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# Effect of vaginal $CO_2$ laser therapy in mixed urinary incontinence

*Efekt waginalnej terapii laserowej $CO_2$ w leczeniu mieszanej inkontynencji moczu*

**Amr N. Badawy[1(A,B,C,D,E,F)], Mahmoud S. El-Basiouny[2(A,B,C,D,E,F)], Mamdouh Bibars[1(A,B,C,D,E,F)], Sameh Salama[1(A,B,C,D,E,F)], Mai Maged[3(A,B,C,D,E,F)], Amr Mostafa[4(A,B,C,D,E,F)], Galal Elshorbagy[4(A,B,C,D,E,F)], Doaa Saeed[5(A,B,C,D,E,F)], M.H. El Ebrashy[5(A,B,C,D,E,F)], Amr H. Elnoury[2(A,B,C,D,E,F)]**

[1]Department of Reproductive Health and Family Planning, National Research Centre, Dokki, Giza, Egypt
[2]Department of Medical Application of Laser, National Institute of Laser Enhanced Sciences, Cairo University, Egypt
[3]Clinical Neurophysiology, Cairo University, Cairo, Egypt
[4]Urology Department, Cairo University, Cairo, Egypt
[5]Department of Physical Therapy for Women's Health, Faculty of Physiotherapy, Badr University in Cairo, Egypt

## Abstract

Objective. This prospective study provides preliminary findings on the clinical effectiveness of minimally invasive $CO_2$ vaginal laser for patients suffering from mixed urinary incontinence.

Materials and Methods. Thirty females suffering from mild to moderate degrees of mixed urinary incontinence underwent $CO_2$ laser treatment with a specialized applicator and wavelength of 10,600 nm in an outpatient setting without anaesthetics or postoperative drugs. All patients received a total of two sessions, each separated by a 4-week period. The ICIQ-UI SF questionnaire (Arabic form) as well as a cough stress test were used to assess the clinical outcome 3 months following treatment in all patients. Patients were given the ICIQ-UI SF to complete before starting treatment and once again three months after completing two sessions of therapy.

Results. A statistically significant decline in the ICIQ UI -SF was observed from baseline (from 8 ± 0.58) to the 3-month follow-up (5.1 ± 0.79). Moreover, eight patients (26.7%) had a negative cough stress test 3 months after the second laser session. During the study duration, there were no severe side effects.

Conclusions. Collagen remodeling and production induced by vaginal $CO_2$ laser may assist in the recovery and repair of pelvic floor function. In patients with MUI, this treatment method demonstrated effective as well as safe clinical outcomes as evaluated by the ICIQ-UI SF questionnaire, despite the limited sample size and short follow-up.

## Keywords

bladder symptoms, quality of life, urinary mixed incontinence, ICIQ UI-SF, cough stress test, vaginal $CO_2$ laser

## Streszczenie

Cel. Niniejsze prospektywne badanie przedstawia wstępne ustalenia dotyczące klinicznej skuteczności minimalnie inwazyjnej terapii laserowej $CO_2$ na pochwę u pacjentek cierpiących na mieszane nietrzymanie moczu.

Materiały i metody. Trzydzieści kobiet cierpiących na łagodny do umiarkowanego stopnień mieszanej inkontynencji moczu przeszło zabieg laserowy $CO_2$, używając specjalistycznego aplikatora i długości fali 10,600 nm, w warunkach ambulatoryjnych, bez znieczulenia i leków pooperacyjnych. Wszystkie pacjentki otrzymały łącznie dwie sesje, każda z nich oddzielona 4-tygodniowym okresem. Do oceny wyników klinicznych po 3 miesiącach od zabiegu u wszystkich pacjentek użyto kwestionariusza ICIQ-UI SF (wersja arabska) oraz testu kaszlowego. Pacjentkom przed rozpoczęciem leczenia oraz ponownie trzy miesiące po ukończeniu dwóch sesji terapii wydano kwestionariusz ICIQ-UI SF do wypełnienia.

