The Mortar & Pestle:

MD Custom Rx's monthly e-newsletter

March 2020

MD Custom Rx
Quality Matters

PCAB ACCREDITED · PHARMACY COMPOUNDING ACCREDITATION BOARD

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Greetings!

Thank you for entrusting in the compounding services at MD Custom Rx to help meet the unique medication needs of your patients. We are excited to share our monthly newsletter with you and look forward to continuing to be your medication problem solvers. Please don't ever hesitate to let us know how we can be of further assistance to you and your practice.

Sincerely,
Dan, Monica and John

Hormonal, Metabolic, and Endometrial Safety of Testosterone Vaginal Cream versus Estrogens for the Treatment of Vulvovaginal Atrophy in Postmenopausal Women: a Randomized, Placebo-Controlled Study

The aim of the study was to evaluate the laboratory and endometrial safety of topical testosterone versus topical estrogen for the treatment of vaginal atrophy in postmenopausal women. This was a randomized, placebo-controlled trial of 60 postmenopausal women aged 40 to 70 years at the Menopause Clinic of CAISM UNICAMP (Brazil). Women were randomized to one of the following groups and received treatment 3 times a week for 12 weeks: 1) testosterone propionate vaginal: one vaginal applicator with 1 gm of cream per application containing 300 mcg/gm testosterone propionate prepared in emollient cream; 2) conjugated estrogens: one vaginal applicator with 1 gm of cream per application containing 0.625 mg conjugated estrogens (Premarin®, Wyeth); or 3) glycerin lubricant (placebo): one vaginal applicator with 3m g of gel per application (K-Y Gel, Johnson & Johnson).

Hormonal laboratory values of follicle-stimulating hormone, luteinizing hormone, estradiol, estrone, androstenedione, total testosterone, free testosterone,

dehydroepiandrosterone (DHEA), DHEA sulfate, and sex hormone-binding globulin were assessed at baseline and at 6 and 12 weeks. Metabolic laboratory values of total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, triglycerides, aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, and gamma-glutamyl transpeptidase were also assessed at baseline and at 6 and 12 weeks. Endometrial safety was assessed using ultrasonography at baseline and at 12 weeks. After 12 weeks of treatment, there were no significant differences in hormonal or metabolic laboratory values among all three groups. Two participants in the estrogen group had increased serum estradiol after 12 weeks of treatment. No change in endometrial thickening was reported in all three groups.

The authors concluded that 12 weeks of treatment with topical testosterone or estrogen in postmenopausal women with symptoms of vaginal atrophy demonstrated laboratory and endometrial safety when compared with placebo.

Menopause. 2018 Jun;25(6):641-647.

Vaginal Testosterone Cream vs Estradiol Vaginal Ring for Vaginal Dryness or Decreased Libido in Women Receiving Aromatase Inhibitors for Early-Stage Breast Cancer

The use of aromatase inhibitors (AI such as anastrozole, letrozole and exemestane) for treatment of breast cancer is associated with significant urogenital atrophy, affecting quality of life and compliance with therapy. A randomized clinical trial evaluated the safety of intravaginal testosterone cream (IVT) or an estradiol-releasing vaginal ring (7.5 microgram/day) in postmenopausal women with hormone receptor-positive stage I to III breast cancer taking AIs with self-reported vaginal dryness, dyspareunia, or decreased libido. Intervention was considered unsafe if more than 25% of patients had persistent elevation in estradiol (E2), defined as E2 greater than 10 pg/mL and at least 10 pg/mL above baseline after treatment initiation on 2 consecutive tests at least 2 weeks apart.

Women were randomized to receive IVT (micronized testosterone 1% in a cream base, 0.5 gm cream vaginally each night for two weeks, then 3 times a week for total of 12 weeks of treatment) or an estradiol vaginal ring (Estring® 2mg ring inserted vaginally once every 12 weeks). Estradiol was measured at baseline and weeks 4 and 12 and follicle-stimulating hormone levels were measured at baseline and week 4. Gynecologic examinations and sexual quality-of-life questionnaires were completed at baseline and week 12.

The primary objective was to evaluate safety of IVT or an estradiol vaginal ring in patients with early-stage BC receiving an AI; secondary objectives included evaluation of adverse events, changes in sexual quality of life, changes in vaginal atrophy, and comparison of E2 levels.

