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Is vaginal hyaluronic acid as effective as vaginal estriol for vaginal dryness relief?

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Abstract

In a multicenter, randomized, controlled, open-label, parallel- group trial hyaluronic acid vaginal gel (Hyalofemme) was compared to estriol vaginal cream (Ovestin) in women with vaginal dryness due to various causes. A total of 144 supposedly postmenopausal women below age 70 years were randomized in a 1:1 ratio to either receive hyaluronic acid vaginal gel (5 g per application) or estriol vaginal cream (0.5 g cream per application = 0.5 mg estriol) every 3 days for a total of ten applications, respectively. Exclusion criteria included vaginal infections, conventional contraindications to estrogens, use of vaginal products other than the investigational compounds, being unmarried, pregnant, or breastfeeding. The aim of the study was to test for non-inferiority of hyaluronic acid vaginal gel compared to estriol vaginal cream. The primary efficacy end point was the percentage (%) improvement in vaginal dryness, with the secondary end points being the percentage (%) improvements in vaginal itching, burning, and dyspareunia. Efficacy was assessed by using a visual analog scale (VAS) (0-10; 0 = absent, 10 = intolerable) at baseline (V0), during telephone contact after the third administration (V1), and at the final visit after the tenth administration (V2). Safety parameters included vaginal pH, endometrial thickness, and a vaginal smear for vaginal microecosystem assessment. Adverse events were recorded according to international guidelines. 133 women completed the study. At baseline, participants' characteristics did not differ significantly. Mean age was 54 years, time since menopause was 5 years on average, and cause of menopause was mostly natural. However, mean menstrual cycle days were also reported, although according to inclusion criteria only postmenopausal women were eligible for the study. At V1, an improvement in vaginal dryness was reported by about 49 % of women using hyaluronic acid vaginal gel, and by 53 % of women using estriol vaginal cream ($p = 0.31$). At V2, the percentage improvement rates were 84 and 89 % ($p = 0.13$), respectively. Improvement rates for vaginal itching, burning, and dyspareunia at V2 were about 86, 85, and 57 % for hyaluronic acid vaginal gel, and 82, 87, and 62 % for estriol vaginal cream ($p[0.05]$), respectively. After treatment, vaginal pH was significantly lower in estriol-treated women compared to those having received hyaluronic acid. Endometrial thickness did not differ between groups. In the majority of women, the vaginal microenvironment remained unaffected by treatment. However, the proportion of women whose abnormal vaginal microecological

results became normal was higher in women using estriol vaginal cream. Adverse events (suspected to be) related to the investigational compounds were minor and included vaginal infection and genital itching. The authors concluded that hyaluronic acid vaginal gel was not inferior to estriol vaginal cream in women presenting with vaginal dryness. They suggest using hyaluronic acid vaginal gel not only as an alternative treatment to vaginal estrogens, but also to consider its general use in women presenting with vaginal dryness of any cause.

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