine leaking affect your sexual life? -Not at all -Slightly -Moderately -Greatly
Do you have frequent bladder infection? -No - (1-5 per year) - (5-10 per year) -More than 10 yearly	Do you need to rush to pass urine when you get urge? -Never - Less than once weekly -More than once weekly -Daily	Does your bladder problem bother you? -Not at all -Slightly -Moderately -Greatly
How many times do you get up at night to pass urine? -Between 0-1 times -About 2 times -About 3 times - More than 3 times	Does urine leak while you are rush to the toilet? -Never -Less than once weekly -More than once weekly -Daily	Do you need to strain to empty your bladder? -Never -Less than once weekly -More than once weekly -Daily

Assessments depend on the following evaluation criteria:- The main result of this study is to describe the change in self-reported SUI symptoms based on urine leaking question of PFQ-UI, other outcomes were quality of life, sexual quality, dysuria, urgency, pad usage and Q tip test mean angles improvement.

Laser safety measures and precautions were considered in the current study including: patient and the surgeon had the appropriate goggles



Figure (2): KES MED-870+ CO₂ Laser system.

Participants were pre-treated with topical anaesthetic cream (Emla cream 5% (2.5 % lidocaine and 2.5 % prilocaine)) at the level of vestibulum, then patient asked to wait 20 minutes for the area to be anaesthetized, in lithotomy position the vagina mobbed a with piece of cotton socked with normal saline. The Laser beam was emitted from a 90° vaginal probe gently inserted up to the level of the bladder neck, then withdrawn in order to provide treatment of the anterior lower one third of the vagina and external urethral meatus. The probe inserted inside the vaginal canal about 4–6 cm from the introitus, with the laser's energy window oriented at 12 o'clock position It was with a 360-degree probe as per (Salvatore et al; 2014). There was no pain reported during procedure in all study patients and no specific postoperative instructions required only avoiding intercourse for 5 days after treatment and returning for the next session then rotated by 1 h at a time after each laser pulse, between positions 10 o'clock and 2 o'clock. After completing the 10–2 o'clock rotation, the hand piece was pulled back by 1 cm and the rotation was repeated. Three passes were repeated with the

same parameters. Each patient also received three total vaginal length laser treatments in scheduled time.

3. Results

This study includes twenty patients of SUI women with a mean age of 43.6 ± 13.9 years suffering from SUI. Each patient was getting ready for the procedure after full explanation and discussion regarding the nature of the procedure, the possible advantages, disadvantages and complications expected. Patient description as in table 2 below;

Table (2) Patients' Statistic

	Category Range/Mode	Number of Patients	Percentage
Age	25-34	4	20%
	35-44	7	35%
	45-55	9	45%
Parity	1-5	7	35%
	6-10	13	65%
Delivery Mode	NVD	9	45%
	Mixed	11	55%
Menstruation Status	Premenopausal	16	80%
	Postmenopausal	4	20%
Previous Urological and gynecological reconstruction	-	-	-

All patients 20 (100%) have completed their follow-up one month after the intervention. The mean age with standard deviation (SD) of the studied group was (43.6 ± 13.9) years, mean of parity with (SD) was (5 ± 1) and the mean time of treatment with (SD) was (20.5 ± 3.7) minutes. All these were shown in table 3.

Table (3): Mean of patient's characteristics and time of treatment:

Patients characteristics	Mean $\pm$ SD
Age (years)	43.6 ± 13.9
Parity	5 ± 1
Treatment time (mean $\pm$ SD)/min.	20.5 ± 3.7

Table 4 shows that grade of incontinence before the beginning of therapy was as follow; 13/20 (65.0%) of the patients presented as mild stress of incontinence, and 7/20 (35.0%) of the patients presented as moderate grade of SUI.