Wyniki. Zaobserwowano istotny statystycznie spadek w ICIQ UI-SF od wartości wyjściowej (z 8 ± 0.58) do kontroli po 3 miesiącach (5.1 ± 0.79). Ponadto, u ośmiu pacjentek (26.7%) test kaszlowy był negatywny 3 miesiące po drugiej sesji laserowej. Podczas trwania badania nie zaobserwowano poważnych skutków ubocznych.

Wnioski. Przebudowa i produkcja kolagenu indukowane przez laser $CO_2$ na pochwę mogą pomóc w regeneracji i naprawie funkcji dna miednicy. U pacjentek z mieszanej inkontynencji moczu ta metoda leczenia wykazała skuteczne oraz bezpieczne wyniki kliniczne, jak oceniono za pomocą kwestionariusza ICIQ-UI SF, pomimo ograniczonej liczby próbek i krótkiego okresu obserwacji.

## Słowa kluczowe

objawy pęcherza moczowego, jakość życia, mieszana inkontynencja moczu, ICIQ UI-SF, test kaszlowy, laser $CO_2$ na pochwę


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## Background

The term "urinary incontinence" (UI) describes an individual's complaint of experiencing involuntary urinary loss. Intimacy avoidance, depression, and social isolation are only some of the ways in which UI negatively affects a woman's quality of life according to the European Journal [1]. It's common for women to avoid seeking medical care because of the shame and social stigma associated with it [2].

Stress incontinence and urgency incontinence represent the two predominant manifestations of urinary incontinence. The definition of incontinence, as established by the International Continence Society and the International Urogynecology Association, refers to the involuntary release of urine triggered by coughing, sneezing, or physical exertion. On the other hand, urge incontinence is characterized by the involuntary loss of urine resulting from an abrupt and urgent sensation to urinate that cannot be postponed. When symptoms from both types of incontinence coexist, this condition is known as "mixed incontinence" [3].

About two-thirds of women suffering from urinary incontinence have stress incontinence (SUI), while another 20% to 25% have urge incontinence (UI), and 12% to 19% have mixed incontinence (MUI) [4].

Although urinary incontinence may be the presenting symptom, it is not always possible to determine the specific type of UI or what may be causing it based solely on the symptom. Exacerbating factors, impact on women's quality of life, and treatment intention must all be determined through a comprehensive evaluation [5].

Adult female urinary incontinence treatment is an iterative process. Urinary incontinence can be embarrassing and irritating for some women. Alterations to one's lifestyle, as well as more invasive surgical interventions, are on the optional range [6]. Without proper pelvic floor training, lifestyle changes (including fluid optimization), pharmaceutical treatment, or surgery, healthy women may prioritize resolving their urinary incontinence. On the other hand, women who are suffering from many major health issues may perceive urine incontinence as a chronic disease for which they should focus on managing symptoms rather than treating the problem entirely [7].

Novel, non-invasive therapy for genitourinary syndrome of menopause (GSM), premenstrual syndrome (PMS), and urinary incontinence (UI) have been introduced in gynecology, with two laser types derived from dermatology: erbium-doped yttrium-aluminum-garnet (Er: YAG) as well as carbon dioxide ($CO_2$). Producers of vaginal and/or intraurethral laser applications believe their products are safe, effective alternatives to surgical and pharmaceutical treatments, with fewer side effects. Laser technology is increasingly becoming the standard in medical and cosmetic settings [8].

First developed in the 1960s, $CO_2$ lasers have been utilized for a variety of applications, including tissue cutting and destruction using a continuous wave mode which ablates tissue to a thickness of 400-500 µm. Many clinical uses were found for this method, including blepharoplasty of the upper eyelids and the management of cervical intraepithelial neoplasia [9, 10].

