http://www.healthylivingmagazine.us/Articles/8062/

By Anne Harding

Vulvovaginal atrophy symptoms improve with prasterone treatment

NEW YORK - Prasterone treatment has parallel beneficial effects on the three main symptoms of vulvovaginal atrophy (VVA), regardless of which symptom a patient finds the most troubling, a new phase III open-label study shows.

"It doesn't depend if it is most bothersome for one woman in particular or not, it will respond in any case the same way," Dr. Fernand Labrie, the founder and CEO of EndoCeutics, in Quebec City, Quebec, and the first author of the new study, told Reuters Health in a telephone interview.

The researchers also found that patients saw additional improvements in their symptoms between 12 and 52 weeks of treatment.

EndoCeutics, who funded this research, developed the intravaginal 0.5% (6.5 mg) DHEA product as a treatment for VVA in postmenopausal women, and has completed all phase III studies, Dr. Labrie said. He said he expected that the U.S. Food and Drug Administration would approve the treatment in 2016.

In the current study, published online February 16 in Maturitas, Dr. Labrie and his colleagues looked at the time course of moderate to severe symptoms including dyspareunia, vaginal dryness, and irritation/itching in 521 women who received prasterone daily for 52 weeks. They looked at the symptoms in women who had 5% or less superficial cells and a vaginal pH above 5.

Dyspareunia pain severity score went from 2.57 at baseline to 0.87 at one year for the women who rated this as their most bothersome symptom (n=183), for a decrease in pain severity of 66.1%. For the women who had

dyspareunia but did not consider it to be their most bothersome symptom (n=57), pain severity decreased from 2.53 at baseline to 0.85 at 52 weeks.

Women who rated vaginal dryness as their most bothersome symptom (n=81) had a 73.4% decrease in severity from baseline to one year, as did those who had vaginal dryness but did not consider it to be their most bothersome symptom (n=170).

A total of 86 women reported irritation and itching at baseline, but only 23 women rated this as their most bothersome symptom. Both groups reported a roughly 70% decrease in symptom severity, on average.

Within the safety population of 454 patients, percentage of parabasal cells was reduced from 55.49% at baseline to 12.81% at 52 weeks, while the percentage of superficial cells increased from 2.02% to 8.72%. Vaginal pH decreased from 6.23 to 5.09. Women also showed significant improvement in vaginal color and vaginal epithelial integrity and thickness.

Application site discharge, the only applicable drug-related adverse event, occurred in 14% of study participants.

While the FDA recommends determining the individual symptom of VVA for which the drug is most effective, the researchers note, this can reduce the number of patients included in an analysis, and make it difficult to perform valid subgroup analyses for each symptom. Based on the finding that each VVA symptom responded similarly to treatment in the new study, they add, analyzing all symptoms together "takes maximal advantage of all the data available during a study."

It's not clear whether treatment would need to be continued indefinitely to result in continued VVA symptom improvement, Dr. Labrie said. In clinical practice, he added, he and his colleagues believe that after three months of treatment with prasterone, a woman and her doctor could decide together whether or not to continue treatment. "You have to adjust the treatment for each woman," he said.

SOURCE: http://bit.ly/1aKtpbb

Maturitas 2015.

References: Reuters Health