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The CO_2 ablative laser treatment in perimenopausal patients with vulvovaginal atrophy

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ABSTRACT

Objectives: The aim of the study was to evaluate the effectiveness of CO_2 fractional laser therapy on perimenopausal urogenital symptoms.

Material and methods: This prospective, open-label study included 205 patients who received three CO_2 laser treatments. Clinical assessment was checked at baseline as well as at six weeks and 12 months post-treatment. The following scores were measured Vaginal Health Index Score (VHIS), International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) and assessment of the severity of selected urogenital symptoms.

Results: Significant improvements in dryness, dyspareunia, burning, vaginal laxity, urinary incontinence, as were the results on the VHIS and ICIQ-UI SF at six weeks post-treatment ($p < 0.05$ for all scores), which were maintained through the follow-up visit at 12 months. No complications were observed either during or after laser therapy.

Conclusions: CO_2 ablative laser treatment can be effective in reducing vulvovaginal atrophy symptoms such as vaginal laxity, dryness, painful sexual intercourse, burning, and decreases the severity of stress urinary incontinence and urge incontinence symptoms. Positive results were maintained at 12 months after the laser treatment.

Key words: vulvovaginal atrophy; fractional CO_2 laser therapy; perimenopausal period

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INTRODUCTION

Vulvovaginal atrophy (VVA) occurs in over 50% of perimenopausal females, starting as soon as at the age of 40 [1]. Changes in the urogenital female system are related to decreasing levels of estrogen in the serum. Due to the decreased concentration of collagen and elastin, the quality of the connective tissue during perimenopause is worsening. Additionally, due to the thinning of the epithelium and reduced number of vessels, active connective tissue cells, and fibroblasts, decreased tissue elasticity and pH changes occur, which consequently make the vulvovaginal area more prone to infections and mechanical injury [2].

The most frequent symptom reported by patients is dryness of vagina, which relates to burning, itching, dyspareunia and urinary incontinence (UI) [3–5]. Urogynecological pathology is noted in around 40% of patients between 40–60 years old and progressing with age, reaching over 75% of patients over 75 years of age [6].

Depending on the initial factor causing UI, we can identify different variants of the pathology. Two of the most frequent are stress urinary incontinence (SUI) and urge incontinence. The first one has its pathology in the pelvic floor and lower segment of the vagina. It is usually recognized as an increased weakening of the vaginal wall and often lowering of the musculofibrous 'hammock' (which normally supports the optimal position of the urethra). Both pathologies can result from previous vaginal deliveries. The overactive bladder (urge incontinence) is often associated with overactivity of the detrusor urinae muscle and is characterized by a triad of symptoms: urgency, urinary frequency and nocturia [7, 8].

There are multiple approaches to treating UI, from lifestyle changes to pelvic floor muscle training, electromagnetic stimulus training and various pharmacological treatments [9]. In the end, there is always an option for surgery; multiple surgical treatment methods for stress urinary incontinence have been described. The multiplicity of surgical techniques itself proves there is no one perfect, universal treatment method. The complication rate of the surgical approach is relatively high [10].

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Because of this, the pursuit of new UI treatment approaches that would improve our patients' quality of life would seem to be the best research direction.

Good methods should be as minimally invasive as possible with simultaneous noticeable and subjective effectiveness, *i.e.*, noted by the patients themselves and not only by the doctors performing the various procedures. One novel method which seems to meet those criteria is the microablative CO_2 laser treatment for VVA and its accompanying symptoms.

There are many works showing the regenerative value of the CO_2 laser in dermatological [1, 12] and gynecological area [13].

Laser light wave triggers the fibroblast activation process, therefore promoting new collagen and elastin fiber formation, extracellular matrix regeneration and vascular proliferation. The special formation of the laser pulse can penetrate the vaginal mucosa, regenerate collagen structures, rejuvenate connective tissue what can be manifested by increased flexibility and elasticity [14, 15].

Objectives

The aim of the work is to evaluate the CO_2 ablative laser treatment in perimenopausal urogenital symptoms.