High-energy pulsed $CO_2$ lasers emerged in the 1990s due to advancements in $CO_2$ laser technology, ablating tissue at a shallower depth (around 20 to 100 µm) with less thermal harm to deeper layers. In less invasive procedures, such as cutaneous resurfacing, high-energy pulsed $CO_2$ lasers shine. In 2004, fractional $CO_2$ laser delivery devices were developed, further enhancing the state of the art. To perform a fractional treatment, a laser beam is first divided into many smaller beams, called microbeams. These microbeams then vaporize the skin in columns, leaving healthy tissue around the edges. Patients with darker skin tones may experience less dyspigmentation following this method of treatment, though to a lesser extent than with non-fractional treatment [11, 12].

Manufacturers assert that the utilization of vaginal and/or intraurethral laser treatments presents a viable alternative to surgical procedures and/or pharmaceutical interventions, yielding comparable or superior outcomes while minimizing the occurrence of side effects [13, 14]. This study provides exploratory data on the efficacy of vaginal $CO_2$ laser therapy for women with MUI.

## Methodology

From June 2019 to April 2022, 30 patients with mild-to-moderate MUI were enrolled in this study. All patients received treatment with a 10,600 nm $CO_2$ vaginal laser (FRAXIS fractional, gynecological, and surgical $CO_2$ laser, model FRX-C1). The Research Ethics Committee of the National Research Centre gave their approval (16/070) to the research protocol, which included utilizing the International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF) Arabic version as well as the Cough stress test as outcome measures.

The study incorporated participants who had no active vaginal bleeding or infection, normal urinalysis, normal pelvic ultrasound, and mild to moderate prolapse (stages I & II of pelvic organ prolapse), and mild to moderate degree of MUI (positive cough stress test, urgency as well as frequency, urge form in addition to stress form UI, ICIQ-UI SF score between 1 & 12). It is noteworthy to state that the ICIQ-UI SF score can be categorized into four distinct levels of severity, which are as follows: slight (1-5), moderate (6-12), severe (13-18), and very severe (19-21) [15].

The exclusion criteria were as follows: aged 70 years old or older; preceding laser or RF treatment in the previous 6 months; prolapse stage > II as defined by the pelvic organ prolapse quantification (ICS POP-Q) method (to exclude advanced prolapse for which first-line treatments are most probably invasive); acute urinary tract infection; active sexual organ infection; undiagnosed vaginal hemorrhage; history of heat-induced herpes virus infection; and history of or active malignancy in the last five years, patients with a history of pelvic surgery, medical treatment, or physiotherapy for incontinence and prolapse, women who are pregnant or breastfeeding, and patients with immunosuppressive disease, hormonal changes, or any severe disease or long-term conditions that could make it hard to follow the rules of the study are excluded from participation.

All patients in the study underwent: a complete history taking, ICIQ-UI SF Questionnaire (Arabic version) to determine the type and severity of the condition (score was between 1 and 12) as severe degrees were excluded from the study, a comprehensive general and abdominal examination, and a thorough pelvic examination (including an evaluation of the degree of uterovaginal prolapse using the POP-Q system), a cough stress test to provide evidence of SUI, and comprehensive urine analysis and pelvic ultrasound to rule out the presence of any organic lesions.


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Cough stress testing was performed while the patient was lying in the supine/lithotomy posture with a bladder full of 200-400 mL of fluid, as recommended by the ICS-UCST (measured by USS). To check for leakage, we had her cough vigorously 1–4 times while simultaneously monitoring the urethral meatus. A positive test result would be fluid leaking from the urethral meatus in conjunction with, or at the same time as, the cough(s) [16].

Hashim et al.'s Arabic translation of the ICIQ-UI SF was utilized to assess UI in clinical and research settings in the Middle East. The Arabic version of the ICIQ-UI SF maintained its validity, reliability, as well as responsiveness. Similarities between the psychometric test outcomes and those of the UK-English ICIQ-UI SF can also be seen [17].

