Testosterone Therapy: Good for Women Too

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Long-term testosterone replacement therapy (TRT) is well tolerated in HIV-positive women and results in significant improvements in body composition, bone mineral density (BMD) and quality of life, according to new data presented by Harvard researchers on Tuesday, February 10, at the 16th Conference on Retroviruses and Opportunistic Infections (CROI) in Montreal.

Until recently, few researchers and health care providers recognized the importance of testosterone in women—and the need for TRT in women deficient in this particular hormone. Testosterone, like estrogen and progesterone, is produced by the ovaries and adrenal glands in women's bodies.

Earlier studies indicate that testosterone deficiency is common in HIV-positive women. Though women don't require nearly as much testosterone as men, below-normal levels can lead to menstrual irregularities, weight loss, muscle wasting, hot flashes, changes in mood and behavior, decreased BMD and fatigue.

Sarah Dolan Looby, PhD, APRN, and her colleagues at Massachusetts General Hospital and Harvard Medical School in Boston conducted a clinical trial to evaluate the long-term safety and effectiveness of long-term TRT in a group of HIV-positive women. Twenty-five volunteers, all with free testosterone levels below 3 picograms per milliliter (pg/mL)—the normal range is between 1.1 and 6.3 pg/mL—were enrolled. Thirteen received skin patches containing testosterone (300 micrograms applied twice weekly) or placebo patches and underwent a variety of tests during the study, including blood testing, body composition analyses, bone density scans and quality of life surveys.

On average, women entered the study with testosterone levels of 1.3 pg/mL, low body weight and low bone density. About 16 percent of the women discontinued treatment during the 18-month follow-up period, with no statistically significant differences between the two groups. In other words, the HIV-positive women were just as likely to discontinue TRT as they were placebo.

Free testosterone levels—the amount of active testosterone in the bloodstream—increased by 7.9 pg/mL after 18 months in the TRT group, compared with a 0.3 pg/mL gain in the placebo group. While this increased free testosterone levels above the normal range in many women, TRT was well tolerated and did not have any virilizing effects (e.g., clitoral enlargement, acne, hair

thickening or thinning, deepening voice, etc.). Nor did TRT, compared with placebo, affect blood lipid levels, liver function or viral load.

Lean body mass—mass of the body minus the fat—increased, on average, by almost four pounds in the TRT group, compared with a lean body mass gain of 1.76 pounds in the placebo group. This difference was statistically significant, meaning that it was too large to have occurred by chance.

Women in both groups saw modest reductions in their fat mass as well, though the difference between those receiving TRT and placebo was not statistically significant. TRT, compared with placebo, had a more pronounced effect on BMD, notably when looking at the ball and socket of the hip joint. It also was more likely to have a positive effect on depression scores and problems associated with sexual function.

Looby and her colleagues remain encouraged by these findings and call for other clinical trials to further evaluate the safety and effectiveness of TRT use among HIV-positive women.