MATERIAL AND METHODS

The inclusion criteria included: 45 years of age or older with at least one of the symptoms reported by the patient in the time of medical visit and confirmed later by a doctor during examination: itching, dryness, burning, urinary incontinence and dyspareunia. In the initial appointment we have assessed also vaginal diameter and the prolapse of the vaginal wall.

The exclusion criteria included: POP-Q greater or equal than two, BMI more than 35, irregular Pap smear results, active infection in the vagina and/or perineum, abnormalities in reproductive organs discovered during gynecological examination (*i.e.*, changes in the endometrium, ovarian pathologies, *etc.*), a history of vaginal operations, neurological problems, past diagnosis of neuropathy, usage of photo-allergic-inducing medications, psychotics, hormonal therapy — estrogens — either general or local, lubricants and urological medications (up to 30 days before the procedure).

Before the first qualification visit the questionnaire including the patient's medical history with obstetrics, previous surgeries and used medications was filled in by the patient. Before each meeting, the patient had to fill in a symptom assessment form presented as a 10-point visual analog scale (VAS) with 0 as "no symptom occurrence" and 10 as "maximal discomfort," evaluated based on the presence of every symptom.

All the patients have been thoroughly examined before determining their qualification for the CO_2 laser treatment. Each examination consisted of:

- colposcopy with the 5-parameter Vaginal Health Index Score (VHIS) assessment (elasticity, fluid volume, pH, epithelial integrity, moisture) to determine the vaginal atrophy stage)
- vaginal culture swab
- Pap smear
- bimanual gynecological examination
- POP-Q scale assessment of the prolapse.
- transvaginal ultrasound

The severity and type of urine incontinence was checked based on the patient's history and International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF).

We have performed three CO_2 laser procedures in each patient, in 4-6 weeks apart, using the SmartXide 2V2LR microablative fractional CO_2 laser system (MonaLisa Touch; Deka, Florence, Italy). We set check-up visits for six weeks and 12 months after the last procedure.

In all the patients whose priority complaint was related to urinary incontinence, the first step of the procedure was performed with a 90-degree probe. After one round of this laser treatment, a 360-degree probe was used. Patients who were not complaining of UI were treated only with the 360-degree laser microablation procedure. The parameters of the laser microablation were set individually according to the vaginal atrophy stage, patient age and effects of the previous laser treatment. Patients did not receive any anesthesia prior to the procedure. The manual adjustment of the probe and insertion technique depended on the severity of the vaginal prolapse.

The effects of the procedure were assessed using a 10-stage VAS scale. Additionally, to quantify the results, there was an ICIQ-UI SF questionnaire given to every patient before each visit and a gynecological examination performed each time.

We gave the information for every patient about the technique, all the steps of the examination and potential complications. Each patient had to sign informed consent to participate in the study prior to the procedure. The study was approved by the Commission of Bioethics at Wroclaw Medical University, Poland and conducted in accordance with the Declaration of Helsinki.

Data were statistically analyzed with the R Project for Statistical Computing v. 3.4.1. The Kolmogorov-Smirnov test was used to test for normal distribution; none of the tested parameters had a normal distribution (for all variables $p < 0.001$). We compared the groups using the nonparametric Kruskal-Wallis rank sum test with the Tukey post-hoc comparison. Correlations were described with Spearman's

Table 1. Demographic characteristics of the study group

Variable	Descriptive characteristics
Age; mean (SD)	58.45 (8.73)
Birth weight; mean (SD)	3505 (916)
Parity; n (%)	0–17 (8.3%) 1–71 (34.6%) 2–91 (44.4%) 3–21 (10.2%) 4–4 (2.0%) 6–1 (0.5%)
Prior vaginal deliveries; n (%)	0–35 (17.1%) 1–67 (32.7%) 2–80 (39.0%) 3–18 (8.8%) 4–4 (2.0%) 6–1 (0.5%)
Prior Cesarean sections; n (%)	0–172 (86.4%) 1–19 (9.5%) 2–6 (3.0%) 9–2 (1.0%) 6–missing

SD — standard deviation

rank correlation coefficient. A p value of < 0.05 was considered statistically significant.