Subjects underwent two laser sessions at intervals of 4 weeks based on the study treatment protocol. Before any treatment, we checked the vaginal canal for symptoms of active infection, injury, as well as bleeding. Treatment with the Gynolaser FRAXIS applicator was conducted without general or local anesthesia. Prior to the commencement of treatment, the vaginal canal underwent a cleansing and drying process to prevent any potential decrease in tissue penetrability caused by laser beams. Before the insertion of the applicator, no oil or gel was utilized. The vaginal treatment involved the use of the unique patent I-slide applicator in conjunction with an applicator. The initial treatment session involved the application of the following parameters for vaginal treatment: an energy level of 72 millijoules, a distance of 0.8 millimeters, an I-stack range of 1-2, and an overlap of 1x. During the subsequent session, there was a notable augmentation of the energy level, which rose by 20% to reach a value of 102 millijoules (mJ).

The applicator was carefully introduced into the vaginal canal until its tip reached the farthest point of the vagina. After firing a laser pulse burst, the handpiece was rotated clockwise by 30 degrees and then fired again. The process of rotation and firing was repeated seven times to complete a full 360-degree turn. Then, the handpiece was pulled back 8 mm, and rotation as well as firing were done 7 more times to complete another circle. The aforementioned process was repeated multiple times until the applicator was retracted to the introitus. Over the course of the following three days, it is recommended that patients abstain from engaging in any sexual activity. No drugs were administered to the patients following each treatment session.

The patients underwent two therapy sessions, spaced four weeks apart. Three months following the completion of the two sessions of therapy, patients were invited to fill out the ICIQ-SF questionnaire as part of a follow-up session, and a cough stress test was done. Subjective outcomes were also documented in the form of categories including cure, improvement, no change, and worse. Adverse occurrences were also documented and sorted into three groups: a) those that occurred while the laser probe was being applied, b) those that occurred soon afterwards, and c) those that occurred a few days later.

The statistical analysis was conducted using Megastat® in the newest version of Microsoft 365 for education, while the graphs were generated using R version 4.2.1. Numerical values are represented as mean as well as standard error (mean ± SE), while count as well as percentage (count (%)) was utilized to represent the categorical variable. If the parametric assumptions were fulfilled, the paired values were compared using the paired t test (Pt), and if not, the Wilcoxon signed-rank test (W) was employed. Fisher's test (F) was used by R version 4.2.1 to compare paired categorical variables. p-Values less than 0.05 are significant in all tests.

## Results

Tables 1 and 2 provide the demographic data for the patients who completed the follow-up for three months. The patients' mean age was 41 years (range: 25-58), the average number of deliveries was 2.6 (0–5), and the mean BMI was 32 (18-44). As presented in Table 2, most patients consume coffee on a daily basis (83.3%), with only 13.3% being smokers. All patients had a positive cough stress test before the laser therapy. The average ICIQ-UI SF was 8 ± 0.58 before treatment (range 3-12).

**Table 1. Demographic data of the study population. Data are set as mean ± standard error (SE)**

| Variable | Mean ± SE | (Min : Max) |
|---|---|---|
| Age (years) | 41 ± 1.82 | (25 : 58) |
| BMI | 32 ± 1.33 | (18 : 44) |
| Parity (number) | 2.6 ± 0.22 | (0 : 5) |

**Table 2. Baseline habitual characteristics of the study population. Data are set as count %**

| Variable | Categories | Count (%) |
|---|---|---|
| Caffeine (cups/day) | 0 | 5 (16.7%) |
| | 1-3 | 18 (60%) |
| | > 3 | 7 (23.3%) |
| Smoking | No | 26 (86.7%) |
| | Yes | 4 (13.3%) |


