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CLINICAL ARTICLE

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Efficacy of termoablative fractional CO_2 laser (Monnalisa Touch) in stress urinary incontinence

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Abstract

Purpose: Usually, in stress urinary incontinence (SUI), nonsurgical therapy such as pelvic floor muscle training (PFMT) and lifestyle changes are proposed before surgical treatment. Laser therapy has recently been recommended for the treatment of SUI, helping to reconstruct the collagen that supports the vagina and the pelvic floor. The aim of the study was to evaluate the efficacy of SUI treatment with a CO_2 intravaginal laser in patients waiting for anti-incontinence surgery (TVT-O).

Methods: This is a prospective, case–control study. Fifty-two patients have been included in our study and we divided them into two groups: atrophy and no atrophy. We also adopted a control group retrospectively identified from our database of patients undergoing PFMT. The subjective estimation of SUI symptoms before and after treatment was evaluated using the Visual Analog Scale before and after 1, 6, and 12 months of treatment. The objective evaluation with the urodynamic study with the stress test and a 3-day voiding diary to count the number of episodes of incontinence, before and after treatment.

Results: The intravaginal CO_2 laser improved all the parameters considered for SUI in both groups. Its results were more relevant in the atrophy group, in comparison to the no atrophy group, even if they were both statistically significant. There were no statistically significant differences for all the parameters evaluated for SUI between laser treatment and PFMT in the control group.

Conclusion: The CO_2 laser is well-tolerated, minimally invasive, safe, and showing efficacy for SUI. More studies are needed to consider it as first-instance therapy, like PFMT, or at least, as a bridge therapy to surgery.

KEYWORDS

atrophy, CO_2 laser, Monnalisa Touch, stress urinary incontinence

1 | INTRODUCTION

Urinary incontinence is a common condition, although often underreported. In the United States, approximately 20 million women experience urinary incontinence during their lives. Additionally, up to 77% of women in nursing homes may have urinary incontinence. Despite such prevalence, only 25% of people affected by incontinence receive treatment.[1] Stress urinary incontinence (SUI) affects almost half of all women with urinary incontinence and it has a negative impact on their quality of life.[2] Typically, the first step of care consists of conservative treatments (e.g., pelvic floor muscle training) and lifestyle changes. Nonsurgical therapy is usually suggested before surgical treatment. The International Continence Society first recommends nonsurgical treatment and then surgical treatment for those who failed or refused nonsurgical treatment. There are many different types of conservative therapies to treat SUI; however, none are consistently more effective than pelvic floor muscle training (PFMT).[2] Women with the persistence of SUI symptoms despite conservative measures may be candidates for surgery.

Many different approaches are being evaluated for the treatment of SUI. In recent years, laser therapy has been proposed in the international literature to treat vaginal atrophy, genitourinary syndrome of menopause (GSM), and SUI.[3–8] The rationale behind this form of treatment is based on collagen reconstruction, which provides vaginal support to structures of the pelvic floor. In the literature, there are not many studies on this topic and most of them are retrospective, observational, while just a few are prospective and observational. To our knowledge, this is the first prospective study having a comparative control group that evaluates the efficacy of CO_2 laser in patients who have SUI with or without vaginal atrophy. The primary endpoints are the objective and subjective assessment of the improvements in SUI, the comparison between the CO_2 laser and the PFMT of the control group, and the safety of treatment.

2 | MATERIALS AND METHODS

This is a prospective case–control study that evaluates the efficacy of the CO_2 intravaginal laser in patients with SUI. This study was conducted in accordance with the Good Clinical Practice regulatory standards and the Declaration of Helsinki (1996) and was approved by the Institutional Review Board. Patients with SUI patients who were waiting for antiincontinence surgery (in our institute TVT-O is the chosen antiincontinence intervention) were evaluated to be enrolled in the CO_2-laser group. The selection of patients for the study followed inclusion and exclusion criteria.

