Menopausal Vaginal Atrophy Treatment with Microablative Fractional CO\textsubscript{2} Laser. A New Approach.
Menopausal Vaginal Atrophy Treatment with Microablative Fractional CO₂ Laser.  
A New Approach.

Pablo González Isaza, M.D. - Pereira, Colombia. Specialist in Gynecology and Obstetrics  
Expert in Laser Surgery and Pelvic Floor Reconstruction Surgery  
International Urogynecological Association Member (IUGA)  
Asociación de Ginecólogos Estéticos del Occidente Colombiano Member

This paper was presented at the X CONGRESO COLOMBIANO DE MENOPAUSIA 2013 Bogotá, DC - Colombia, where it was placed second in the category of experimental clinical work.

Abstract

Vulvovaginal atrophy is a public health problem[1] involving 50% of women in menopause who may have a variety of symptoms: itchiness, decreased vaginal lubrication, dyspareunia, vaginal bleeding during sexual intercourse, polyuria, leukorrhoea and so on. These symptoms are correlated to the natural physiological ageing process[2] that also involves the vaginal mucosa. The loss of the reticular configuration by the extracellular matrix of the connecting tissues gives rise to trophism and incorrect hydration of the tissues.

Local oestrogen therapy only acts on the surface of the vaginal mucosa generating a transient improvement in patients[3]. Several alternative treatments have been investigated including carboxytherapy, the use of PRP (Platelet-Rich Plasma), lubricants and/or moisturisers, acupuncture, traditional Chinese medicine[4], and the administration of non-reticulated hyaluronic acid[5], without ever obtaining significant and/or lasting improvements however[6].

By applying the principles of regenerative and anti-ageing medicine to the vaginal mucosa it has been possible to perfect a new and specific treatment for vaginal atrophy in menopause which uses a special fractional CO₂ laser system with pulsed emission created specifically to treat the vaginal mucosa (SmartXide² V²LR laser system by DEKA MELA – Florence, Italy). In order to clinically assess the results, the VHI (Vaginal Health Index) of Bachmann et al. [2],[7] was considered.

The histological analysis conducted on several patients following treatment revealed the role of the Heat-Shock Proteins (in particular, HSP47, the collagen-specific chaperone[8]) which are activated through the localised increase in temperature in the matrix of the connective tissue of the vaginal mucosa and promote the synthesis of new fibrillar components[9]. This process gives rise to an improvement in the trophism of the vagina with significant clinical benefits that result in a relevant change in the VHI compared to the value of the baseline condition, also associated with an improvement in the sexual function[9].

Introduction

The failure of the ovaries to produce estrogen is directly related to the onset of vaginal atrophy, due to the particular sensitivity of the genital tract to the decreased levels of estrogen[11,10].

Vaginal atrophy symptoms usually appear 4-5 years after menopause and can affect up to 50% of women[1] at this stage of their lives. In contrast to menopausal symptoms, which are usually transient, vaginal atrophy can worsen over the years with negative consequences on sexuality[11] and quality of life; however, despite this, only 25% of patients decide to seek medical attention, which often leads to an underestimation of the disorder.

Patient perception of vaginal atrophy varies in different countries and is often affected by socio-cultural barriers and the lack of health care. In South America, for example, the problems related to vaginal atrophy are usually associated with the idea of loss of femininity[12,13]. In the
sub-Saharan countries of Africa, the problem is not a priority: life expectancy for women does not exceed 55, due to diseases such as HIV - AIDS which receive priority in medical care for this patient group[1].

The main changes associated with decreased estrogen levels in menopausal women are due to morphological changes of the vaginal mucosa, such as epithelium thinning and loss of vaginal folds; in addition, there is a reduction of blood flow[8] and vaginal secretions, which causes changes in the alterations of the vaginal bacterial flora (lactobacillus). This results in a reduced concentration of lactic acid and changes in pH, that make the vagina more infection-prone as a result of the vaginal non pathognomonic flora. In terms of sexuality, all these changes have a major impact on the quality of sexual intercourse, resulting in, among other things, dyspareunia, sinusorragia and alterations in the female sexual response[3,9].

The primary goal of vaginal atrophy treatment is to restore the normal physiological conditions of the vagina, thus reducing the symptoms[1].

Various therapies are available for the treatment of vaginal atrophy, some dating back to the Middle Ages, from natural herbs for the stimulation of menstrual flow (Emmenagogo), to fruits applied to the vaginal lips. At the start of the twentieth century, Fritch and Pals used electroshock and radiotherapy treatment respectively, while Graft proposed the development of ovarian grafting and transplantation[9].