RESULTS

A total of 205 patients were accepted into the study. The demographics of the tested group are shown in Table 1. The average age of the patients was 58.45 (8.73). A total of 44.4% of patients had two pregnancies and two deliveries. Another 82.9% of the patients had vaginal delivery; most had two natural deliveries. The average birth weight of the patients' newborns was 3505 g.

The changes in occurrence and severity of the symptoms noted by patients during subsequent visits are represented in Tables 2 and 3.

We have noticed a statistically significant improvement in all tested symptoms at both the six-weeks and 12-month observation window. Adequate improvement was observed via colposcopy (VHIS). At the 12-month observation, there was significantly greater improvement in all urinary incon-

Table 2. Comparison between occurrence and severity of symptoms noted by patients during subsequent visits

variable	baseline		6 weeks		12 months		K–W test	Post hoc comparison		
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)		0–3	3–12	0–12
ICIQ-UI SF	10.67 (6.44)	10 (6–16)	6.81 (5.97)	6 (2–10)	5.32 (5.48)	4 (0–8)	< 0.001	< 0.001	0.0117	< 0.001
urinary incontinence	4.67 (3.51)	5 (1–8)	2.96 (3.02)	2 (0–5)	2.09 (2.56)	1 (0–3.5)	< 0.001	< 0.001	0.0041	< 0.001
vesical tenesmus	2.73 (3.25)	1 (0–5)	1.56 (2.59)	0 (0–2)	1.26 (2.32)	0 (0–2)	< 0.001	< 0.001	0.274	< 0.001
VHIS	13.84 (7.53)	15 (5–21)	18.98 (5.75)	21 (15–25)	19.60 (5.66)	21 (15–25)	< 0.001	< 0.001	0.329	< 0.001
dryness	5.58 (3.77)	5 (2–10)	3.00 (2.88)	2 (0–5)	1.93 (2.47)	1 (0–3)	< 0.001	< 0.001	0.0005	< 0.001
vaginal diameter	4.18 (3.73)	5 (0–7)	2.62 (3.05)	2 (0–5)	2.04 (2.75)	0 (0–4)	< 0.001	< 0.001	0.0679	< 0.001
prolapse uteri	2.61 (3.67)	0 (0–5)	1.77 (2.97)	0 (0–3)	1.47 (2.85)	0 (0–1)	0.0033	0.0075	0.3452	0.0003
dyspareunia	1.96 (3.39)	0 (0–4)	0.83 (2.14)	0 (0–0)	0.42 (1.43)	0 (0–0)	< 0.001	< 0.001	0.0889	< 0.001
burning	1.28 (2.75)	0 (0–0)	0.49 (1.70)	0 (0–0)	0.31 (1.28)	0 (0–0)	< 0.001	< 0.001	0.346	< 0.001

SD — standard deviation; ICIQ–UI SF — International Consultation on Incontinence Questionnaire-Urinary Incontinence Short; VHIS — Vaginal Health Index Score; IQR — inetrqua trile range; K–W, — Kruskal-Wallis

Table 3. Changes in urogenital symptoms noted by patients between baseline and at 6 weeks post-treatment and between baseline and at 12 months post-treatment

variable	Δ baseline-6 weeks		Δ baseline-12mts	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
ICIQ-UI SF	3.86 (4.16)	4 (0–6)	5.35 (5.24)	4 (0–8)
urinary incontinence	1.73 (2.15)	1 (0–3)	2.58 (2.67)	2 (0–4)
vesical tenesmus	1.18 (2.26)	0 (0–2)	1.46 (2.81)	0 (0–3)
VHIS	–5.14 (5.32)	–4 (–10–0)	–5.76 (5.94)	–6 (–10–0)
dryness	2.59 (2.69)	2 (0–5)	3.72 (3.31)	4 (0–6)
vaginal diameter	1.55 (2.48)	0 (0–3)	2.13 (3.05)	1 (0–4)
prolapse uteri	0.84 (2.31)	0 (0–1)	1.14 (2.91)	0 (0–2)
dyspareunia	1.12 (2.73)	0 (0–0)	1.53 (3.19)	0 (0–2)

SD — standard deviation; ICIQ–UI SF — International Consultation on Incontinence Questionnaire-Urinary Incontinence Short; VHIS — Vaginal Health Index Score; IQR — inetrqua trile range

tinence symptoms compared to the improvement noted six-weeks after the last CO_2 laser treatment. Statistical significance was achieved on the VAS scale for UI and vaginal dryness. The greatest improvement on the VAS scale was seen in the vaginal dryness parameter: 3.72 (SD –3.31); the smallest was for vaginal prolapse (lowering of the vaginal walls), 1.14 (SD –2.91). Table 4 presents the correlations of overall improvement with age, gravidity, newborn birth weight, and prolapse stage.