Inclusion criteria were: age > 18 years, presence of involuntary loss of urine due to events that put pressure on the bladder (coughing, laughing, sneezing, running, heavy lifting) or mixed urinary incontinence (stress and urgency), patients with SUI with a positive stress test, body mass index (BMI) < 26, any previous vaginal laser treatments (at least 4 sessions), any previous urogynecological surgery.

Exclusion criteria were age less than 18 years or older than 75 years, BMI ≥ 26, previous urogynecological surgery, pregnancy, symptomatic genital or urinary infections, hematuria, presence of abscess, fistula, or any anatomical abnormality that could interfere with treatment, use of local therapy 15 days before enrollment, stage of prolapse greater than 2 according to the Pelvic Organ Prolapse Quantification System (Baden–Walker grading system), stenosis, trauma or necrosis of the urethra; alcohol or drug addictions, intolerance to laser treatment, previous urogynecological surgery, lichen, vulvar dystrophic diseases, active carcinoma, any contraindications for laser treatment (patients with recurrent urinary tract infections, genital herpes infection or STD and/or severe systemic disease).

After the evaluation of the inclusion and exclusion criteria, all patients were asked to sign a consent. Fifty-two patients have been included in our study. Then we divided our results into two groups: atrophy and no atrophy. We also adopted a control group (retrospectively identified from our database of patients undergoing PFMT). All patients in the group of "atrophy" and "no atrophy" underwent four CO_2 laser sessions (one treatment every 4 weeks).

During the laser procedure, a microablative fractional CO_2 laser system (SmartXide2V2LR, Deka m.e.l.a.) was used with a vulvovaginal laser reshaping (V2LR) scanning system and appropriate handpieces for the vaginal area. Patients were treated with a 360° vaginal probe to cover all sides of the vaginal wall. Our group, according to the bioengineer, has proposed, for all enrolled patients, a protocol with power 40 W, scan time 1000 ms, spacing 1000 mm, and smart stack (tissue penetration) 1 (this is the same protocol used for vaginal atrophy). Each patient was retreated throughout the anterior wall of the vagina with a 90° vaginal probe to reinforce the effect of treatment on the periurethral tissue with the same protocol as before but used a greater penetration with smart stack 2 in order to have a deeper effect on the tissue in the anterior vaginal wall. Every pulse consisted of constant high-energy peak power to produce rapid microablation of the epithelial component of the mucosa followed by longer emission times that

allow the CO_2 laser to penetrate further into the mucosa. The pulses were distributed over the vaginal wall and spaced (DOT spacing) to cover the entire treatment area. To completely treat the vaginal area, many laser spots were emitted while progressively removing the handpiece from the vaginal fundus followed by another treatment of the anterior vaginal wall as described. During all treatment sessions, the following two-phase protocol was followed; initial positioning of the speculum and observation of the vagina, and then careful introduction of the handpiece deep into the vaginal canal before starting the procedure. Each session took 6 min on average. Local therapy was not recommended during and after vaginal laser sessions.

A control group with the same characteristic as the experimental group was retrospectively identified from our database. This control group included all patients who underwent four sessions of PFMT. We have objectively and subjectively evaluated the improvements of SUI. The objective evaluation was carried out with a urodynamic study that evaluated the stress test and the 3-day voiding diary to count the number of episodes of incontinence. The subjective evaluation of symptoms has been performed using a Visual Analog Scale (VAS) before, after 1 month of treatment, and after 6 months. After 12 months, we again submitted the VAS scale to evaluate the long-term efficacy. We defined the treatment as successful when it reported an improvement in VAS of at least 3 points. Statistical analysis was performed using Student's *t*-test and the Wilcoxon rank-sum test for parametric and nonparametric continuous variables, respectively, and the χ^2 test or Fisher's test, where appropriate, for categorical variables. A $p < 0.05$ is considered statistically significant. The number of patients required for the study was calculated on the basis of 95% power to detect a significant difference at a 5% significant level; based on data from previous studies, the minimum number of patients to reach statistical significance for each group was 20 patients for subjective evaluation and 12 patients for objective evaluation.

