

EFFECT OF A NON-HORMONAL MUCOADHESIVE POLYCARBOPHILIC VAGINAL GEL ON PREVALENT VAGINAL SYMPTOMS IN WOMEN WHO DEVELOP VAGINAL ATROPHY

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INTRODUCTION/BACKGROUND

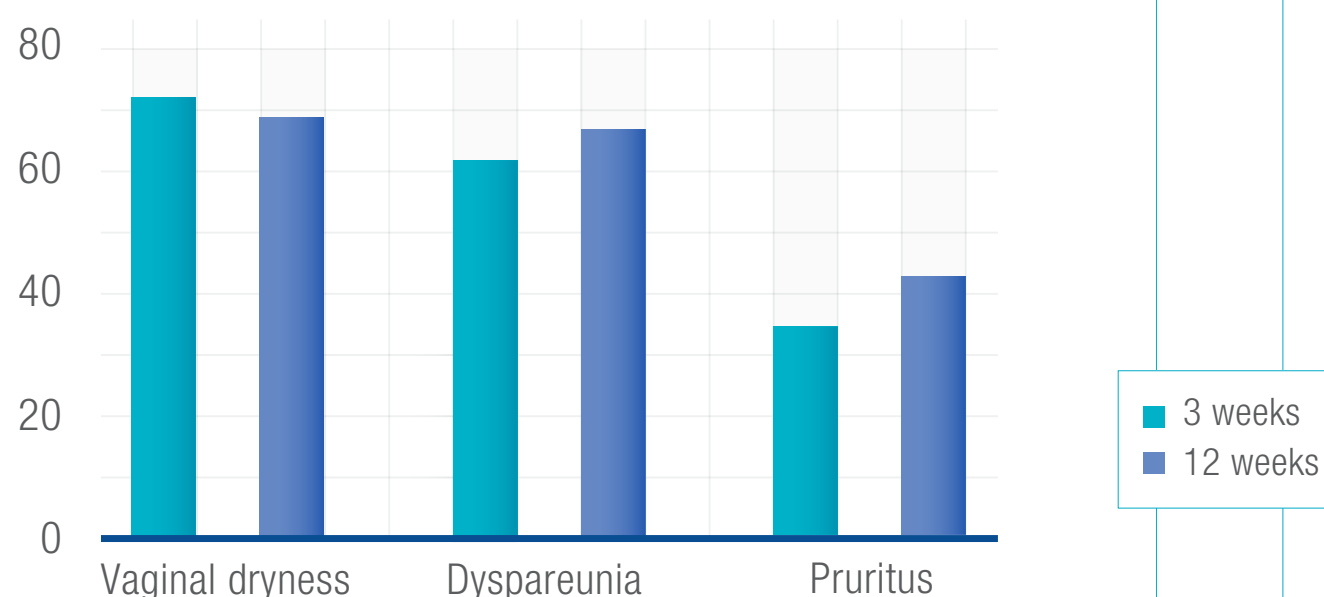
Treatments for breast cancer and other gynecological tumors based on surgery or chemotherapy often cause early ovarian failure and as a consequence, women eventually develop vulvovaginal atrophy (VVA) in the medium and long term. Furthermore, the use of external radiotherapy or brachytherapy for cervix, endometrium or digestive cancer increases the risk of developing VVA, loss of genital elasticity and vaginal stenosis. These changes alter vaginal and sexual health in up to 90% of patients. The use of vaginal moisturizers is recommended periodically for the prevention and treatment of these disorders. Vaginal moisturizers are used as first-line treatment several times a week to improve vaginal symptoms, help hydrate the vaginal lining, and facilitate the flexibility of vaginal tissues. The efficacy of a non-hormonal polycarbophilic mucoadhesive moisturizing vaginal gel (Ainara®) is evaluated in women presenting symptoms of VVA.

METHODOLOGY

A group of 62 women presenting bothering symptoms of VVA (98% with moderate or severe symptoms) received 1g of a mucoadhesive polycarbophilic moisturizing vaginal gel daily for 3 weeks and twice weekly up to 12 weeks. Vaginal dryness, dyspareunia and pruritus were registered at baseline, week 3 and week 12, and symptom intensity was individually scored as 0=absent, 1=mild, 2=moderate, 3=severe at each time-point. A Global Symptom Score comprising the sum of all individual scores was calculated to estimate the effect of the treatment on the global symptomatology (score range 0–9). Symptom variation at week 3 and week 12 vs baseline was evaluated. Responses were considered as improvement (change of the symptom intensity) or cure (the symptom turned absent). Statistical evaluation was performed through Pearson Chi-squared tests. A security level of statistical significance of at least 95% was considered (values of $p < 0.05$).