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Neither throughout the procedure nor throughout the 3-month follow-up did any major adverse events occur. Minor treatment-related adverse effects were categorized as follows: During application, a majority of the population (53.3%) did not experience any side effects, while the remaining individuals experienced mild discomfort (46.67%) (Table 3). Moreover, a significant majority of patients (93.3%) did not exhibit any adverse effects immediately after application; in contrast, a solitary patient (3.3%) reported experiencing vulval discomfort, while another patient (3.3%) reported minor pain. However, about half of the patients suffered from adverse effects during the first few days after application, with over one-third (36.7%) noting a change in vaginal discharge, two patients experiencing dysuria (6.67%), and one patient (3.3%) suffering from both change in vaginal discharge and dysuria. The rest of the patients (53.3%) did not suffer from any side effects (Table 3).

**Table 3. Adverse events during, immediately as well as a few days after the application of laser therapy. Data are given as count (%)**

| Adverse effect | | | | | |
|---|---|---|---|---|---|
| During application | | Immediate after application | | First few days after application | |
| None | 16 (53.3%) | None | 28 (93.3%) | None | 16 (53.3%) |
| Mild Discomfort | 14 (46.67%) | Vulval discomfort | 1 (3.3%) | Change in vaginal discharge | 11 (36.7%) |
| | | Mild pain | 1 (3.3%) | Dysuria | 2 (6.67%) |
| | | | | Change in vaginal discharge & dysuria | 1 (3.3%) |

The initial findings of our study indicate that a significant majority of patients, specifically over two-thirds, reported experiencing positive changes in their condition. A total of 23.3% of participants indicated that they no longer had incontinence, while 46.7% reported experiencing some level of improvement in their condition. Nevertheless, over 30% of the patients did not exhibit any improvement or deterioration, as presented in Table 4.

**Table 4. Improvement status of the patients**

| Improvement status | | | |
|---|---|---|---|
| Cure | Improved | Same | Worse |
| 7 (23.3%) | 14 (46.7%) | 9 (30%) | None |

The ICIQ-UI SF score, which measures bladder symptoms, decreased significantly from the initial assessment to the final assessment three months after treatment started. As revealed in Fig. 1, the average ICIQ-UI SF score significantly decreased from 8 ± 0.58 before treatment to 5.1 ± 0.79 after treatment (P-value less than 0.001). Seven patients had an ICIQ-UI SF score of 0 (a score of 0 means no escape of urine by the scoring system).

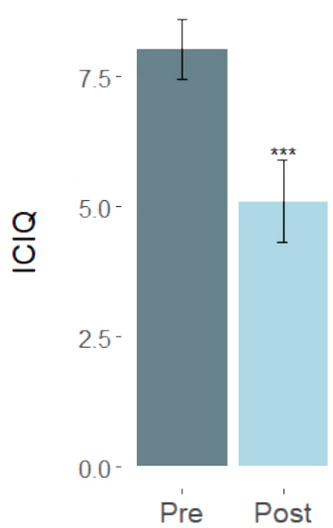


**Figure 1. Bar chart represents the mean of ICIQ scores pre and post to laser therapy where error bars represent standard error and (***) represents a highly significant difference among pre and post scores.**


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Moreover, as a response to the 2 laser sessions, about 26% of patients had a negative stress test. The results showed that this difference was significant. ($P < 0.001$) as shown in Table 5. Although further research is required to get randomized, controlled, prospective data with a larger sample size and longer follow-up duration, the present findings indicate that the $CO_2$ vaginal laser could potentially serve as a viable therapy option for individuals with mild to severe mixed UI.

**Table 5. Cough stress test. Data are set as mean ± standard error (SE)**

| Variable | Pre | Post | P-value |
|---|---|---|---|
| Stress test (-ve) | 0 (%) | 8 (26.7%) | 0.007 |

## Discussion

Vaginal $CO_2$ laser therapy for MUI was evaluated in this study pre and 3 months post-treatment. Seventy percent of patients showed improvement at the three-month follow-up, and half of those patients showed a full recovery with no incontinence at all. Three-month ICIQ-UI SF scores also showed statistically significant increases ($P < 0.001$). Similarly, the cough stress test was negative for about 26% of individuals three months after the second laser session.