3 | RESULTS

From January 2016 to November 2019, we evaluated for surgery 95 patients with SUI or Urge + SUI. Forty-three patients were excluded due to the inclusion criteria. Fifty-two patients were included in our study. All of those patients were eligible to use the CO_2 laser before surgical treatments. Thirty of these patients (56%) were affected by vaginal atrophy, 22 (44%) were affected by urinary incontinence without atrophy, 20 patients (38%) had SUI + Urge, and 32 (62%) just SUI. Then we divided our results into two groups: atrophy and no atrophy. We collected a retrospective control group treated with PFMT.

We gathered the data of the 2 groups in the pre- and posttreatment. We first compared the group "atrophy" versus "no atrophy" and then all treated patients versus the control group (Figure 1).

In the "atrophy" group, the results were the following (Table 1). Regarding the VAS scale, the mean values were 7.67 before laser treatment, 1.63 after 1 month of treatment (6.04 points of difference, $p < 0.001$), and 1.63 after 6 months of treatment (difference 6.04, $p < 0.001$). After 12 months of treatment, the mean VAS value was 2.17 ($p < 0.001$). The 3-day diary had a mean number of urinary incontinence episodes of 14.77 before laser treatment and 2.63, 12 months after the last laser treatment ($p < 0.0001$, extremely significant). The stress test was positive in 30 patients (100%) before treatment and only 19 (63.33%) patients ($p < 0.0003$, extremely significant) after treatment. Only 12 patients underwent surgery (40%) due to subjective persistence of symptoms after treatment. The mean number of laser sessions was 4. Any complication was reported in this group.

In the "no atrophy" group, the results were the following (Table 2). The mean values of the VAS scale were 8.23 before laser treatment, 3.64 after 1 month of treatment (4.59 points of difference, $p < 0.001$), and 3.41 after 6 months of treatment (difference 4.82, $p < 0.001$). After 12 months of treatment, the mean VAS value was 3.77 ($p < 0.001$). The 3-day diary had a mean number of urinary incontinence episodes of 17.86 before laser treatment and 6.95 after laser treatment ($p < 0.0001$, extremely significant). The stress test was positive in 22 patients (100%) before treatment and only 15 patients (68.18%) patients ($p < 0.0089$, very significant) after treatment. Only 10 patients underwent surgery (45.5%), due to subjective persistence of symptoms after treatment. The mean number of laser sessions was 4. Any complication was reported in this group.

When comparing the "atrophy" group with the "no atrophy" group, the results were the following (Table 3). The mean value of the VAS scale before treatment in the atrophy group was 7.67 and in the no atrophy group 8.23 ($p = 0.1308$, not significant). After 1 month in the atrophy group, the mean value was 1.63 and in the no atrophy group 3.63 ($p = 0.0002$, extremely significant). After 6 months in the atrophy group, the mean value was 1.63 and in the no atrophy group it was 3.41 ($p = 0.0013$, very significant). After 12 months in the atrophy group, the mean value was 2.17 and in the no atrophy group 3.77 ($p = 0.0057$, very significant). Regarding the 3-day diary, the average number of incontinence episodes was 14.77 in the atrophy group and 17.86 in the no-atrophy group ($p = 0.0016$, very significant)

