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INTRODUCTION

Lichen sclerosus is a chronic inflammatory dermatitis, with a predilection for the anogenital area predominantly female (female / male ratio 6 to 1), which in some cases can be seriously affected (atrophy of the labia minora, phimosis, introital stenosis, etc.). Most cases are diagnosed in postmenopausal women, but it can affect women and men of any age. Lichen sclerosus is usually an itchy condition, although it can also be asymptomatic.

The pathology of lichen is characterized by symptoms such as burning and itching that can afflict the woman in her daily life. These symptoms can lead to dyspareunia and vulvar lesions, both caused by scratching and by tissue fragility. In the advanced stages there is a radical change in the anatomy of the genitals: disappearance of the clitoris, incorporated in fibrosis, disappearance of the labia minora and labia majora, reduction of vulvar intake to the point of impossibility of having sexual intercourse and in extreme cases not even undergoing at gynecological examination. In addition, fibrosis can involve the peri-urethral region with displacement of the urethra and cause the so-called vaginal urination. Such sclerotic tissues undergo ulceration causing intense pain and burning. In women, Lichen sclerosus is considered a rare disease (1.7% of gynecological patients) due to the low incidence, but it is also an underestimated disease because it is hidden or not recognized: patients, in fact, sometimes consider the symptoms of Lichen Sclerosus related to menopause.

In men, phimosis or fusion of the foreskin over the coronal sulcus may occur. Those affected perceive a progressive discomfort.

The treatment of lichen, aimed at reducing the disabling symptoms, is mainly carried out using cortisone for topical use. However, prolonged use can lead to drug resistance and cause important

side effects such as aggravation of atrophy. Furthermore, cortisones have no effect on the repair of the scarring of the disease.

To overcome the problems associated with the prolonged use (often for a lifetime) of corticosteroids, new approaches have been tried to reduce symptoms.

Hyaluronic acid is a natural polysaccharide that forms a fundamental part of the extracellular matrix of the skin and cartilage, has remarkable adhesive, moisturizing and repairing properties of the mucous membranes and skin. The use of hyaluronic acid for topical use has been used with positive results in the treatment of lichen planus, suggesting that even non-pharmacological active ingredients can have a significant effect in reducing the symptoms of this type of chronic dermatosis. Oxygen therapy has a powerful regenerative, antibacterial and biostimulating effect, it is therefore believed that it can also be very useful in the treatment of this pathology for the healing of lesions and the treatment of symptoms such as itching and burning. Oxygen therapy increases the availability of oxygen to the tissues, promotes the increase in tissue repair processes and increases the synthesis of collagen allowing normal hydroxylation of this protein. In fact, at tissue oxygen tensions lower than normal, collagen is not synthesized correctly, slowing the healing of ulcers and wounds. In addition, oxygen induces a neo-angiogenic stimulus by releasing factors such as the Vascular Endothelial Growth Factor (VEGF). This function is essential for the restoration of the microcirculation in compromised vascular situations, re-establishing a vascular flow in the hypoxic areas that guarantees correct tissue regeneration. With regard to dermatological pathologies, topical oxygen therapy has proven effective in the treatment of psoriasis, as well as atopic dermatitis and acne, suggesting the usefulness of the regenerating and anti-inflammatory capabilities of oxygen in this therapeutic area.

The combination of high concentration oxygen and hyaluronic acid has proven to have therapeutic efficacy in the treatment of vulvo-vaginal atrophy, a condition characterized by atrophy of the vaginal mucosa and alterations in tissue regeneration, and which presents symptomatic aspects similar to lichen.

The goal of the study is to use the association between high concentration oxygen and hyaluronic acid for the treatment of disorders caused by lichen and to improve the quality of life of people affected by this disease.

