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Research Article

Evaluating the Effectiveness of Co2 Laser, Versus Radiofrequency Therapy for Genitourinary Syndrome of Menopause

Huda Mahmoud Alfatal
Ibnsina University for Medical and Pharmaceutical Sciences, Baghdad, Iraq

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Corresponding Author
Huda Mahmoud Alfatal,
Ibnsina University for Medical and Pharmaceutical Sciences, Baghdad, Iraq

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Abstract
Post menopause, estrogen deficiency results in vulvovaginal atrophy. Scientists and gynecologists regard the fractional CO2 laser as a disruptive technology because of its novelty and innovative potential to transform healthcare, and it may enhance feminine health. Radiofrequency employs electrical energy in the form of heat to ablate tissue, like fractional laser technology, resulting in minimal tissue damage and expedited recovery. monopolar radiofrequency previously modulated injury-induced inflammation and re-epithelialization. Evaluating the Efficacy of Fractional CO2 Laser Compared to Radiofrequency in the Management of Vulvovaginal Atrophy. This comparative study was conducted from June to October 2024 at the University of Baghdad Institute of Laser for Postgraduate Studies. Radiofrequency and fractional CO2 laser treatments were given to 20 women. Sexually active postmenopausal women aged 48–55 with two or more genito-urinary symptoms of menopause (GSM), vulvovaginal atrophy and over one year of amenorrhea were eligible. Genital neoplasms, active infections, previous genital cancer treatment, and stage II or higher organ prolapse were excluded. Before treatment, the Visual Analogue Scale was used to assess pain, and the Vaginal Health Index to assess vaginal symptoms. The Female Sexual Function Index(FSFI) was also assessed. Patients received four CO2 laser sessions at four-week intervals and radiofrequency treatments received four session lasted 25 minutes every 14–16 days.(2 weeks in average). The t-test showed no significant difference in VAS (visual analogue scores) between groups before treatment. Both groups' VAS scores decreased post-treatment, with no significant difference, as shown by the t-test's p-value greater than 0.05. The two groups VHI(Vahinal health index) ,did not differ statistically before treatment. The VHI showed a statistically significant difference between the two groups, with the CO2 laser group scoring higher (t-test p-value 0.017). FSFI scores, pre- and post-treatment did not differ between groups, as the t-test showed a p-value greater than 0.05. Both cohorts' FSFI scores improved after treatment. It can be concluded that both laser therapy and radiofrequency (RF) treatments are effective in alleviating symptoms of vaginal atrophy (VVA).

INTRODUCTION

Vulvovaginal atrophy (VVA), in literature, often named atrophic vaginitis, is a common disorder that is especially prevalent in postmenopausal women[1]. By new terminology, VVA is a component of a collection of various subjective symptoms and objective examination findings named genitourinary syndrome of menopause (GSM)[2]. GSM is an all-encompassing term that underlines the multitude of genital, sexual, and urinary symptoms associated with the collection of anatomical and functional changes in vulvovaginal tissues occurring with menopause and aging, mainly the aforementioned decrease in estrogen and other sex steroids[3].

Nearly half of women who have undergone menopause have vaginal discomfort that can be attributed to VVA[1,4,5]. Menopausal women with VVA experience symptoms such as vaginal dryness, itching, burning, irritation, discharge, or bleeding, as well as dyspareunia, with lack of lubrication, discomfort, or pain[6,7].

A significant number of postmenopausal women experience progressive and chronic VVA symptoms that greatly diminish their quality of life, which is particularly pronounced in sexually active women[8] When disclosing these symptoms to their physician, women are rather redundant, as only 25% of patients with symptoms of VVA seek medical attention[9].

Generally, women are poorly aware that VVA is a chronic condition with a significant impact on quality of life and mainly their sexual health[4,5]. Vaginal symptoms, whether minor or severe, negatively influence activities of daily living, as well as sexual activity[10] Maintaining sexual activity in older age is a crucial component of achieving effective aging, as numerous postmenopausal women continue to engage in sexual activity, particularly if they are in a stable relationship[11,12] The overall state of physical, psychological, and genital well-being has a considerable impact on several aspects of sexual responsiveness following menopause. Sexual function declines as individuals age, particularly in women experiencing menopause, with frequently reported symptoms such as lower libido and pain during intercourse (dyspareunia) affecting approximately half of postmenopausal women .

