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Vulvo-vaginal atrophy: A new treatment modality using thermo-ablative fractional CO_2 laser

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ABSTRACT

Objective: To evaluate the efficacy and feasibility of thermo-ablative fractional CO_2 laser for the treatment of symptoms related to vulvo-vaginal atrophy (VVA) in post-menopausal women.
Methods: From April 2013 to December 2013, post-menopausal patients who complained of one or more VVA-related symptoms and who underwent vaginal treatment with fractional CO_2 laser were enrolled in the study. At baseline (T0) and 30 days post-treatment (T1), vaginal status of the women was evaluated using the Vaginal Health Index (VHI), and subjective intensity of VVA symptoms was evaluated using a visual analog scale (VAS). At T1, treatment satisfaction was evaluated using a 5-point Likert scale.
Results: During the study period, a total of 48 patients were enrolled. Data indicated a significant improvement in VVA symptoms (vaginal dryness, burning, itching and dyspareunia) ($P < 0.0001$) in patients who had undergone 3 sessions of vaginal fractional CO_2 laser treatment. Moreover, VHI scores were significantly higher at T1 ($P < 0.0001$). Overall, 91.7% of patients were satisfied or very satisfied with the procedure and experienced considerable improvement in quality of life (QoL). No adverse events due to fractional CO_2 laser treatment occurred.
Conclusion: Thermo-ablative fractional CO_2 laser could be a safe, effective and feasible option for the treatment of VVA symptoms in post-menopausal women.

1. Introduction

Before the climacteric period, the vagina is composed of thick layers of healthy cells, and estrogen encourages the growth and development of these cells; therefore, the vaginal epithelium remains multi-layered, and vaginal walls are supple and elastic [1,2]. The progressive reduction in circulating estrogen, which occurs following the cessation of ovarian function during menopause, induces various metabolic and tissue changes, which are most prominent in the genital tract due to its particular sensitivity to variations in sex hormone levels [2,3]. Vulvo-vaginal atrophy (VVA) is a progressive, chronic condition that manifests as involution of the vulvo-vaginal mucous membranes and tissues due to the menopausal drop in estrogen levels [4,5].

Typical symptoms of VVA, which reflect these vulvo-vaginal morpho-functional changes, include vaginal dryness, itching, burning, irritation, dysuria and dyspareunia [6,7]. In particular, the vaginal walls appear thinner and less elastic with loss of rugations. The entire vaginal canal becomes narrower and shorter. The vaginal surface appears dry and friable and often bleeds after minimal trauma. The vulvar area, particularly the clitoris, becomes atrophic and more vulnerable [8].

Vaginal atrophy can worsen over the years and negatively influence quality of life (QoL) [9]. Approximately 50% of postmenopausal women experience symptoms of VVA [10,11], which can range from mild (*annoying*) to severe (*very bothersome*).

These symptoms may cause significant emotional distress and may result in sexual dysfunction. The burden of VVA on the individual and the population is greater than physicians may realize, especially due to socio-cultural barriers and a lack of access to health care in certain countries [12].

Because of the progressive aging of the general population, women may complain of vaginal aging symptoms (itching, burning, reduced lubrication, superficial and/or severe dyspareunia related to vulvovaginal atrophy) for more than one third of their lives [13].

Several therapeutic options are available to alleviate VVA symptoms, including non-hormonal products for mild cases, vaginal hormone therapy for persistent symptoms, and systemic hormonal

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replacement therapy (HRT) as a broader approach for severe symptoms [2,14]. Lubricants have been demonstrated to decrease vaginal irritation during sexual activity but do not provide a long-term solution [15]. Few clinical data have indicated that vaginal moisturizers improve VVA symptoms [16]. Systemic HRT may be considered for climacteric symptoms in the absence of contraindications; however, this type of treatment is associated with more side effects than the local administration of HRT and is not recommended unless vasomotor symptoms need to be controlled [2,14]. Several clinical trials have demonstrated the efficacy of low-dose local estrogen therapies in women with only VVA symptoms in the absence of contraindications. However, limited data are available on the long-term safety of these therapies, and no information is available on high-risk patients [2,14,17].

Moreover, the major drawback of this approach is the recurrence of symptoms once treatment has been suspended, and this treatment is only effective in the superficial layer of the vaginal walls [18].

In recent years, there has been a greater demand for a safe, long-term therapeutic option that can effectively treat the deeper layers of the vaginal mucosa in addition to the epithelium. By applying the principles of regenerative and anti-aging medicine to the vaginal mucosa, the use of fractional CO_2 laser may be extended to treat patients with VVA [19].