Table (4): Grades of SUI

Grade of SUI	No. (n=20)	%
Mild	13	65.0
Moderate	7	35.0

Change in SUI symptoms before and after fractionated CO2 laser women with SUI as following: The primary result of this study depends mainly on change in self-reported SUI symptoms based on question two of PFQ-UI, (figure 3). in which baseline data was 35% for once a week, 55% twice a week and 10% daily, while after one month; 60% not suffer from SUI symptoms, 10% with SUI symptoms for once a week, 25% twice a week and only 5% were daily.

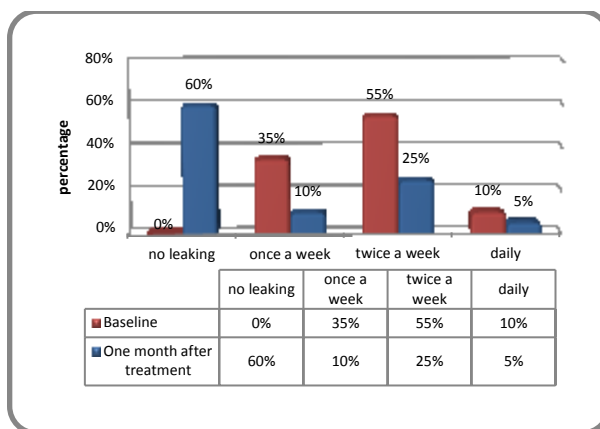


Figure (3): SUI symptoms before the treatment and at one month follow up.

4. Dysuria, urgency and pad usage:

As shown in figure 4, data shows that one month follow up after laser treatment, those patients complained from dysuria, urgency and pad using improvements as follows:

Dysuria improved in 45% of the patients, 30% of patients with urgency improved and 25% of patients no more pad using.

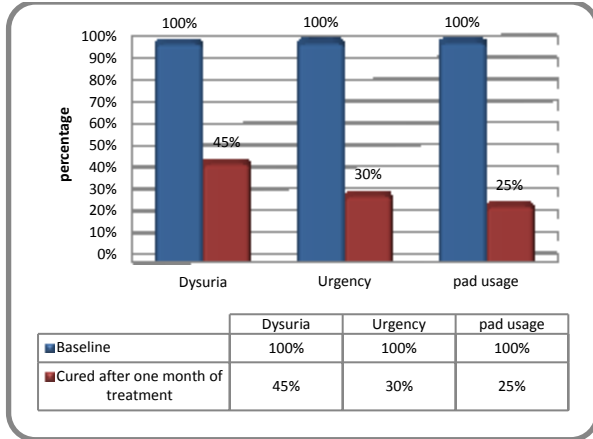


Figure (4): Dysuria, urgency and pad using before the treatment and at one month follow-up.

5. Q tip test angle table at baseline and at one month follow up:

The mean angle of the Q-tip was significantly decreased in follow-up compared to baseline. In Figure 5, the results of the mean angle of the Q-tip before the treatment and at one month follow up are represented. The mean angle before the treatment was 61.5° and at one month follow up, it was 47.3°.

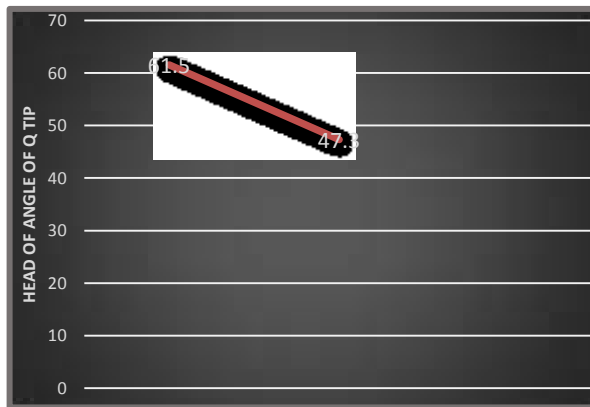


Figure (5): Angle of the Q-tip mean before the treatment and after one month follow up.

6. The overall laser therapy effect in this study:

As shown in figure 6, after one month following three laser treatment sessions 3-4 weeks apart regarding:

1. SUI Symptoms 60 % (12 patients) are completely cured, six patients improved, only two patients not improved.
2. Great changes in both life and sexual qualities.