In most of the checked parameters, we had no statistically significant correlation between improvement and patient age nor between improvement and number of deliveries, natural vs Caesarean deliveries, mean neonates weight and the grade of prolapse.

Table 4. Correlations between demographic and clinical parameters and improvement in urogenital symptoms

	Δ baseline-3 mts		Δ baseline-12 mts	
	Correlation coef.	**P value**	**Correlation coef.**	**p-value**
	Age			
ICIQ-UI SF	0.05465	0.4364	0.009694	0.8903
urinary incontinence	0.06841	0.3321	0.07602	0.2810
vesical tenesmus	–0.04636	0.5124	–0.04561	0.5192
VHIS	–0.145	0.0380	–0.2324	<0.001
dryness	0.1398	0.0456	0.2087	**0.0029**
vaginal diameter	0.05781	0.4103	0.03309	0.6393
dyspareunia	–0.1323	0.0586	–0.1152	0.1017
burning	–0.04435	0.5278	–0.07255	0.3036
	Parity			
ICIQ-UI SF	0.03833	0.5853	0.03977	0.5713
urinary incontinence	0.01279	0.8562	0.01111	0.8750
vesical tenesmus	0.05933	0.4016	0.03084	0.6631
VHIS	0.05993	0.3933	0.01651	0.8143
dryness	–0.05657	0.4205	0.0007353	0.9917
vaginal diameter	0.2171	**0.0018**	0.2135	**0.0022**
dyspareunia	–0.1077	0.1244	–0.1405	**0.0456**
burning	0.04189	0.5509	–0.0004221	0.9952
	Prior vaginal deliveries			
ICIQ-UI SF	0.04354	0.5354	0.04546	0.5175
urinary incontinence	0.04548	0.5194	0.03771	0.5932
vesical tenesmus	0.03221	0.6491	0.03476	0.6233
VHIS	0.0455	0.5171	0.01675	0.8116
dryness	–0.03837	0.5849	0.02027	0.7746
vaginal diameter	0.2186	**0.0016**	0.228	**0.0011**
dyspareunia	–0.122	0.0814	–0.1494	**0.0333**
burning	0.03486	0.6197	0.01791	0.7998
	Prior Cesarean sections			
ICIQ-UI SF	–0.07355	0.3019	–0.09268	0.1929
urinary incontinence	–0.09967	0.1635	–0.09935	0.1648
vesical tenesmus	0.002057	0.9772	–0.06482	0.3667
VHIS	0.02113	0.7671	–0.001501	0.9832
dryness	–0.03608	0.6129	–0.02275	0.7516
vaginal diameter	–0.0816	0.2519	–0.1076	0.1323
dyspareunia	0.04951	0.4874	0.04975	0.4876
burning	–0.02259	0.7514	–0.03582	0.6172

→

Table 4. cont. Correlations between demographic and clinical parameters and improvement in urogenital symptoms

