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TESTOSTERONE THERAPY FOR HYPOACTIVE SEXUAL DESIRE DISORDER IN WOMEN

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ABSTRACT

Introduction and Purpose:

Testosterone plays a pivotal role in women's sexual health, influencing sexual desire, arousal, and satisfaction. This hormone, primarily produced in the ovaries, adrenal glands, and adipose tissue, declines with age, especially during menopause, leading to sexual dysfunction such as hypoactive sexual desire disorder (HSDD). The purpose of this article is to review the role of testosterone in female sexual function, evaluate the efficacy and safety of testosterone therapy (TRT) for women with HSDD, and discuss the ongoing challenges in its use.

Materials and Methods:

The article is a comprehensive review of current literature, including clinical studies and trials involving testosterone therapy in women with low libido, especially in postmenopausal women. It highlights the various forms of testosterone supplementation, such as transdermal patches and topical gels, as well as monitoring recommendations for assessing testosterone levels and side effects during treatment.

Results:

Testosterone therapy has shown promising results in improving sexual desire, arousal, and satisfaction in women, particularly those postmenopausal or following surgical castration. While the therapy is generally well-tolerated, common side effects include acne, hirsutism, and voice deepening. The optimal dosing regimen and long-term safety, especially in premenopausal women, remain unclear, with ongoing studies indicating positive short-term outcomes. Clinical guidelines recommend individualized treatment.

Conclusion:

Testosterone replacement therapy is a viable option for women with HSDD, particularly in those with diminished testosterone levels due to menopause or surgical intervention. While promising, careful management is essential to mitigate side effects and ensure patient safety. Continued research is necessary to establish standardized treatment protocols and to further assess the long-term effects of testosterone therapy on women's sexual health.

Keywords: systemic testosterone, hypoactive sexual desire disorder, female sexual dysfunction, ISSWSH, testosterone therapy, menopause, sexual arousal

Introduction

Testosterone is an essential hormone for women, contributing to various physiological processes such as sexual desire, arousal, muscle mass maintenance, bone health, and psychological well-being. Despite being a predominantly male hormone, testosterone is present in much lower levels in women, where it plays a critical role in maintaining sexual function and overall quality of life. Women typically produce testosterone in their ovaries, adrenal glands, and adipose tissue. It is important to note that while testosterone is much less abundant in women compared to men, its effects on sexual health are profound and far-reaching. [1]

The decline in testosterone levels with age - particularly during menopause or after surgical castration - can lead to significant sexual dysfunction, including diminished libido, reduced sexual satisfaction, and difficulty achieving orgasm. Given the central role of testosterone in sexual desire and function, testosterone replacement therapy (TRT) has emerged as a potential treatment for women experiencing hypoactive sexual desire disorder (HSDD), a condition characterized by a lack of sexual desire that causes significant distress and impairment in women's relationships and quality of life.

Although testosterone therapy has shown promising results in improving sexual desire in women, the precise mechanisms by which testosterone influences sexual function in women remain only partially understood.[2]

Testosterone and Its Role in Female Sexual Function

Testosterone exerts its effects in women through its direct actions and its conversion into estradiol, a potent estrogen, via aromatization. Testosterone impacts multiple areas of sexual function, including arousal, lubrication, and orgasm. Unlike estrogen, which primarily enhances vaginal lubrication and increases blood flow to the genital organs, testosterone's action is more direct in influencing libido and sexual desire. This is particularly important for women experiencing sexual dysfunction due to hormonal changes related to menopause or medical interventions such as oophorectomy (ovary removal).[3]

Testosterone levels in women decline gradually with age, reaching a significant drop after menopause. This decrease in testosterone is associated with a reduction in sexual desire, diminished arousal, and lower sexual satisfaction. While estrogen therapy can alleviate some menopausal symptoms, it is less effective in directly addressing low libido. In contrast, testosterone supplementation has been shown to improve sexual desire and arousal, especially in postmenopausal women, by targeting the underlying hormonal deficiencies.[3, 4]