As demonstrated in other areas of the body [20–24], this system induces the topical remodeling of connective tissue and the production of collagen and elastic fibers. Based on results that were obtained on the skin, we applied a fractional CO_2 laser treatment that was specifically designed for the vaginal mucosa to determine the safety and efficacy of this treatment in improving VVA symptoms in postmenopausal women.

2. Materials and methods

2.1. Patients

For this observational pilot study, post-menopausal patients who complained of one or more symptoms related to VVA and who underwent vaginal treatment with fractional CO_2 laser from April 2013 to December 2013 were included in the study. The inclusion criteria consisted of menopausal status (including early forms), one or more vulvo-vaginal symptoms (e.g., itching, burning, reduced lubrication, superficial and/or severe dyspareunia), and non-response to previous estrogen or local therapies. Patients with active genital infections, pelvic organ prolapse (POP) stage >II (according to the Half Way System for the quantification of POP) [25] and/or the use of HRT (systemic or local) up to 6 months before the study recruitment period were excluded from the study. Patients who used vaginal lubricants or any other local preparations were asked to suspend the application of these treatments and were included in the study after 30 days. Women who were using psychotropic drugs were excluded. The study was approved by the Hospital Research Committee. All patients who were recruited for the study signed an informed consent form.

2.2. Laser device

A fractional CO_2 laser system (SmartXide2V_2LR, Deka m.e.l.a., Florence, Italy) was equipped with a VulvoVaginal Laser Reshaping (V_2LR) scanning system and appropriate probes for the vaginal area. This treatment modality is based on the interaction between a specific CO_2 pulsed laser and the vaginal mucosa. A laser beam is emitted fractionally, and the CO_2 laser is focused in small spots (called DOTs) that are separated by healthy tissue. The laser beam penetrates the tissue and releases heat only when the set depth is reached. With software control and a radiofrequency system that feeds the laser source, it is possible to select the *D-Pulse* mode, the depth (*SmartStak* parameter, from 1 to 3) and the quantity (*power*, *dwell time* and *spacing*) of heat to be transferred to the tissue. The *SmartStak* function allows for careful control of vaporization depth and thermal action. Successive pulses are emitted in the same area for a Stack variable of 1–3 (in the vaginal application). This procedure allows the mucosa to cool between two successive pulses and minimizes thermal damage.

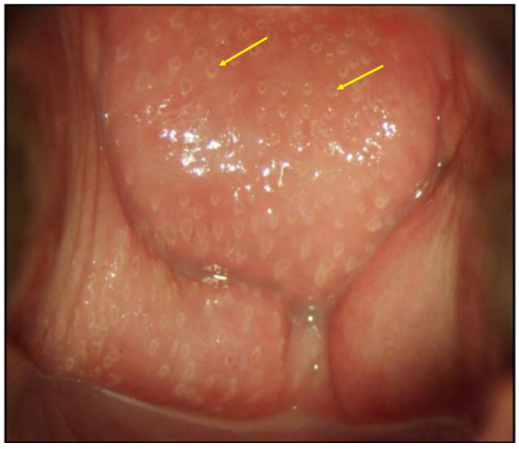

Fig. 1. Colposcopic view of vaginal walls immediately after a session of fractional CO_2 laser therapy. Arrows indicate macroscopic ablation zones.

Fig. 2. New specifically designed vaginal probe with a pyramidal tip that allows laser beam emission at 360°.

Every pulse is composed of a constant high-energy peak power to produce rapid ablation of the epithelial component of atrophic mucosa, followed by longer emission times (*dwell time*) that allow the CO_2 laser to penetrate further into the mucosa.

The pulses are distributed over the vaginal wall and are spaced (*DOT spacing*) to cover the entire treatment area. A specific probe is used to deliver the pulses, which allows for energy emission at 360° (Fig. 1). In this study, a calibrated probe was specifically utilized for vaginal application, and this probe can be easily inserted into the vaginal canal (Fig. 2). The laser is projected toward a 45°-oriented mirror that is placed at the tip of the probe to be reflected on the vaginal walls but not the uterine cervix. To completely treat the vaginal area, it is necessary to emit many laser spots while progressively extracting the probe from the vaginal fundus. Each treatment spot consists of two passages. After the first energy release, the probe is rotated approximately 2 cm (using the regulatory tool) clockwise while remaining at the same vaginal distance.

2.3. Laser treatment

Each patient was treated with the fractional CO_2 laser system using the vaginal probe.

In all cases, introduction of the probe into the vaginal canal was successful, and treatment was completed. In several difficult cases, a gel was applied to the top of the probe to facilitate entry. All patients underwent a complete cycle of three treatment sessions that were spaced over a period of at least 30 days. For each patient, a Pap test and vaginal swabbing were performed to rule