	Δ baseline-3 mts		Δ baseline-12 mts	
	Correlation coef.	**P value**	**Correlation coef.**	**p-value**
	Age			
	Mean birth weight of newborns			
ICIQ-UI SF	0.1163	0.1138	0.07093	0.3360
Urinary incontinence	0.1242	0.0930	0.08219	0.2674
Vesical tenesmus	0.1193	0.1077	0.04724	0.5254
VHIS	–0.03219	0.6627	–0.01792	0.8082
Dryness	0.041	0.5785	–0.02463	0.7407
Vaginal diameter	0.06379	0.3870	0.02034	0.7840
Dyspareunia	–0.07619	0.3013	–0.08427	0.2554
Burning	–0.0883	0.2307	–0.1128	0.1275
	Baseline prolapse uteri stage			
ICIQ-UI SF	–0.05495	0.4339	–0.01939	0.7826
Urinary incontinence	–0.1068	0.1293	–0.04379	0.5350
Vesical tenesmus	0.06972	0.3241	0.1285	0.0684
VHIS	0.2056	**0.0031**	0.1314	0.0603
Dryness	–0.2029	**0.0035**	–0.02158	0.7605
Vaginal diameter	0.2014	**0.0038**	0.2122	**0.0024**
Dyspareunia	–0.02611	0.7102	–0.06993	0.3215
Burning	–0.06523	0.3527	–0.01376	0.8455

ICIQ–UI SF — International Consultation on Incontinence Questionnaire-Urinary Incontinence Short; VHIS — Vaginal Health Index Score

The older the patient, however, the greater the correction in vaginal dryness at the 12-month observation. With regards to vaginal diameter, the more natural deliveries the patient had, the better results (*i.e.*, the greater improvement) of the CO_2 laser procedure in this area. The least spectacular change in this group of patients (multiple natural deliveries in the past) is noted in the area of dyspareunia. The number of prior Caesarean sections and the weight of the newborn do not influence the improvement of any of the tested symptoms in a statistically significant way.

The improvement rate for urge incontinence and stress urinary incontinence had no statistical correlation with the stage of the prolapse.

No complications or negative outcomes were reported after the laser therapy. The treatment was well-tolerated by patients.

DISCUSSION

The first paper to test and verify the CO_2 microablative laser appliance in the treatment of vulvovaginal atrophy was published by Gaspar in 2011. By taking biopsies from the vaginal wall, he compared tissue remodeling processes after the use of CO_2 laser treatment with additional platelet-rich plasma injections to local estrogen therapy. The difference in the depth of the noted changes in the vaginal wall was more positive for the laser, which worked not only on the superficial layer as the estrogens did, but also on two of its deeper layers. In a clinical setting, he noticed a significant improvement in vaginal dryness, burning and dyspareunia [13]. In 2015, Salvatore confirmed the effectiveness of laser CO_2 in connective tissue remodeling in five patients operated on due to vaginal prolapse, noting no harm to the surrounding structures in histopathological testing [15]. Other authors reported similar results [16]. There have been multiple papers confirming the positive role of the CO_2 laser in the treatment of VVA symptoms. Most of the examined patients reported an improvement regarding dryness, burning, dyspareunia and dysuria after a series of three laser treatments performed in the course of 30 days to 12 weeks.

In all publications, the procedure has been described as safe and well-accepted by patients [14, 16, 17]. In one of the papers, an additional beneficial influence of the laser — the restoration of the vaginal microbiological balance — was reported. In 53 treated patients, the Lactobacillus count increased from 30 to 79% after a series of treatments. None of the treated patients developed bacterial vaginosis, candidiasis, or other vaginal infections [18].

CO_2 laser treatment has also been shown to be effective in patients who developed atrophic vestibulodynia. The improvement was noted in 70 patients four months after

the initial treatment, not only in the area of the urogenital symptoms related to the menopause itself, but mostly with permanent perineal pain [19].

New data is being released regarding the treatment of oncological patients for whom hormonal treatment methods are impossible due to their breast cancer diagnosis. Laser treatment seems to be an alternative solution and a safe and effective treatment method [20, 21].

In our study, like the ones mentioned above, we achieved a significant positive therapeutic effect on VVA as assessed using two scales: the VAS scale and the more objective VHIS. The therapeutic effect was maintained even a year after the initial treatment.

In a 2017 study conducted by Pieralli et al. [22], the therapeutic effect was proven to last as long as 24 months. Unfortunately, some patients started to notice the relief lessened after 18 months [22].

In our group of patients, we noticed a positive impact of VVA laser treatment on the relief of UI symptoms for both stress urinary incontinence and urge incontinence.