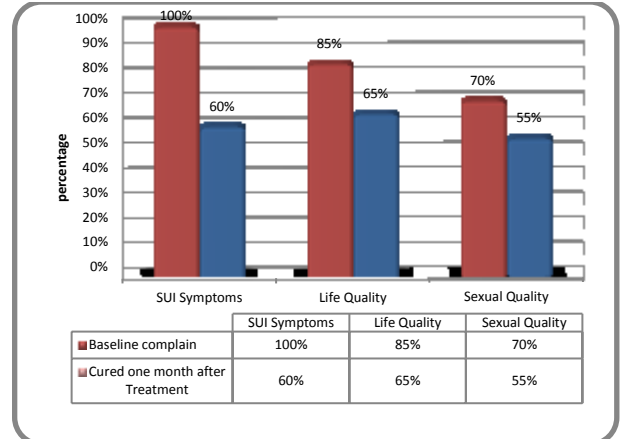


Figure (6): overall laser therapy effect at one month after complete three session treatments.

The Patients overall satisfaction level with the treatment procedure and outcome was assessed at one month following treatments as can be seen in figure 7. At one month after treatment follow-up 16 patients (80%) of women expressed satisfaction with the treatment and the rest 4 patients (20%) of the patients were unsatisfied.

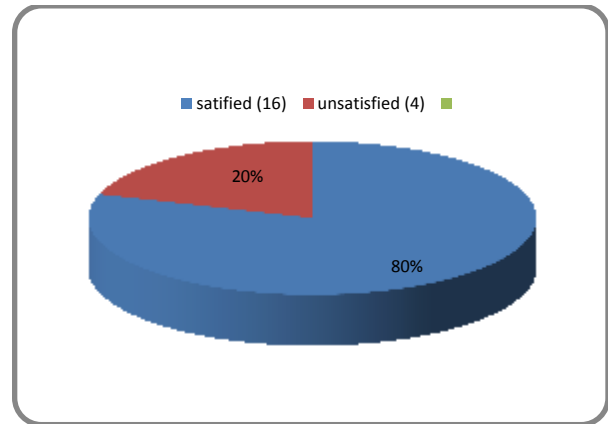


Figure (7): patient satisfaction after one month follow-up visit

7. Discussion

Laser photo thermal energy can improve collagen structure and initiate neocollagenesis in the skin and pelvic floor with nearby tissue (Tadir Y et al; 2017). Elevation in temperature up to 63°C increases the contraction of collagen fibers in vaginal epithelium and provokes neocollagenesis, elastogenesis, neoangiogenesis, and increased fibroblast. In addition, histopathology showed an increase in the volume

density of blood capillaries and the thickness of the epithelial layer (Oshea et al; 1978).

Data from our study shows an improvement in stress urinary incontinence symptoms in patients who underwent three sessions of fractional CO₂ laser vaginal treatment three-four weeks apart, with the majority of patients reported improvement in urine leaking after exertion. The use of fractional CO₂ laser is very effective in improving and reducing symptoms of SUI with short operating time, maximum operating time was 20 ± 5 minutes with minimum or no complication comparing with surgical technique.

In our study we found that SUI increase with age and parity, high percent of women with SUI coming at age ranged (35-55 year) which represent 16 (80%) most of them are vaginally delivered, that is mean the most predisposing factor for SUI is multiparity and the explanation of that frequent pregnancy cause frequent stretching effect on pelvic floor muscle that lead to weakness of the pelvic floor muscle.

Patients in this study showed improvement in SUI Symptom, life and sexual qualities. The Secondary outcomes improvement includes dysuria, urgency and pad using. There is significant decrease in the mean of the Q tip angles at follow-up compared to baseline. The overall patients satisfactions after treatment were 80% (16 patients) while 20% (four patients) were not satisfied.

Since 2014, a growing number of studies have been published exploring the use of trans-vaginal laser treatment for gynaecological conditions such as SUI, mixed UI (MUI) and genitourinary symptoms of menopause (GSM) (K Mackova et al; 2020).

