

Survey shows postmenopausal women with VVA report improved satisfaction with VagiCap

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Newly released patient satisfaction survey results from a study of a novel investigational vaginal estrogen treatment show promise for improving quality of life and satisfaction for postmenopausal women who experience pain during sex and other symptoms associated with vulvar and vaginal atrophy (VVA).

University Hospitals (UH) Case Medical Center and TherapeuticsMD, Inc. announced that Sheryl A. Kingsberg, PhD, will present results today from a patient experience survey of investigational compound TX-004HR (VagiCap) at the International Society of Women's Sexual Health (ISSWSH) 2015 Annual Meeting, February 19-22 at the Sheraton Hotel in Austin, Texas.

Dr. Kingsberg, Chief of the Division of Behavioral Medicine Department of OB/GYN at UH Case Medical Center in Cleveland, will present the findings of a survey evaluating use and satisfaction of a vaginal softgel capsule utilized in a pilot phase 2, 14-day study on VVA. The presentation, "Patient Experience with Solubilized Estradiol Given Vaginally in a Novel Softgel Capsule (VagiCap™)" is scheduled for today at 11:40 a.m. CST. The ISSWSH Annual Meeting brings together scholars, researchers and practitioners to further their knowledge and commitment to the field of [women's](#) sexual health.

"Menopause is typically associated with hot flashes, but there are other

common and distressing symptoms such as pain and discomfort during sex due to lack of estrogen. Approximately 30 million women in the United States experience this condition, which can really impact their quality of life," said Dr. Kingsberg. "It's important that women have options when it comes to their sexual health, and TX-004HR VagiCap may, if approved by the FDA, represent a novel treatment for VVA that women may find to be convenient and easy to use."

Between 25 and 45 percent of [postmenopausal women](#) find sex painful, a condition called dyspareunia. While there are many causes, the most common in women over 50 is VVA. Symptomatic VVA can significantly impair the quality of life in postmenopausal women and impact their sexual function and health. Although more than 50 percent of postmenopausal women will experience VVA symptoms, the condition remains underdiagnosed and undertreated - only 7 percent are on prescription therapy.

VVA is a chronic condition resulting from the decrease in naturally occurring estrogen during menopause, resulting in thinning of the vaginal lining and an increase in vaginal pH levels. Women with VVA may suffer mild to severe symptoms that include vaginal and vulvar pain and discomfort, irritation, itching, burning, discharge, pain with urination (dysuria) and painful intercourse (dyspareunia).

The pilot phase 2 randomized study involved women between the ages of 40-75. The research team found based on a qualitative survey that 63 percent of women on TX-004HR VagiCap reported an improved "[change] in quality of life after treatment in this study" with only two weeks of therapy treatment, compared to 48 percent on the placebo.

"For many women, symptoms such as these have a major impact on frequency and spontaneity of their sexual activity. It is essential that health care attendants routinely engage in open and sensitive discussions

with postmenopausal women to ensure that symptomatic atrophy is detected early and appropriately managed," said Dr. Kingsberg, who is also a professor at Case Western Reserve University School of Medicine. "New treatment options—such as this VagiCap, if approved by the FDA—have the potential to improve satisfaction for these women. There is medical consensus that estrogen administered locally is the preferred mode of treatment for both symptom reduction and restoring and maintaining healthy vaginal tissue and sexual function."

VVA and dyspareunia fall under the umbrella of "genitourinary syndrome of menopause" (GSM) that refers to the collection of symptoms associated with decreased estrogen levels that can involve the genital system or the lower urinary tract.

More information: Kingsberg, Sheryl A., et. al. "Vulvar and Vaginal Atrophy in Postmenopausal Women: Findings from the REVIVE (REal Women's Views of Treatment Options for Menopausal Vaginal ChangEs) Survey." *Journal of Sexual Medicine* 2013, no. 10, 1790-1799.

Provided by University Hospitals Case Medical Center

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