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LeAnn Chambers, Pharm.D. and Matthew Chambers, Pharm.D.

Local Ultra-Low-Dose Estriol Gel Treatment of Vulvo-Vaginal Atrophy

Vulvo-Vaginal Atrophy (VVA), also known as Genitourinary Syndrome of Menopause (GSM), is a chronic condition affecting over half of postmenopausal women. Local estrogen treatment is recommended. To evaluate efficacy and safety of long-term VVA treatment with ultra-low-dose estriol gel, 120 postmenopausal VVA women were enrolled in a prospective study. They received the first cycle of vaginal gel containing 50 µg (micrograms) estriol for 3 weeks and then twice a week for 12 weeks. Moderate or severe VVA women received a second treatment cycle reaching treatment of 30 weeks. Vaginal pH measurement, subjective symptoms, and objective signs assessment of VVA, endometrial thickness, and adverse events (AE) were recorded. Of the 99 women, completing the first phase, 43% experienced a complete VVA symptom relief, and 65% presented a milder VVA degree. After 30 weeks, VVA signs significantly improved compared with baseline and first phase results; total objective symptom evaluation including Schiller's test, flattening of folds, and vaginal pH significantly improved. At the study endpoint, none of the patients had severe VVA, 93% had a positive response, 75% had complete resolution of signs and symptoms. No treatment-related endometrial adverse effects were observed.

Gynecol Endocrinol. 2020 Jun;36(6):535-539.

Testosterone and Vaginal Function

Androgens have been shown to exert beneficial effects on vaginal physiology, at least partially independent of their aromatization to estrogens. Preclinical and clinical data consistently suggest that testosterone (T) plays an important role in maintaining vaginal health and genital sexual function. T is essential for the integrity of vaginal tissue structure

(including non-vascular smooth muscle thickness and contractility and collagen fiber compactness) and for the complex neurovascular processes that regulate arousal and lubrication. T has also been reported to modulate nociception, inflammation, and mucin secretion within the vagina. Androgen deficiency in the vagina and in the other genitourinary tissues contributes to the development of vulvovaginal atrophy and genitourinary syndrome of menopause (GSM), resulting in impaired arousal and lubrication and dyspareunia. Various androgen-based preparations are available to treat vulvovaginal atrophy/genitourinary syndrome of menopause and for other conditions leading to female genital arousal disorder and dyspareunia.

Sex Med 2020;8:379–392.

Vaginal DHEA May Improve Sexual Function in Women With Breast/Gynecologic Cancer

Breast and gynecologic cancer patients can experience a range of symptoms associated with sexual dysfunction, among them vaginal dryness and dyspareunia. Vaginal estrogen is the gold standard for treatment of vaginal symptoms, but it is a last resort in women with cancer due to safety concerns. There is a need for effective treatment without systemic estrogenic effects.

Vaginal dehydroepiandrosterone (DHEA) may improve sexual function, without negative systemic effects, in women with breast and gynecologic cancer with vaginal and sexual-related complaints. DHEA is a prohormone that is converted in target tissue. Previous work with DHEA has supported the hypothesis that when used vaginally it does not produce systemic effects.

Barton et al. of the University of Michigan conducted a study on postmenopausal women with a history of breast/gynecologic cancer who had completed chemotherapy and radiation and had no evidence of disease. Women were eligible if they reported at least moderately severe vaginal complaints present for no less than 2 months. 441 women were randomized to study arms of 3.25 versus 6.5 mg of DHEA versus plain moisturizer (PM). DHEA was compounded into a bioadhesive vaginal moisturizer gel, which was designed to adhere to the vaginal wall. Women inserted the DHEA using a prefilled syringe nightly for 12 weeks, just before sleep and subsequent to any sexual activity. Laboratory tests, maturation index, and vaginal pH were evaluated at baseline and again at 12 weeks.

Vaginal cell maturation was observed in 100% receiving DHEA 3.25 mg, 86% with DHEA 6.5 mg, and 64% with PM. In all arms, a significant reduction in the primary symptom was observed compared with baseline, with severity reduced by almost half, and there were no significant differences between the study arms. “However, the 2 doses of DHEA did significantly improve sexual function, with the 6.5-mg dose improving every single subscale of sexual function except for orgasm,” Barton noted. Systemic DHEA levels increased in each DHEA arm, but were consistent with the normal range for women in that age group. Based on these data, Barton and her colleagues concluded that DHEA improved physiological vaginal health and overall female sexual function more than PM alone.

Barton D, Sloan JA, Shuster LT, et al. Physiologic effects of vaginal dehydroepiandrosterone (DHEA): Alliance Trial N10C1. Presented at: 2014 Annual Meeting of the Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology; June 26-28, 2014; Miami, FL

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