Non-hormonal treatments, such as lubricants and / or moisturisers, do not provide a long-term solution, and research studies have not proven them to be more effective[8].

Systemic hormone replacement therapy should be administered in the lowest possible dose and to an appropriate selection of patients[3]. As for local estrogen therapy, its beneficial effects to the vaginal mucosa are well known, but its major drawback is the recurrence of symptoms once treatment is suspended, and also that it is only effective in the surface layers of the vagina[3].

For this reason, in recent years, there has been a greater necessity to identify treatments which are effective beyond the epithelium of the vaginal mucosa, intervening at a molecular level in desmosomes and in the connective tissue, where most damage is caused as a result of the symptoms of vaginal atrophy.

Carboxytherapy, well known in cosmetic medicine for its effects in micro-circulation, showed good results at a vaginal mucosa level, with an improvement in trophism. These effects, however, are not permanent.

Dr. Gaspar and his colleagues showed resulting positive changes in biopsy specimens which were treated with fractional microablative CO₂ laser in combination with platelet-rich plasma. Subsequently, Prof. Calligaro[9] and Dr. Salvatore, at the University of Pavia and the San Raffaele Hospital in Milan in Italy, have verified the induction of molecular changes, demonstrating the stimulation of new collagen synthesis and the activation of fibroblasts in the surgical specimens of patients who had to undergo surgery for pelvic floor dystopia, and who underwent a particular fractional CO₂ laser treatment before the biopsy. The following clinical study carried out on 40 patients showed significant histological changes after fractional microablative CO₂ laser treatment, with a significant positive impact on the symptoms of vaginal atrophy. All patients were assessed using internationally validated questionnaires such as the “PISQ-12 Vaginal Health Index.” The main advantage of this type of technology is the use of a fractional emission with a D-Pulse impulse, specially made by the Company DEKA (Florence - Italy). Its mechanism has a fundamental characteristic for its application to the genital mucosa, namely the emission of a particular type of laser energy that can adapt to the tissue characteristics, thus stimulating it effectively, avoiding thermal damage and side effects.

Similar experiences have been reported following the use of different Er:YAG laser technologies Dynamics SX Fotona (Slovenia) by Dr Zdenko, Dr Vizintin et al[15,16] in a study of 21 patients: the results indicate an improvement in menopausal vaginal atrophy and even in the initial stages of stress urinary incontinence. The main limitation of this type of technology lies in the lack of effectiveness on tissues with a high water component, which limits the diffusion of energy deep into the tissues, resulting in only temporary effects.

Objectives

- To demonstrate the effectiveness of fractional microablative CO₂ laser SmartXide² V²LR in the treatment of menopausal vaginal atrophy (treatment called MonaLisa Touch™).
- To demonstrate the objective changes in the characteristics of the vaginal mucosa with the MonaLisa Touch™ treatment with fractional microablative CO₂ laser SmartXide² V²LR.
- To demonstrate significant improvements in the Vaginal Health Index of G. Bachmann as a result of the application of the protocol MonaLisa Touch™ with SmartXide² V²LR.
Reasons for Study or Analysis

Traditional treatments for menopausal vaginal atrophy are limited only to the vaginal mucosa and their effects are temporary and reversible. The fractional microablative CO₂ laser treatment not only induces molecular changes where the damage originates, but its effects are also permanent. This is to date the only study of its kind in our country (Colombia) and therefore seeks to stimulate the interest of our scientific community.

Materials and Methods

The Gloria Bachman Vaginal Health Index (VHI) was applied to 8 voluntary patients in menopause, all with baseline symptoms of vaginal atrophy. With the informed consent of the patients, the treatment protocol was started with the fractional microablative CO₂ laser system SmartXide² V²LR (Vulvo-Vaginal Laser Reshaping) produced by DEKA (Florence - Italy). 3 sessions were carried out at intervals of three weeks. At the end of the treatment, the Bachman VHI evaluation questionnaire was completed again.

Inclusion Criteria

- perimenopausal and menopausal patients who have not undergone hormone replacement therapy in the previous six months.
- Patients with reduced lubrication.
- Patients with vaginal itching and atrophic vaginitis.
- Patients with superficial and deep dyspareunia.

