

Intravaginal DHEA Eases Postmenopausal Vaginal Dryness, Pain

Marcia Frellick
January 06, 2016

Source: <https://www.medscape.com/viewarticle/856796>

Positive results from a phase 3 trial of intravaginal dehydroepiandrosterone (DHEA; EndoCeutics) suggest it may be a viable alternative to intravaginal estrogen in combatting dryness and painful sex after menopause.

"The fact that we would have another new hormonal treatment that is not estrogen is exciting," JoAnn Pinkerton, MD, NCMP, executive director of the North American Menopause Society, told *Medscape Medical News*. "And unlike lubricants and moisturizers, it actually corrects the problem. For women who are fearful of or don't want to use vaginal estrogens, it gives them a hormonal vaginal product that works."

DHEA is a hormone, but the effects appear to be localized, which means no significant amount of sex hormone gets released into the bloodstream. All estrogen-based vaginal formulations increase estrogens in the bloodstream, even at low doses, say lead author Fernand Labrie, MD, PhD, president and chief executive officer of EndoCeutics Inc, Quebec City, Quebec, Canada, and colleagues. Findings of the study, funded by EndoCeutics, were [published online](#) December 28, 2015, in *Menopause*. In an [earlier interview](#) with Reuters Health, Dr Labrie said he expects approval by the US Food and Drug Administration this year.

Significant Gains in Key Measures

Compared with the 157 women who used a placebo, the 325 women in the trial who used the daily 0.5% DHEA (6.5 mg) suppositories saw significant improvements in key areas after 12 weeks.

Their pain with sex scores on a scale from 0 to 3 dropped a significant 0.36 points more than for the women who used the placebo ($P = .0002$). DHEA also improved vaginal pH, reducing it by 0.66 pH over placebo ($P < .0001$).

In addition, among the 84.0% of women with moderate to severe vaginal dryness, those in the DHEA group had a 0.27 unit greater improvement than those in the placebo group (also on a scale of 0 - 3; $P = .004$).

Gynecologists saw 86% to 121% improvements in vaginal secretions, lining thickness, and tissue color in the women who used DHEA ($P < .0001$ for all comparisons with placebo).

Nonhormonal creams and lubricants are also alternatives to intravaginal estrogen and can temporarily ease pain with sex, but they cannot correct the physical changes that produce the symptoms as DHEA can, according to the authors.

The safety profile was also positive. "The only side effect reasonably related to treatment is vaginal discharge due to melting of the vehicle at body temperature," the authors write. "[T]his was reported in 6% of the participants."

Without hormonal treatment after menopause, vaginal tissues atrophy, the lining thins and secretes less fluid, and the pH becomes more alkaline, which leads to painful sex as well as increased susceptibility to infections and urinary problems.

The findings should spark conversations among patients and providers, said Dr Pinkerton, who is also a professor of obstetrics and

gynecology and division director of Midlife Health at the University of Virginia Health Center in Charlottesville.

"Many women are fearful about talking about painful intercourse, and therefore don't know that there are therapies out there: over-the-counter products and vaginal estrogen products that are safe for most women and have minimal risks," she said. "Women are not talking about having painful sex. Providers aren't asking about it." She noted that women who have had complications with vaginal estrogen or who have had a prior estrogen-sensitive cancer would need to talk with their oncologist.

A similar conversation would need to happen around the DHEA vaginal suppositories, she said, which have not been tested in women who have had or are at risk for breast cancer.

"We think that there would be minimal risk, but until you test something in the population, you don't know that there's no risk," she said.

Dr Labrie is president and chief executive officer of EndoCeutics. Various coauthors report consulting for EndoCeutics, Sprout, Palatin, Nuelle, Actavis, Noven, Shionogi, and Pfizer. One coauthor received a grant from TherapeuticsMD. Dr Pinkerton reports receiving royalties from Henry Stewart Publications, consultant work for Pfizer, and grant/research support from TherapeuticsMD. Menopause. Published online December 28, 2015. [Abstract](#)