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HIGHLIGHTS:

A testosterone patch has been found to significantly increase sexual desire and the frequency of satisfying sexual activity in women experiencing low libido after menopause following the surgical removal of both ovaries. Results from the large, phase III, double-blind clinical trial are reported at the 52nd Annual Clinical Meeting of the American College of Obstetricians and Gynecologists (ACOG), and may lead to a new way for surgically menopausal women to regain a satisfying sex life.

MAJOR STUDY FINDS THAT AN EXPERIMENTAL TESTOSTERONE PATCH SIGNIFICANTLY IMPROVED SEXUAL DESIRE AND ACTIVITY IN SURGICALLY MENOPAUSAL WOMEN EXPERIENCING LOW LIBIDO

LOS ANGELES (May 4, 2004) – A testosterone patch has been found to significantly increase sexual desire and the frequency of satisfying sexual activity in women experiencing low libido after menopause following the surgical removal of both ovaries. The findings, reported at the 52nd Annual Clinical Meeting of the American College of Obstetricians and Gynecologists (ACOG), in Philadelphia, may lead to a new way for surgically menopausal women to regain a satisfying sex life.

The large, Phase III, double-blind clinical study, which was conducted at multiple centers across the United States, evaluated 562 women diagnosed with Hypoactive Sexual Desire Disorder, a condition characterized by a lack of sexual desire that causes personal distress. The study, conducted over a six-month period, found that women experienced a great improvement in their sexual function and desire when small amounts of testosterone were released via a testosterone patch – a thin, transparent patch worn on the abdomen.

“A loss of libido is especially prevalent at menopause and can seriously impact a woman’s relationship with her partner,” said Glenn Braunstein, M.D., the senior author of the study and the Chairman of the department of Medicine at Cedars-Sinai Medical Center in Los Angeles. “Our findings show that giving women back some of the testosterone that they lose after surgical menopause, may provide a new way to treat them so that they can enjoy their sex life once again.”

As a sex hormone, testosterone plays a key role in sex drive and function in both men and women, and is not exclusive to males even though they produce much more of it. In fact, women produce testosterone in their ovaries and adrenal glands, each of which produce about half of the total testosterone in the body prior to menopause. But when testosterone declines, either through the natural course of aging or through menopause brought on by the surgical removal of both ovaries, many women are left experiencing a significantly lower libido.

For many women, lower libido translates into personal distress and leads to a condition known as Hypoactive Sexual Desire Disorder (HSDD). This includes a decline in or absence of sexual thoughts or fantasies, and a lack of interest in sex or being sexual. HSDD is one of the most prevalent female sexual problems.

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“An estimated one in three American women suffer from low sexual desire, making it the most common sexual problem in women,” said Dr. Braunstein. “No medications are currently approved by the U.S. Food and Drug Administration for treating diminished sexual desire. This study may bring us closer to providing surgically menopausal women with an effective treatment to improve their sex life and overall feelings of well-being.”

In the study, investigators enrolled 562 women at multiple centers who had been diagnosed with HSDD, had gone through surgical menopause, and were on estrogen replacement therapy. On average, the women were 49-years-old, had been in stable relationships for an average of 19 years, and had their ovaries removed about eight years prior to the study. Patients were randomly selected to receive either an active patch at 300 micrograms (mcg) of testosterone per day or to receive an inactive placebo patch, for a 24-week period. The patches were changed twice weekly.

To assess the effectiveness of the testosterone patch, investigators first measured the change in total satisfying sexual activity, as had been recorded by the women in a Sexual Activity Log, at the end of the 24-week period. In addition, the investigators used two standardized, validated questionnaires called the Profile of Female Sexual Function and the Personal Distress Scale to measure seven areas of sexual function and distress: desire, arousal, orgasm, pleasure, responsiveness, concerns and self-image.

At 24 weeks, the investigators found that the frequency of total satisfying sexual activity had increased by 74 percent over the established baseline rate. In addition, they found that sexual desire had increased by 56 percent over baseline among the women receiving the testosterone patch – responses that were significantly greater than in those receiving placebo.

Side effects from the testosterone patch were comparable to the placebo, with the most common being a site reaction where the patch was applied, upper respiratory infection, and headache.

“This study suggests that replacing small amounts of testosterone normally produced by a woman’s ovaries is important to normal sexual function,” said Dr. Braunstein. “These patients not only benefited, but experienced very few side effects.”

Cedars-Sinai Medical Center is one of the largest non-profit academic medical centers in the Western United States. For the fifth straight two-year period, Cedars-Sinai has been named Southern California’s gold standard in health care in an independent survey. Cedars-Sinai is internationally renowned for its diagnostic and treatment capabilities and its broad spectrum of programs and services, as well as breakthrough in biomedical research and superlative medical education. The Medical Center ranks among the top 10 non-university hospitals in the nation for its research activities.

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