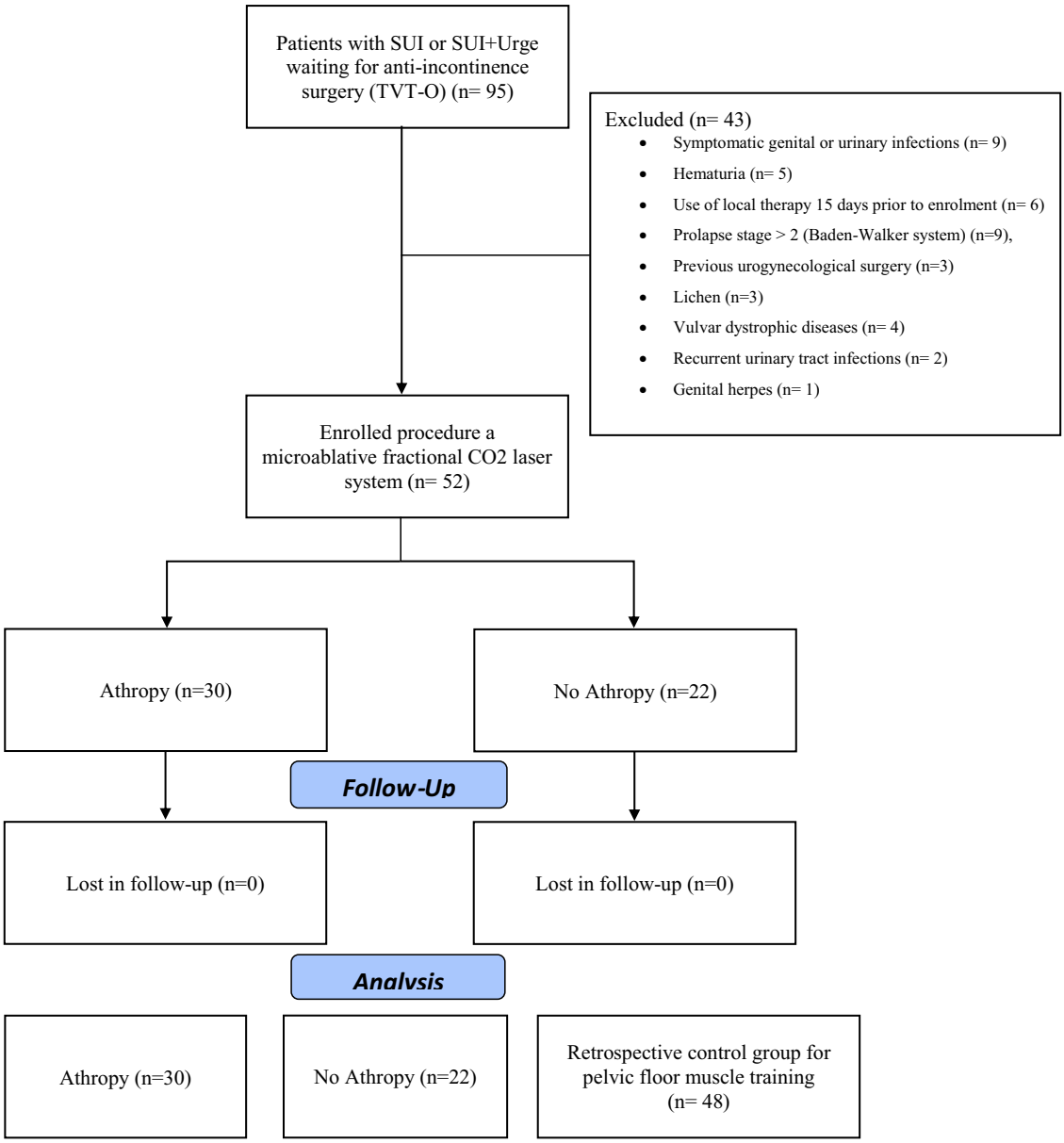

FIGURE 1 Study flow chart

TABLE 1 Results in the "atrophy" group

Comparison			Mean difference	*p* Value
VAS pre versus VAS 1 month, mean (±SD)	7.67 ± 1.24	1.63 ± 1.45	6.03	<0.001
VAS pre versus VAS 6 months, mean (±SD)	7.67 ± 1.24	1.63 ± 1.38	6.03	<0.001
VAS pre versus VAS 12 months, mean (±SD)	7.67 ± 1.24	2.17 ± 1.66	5.50	<0.001
VAS 1-month versus VAS 6 months, mean (±SD)	1.63 ± 1.45	1.63 ± 1.38	0.00	>0.05
VAS 1-month versus VAS 12 months, mean (±SD)	1.63 ± 1.45	2.17 ± 1.66	−0.53	>0.05
VAS 6 months versus VAS 12 months, mean (±SD)	1.63 ± 1.38	2.17 ± 1.66	−0.53	>0.05