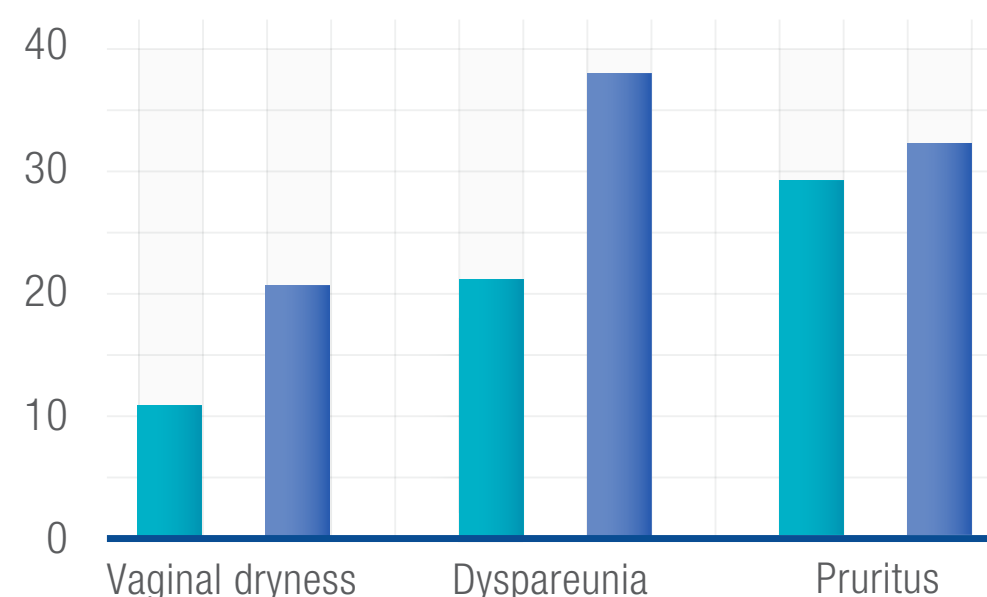
RESULTS

% Women who improve symptoms after treatment



- ▶ **Vaginal dryness** significantly improved in **71%** of women at week 3 ($p=0.01$) and in **69%** at week 12 ($p=0.02$).
- ▶ **Dyspareunia** significantly improved in **62%** of women at week 3 ($p<0.001$) and in **67%** at week 12 ($p<0.001$).
- ▶ **Pruritus** significantly improved in **34%** of women at week 3 ($p=0.03$) and in **42%** at week 12 ($p=0.008$).

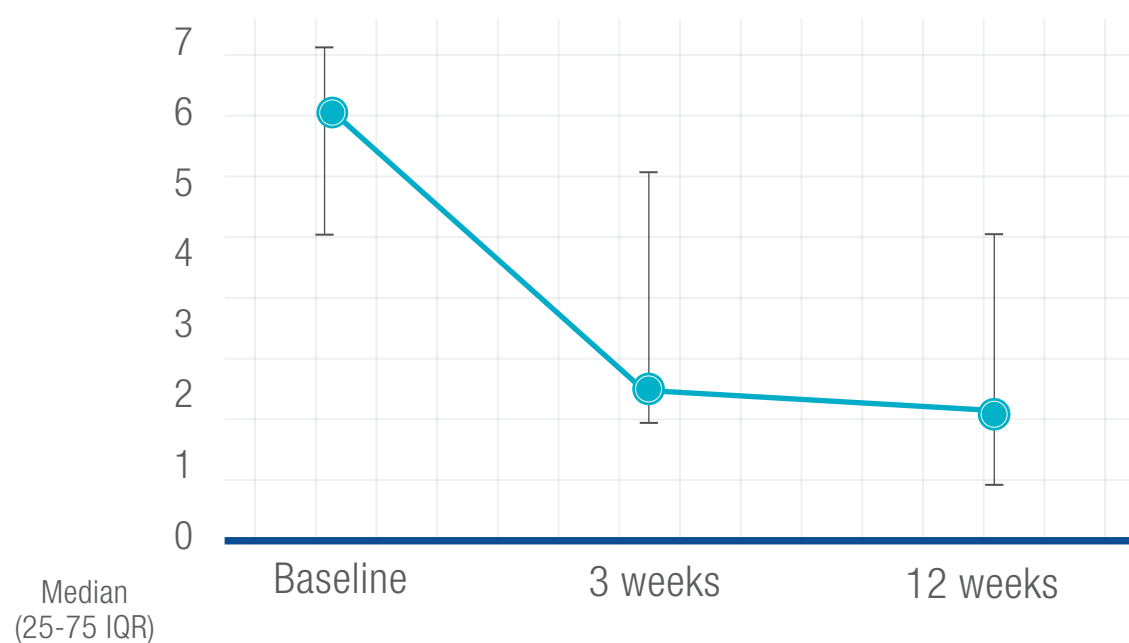
% Women who present symptom absence after treatment



- ▶ **Vaginal dryness, dyspareunia** and **pruritus** disappeared in **13%, 22%** and **29%** of women at week 3, and in **21%, 38%** and **34%** at week 12.
- ▶ **42%** of women who presented moderate or severe vaginal dryness at baseline, presented mild or absence of this symptom at week 12.
- ▶ Regarding dyspareunia, by the end of treatment almost half of the women (**48%**) were symptom free or they presented this symptom with a mild intensity.

Global Symptom Score (Median values)

- ▶ The **Global Symptom Score** changed from **6 (4-7)** to **2.5 (2-5)** after 3 weeks and to **2 (1-4)** after 12 weeks showing significant improvements in the general vaginal disturbances these women suffer, both after 3 and 12 weeks of treatment ($p<0.001$).
- ▶ This reduction in the global symptomatology was considered clinically relevant for these women.



CONCLUSIONS

- ▶ These results show the efficacy of the regular use of this non-hormonal polycarbophilic mucoadhesive vaginal gel for the substantial relief of moderate to severe vulvovaginal symptoms.
- ▶ Vaginal dryness, dyspareunia and pruritus assessed individually and the general disturbances considered as a whole (Global Symptom Score) improved significantly after only 3 weeks of daily treatment. This early effect observed at week 3 was maintained until the end of treatment.
- ▶ Treatment with Ainara® vaginal gel was effective in the improvement of the most prevalent and annoying vaginal symptoms in 2/3 of women.
- ▶ Management of these symptoms can impact significantly on patients' quality of life as symptoms are very prevalent, disturbing and often lead to a gradual deterioration on women's urogenital health. Therefore, discussing vaginal health concerns and treatment options should be considered in the oncologist's regular clinical practice.