The treatment options currently available for this condition consist of vaginally administered hormones, such as estrogens and dehydroepiandrosterone (DHEA), as well as non-hormonal alternatives like lubricants and long-acting vaginal moisturizers.

Additionally, systemic hormone therapy and non-hormonal oral selective estrogen receptor modulators (SERM) such as Ospemifene can also be implemented(15) and have all received approval and recommendation by the "International Society for the Study of Vulvovaginal Disease"[16] as well as "The North American Menopause Society"[17]. However, such therapies have some problems that include contraindications, mainly in women with breast cancer[18] particularly when there is currently inadequate data to verify the safety of vaginal estrogens, DHEA, or SERMs in this specific population[17].

Low adherence to vaginal estrogens is commonly attributed to patient discontent with the use of the vaginal route, worries regarding the potential long-term effects of estrogen usage, and the high expense of medication[19]. Therefore, the implementation of a novel, efficient, and reliable treatment is paramount. The available results indicate that vaginal laser is highly effective and safe for treating symptoms and enhancing sexual function in people with VVA[15].

VVA Symptoms Questionnaire and Vaginal Health Index Score (VHIS). The severity of VVA symptoms (vaginal burning, vaginal itching, vaginal dryness and dyspareunia) was self-evaluated by study participants using a 10cm visual analogue scale (VAS), where the left extreme of the scale (number 1) indicated "absence of symptom" and the right (number 10) indicated "symptom as bad as it could be"[19].

Before treatment and 4 weeks after the third laser treatment, the condition of the vaginal mucosa was evaluated by using the Vaginal Health Index Score (VHIS), which consists of 5 characteristics of the vaginal wall: elasticity, fluid volume, pH, epithelial integrity, and moisture. The severity of each characteristic is evaluated based on the 5-point Likert scale, ranging from 1 to 5. The VHIS has a range of scores from 5 to 25, with a cut-off point below 15. A score below 15 suggests the presence of atrophic vaginitis[20].

Female Sexual Function Index (FSFI): Sexual function was evaluated before starting the first laser application and 4 weeks after the third treatment using the Female Sexual Function Index Questionnaire. The Female Sexual Function Index (FSFI) is a published instrument assessing six domains of sexual function in women: desire, arousal, lubrication, orgasm, satisfaction, and pain, as well as a total score for sexual functioning. This instrument has shown high reliability and psychometric (as well as clinical) validity in the assessment of key dimensions of female sexual function in clinical and nonclinical samples[21]. An FSFI cut-off score of 26 and scores below are classified as Female Sexual Dysfunction[22].

Radiofrequency harmless electrical energy as heat for tissue destruction, and its working mechanism resembles that of fractional laser. Its newest applications involve fractional energy emission, favoring targeted

areas with minimal tissue injury and fast recovery. Introducing a cooled tip mitigates surface thermal injury, allowing deeper induction lesions. Fractional monopolar radiofrequency has been previously shown to modulate the inflammatory response and re-epithelization following injury[23].

Some scientists and gynaecologists consider the fractional CO2 laser a disruptive technology because of its nobility and innovation, which aims to change the care status quo. It has been suggested that it brings feminine health close to the skin due to the emerging knowledge of laser interaction with tissue. The laser device can moisten the inside of the vagina via heat induction and thermal action, in addition to local ablation of the epithelium, stimulating regeneration and remodeling of new tissue in the deeper layers, modulating the response in benefit of regeneration, in the "no pain no gain" mechanism.

Laser treatment induces tissue remodeling, with histological evidence of the restoration of vaginal mucosa, a thickening of the epithelium, with the maturation of epithelial cells, a new formation of papillae indenting the epithelium with newly formed and extended small vessels. In addition, in the connective tissue underlying the epithelium, the formation of new thin fibrils and morphological features of fibroblasts supporting a renewal of the extracellular matrix with functional restoration[25,26] are generated.

Fractional CO2 laser was the first used to treat vaginal atrophy. According to the concept of fractional photothermolysis, these lasers ablate a fraction of the vaginal mucosa in the treatment area. An array of microscopic thermal wounds is created that ablates the vagina within very tiny zones; adjacent to these areas, the mucosa is spared and leads to natural healing process that builds new healthy tissue[33].