A study published by Jorge Alberto Elias (Jorge Alberto Elías MD et al 2015) for treatment of 30 patients by CO₂ for stress urinary incontinence (SUI). All 30 patients appropriately responded to SUI treatment, 60% presented resolution and 40% improved significantly. While in our study patients responded to SUI treated by CO₂ laser as follows: 60% completely cured, 30% improved and 10% not responded.

Behnia-Willison et al. showed in a study treating 102 women with GSM with fractional CO₂ laser having improvements up to 24 months by colposcopic examinations and responses to APFQ (F. Behnia-Willison et al; 2017).

Ogrinc et al. in a study included 175 women suffering from UI treated by Er: YAG Laser, a significant improvement was found after a year follow-up in 77% of patients by evaluating International Consultation on Incontinence Questionnaire– Urinary Incontinence (ICIQ-UI) and Incontinence Severity Index (ISI) (U.B. Ogrinc et al; 2015).

Ibrahim, N et al. in a study which was conducted over six month from December 2016 in Consultation Gynecologist Clinic in Al-Hila city, Iraq and published in Iraqi Journal of Laser included a sample of twenty patients had stress urinary incontinence were treated with CO₂ laser, (5) patients started to response after one session, most of them (14) were starting improvement after two sessions and with one case not improved after three sessions was being referred for surgery.

8. Conclusions:

In this study patients had significant improvement in most parameters analyzed, as there are significant improvements in SUI symptoms, great changes in life and sexual quality, dysuria, urgency.

Laser therapy seems to be a promising alternative approach to urinary incontinence in women. It seems effective in short term, well tolerated, with few and transient side effects.

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استخدام ليزر ثنائي اوكسيد الكربوني التجزيئي لعلاج سلس البول الإجهادي عند النساء

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الخلاصة: الخلفية: سلس البول الإجهادي هو تسريب لا إرادي للبول خلال القيام بأي مجهود مثل: السعال، العطس، رفع اوزان، الضحك او ممارسه الرياضة. السلس البولي يؤثر على نوعية حياة المرأة بأشكال مختلفة، قد تحد من العلاقات الاجتماعية والشخصية للمرأة، فضلاً عن الحد من النشاط البدني. النسبة الأكبر من هؤلاء النساء لا يعرفن بوجود طرق سهلة و بسيطة وفعالة لعلاج سلس البول. ليزر ثنائي أكسيد الكربون التجزيئي (١٠٦٠٠ نانومتر) هو الطريقة الحديثة لعلاج أعراض سلس البول الإجهادي لدى النساء. **الأهداف:** كان الغرض من هذه الدراسة هو تقييم فعالية ليزر ثنائي اوكسيد الكربون التجزيئي في علاج أعراض سلس البول الإجهادي. **المواد والطرق:** أجريت هذه الدراسة في عيادة خاصة من يوليو ٢٠٢٠ إلى شباط ٢٠٢١. شملت الدراسة عشرون امرأة يعانين من أعراض سلس البول الإجهادي في هذه الدراسة ، وتراوحت أعمارهم بين ٢٥ - ٥٥ سنة. كانت معلومات الليزر المستخدمة هي الطول الموجي للليزر ١٠٦٠٠ نانومتر ثنائي اوكسيد الكربون التجزيئي ، الطاقة ٣٥ وات ، المدة واحد مللي ثانية ، المسافة واحد ملم ، وضع المسح العادي ، أوقات المسح الصفوف الرابع والمسح الضوئي اربعة. النتائج: أبدت معظم النساء العشرون المشمولات في الدراسة ٨٠٪ عن رضاهم عن العلاج بعد ثلاث جلسات من ليزر ثنائي أكسيد الكربون التجزيئي ١٠٦٠٠ نانومتر. **الاستنتاج:** يعتبر العلاج بالليزر ثنائي اوكسيد الكربون التجزيئي طريقة فعالة لعلاج اعراض السلس البولي مع تأثير جانبي أقل.