before laser treatments. Twelve months after treatment, the average number of incontinence episodes was 2.63 in the atrophy group and 6.95 in the non-atrophy group ($p = 0.0002$, extremely significant).

In the control group 46 patients were enrolled, each patient was submitted to four PFMR sessions and 24 underwent surgery. We evaluated the VAS scale before the first PFMT session (medium value: 7.89), after 1 month (medium value: 2.91), after 6 months (medium value: 2.85), and after 12 months (medium value 3.2). The 3-day diary had a mean number of urinary incontinence episodes of 16.5 before treatment and 5.2 after PFMT. All patients had a positive stress test before rehabilitation sessions, while, after treatment, only 29 patients remained with a positive stress test. No complications were reported after treatments. More than 52 patients, only 22 (42.3%) were submitted to surgery for subjective persistence of symptoms after treatment.

Comparing all patients in the "atrophy" group + the "no atrophy" group versus the control group (Table 4) was not obtained statistically significant results for the VAS scale and the 3-day diary. The mean value of the VAS scale before laser treatment compared to the control group was not significant after treatment at 1 month ($p = 0.36$), 6 months ($p = 0.28$), and 12 months ($p = 0.42$). The same result for the 3-day diary, comparing the average number of incontinence episodes between laser-treated patients and the control group, was not significant ($p = 0.41$). No complications were reported after treatment in both groups.

4 | DISCUSSION

SUI is the most common type of urinary incontinence.[9–12] The midurethral sling is the most extensively studied anti-incontinence operation, with documented short-term

TABLE 2 Results in the "no atrophy" group.

Comparison			Mean difference	*p* Value
VAS pre versus VAS 1 month, mean (±SD)	8.23 ± 1.38	3.63 ± 2.15	4.60	<0.001
VAS pre versus VAS 6 months, mean (±SD)	8.23 ± 1.38	3.41 ± 2.36	4.82	<0.001
VAS pre versus VAS 12 months, mean (±SD)	8.23 ± 1.38	3.77 ± 2.35	4.46	<0.001
VAS 1-month versus VAS 6 months, mean (±SD)	3.63 ± 2.15	3.41 ± 2.36	0.23	>0.05
VAS 1-month versus VAS 12 months, mean (±SD)	3.63 ± 2.15	3.77 ± 2.35	−0.14	>0.05
VAS 6 months versus VAS 12 months, mean (±SD)	3.41 ± 2.36	3.77 ± 2.35	−0.36	>0.05

TABLE 3 Comparing all the patients from the "atrophy" group versus "no-atrophy" group after treatment

	Atrophy ($n = 30$)	No atrophy ($n = 22$)	*p* Value
VAS 1-month, mean (±SD)	1.63 ± 1.45	3.63 ± 2.15	0.0002
VAS 6-months, mean (±SD)	1.63 ± 1.38	3.41 ± 2.36	0.0013
VAS 12-months, mean (±SD)	2.17 ± 1.66	3.77 ± 2.35	0.0057
Three-day diary, mean (±SD)	2.63 ± 2.09	6.95 ± 5.26	0.0002
Positive stress test, *n* (%)	19 (63)	15 (68)	0.78

TABLE 4 Comparing all the patients from the "atrophy" group + the "no atrophy" group versus the control group after treatment.