<table>
<thead>
<tr>
<th>Score</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elasticity</td>
<td>none</td>
<td>poor</td>
<td>fair</td>
<td>good</td>
<td>excellent</td>
</tr>
<tr>
<td>Fluid Volume (Pooling of Secretion)</td>
<td>none</td>
<td>Scant amount, vault not entirely covered</td>
<td>superficial amount, vault entirely covered</td>
<td>moderate amount of dryness (small areas of dryness on cotton tip applicator)</td>
<td>normal amount (fully saturates on cotton tip applicator)</td>
</tr>
<tr>
<td>pH</td>
<td>≥ 6.1</td>
<td>5.6 - 6.0</td>
<td>5.1 - 5.5</td>
<td>4.7 - 5.0</td>
<td>≤ 4.6</td>
</tr>
<tr>
<td>Epithelial Integrity</td>
<td>petechiae noted before contact</td>
<td>bleeds with light contact</td>
<td>bleeds with scraping</td>
<td>not friable – thin epithelium</td>
<td>normal</td>
</tr>
<tr>
<td>Moisture (Coating)</td>
<td>none, surface inflamed</td>
<td>none, surface not inflamed</td>
<td>minimal</td>
<td>moderate</td>
<td>normal</td>
</tr>
</tbody>
</table>

Table 1: Gloria Bachman Vaginal Health Index (VHI).
Inclusion Criteria

- Patients with recurring urinary tract infections.
- Patients with a current infection of genital herpes or candida.
- Patients with a serious systemic disease.
- Patients who have previously undergone pelvic floor surgery.

Scope

Analytic, prospective and descriptive cross-case study.

Ethical Considerations

The patients recruited for this study were volunteers from a private practice. They offered to participate prior to the issue of a declaration of informed consent and a written authorization to be included in their medical records.

Informed Consent

The type of informed consent used was specifically designed for the treatment of menopausal vaginal atrophy with fractional microablative CO₂ laser.

Results

The following are the preliminary results of the study, which will be followed up in the future with the inclusion of a greater number of patients. The follow-up period of the patients lasted 90 days.

From a statistical and descriptive point of view, the patient group had an average age of 50 years, with a median of 49 years and a gap of thirteen years between the maximum age and the minimum age. The score values of the vaginal health index, respectively at the beginning and at the end of the study, are as follows: average of 13 and 23, median 13.5 and 22.5, range 11 and 8, and variance of 12 and 6.2, with a standard deviation of 3.46 and 2.5.

In the analysis of the vaginal health index, a significant change was observed in the score recorded at the end of treatment, compared to that of the baseline value. In addition, all patients reported a subjective improvement in all symptoms of vaginal atrophy. The first results seem to highlight important differences between the two measures, but the small sample size requires studies on a larger patient group in order to achieve more consistent results from a statistical point of view.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Baseline Score</th>
<th>Final Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12</td>
<td>23</td>
</tr>
<tr>
<td>2</td>
<td>14</td>
<td>22</td>
</tr>
<tr>
<td>3</td>
<td>19</td>
<td>23</td>
</tr>
<tr>
<td>4</td>
<td>09</td>
<td>21</td>
</tr>
<tr>
<td>5</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>6</td>
<td>13</td>
<td>20</td>
</tr>
<tr>
<td>7</td>
<td>08</td>
<td>22</td>
</tr>
<tr>
<td>8</td>
<td>14</td>
<td>25</td>
</tr>
</tbody>
</table>

Table 2: VHI score before and after three MonaLisa Touch™ treatment sessions.

Graphic 1: Comparison of Vaginal Health Index score before and after three MonaLisa Touch™ treatment sessions.

Discussion

Vulvo-vaginal atrophy is a well known public health problem. The treatment options currently available fail to resolve the source symptoms with a molecular type intervention. The SmartXide² V²LR (Vulvo-Vaginal
Laser Reshaping) is a complementary alternative to local hormone replacement therapy and, as such, has been shown to produce safe, effective and long-term effects for patients. Previous experiences have shown the effectiveness of the MonaLisa Touch treatment in generating definitive histological changes such as in the production of elastic fibres, the stimulation of neocollagenesis that leads to the recovery of acid pH and proper lubrication, ultimately leading to an improvement in all symptoms of menopausal vaginal atrophy. The small sample size examined makes it necessary to recruit a greater number of patients to obtain more consistent results from a statistical point of view.

Acknowledgements

- DEKA Company, Florence - Italy, for supplying scientific information essential for the preparation of this project.
- The Colombian Association of Menopause, its management and employees for agreeing to the disclosure of this new, safe and promising alternative for the treatment of menopausal vaginal atrophy to the scientific community.
- Dr. Carlos Andres Fandiño for his support and statistical analysis of the data involved.

Bibliography
