**Efficacy and safety of a 20 mg/ml HA filler for vulvovaginal atrophy treatment**

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| Leticia Lazzaletta, MD; Gaspar Adrian M.D, Gómez-Escalante Susana, PhD; Luis Luis M.D.; Alejandro Carbone M.D. |
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Background / Objectives

The dermal fillers based on cross-linked form of hyaluronic acid are nowadays routinely used in the everyday medical and aesthetic practice with favorable benefit/risk profile. The VVA atrophy is common and underreported condition (according to some sources it affects more than 50% of women after a certain age) associated with decrease of estrogens of the vaginal tissue. This shows the dire need of alternative to manage those people’s discomfort, improve their quality of life and decrease the VVA symptoms. Currently, the standard medical practice provides poor set of treatment options, including non-hormonal and hormonal local or oral treatment, hiding some risks of its own. The medical literature provides almost no data regarding the possibilities of counteracting the VVA by the means of hyaluronic acid treatments. This investigation is one of the first of its kind. The HA fillers are not considered a surgical treatment and are very well accepted by the public. The therapy is non-traumatic and the manipulation itself is quick and requires next to no previous preparation and consequential limitations.

The primary objective of this study was to assess the safety and efficacy of 20 mg/ml HA dermal filler in the hydration and restoration signs of vaginal atrophy. Secondary objectives were to assess the improvement of tissue morphology, mucosa firmness, moisturizing and elasticity of mucosal tissue, maintenance of optimal vaginal pH, relief of the subjective symptoms of discomfort, sexual functions, urinary symptoms and vaginal flora.

Methods

An open-label uncontrolled single centre study with 40 subjects (3 drop-out due to reasons not related to this study) was performed during November 2019-June 2020. 1 ml of 20 mg/ml HA dermal filler was administered at each volunteer via intramucosal injection in the vagina. Three control sessions were performed Day 0 (screening), Day 30 and Day 60.

The Vaginal Maturation Index (VMI) was used to measure improvement of the vaginal wall from baseline (cytological screening) to day 60 (Session 3) and the proportion of successes calculated via z-test. The change in the Gloria Bachmann Vaginal Health Index (VHI) Score from screening to Day 30 and Day 60 (Sessions 2 and 3) was used to determine improvement in elasticity, fluid volume, epithelial integrity, pH and moisture. The Visual Analogous Scale (VAS) from Day 0 (Session 1) to Day 30 and Day 60 (Sessions 2 and 3) was measured by the investigator/subjects to evaluate the possible pain during medical examination as it can be associated to improved vagina properties. The change of sexual function was evaluated with the Female Sexual Function Index (FSFI) between Session 1 and Session 3. The change of vaginal flora properties was determined via the Nugent Score between Screening and Session 3. The pH was measured using specific *in vivo* test at Screening and Session 2 and 3. Subject’s satisfaction at Days 30 and 60 (Sessions 2 and 3) was evaluated by a questionnaire.

Results

VMI results indicated that 67.50% of the volunteers showed a statistically significant improvement (p=0.0459). VHI results demonstrated a statistically significant improvement (p<0.01) from session 1 to session 3. VAS measurement detected a statistically significant decrease (p<0.01) from Session 1 to Session 3, evaluated both by volunteers/investigator. FSFI showed a statistically significant change (p<0.01). Nugent Score suggested a statistically significant improvement from baseline (Session 1) to Session 3 (p<0.01). The pH measurement indicated a statistically significant change (p<0.01) from baseline (measured during Session 1) to both Session 2 and Session 3. Subject’s questionnaire revealed a positive degree of satisfaction, with 67.57% “very satisfied” and 29.73% “satisfied” at Session 3. Most of the participants (29) experienced some type of improvement in symptoms of discomfort in intimate area and over 70% of the subjects reported that they would repeat the same treatment.

Conclusion

This research has shown with statistical significance that the studied medical device produces several beneficial effects on the functioning of the female intimate area, therefore it can be indicated for hydration and treatment of atrophy of internal vagina.