	Atrophy + no atrophy ($n = 52$)	Control group ($n = 48$)	*p* Value
VAS 1-month, mean (±SD)	2.48 ± 2.02	2.91 ± 2.56	0.36
VAS 6 months, mean (±SD)	2.38 ± 2.04	2.84 ± 2.15	0.28
VAS 12 months, mean (±SD)	2.85 ± 2.12	3.20 ± 2.10	0.42
3-day diary, mean (±SD)	4.46 ± 4.30	5.20 ± 4.44	0.41
Positive stress test, *n* (%)	34 (65)	29 (56)	0.85

efficacy (62%–98%) and long-term efficacy (>5 years: 43%–92%). Complication rates are low and synthetic mesh erosion occurs in less than 5% of patients.[13]

Classically, the CO_2 laser is used in the treatment of vulvo-vaginal atrophy and genitourinary syndrome (GSM) associated with menopause. This study is the first to evaluate the efficacy of CO_2 laser in patients with SUI and no vaginal atrophy and is the first study with a comparative control group studying the effects of CO_2 laser compared to other techniques.

In this study, the efficacy of the fractional CO_2 laser is evaluated, which emerged as an efficient, well-tolerated, and safe procedure for the treatment of GSM, to find an effective noninvasive treatment alternative for the treatment of SUI.

The lasers used in SUI treatment emit thermal energy at 10.600 nm for the CO_2 laser and spread to a depth of 50–125 μm in the vaginal tissue inducing changes related to increased tissue tropism such as collagen retraction, neocollagenesis, blastogenesis, enhanced density of connective particles, and neovascularization.[3,14] Laser therapy results in controlled heating (60–70°C) of the underlying mucosal layers, without burning the mucosa; this way, the collagen fibrils are shortened, but without denaturation.[14] The available data indicate that this effect lasts due to collagen remodeling and neocollagenesis, which can take up to 6 months to complete.[14]

The evaluation of the effectiveness of the laser on SUI is known and documented in the literature. Two recent studies by different authors report subjective data. The first is a prospective cohort study conducted by Behnia-Willison et al. and involving 54 individuals evaluating SUI symptoms with the Australian Pelvic Floor Questionnaire before and after laser treatment with a follow-up at 3, 12, and 24 months. Of these patients, 82% reported an improvement in SUI symptoms at the end of treatment, with their score resulting between mild SUI to no SUI result ($p \leq 0.01$) and 71% of participants reported persistent improvement in SUI symptoms at 12–24 months ($p < 0.01$).[4] The second study conducted by Nalewczynska et al. is a prospective open-label study with a cohort of 59 women, treated with a CO_2 laser every 4–6 weeks for a total of three treatments and follow-up at 3, 6, and 12 months. They report a statistically significant improvement of the subjective index at the third treatment, 6 and 12 months follow-up ($p < 0.001$).[5]

This study agrees with recent studies in the literature on subjective improvement reported by patients after laser treatment, although it is not possible to make a direct comparison due to the different methods used in the studies. Another difference to highlight between our and other studies is that the improvement is reported only with subjective questionnaires and not an objective evaluation. Additionally, the presence of atrophy in patients is not specified or not.

The other two studies reported objective assessments, and the data reported by these two studies show improvement results comparable to ours. Nalewczynska et al. performed an objective evaluation with a 1-h pad test and reported a gradual improvement of SUI symptoms. The weight of the pad was reduced at the third treatment with stabilization at 12 months of follow-up.[5] Another multicenter, prospective, open-label cohort study conducted by Alcalay et al. studied 52 patients with SUI, treated with CO_2 laser with a follow-up at 6 and 12 months. This study reported a significant reduction in the 1-hour pad test from baseline to 12 months of follow-up and for the 3-day diary a significant reduction only after the third treatment ($p < 0.05$), but the result of the 3-day diary did not reach significant levels at 6 and 12 months.[6] This result obtained by Alcalay et al., while statistically significant, is worse than our 3-day diary result. Alcalay et al. performed a urodynamic evaluation, as in our study, and at 6 months showed that 41.4% of the patients did not have stress incontinence[6]; this value is consistent with the results of our study with a rate resolution of stress incontinence of 42% and 47%, respectively, in the "no atrophy" and "atrophy". The improvement was statistically significant, maintained throughout the treatment period and persisted after 12 months according to our study. The previously cited studies did not have a control group and the presence of atrophy was not specified in the patients.