Reported in a short-term study that after CO2 laser treatment, vaginal symptoms and dyspareunia improved in postmenopausal women[34].

The microablative fractional CO2 laser effects on vaginal atrophy lead to an improvement of both sexual function and quality of life[13]. Other CO2 laser systems are marketed for the treatment of GSM, using different devices and different technologies, claiming the effects obtained using the abovementioned apparatus[26-40].

MATERIALS AND METHODS

This study involved a total of 20 postmenopausal females with VVA. 10 females were treated with CO2 laser, and the rest were treated with radiofrequency laser

A case sheet was prepared to record all the necessary information. Medical and surgical histories were taken from the patients with clinical examination for each patient as displayed in the attachment.

Case Sheet:

- Before and after radiofrequency
- Before and after radiofrequency

Clinical Assessment: All patients underwent clinical examinations before laser sessions and radiofrequncy session most patients returned for a follow-up regarding the session after four weeks in co2 laser and two weeks in radiofrequncy.

The Visual Analogue Scale (VAS), which measures the pain intensity of fissures, pruritis, dyspareunia, thining valvular, and tropism reduction, was used to conclude that the improvement had occurred.

Additionally, the Vaginal Health Index (VHI) was evaluated, which is to the evaluation of VVA symptoms, the VHI is one of the clinical tools that is utilized the most frequently used With this instrument co2 laser and radiofrequncy, five parameters have used vaginal elasticity, vaginal secretions, pH, epithelial mucous membrane, and vaginal hydration were evaluated. A score of zero indicates bad symptoms, while a score of five indicates that it is excellent. Additionally, we measured the FSFI score(female sexual function index), which is a measure of the sexual functioning of women in six distinct domains: desire, arousal, lubrication, orgasm, satisfaction, and pain. It has a maximum score of thirty and ranges from 0 to five marks.

Laser Consideration and Parameters: The Laser Generator is a 60WRF Glass Tube with a wavelength of 10600 nm . The operating modes include Fractional, Ultra Pulse, and Vaginal 7, with geometric options of Circle, Triangle, Square, Rectangle, Rhombus, Line, and Ellipse. The cooling system is air cooling. All laser procedures were conducted in an outpatient environment after applying local anaesthesia amla gel. In each session, the laser energy was calibrated to 30 watts and delivered via an intravaginal 360 probe, with a dwell time of 1000 µs, dot spacing of 1000 µm, and an smart stack parameter of 1. This setting was derived from prior studies to guarantee that surplus energy was not conveyed. The laser machine used in this study is EXMatrix Laser Therapy System manufactured in China.

Radio frequency consideration and parameters: The protocol consists of four to five 25-minute sessions every 14 to 16 days, utilising coupling gel with hyaluronic acid; this is followed by an additional DQRF/UPR™ (Dynamic Quadripolar Radiofrequency)/Ultra Pulsed Radiofrequncy) maintenance session after four months

Fig. 1: The speculum cage of Laser machine used

Fig. 2: The speculum cage of Laser machine used

and a final assessment visit, without treatment, after six months.

Laser treatment induces tissue remodeling, with histological evidence of the restoration of vaginal mucosa, a thickening of the epithelium, with the maturation of epithelial cells, a new formation of papillae indenting the epithelium with newly formed and extended small vessels.

In addition, in the connective tissue underlying the epithelium, the formation of new thin fibrils and morphological features of fibroblasts supporting a renewal of the extracellular matrix with functional restoration

Safety Measures: All individuals need to wear procedure-specific protective eyewear to mitigate the risk of ocular injury. These glasses are engineered with specific wavelengths and optical density for CO2 laser applications. The doctor's goggles were transparent.

In this study, the patient's eyes were obscured with cotton or gauze pads, or they were instructed to close their eyes and tilt their head away from the field of view. The smoke and vapour plume were meticulously extracted using a vacuum system to mitigate hazards to both the patient and staff, as various infections may be present in the vapour produced by the CO2 laser. This research involved a laser device situated in an isolated room, with the patient accessing this room through an adjacent office, separated by a closed door during the laser treatment procedure.

Postoperative Instructions:

- No post-op therapy was needed.
- Patients were only requested to restrain from sexual activities for aperiod of 7 days after eacg of the treatment sessions.