For patients experiencing mixed urinary incontinence, the vaginal $CO_2$ laser was shown to be a safe therapeutic option with minimal and transient adverse effects (mainly enhanced vaginal secretion).

The results of our study align with previous research utilizing the Er:YAG laser, such as Blaganje et al.'s investigation. In their study, they observed that 21.4 percent (12 out of 56) of patients in the laser group experienced dryness three months after undergoing a single session of therapy utilizing the ICIQ UI SF (a score of 0 indicates no outflow of urine by the scoring system). In addition, Bizjak Ogrinc et al. discovered that two sessions were enough to eliminate incontinence for 60% of 175 women suffering from SUI or mixed incontinence. It's also comparable to a study conducted by Alcalay et al., in which 52 patients with SUI received three fractional - Pixel $CO_2$ laser treatments and had their outcomes evaluated at 3, 6, 12, and 24 months. Three, six, and 12 months revealed improvements of 75.0, 61.9, and 64.3 percent in PGII, respectively. From the beginning to 12 months, PFDI improved from 37.2 ± 3.89 to 16.1 ± 3.7, a statistically significant improvement ($P < 0.05$). Similarly, the long-term benefits of treating PFIQ were evident from the start of treatment to a year later [18, 19, 20].

The vaginal $CO_2$ laser, on the other hand, was shown to be less efficient by Dabaja et al., and its effects returned to baseline after 6 months [21].

Our results indicate that the vaginal $CO_2$ laser could be utilized as one of the conservative options for MUI and should be taken into account as a therapeutic alternative for MUI management.

The vaginal canal, containing both epithelium and lamina propria, is known to be affected by the vaginal $CO_2$ laser. The laser's biostimulating as well as biothermal actions may give insight into how it enhances mixed UI symptoms. Several vaginal functions, such as secretion, absorption, flexibility, lubrication, in addition to vaginal epithelial thickness, are restored by laser biostimulation [22, 23], whereas the laser's photothermal impact penetrates the vaginal tissue 0.5 mm deep, leading to a 30% reduction in tissue volume. This leads to mechanical traction of the inner tissues which contributes further to the adjustment impacts – due to the production of elastin fibers and neocollagenesis – providing increases in vaginal epithelium thickness, flexibility, and wall hardness which may be related to the restoration of the urethral coaptation mechanisms involved in the pathophysiology of MUI [24].

To maintain the trophic impact of the laser on vaginal tissue in the long run, long-term impact treatments must be administered at regular intervals as it is well known that trophic changes in vaginal epithelium take time. González et al. found that an extra year of treatment each year could maintain clinical efficacy for three years [25].

A study conducted by Athanasiou et al. revealed that the administration of more than three treatments can result in a more significant therapeutic advantage compared to the use of only three treatments in menopausal women. On the other hand, Pitsouni et al. provided evidence supporting the recommendation of three treatment sessions in the majority of therapy protocols. Several studies have been deficient in long-term follow-up and control groups. However, a recent consensus study conducted by Alshiek et al. demonstrated that fractional laser treatment can lead to short-term improvement [26, 27, 28].

The limitations of the study were that there were many patients who didn't complete the study's follow-up, mostly because of issues with compliance, so our findings can't be generalized to other treatment alternatives. It also demonstrates the effect on mild to moderate degrees of MUI and lacks the effect on severe forms of MUI.

## Conclusion

Our study examines the effectiveness of vaginal $CO_2$ laser therapy for individuals with MUI, and our findings suggest that this treatment may be especially helpful for those with mild to moderate incontinence. This suggests that a simple, easy-to-apply management option exists, with minimal potential for side effects, for the management of mixed UI.

Adres do korespondencji / Corresponding author

**Amr Badawy**

E-mail: dr_amronabil@yahoo.com


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