Regarding other additional maintenance treatments, the CO_2 laser should be considered in the 6–12 month posttreatment period to maintain the beneficial effects.[5]

All CO_2 laser studies, including this, did not report serious adverse events, despite FDA warnings on the use of energy-based devices to perform vaginal rejuvenation, cosmetic vaginal procedures, or nonsurgical vaginal procedures to treat symptoms related to menopause, urinary incontinence, or sexual function.[4–7,15]

In addition, a greater improvement was observed in women over 55 years of age compared to women under 55 years of age, possibly attributed to the predominance of vaginal atrophy in older women. Data from our study also demonstrate efficacy in the group without atrophy at 6 and 12 months ($p < 0.001$). Recent published prospective studies agree with ours on the efficacy and safety of SUI treatment, which shows more benefits in older women with vaginal atrophy but may also be helpful in non-vaginal atrophy.[8] The CO_2 laser procedure is equally successful in SUI and SUI + Urge with predominant SUI. In women with SUI, the presence of vaginal atrophy can

best predict the success of CO_2 laser therapy.[4] Therefore, the ideal candidates for CO_2 laser therapy appear to be older women with vaginal atrophy. This conclusion does not agree with those reported by other authors, who said that the best results should be expected, after laser treatment of SUI, in women younger than 47.5 years of age.

By comparing our efficacy results from laser treatment with the data obtained from studies in the literature on PFMT, we can observe a comparable benefit. In fact, we can see how the PFMT reported in the study by Serati et al.[16] showed statistically significant results after 3 months of treatment, from a subjective point of view, with a reduction in the scores of the International Consultation on the Short Form Incontinence Questionnaire ($p = 0.01$).

In general, laser therapy emerges as a useful, minimally invasive approach for the treatment of SUI. The results of our study assert that four laser applications, scheduled at monthly intervals, provided a beneficial effect right after 1 month of the first session, which lasted 12 months as a minimum. The beneficial effect of laser treatment in women without vaginal atrophy was weaker at 12 months of follow-up than in patients with vaginal atrophy.

The strengths of this study are the evaluation of efficacy in a prospective and nonobservational way, and to evaluate its efficacy not only in the population with atrophy, classically treated with laser, but also in that without atrophy. A further strength is the evaluation of the effectiveness of the laser treatment both from an objective point of view and from a subjective point of view and further compared with a retrospective PFMT group. Regarding the weaknesses of the study conducted, selection bias is not a randomized study and is not compared to another treatment prospectively. Other factors limiting the study are the use of the VAS scale, which is not a validated questionnaire, the limited number of patients in the groups (despite being adequate for simple size), and the study was also conducted in a single center.

5 | CONCLUSION

Based on this study and according to the literature, microablative fractional CO_2 laser therapy emerges as a well-tolerated treatment, minimally invasive compared to surgery and with few complications, showing efficacy for SUI. Fractional CO_2 laser therapy, having a trophic and regenerative effect on both the lower urinary tract tissue and the vulvo-vaginal region, could be considered an alternative treatment for women with SUI, not necessarily associated with vaginal atrophy. Despite this, postmenopausal patients with associated SUI and vaginal atrophy respond better to fractional CO_2 laser therapy. To conclude, laser therapy could be considered in the future as first-degree therapy, like PFMT, or at least as a bridge to surgery. More randomized trials are needed to confirm the data obtained.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation. The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

Approval was granted by the IRB of University "Campus Bio-Medico" of Rome. This study was performed in line with the principles of the Declaration of Helsinki. The patients/participants provided their written informed consent to participate in this study.

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