A similar impact of the CO_2 laser on UI treatment was presented in a study of 53 female patients of postmenopausal age complaining of not only dyspareunia, dryness, burning and itching, but also stress urinary incontinence and urge incontinence. The assessment of the severity of the symptoms was done with multiple scales: Urinary Incontinence Short Form (ICIQ-UI SF), the International Consultation on Incontinence Questionnaire of Female Urinary Tract Symptoms (ICIQ-FLUTS), King's Health Questionnaire (KHQ) and Urogenital Distress Inventory (UDI-6). The improvement in all reported symptoms, including stress and urge incontinence, was recorded four months after the first session. The authors did not examine the factors which contributed to the better response of laser treatment on urinary incontinence [23].

In our study, we checked the influence of the severity of vaginal prolapse on the positive results of the treatment. We found that the smaller the prolapse, the better response to the laser in the relief of stress urinary incontinence symptoms. However, this correlation was not statistically significant. We did not note a similar correlation regarding urge incontinence. With regards to other symptoms, we found a connection between the reduction in the diameter of the vagina three months after the initial treatment and a greater prolapse at the beginning. After 12 months, the biggest improvement in the vaginal width/diameter was found for patients with the greatest prolapse on the POP-Q scale.

It is important to monitor the long-term effectiveness of the laser treatment. In a study from 2017 involving 30 postmenopausal patients, the results of the initial laser treatment remained for up to a year after the first treatment, with regards to VVA symptoms. When checking UI symptoms, there has been a worsening of the therapeutic effect noted in a shorter time [24].

In our study, we decided to schedule a check-up appointment both three and 12 months after the initial treatment. We noted continued improvement in both types of UI among our patients. The improvement rate regarding SUI was greater (2.58) when compared to the improvement rate of urge incontinence (1.46).

Similar long-term positive CO_2 laser treatment results in the analysis of benign forms of SUI were presented by Gonzales et al., in a 2017 paper. The assessment was done using the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) and International Continence Society 1-hour pad test after 12, 24 and 36 months. The improvement in SUI was maintained after 36 months of observation. Additionally, positive histopathological changes of the periurethral vaginal mucosa were confirmed. The study did not include females over 65 years of age nor patients with urge incontinence [25].

In a study from 2017 conducted by Patel Falguni on 20 females aged 31–69 with a diagnosis of SUI, a three-month therapeutic effect was maintained and confirmed not only on a questionnaire but also via urodynamic testing with the increase of the maximum urethral closure pressure from 19–33 cm H_2O to 45–73 cm H_2O [26].

The study clearly presents that the improvement in SUI was achieved in a younger population of patients, as well, which may lead us to qualify younger females to CO_2 laser treatment, not only perimenopausal women.

In our study, we have also confirmed that the positive effect of the CO_2 laser on treating symptoms of atrophy and urinary incontinence does not depend in a statistically significant way on the age of the patient. The only symptom which was resolved with the highest success rate after laser treatment in the oldest patients (*i.e.*, was age-related) was the vaginal dryness at the 12-month observation.

At the end it is important to noticed that the latest works confirm the safety and efficiency of CO_2 laser treatment in genitourinary syndrome are randomized trials with good quality data [27–29].

CONCLUSIONS

Our study proves and helps to confirm previous, quite similar measurements, that the CO_2 laser treatment can decrease the severity of vulvovaginal atrophy with reported dryness, widening, burning, painful sexual intercourse, itching and mild prolapse. It can additionally treat some symptoms of stress urinary incontinence and urge incontinence. The results achieved with three subsequent laser treatments lasted for at least 12 months after the initial procedure. In our study, we tested which group of the treated patients benefited the most from the treatment. The improvement

in most fields occurs regardless of age, number of previous pregnancies, type of delivery, newborn birth weight or prolapse grade. Our results show that the success of the treatment with laser is reached due to established special technique and specialized approach. Each time after individual qualification we carefully set laser beam parameters. Low invasiveness of the procedure, no complications, side effects or patient discomfort make it a great choice for the next effective therapy of vulvovaginal atrophy and urinary incontinence.

Further studies should explore the long-term effectiveness of the laser beam on the vaginal wall, as well as the timeframe for which the improvement lasts, following a treatment series.

Conflict of interest

The authors declare no conflict of interest.

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