MATERIALS AND METHODS

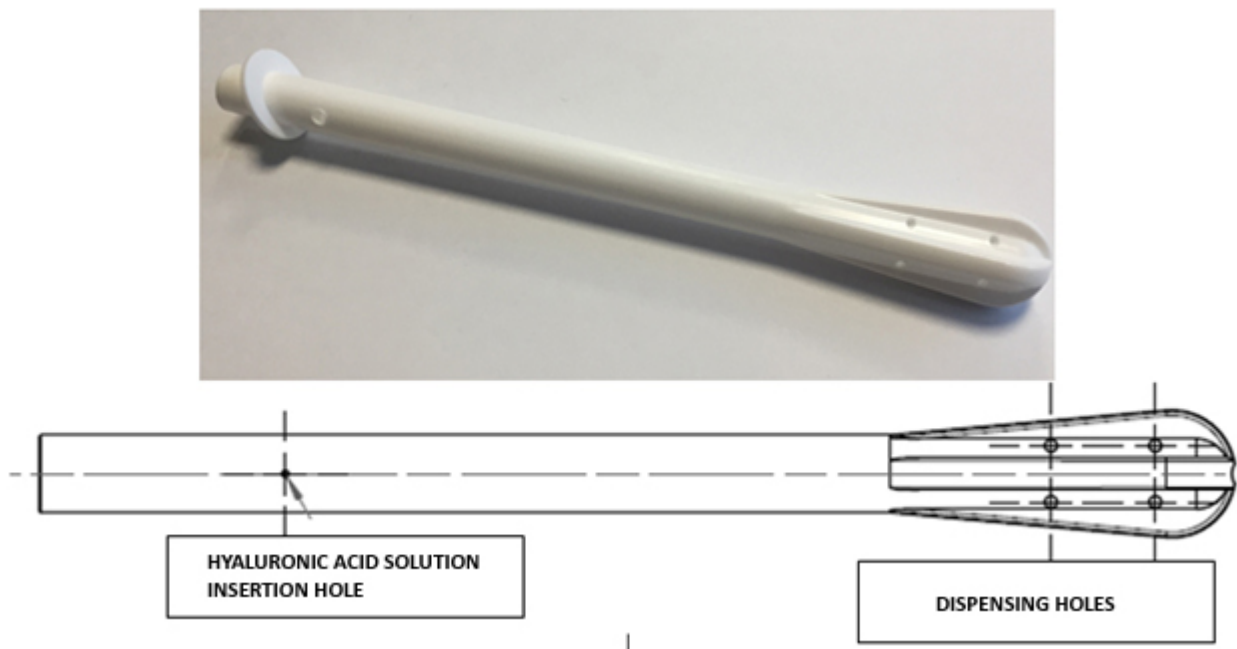
Twenty-five (25) women diagnosed with lichen, carried out by vulvoscopy and biopsy, underwent a weekly session for 5 weeks which included vulvar oxygen therapy for 10 minutes with low molecular weight hyaluronic acid nebulization, at a concentration of 0, 2%, followed by vaginal oxygen therapy combined with hyaluronic acid for 5 minutes.

For the treatment, the Caress Flow system was used, an oxygen therapy device for gynecological use that allows the topical administration of oxygen with a high degree of purity up to $93 \pm 3\%$, at a flow of 1-6 l / minute.

The device consists of a compressor that generates compressed air by sucking air from the external environment, filtering and compressing it. Inside the machine body there are zeolite molecular sieves that exploit the principle of the different absorption of gas molecules, letting the O₂ pass and retaining the other gases present in the air, such as nitrogen, argon, helium and hydrogen. The machine body transforms the outside air into $93 \pm 3\%$ pure oxygen.

Two dispensers were used, the first consisting of a vaginal cannula, connected to the machine body. The cannula is equipped with outlet holes for the delivery of oxygen and hyaluronic acid, which is inserted through a special insertion hole located in the upper part of the cannula (Figure 1). The vaginal cannula is used for treatment inside the vaginal canal.

FIGURE 1



In addition to the cannula, an airbrush was used (Figure 2), always connected to the machine body, capable of delivering oxygen in combination or not with the hyaluronic acid solution. The airbrush is used for the treatment of the external genitalia, nebulizing the combination of oxygen and hyaluronic acid directly on the areas affected by the lesions.

Hyaluronic acid is previously dissolved in distilled water, to form a 0.2% (w / v) solution.

