



## P55. AN OPEN-LABEL PROSPECTIVE STUDY TO EVALUATE THE EFFICACY AND TOLERABILITY OF A MEDICAL DEVICE WITH GLYCERYL POLYACRYLATE MOISTURIZER AND GLYCERIN FOR VAGINAL DRYNESS AND ATROPHY.

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**Context:** Vaginal dryness is usually a symptom of vaginal atrophy, caused by thinning and shrinking of the vaginal mucosa, as a result of exogenous and endogenous factors such as a lack of estrogen that happens naturally during perimenopause and even more so in post-menopause. However, this condition can occur in other circumstances that result in decreased estrogen. Vaginal dryness is usually accompanied with irritation, burning sensation, itching and dyspareunia.

**Objectives:** To evaluate the efficacy and tolerability of a medical device (MD) with glyceryl polyacrylate moisturizer and glycerin in women with vaginal atrophy.

**Methods:** An open-label prospective study.

**Patients:** 40 women with established menopause and vaginal atrophy (confirmed by cytology) and related symptoms.

**Interventions:** Women were instructed to apply the product on alternate days for 3 months (M). The efficacy and safety of the product were evaluated at 3M, 6M and 9M after study inclusion to evaluate the persistence of efficacy of the product.

**Main outcome measures:** The efficacy of the product was evaluated by assessing data obtained from vaginal cytology, cervical mucus characteristics and colposcopy. This last technique evaluated the paleness, presence of petechiae, vaginal elasticity and mucus friability on a 3-point score (from mild to marked). In addition, symptoms of itch, burning sensation, vaginal dryness and pain during intercourse were scored as mild, moderate or severe, as reported by patients to the gynecologist.

**Results:** At 3 months, the percentage of women with moderate or severe score decreased significantly ( $p < 0.5$ ) for vaginal dryness (48.7%), burning sensation (41%), itch (43.6%) and pain during intercourse (35.9%). These decreases persisted at 6 and 9 months: the percentage decreases were 87.2%, 74.4%, 59% and 69.2% at 6M and 74.4%, 69.2%, 61.5% and 66.7% at 9M respectively for vaginal dryness, itch,

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burning sensation and pain during intercourse. In addition, an improvement in cervical appearance was confirmed, evidenced by a significant decrease in the percentage of women with moderate or severe scores for paleness of mucous membranes, friability of the mucus at each visit, and a reduction of vaginal elasticity and presence of petechiae at 6M and 9M.

Conclusion: The MD with glyceryl polyacrylate moisturizer and glycerin for vaginal atrophy showed persistent improvement in symptoms in women with vaginal atrophy, thus improving their quality of life.