RESULTS AND DISCUSSIONS

This study involved a total of 20 postmenopausal females with VVA. 10 females were treated with CO2 laser, and the rest were treated with radiofrequency laser.

The t-test revealed no statistically significant difference in VAS scores between the two groups before treatment, with a p-value exceeding 0.05. Nonetheless, the VAS scores for both groups decreased post-treatment so VVA symptoms improved after co2 laser and radiofrequency , with no significant difference observed between the groups, as evidenced by the t-test yielding a p-value greater than 0.05 (Figure 4).

Regarding the VHI, no statistical significance was observed between the two groups before treatment. However, there was a statistically significant difference between the two groups in the VHI, with the CO2 laser group achieving a higher score, as demonstrated by the t-test yielding a p-value of 0.017 (Figure 5).

The FSFI scores pre- and post-treatment exhibited no significant difference between the two groups, as the t-test yielded a p-value greater than 0.05. Nevertheless, the FSFI score was enhanced in both cohorts following the treatment (Figure 6).

Currently, minimally invasive techniques are recommended to enhance symptoms of vaginal atrophy (VVA). Radiofrequency (RF) is a secure, non-invasive technique with minimal risk of adverse effects that emits high-frequency wavelengths to tissue impedance, causing a localized temperature elevation that stimulates collagen synthesis by fibroblasts and collagen denaturation without substantial necrosis or damage to adjacent vascular or nerve tissues Laser treatment utilising depth-controlled photo-thermal action with pulsed CO2 or Er: YAG lasers induce collagen denaturation, resulting in mucosal shrinkage and contraction of underlying supportive tissue without destruction, thereby enhancing tightness and elasticity.

These two techniques are employed for collagen contraction, neocollagenesis, vascularisation, and enhancement of elasticity, tension, and rejuvenation of the vulvovaginal area[38].

Our results align, in some respects, with a study conducted by Isadora B. Seganfredo and colleaques[39]

Fig. 3: The Radiofrequency device and the vaginal piece

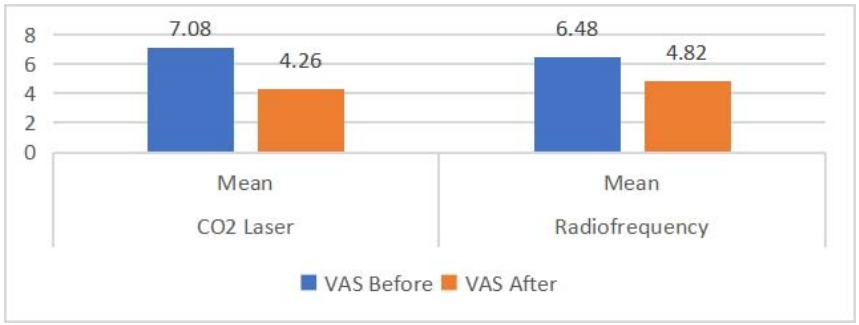

Fig. 4: Visual analogue scale score before and after radiofrequency and co2 laser

