Ospemifene for Vulvar and Vaginal Atrophy

Just over a year ago, the U.S. Food and Drug Administration (FDA) approved ospemifene, marketed under the name Osphena, for postmenopausal women experiencing moderate to severe dyspareunia (painful intercourse).

When a woman’s estrogen levels drop at menopause, cellular changes occur in her vulvar and vaginal tissues. This can lead to a condition called vulvar and vaginal atrophy (VVA). VVA is estimated to affect about 60% of women.

For women with VVA, vaginal tissues become drier and less flexible. There may be an increase in vaginal pH. The vagina can also narrow and shorten, especially if a woman doesn’t have sex regularly.

The result can be irritation, burning sensations, and vaginal discharge. Intercourse may become painful, as there is less vaginal lubrication and greater risk of tearing and bleeding.

VVA symptoms usually do not get better without treatment. Typical therapies include systemic hormone therapy, vaginal estrogen products, and nonhormonal lubricants and moisturizers that can be purchased over the counter. However, some women cannot take estrogen-based products or prefer not to.

Ospemifene offers postmenopausal women an alternative to estrogen treatments for VVA. Taken as a pill once daily with food, the drug acts like estrogen to keep vaginal tissues healthy and elastic.

Last fall, Chinese researchers published a study in the Journal of Sexual Medicine that examined the efficacy and safety of ospemifene in treating painful sex in postmenopausal women with VVA. Today, we’ll take a closer look at this research.

The Study

The researchers performed a meta-analysis of six randomized controlled trials that compared ospemifene with a placebo. Taken together, the studies involved almost 1,800 postmenopausal women. Three studies were considered short-term, lasting for twelve weeks. The other three were long-term, covering a 12-month period.
Studies were rated as A, B, and C according to their quality, as deemed by the researchers. Studies labeled A were considered the highest quality, with those labeled C considered poorer quality. The studies analyzed here were classified as A or B.

The researchers found that when compared to placebo, ospemifene significantly decreased vaginal pH levels and reduced vaginal pain during intercourse. In the short term studies, women taking ospemifene reported more adverse effects, but these did not appear to affect discontinuation rates.

_Endometrial Concerns_

Both short-term and long-term studies found greater increases in endometrial thickness for women taking ospemifene compared to those taking the placebo, although the authors called these increases “negligible.”

Still, this concern has been addressed by the FDA, which issued a “boxed warning” with the drug’s approval.

The endometrium refers to the lining of the uterus. In menstruating women, the endometrium naturally thickens once a month to prepare for a possible pregnancy. If no pregnancy occurs, the endometrium “sheds” and leaves the body during a woman’s period.

In postmenopausal women, it is not normal for the endometrium to thicken. Women taking ospemifene should see their healthcare professionals if they have any unusual bleeding, as this can be a sign of endometrial cancer.

Ospemifene may also increase the risk of strokes and blood clots.

_Is Ospemifene Right For Your Patients?_

The study authors concluded, “This meta-analysis indicates ospemifene to be an effective and safe treatment for dyspareunia associated with postmenopausal VVA.” But is it right for your patients?

It could be. Before recommending any medication, it’s important to assess a woman’s overall health and consult prescribing information.

However, it’s very possible that ospemifene could help make sex more comfortable for postmenopausal patients suffering from VVA.
Resources

*The Journal of Sexual Medicine*

Cui, Yuanshan, MD, et al.

“The Efficacy and Safety of Ospemifene in Treating Dyspareunia Associated with Postmenopausal Vulvar and Vaginal Atrophy: A Systematic Review and Meta-Analysis”

(Full-text. First published online: November 23, 2013)


*The North American Menopause Society*

“Changes in the Vagina and Vulva”


*Osphena.com (Shionogi Inc.)*

“Important Safety Information”

http://www.osphena.com/#isi

*Sexual Medicine Society of North America*

“Osphena Approved to Treat Painful Sex”

(April 9, 2013)


“Vulvar and Vaginal Atrophy”

(June 26, 2013)

http://www.sexhealthmatters.org/sex-health-blog/vulvar-and-vaginal-atrophy
**U.S. Food and Drug Administration**

“FDA approves Osphena for postmenopausal women experiencing pain during sex”

(News release. February 26, 2013)

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm341128.htm