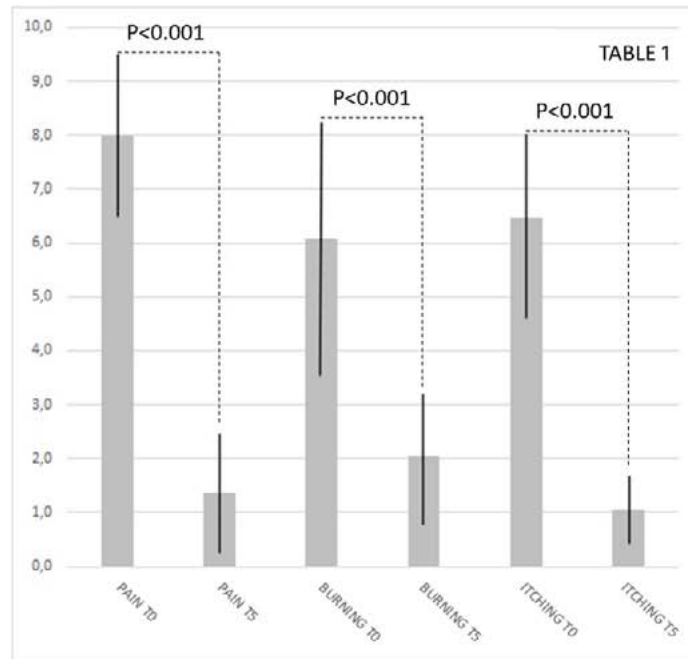
FIGURE 2



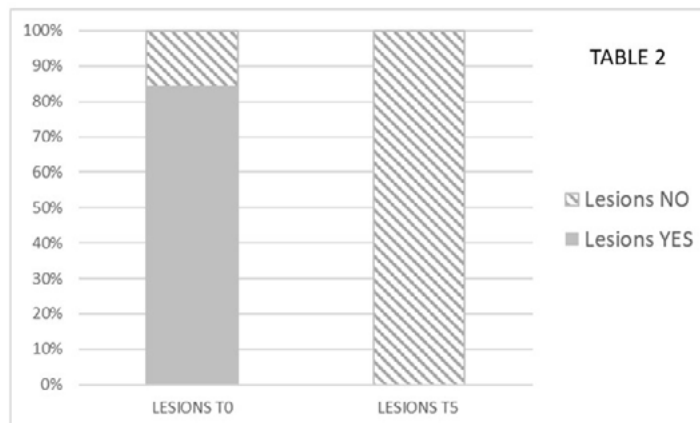
A double evaluation was performed on the treated subjects: one subjective by the patients and one by the doctor. The subjective scale was compiled using an analog graded card that assessed pain during sexual intercourse (dyspareunia), itching and burning with a VAS scale from 0 to 10, where 10 represents the maximum intensity and 0 the absence of the disorder, analyzing symptoms at T0 (before the first treatment session) and at the end of the 5 sessions (T5). Finally, the presence or absence of lesions was assessed by the doctor.

RESULTS

Thanks to the qualitative improvement of the tissues, the patients reported a significant improvement of all the indexes analyzed (Table 1), with the greatest effect regarding pain reduction (VAS T0 = 8.0; VAS T5 = 1.4, Wilcoxon signed-rank test $P < 0.0001$), but also with regard to burning (VAS T0 = 6.1; VAS T5 = 2.0, Wilcoxon signed-rank test $P < 0.0001$) and pruritus (VAS T0 = 6.5; VAS T5 = 1.1, Wilcoxon signed-rank test $P < 0.0001$).



The fundamental observation for this study was the evaluation of the presence of vulvar lesions at T0 and at the end of the treatment. All women who initially had lesions (84%), particularly in the fork area, no longer presented this problem, demonstrating the complete resolution of the problem (Table 2). No side effects associated with the treatment were reported by the patients.



Lichen is a very complex pathology, with autoimmune aetiology, the treatment used does not aim to have a therapeutic effect but to improve the symptoms that afflict women and that affect their quality of daily and sexual life.

Combined oxygen therapy with hyaluronic acid has proven to be a valid method for healing vulvar lesions and improving lichen symptoms. It is a totally painless therapy, with excellent compliance by patients. It is a fast, non-invasive and repeatable treatment, with no side effects.