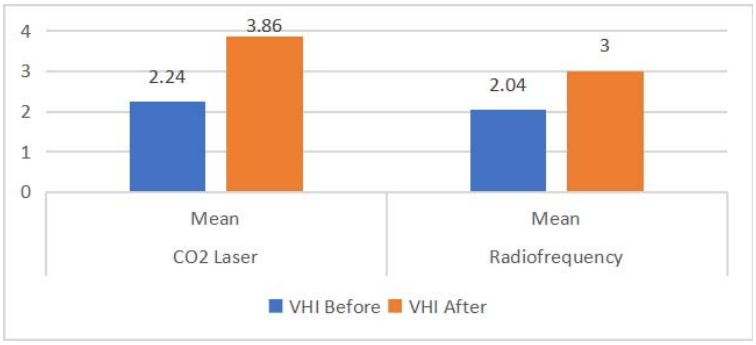

Fig. 5: Vaginal health index before and after radiofrequency and co2 Laser

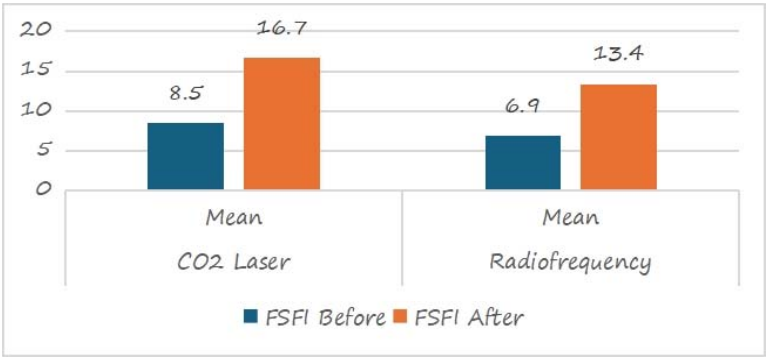

Fig. 6: Female sexual function index before and after radiofrequency and co2

which involved a prospective randomized open-label clinical trial on 62 postmenopausal women assigned to three intervention groups: a) topical promestriene for 90 days (n = 17); b) fractional CO2 laser treatment (n = 24); and c) micro ablative fractional radiofrequency treatment (n = 21).

All baseline parameters were found to be comparable among the studied groups. Upon conclusion of the study, all three treatments yielded comparable outcomes: a decrease in vaginal pH and an enhancement of vulvovaginal symptoms (as indicated by the Vaginal Symptom Score and Vaginal Health Index scores)

alongside sexual function (reflected in elevated total Female Sexual Function Index scores, as well as improvements in the desire, arousal, lubrication, and pain domain scores), with no discernible differences among the groups. We observed a superior Vaginal Health Index using CO2 laser compared to their results.

Our findings corresponded with those of S. Salvatore and colleagues[40] who evaluated VVA symptoms before and after three laser applications over 12 weeks in 50 women (mean age 59.6±5.8 years) dissatisfied with prior local estrogen therapies. Subjective (visual analog scale) and objective (Vaginal Health Index Score, VHIS) metrics were employed throughout the study period to evaluate VVA. Fractional CO2 laser treatment was determined to be effective in alleviating VVA symptoms (vaginal dryness, burning, itching, dyspareunia, dysuria; $p < 0.001$) at the 12-week follow-up, as well as improving the VHIS (13.1 ± 2.5 at baseline vs. 23.1 ± 1.9; $p < 0.001$).

Furthermore, our findings align with those of Matthias Kiesel, and colleagues, who discovered Pain decreased from a mean of 2.5 points (minimum 0, maximum 9 points) to 1.1 points (minimum 0, maximum 8 points) prior to the third laser treatment. Pruritus exhibited a mean score of 3.8, with a minimum of 0 and a maximum of 10 points. This diminished to 1.4 (minimum 0, maximum 8 points). Dyspareunia received a mean score of 6.8, with a minimum of 0 and a maximum of 10 points. Following two laser treatments, the score was 3.3 (minimum 0, maximum 8 points). Burning scored 4.2 points, with a minimum of 0 and a maximum of 10 points. After two laser therapy sessions, the patients scored 1.5 (minimum 0, maximum 9 points). The intensity of dryness decreased from 6.5 (minimum 0, maximum 10 points) to 3.3 (minimum 0, maximum 9 points). Dysuria was recorded at 1.8 points (minimum 0, maximum 10 points) before the first laser therapy and at 0.5 points (minimum 0, maximum 6 points) before the third laser therapy. All alterations demonstrated statistical significance ($p < 0.002$).

Our findings contradict those of Tahereh Eftekhar and colleagues[38], who conducted a study involving two hundred and forty women.

Participants were randomly assigned to the RF group ($n = 80$), the laser group ($n = 80$), and the placebo group ($n = 80$). they found that VVA symptoms decreased in RF and laser groups after the intervention, although changes in the RF group were more compared to the laser group (15.813 vs. 10.075, $P < 0.001$). In contrast, VHI showed enhancement in both RF and laser groups post-intervention, with the RF group exhibiting significantly more significant changes than the laser group (10.425 vs. 2.231, $P < 0.001$).

CONCLUSIONS

It can be concluded that both laser therapy and radiofrequency (RF) treatments are effective in alleviating symptoms of vaginal atrophy (VVA). These minimally invasive techniques have demonstrated significant improvements in vaginal dryness, burning, itching, dyspareunia, dysuria, and overall vaginal health as measured by various indices.

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