

Testosterone may significantly improve sexual function and sexual well-being in postmenopausal women

July 26 2019

However, authors note that non-oral formulations are preferred because of the adverse lipoprotein effects of oral testosterone. So far, adverse side effects of non-oral formulations appear to be restricted to small weight gain, mild acne and increased hair growth, but more research on long-term effects is needed.

The most comprehensive systematic review and meta-analysis of testosterone treatment for <u>women</u> undertaken, including 46 reports on 36 trials involving 8,480 women, published in *The Lancet Diabetes & Endocrinology* journal, suggests it can significantly improve sexual wellbeing for <u>postmenopausal women</u>. Benefits include improved sexual desire, function and pleasure, together with reduced concerns and distress about sex.

Although best known as a male hormone, testosterone is important for female sexual health, contributing to libido and orgasm as well as helping to maintain normal metabolic function, muscle strength, cognitive function and mood. Levels decline naturally over a woman's lifespan, and can also drop sharply following surgical menopause. Prior research has suggested that testosterone therapy can improve sexual function in women, but the available formulations have been designed for men and evidence for their safety or for <u>adverse side-effects</u> in women is scant.

"Our results suggest it is time to develop testosterone treatment tailored



to postmenopausal women rather than treating them with higher concentrations formulated for men," says senior author Professor Susan Davis from Monash University, Australia. "Nearly a third of women experience <u>low sexual desire</u> at midlife, with associated distress, but no approved testosterone formulation or product exists for them in any country and there are no internationally-agreed guidelines for testosterone use by women. Considering the benefits we found for women's sex lives and personal wellbeing, new guidelines and new formulations are urgently needed."

In this study, scientists reviewed 46 reports about 36 randomised controlled trials, conducted between January 1990 and December 2018 and involving 8,480 participants aged 18 to 75 years, approximately 95% of whom were post-menopausal. The trials compared testosterone treatment to a placebo or to an alternative hormone treatment such as oestrogen, with or without progestogen.

The authors reviewed the effects of treatments on sexual function and on measures of heart, cognitive and musculoskeletal health. The authors also looked for other <u>serious side effects</u> such as increased risk of heart disease or breast cancer, as well as the impact on mood and wellbeing, other measures of breast health such as mammographic density, metabolic effects, lipid profiles, and the development of androgenic effects such as increased hair growth.

As there were few studies available for premenopausal women (three studies in 226 women), the authors noted that no conclusions could be drawn about the efficacy of testosterone treatment for sexual dysfunction in this group, and larger studies are needed to inform clinical recommendations.

In 15 studies involving 3,766 naturally and surgically postmenopausal women, consistent beneficial effects were seen for all measures of



sexual function. Testosterone treatment resulted in an increase in the frequency of satisfactory sexual events. Treatment significantly increased <u>sexual desire</u>, pleasure, arousal, orgasm, responsiveness to sexual stimuli and self-image. Women treated with testosterone also showed reduced measures of sexual concerns and sexually-associated distress.

"The beneficial effects for postmenopausal women shown in our study extend beyond simply increasing the number of times a month they have sex," says Professor Davis. "Some women who have regular sexual encounters report dissatisfaction with their sexual function, so increasing their frequency of a positive sexual experience from never, or occasionally, to once or twice a month can improve self-image and reduce sexual concerns, and may improve overall wellbeing."

The study found no beneficial effects on cognitive measures, bone mineral density, body composition or muscle strength. No benefits were seen for depressive mood irrespective of menopausal status or in psychological wellbeing. However, the number of women included in these studies was small, and further research is needed.

No serious adverse effects on postmenopausal women were recorded for glucose or insulin in the blood, for blood pressure, or for measures of breast health. However, only limited data were available for breast cancer risk and further research is needed to clarify the effects. With non-oral testosterone, the authors found no effects on lipid profiles or metabolic variables such as cholesterol (10 studies involving 1774 women). However, oral formulations of testosterone increased LDL cholesterol, and reduced HDL cholesterol, overall cholesterol and triglycerides (a type of fat associated with an increased risk of heart disease). Postmenopausal women treated with testosterone were also not more likely to experience a serious cardiovascular event such as a heart attack or stroke (9 clinical trials with 4,063 women).



Although an increase in acne was shown in 11 studies involving 3,264 women, and an increase in hair growth was shown in 11 studies involving 4,178 women, the number of participants who withdrew from clinical trials due to these side-effects was not greater for women treated with testosterone compared with placebo, suggesting the effects are mild and not a major concern for participants. Five studies involving 2,032 participants indicated that testosterone treatment was associated with some weight gain. The authors recommend that patients are advised of these effects so they can make an individual choice whether to go ahead with testosterone treatment.

In a linked Comment, Dr. Rossella Nappi from the University of Pavia, Italy, writes about the potential benefits of testosterone highlighted in the study: "Notwithstanding these findings, we must gain insight into the therapeutic role of testosterone for women by designing adequate longterm studies to address benefits and risk in specific clinical conditions relevant to healthy female longevity. In particular, there is an urgent need in the area of sexual medicine to ensure gender equality in treating effectively those women with female sexual dysfunction clearly related to hypoandrogenic states. However, products specifically approved in women should become available to achieve this goal; at present, only male formulations are available, with clinicians adjusting the dose to the female circulating testosterone range."

More information: Rakibul M Islam et al, Safety and efficacy of testosterone for women: a systematic review and meta-analysis of randomised controlled trial data, *The Lancet Diabetes & Endocrinology* (2019). DOI: 10.1016/S2213-8587(19)30189-5

Provided by Lancet



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