Overall, 76 women signed consent (mean [range] age, 56 [37-78] years), and 69 completed 12 weeks of treatment. The trial concluded that in postmenopausal women with early-stage breast cancer receiving AIs, treatment with an estradiol vaginal ring or intravaginal testosterone over 12 weeks met the primary safety end point. Baseline elevation in E2 was common. Vaginal atrophy, sexual interest, and sexual dysfunction were improved.

JAMA Oncol. 2017 Mar 1;3(3):313-319.

Vaginal Dehydroepiandosterone for Vaginal Symptoms in Postmenopausal Cancer Survivors: Efficacy, Local and Systemic Effects

Women with estrogen deficiencies can suffer from vaginal symptoms that negatively impact sexual health. This study evaluated vaginal dehydroepiandrosterone (DHEA) for alleviation of vaginal symptoms.

This three-arm randomized, controlled trial evaluated DHEA 3.25 mg and DHEA 6.5 mg, each compared to a plain moisturizer over 12 weeks, to improve the severity of vaginal dryness or dyspareunia, measured with an ordinal scale, and overall sexual health using the Female Sexual Function Index (FSFI). Postmenopausal women with a history of breast or gynecologic cancer who had completed primary treatment, had no evidence of disease, and reported at least moderate vaginal symptoms were eligible. The mean change from baseline to week 12 in the severity of vaginal dryness or dyspareunia for each DHEA dose was compared to plain moisturizer.

Women (n=464) were randomized. All arms reported improvement in either dryness or dyspareunia. Neither DHEA dose was statistically significantly different from plain moisturizer at 12 weeks, although a significant difference at 8 weeks for 6.5 mg DHEA was observed. Women on the 6.5 mg arm of DHEA reported significantly better sexual health on the FSFI. There were no significant differences in provider-graded toxicities and few significant differences in self-reported side effects.

A secondary analysis evaluated the impact of vaginal DHEA on hormone concentrations, bone turnover, and vaginal cytology in women with a cancer history.

Postmenopausal women, diagnosed with breast or gynecologic cancer, were eligible if they reported at least moderate vaginal symptoms. Participants could be on tamoxifen or aromatase inhibitors (AIs). Women were randomized to DHEA 3.25 mg versus 6.5 mg/day versus a plain moisturizer as control. Sex steroid hormone levels, biomarkers of bone formation, vaginal pH, and maturation index were collected at baseline and 12 weeks. Analysis included independent Wilcoxon rank tests and t-tests, comparing each DHEA arm with the control.

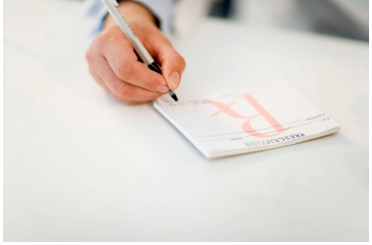
345 women contributed evaluable blood and 46 contributed evaluable cytology and pH values. Circulating DHEA-S (dehydroepiandrosterone sulfate) and testosterone levels were significantly increased in those on vaginal DHEA in a dose-dependent manner compared to plain moisturizer. Estradiol was significantly increased in those on DHEA 6.5 mg/day but not in those on DHEA 3.25 mg/day, and not in those on AIs. Biomarkers of bone formation were unchanged in all arms. Maturation of vaginal cells was 100% (3.25 mg/day), 86% (6.5 mg/day), and 64% (plain moisturizer); pH decreased more in DHEA arms.

DHEA resulted in increased hormone concentrations, though still in the lowest half or quartile of the postmenopausal range, and provided more favorable effects on vaginal cytology, compared to plain moisturizer. Estrogen concentrations in women on AIs were not changed. Vaginal DHEA 6.5 mg/day significantly improved sexual health. Further research on the benefit of vaginal DHEA is warranted in women with a history of hormone-dependent cancers.

Support Care Cancer. 2018 Feb;26(2):643-650.
Support Care Cancer. 2018 Apr;26(4):1335-1343.

MD Custom Rx Educational Events

We regularly offer educational events at the pharmacy. Be sure to share our events with your patients. **VISIT OUR WEBSITE** to see our schedule and to register. If you are interested in speaking on a topic, please contact the pharmacy.



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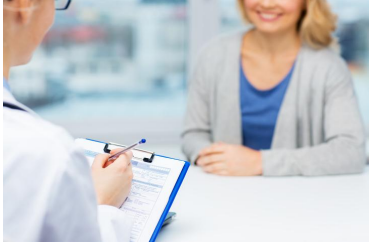

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