Research has consistently demonstrated that testosterone is essential for sexual motivation, desire, and satisfaction in women. Studies have shown that women with low testosterone levels often experience decreased sexual interest, and supplementation with testosterone has led to improvements in sexual function. However, it is crucial to note that testosterone therapy must be carefully managed, as high doses or prolonged use may lead to unwanted side effects, such as acne, excessive hair growth, deepening of the voice, and changes in lipid profiles. [3, 4]

Synthesis of Androgens in Women

In women, androgens are synthesized primarily in the ovaries, adrenal glands, and adipose tissue. The ovaries produce androgens in response to luteinizing hormone (LH) and follicle-stimulating hormone (FSH), while the adrenal glands generate dehydroepiandrosterone (DHEA) and DHEA sulfate (DHEAS), which are converted into testosterone and dihydrotestosterone (DHT) through enzymatic processes. (Figure 1) Testosterone, a key metabolic, vascular, and reproductive hormone, is produced at 0.2–0.25 mg/day in premenopausal women, with circulating levels of 300–400 pmol/L. It binds to albumin (~30–45%) and SHBG (~65%), with only 1–3% as free testosterone.

Testosterone exerts its effects through direct action or conversion into DHT or estradiol, influencing cellular metabolism, sexual differentiation, secondary sexual characteristics, and sexual behavior. Its effects are mediated by genomic mechanisms, where it binds to the androgen receptor (AR) to regulate gene expression, and nongenomic pathways, involving membrane receptors and intracellular signaling. The wide expression of AR in the central nervous system, genital, and reproductive tissues suggests a significant role for testosterone and its metabolites in maintaining female sexual function, hair growth, and overall physiological balance. [1, 4]

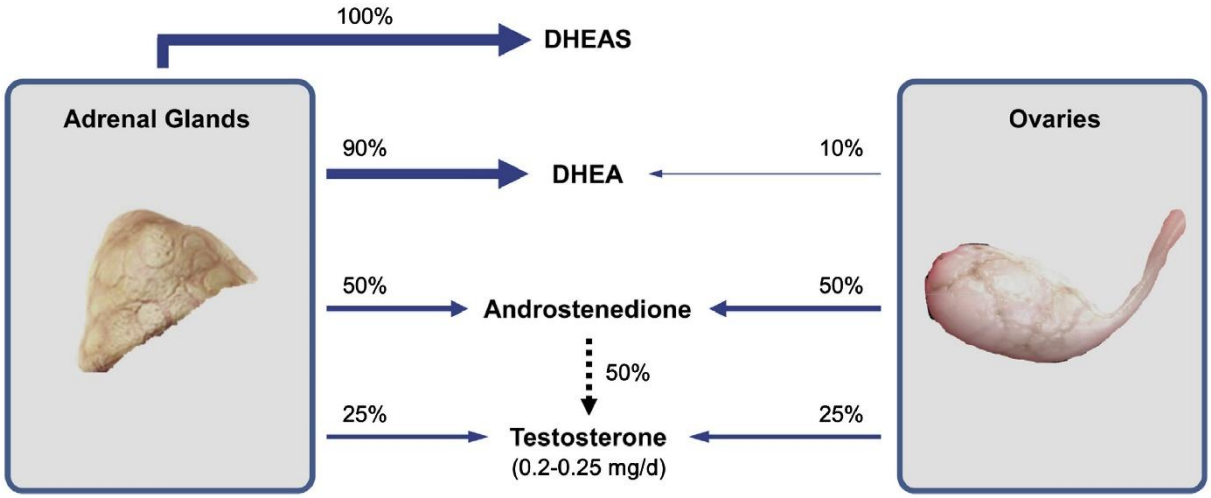

Figure 1 Relative production of circulating androgens in the adrenal glands and ovaries. The substantial contribution of androstenedione to circulating testosterone is shown by a dashed arrow and involves peripheral tissue conversion. DHEA = dehydroepiandrosterone; DHEA-S = dehydroepiandrosterone sulfate. [1]

Role of Androgens in Women's Bodies

Androgens, particularly testosterone, exert influence over a wide array of bodily functions, including reproduction, metabolism, mood regulation, and sexual function.

1. **Reproductive Function and Menstrual Cycle**
   Androgens help regulate ovarian function and are integral in the menstrual cycle. Although estrogen is the dominant hormone in regulating the menstrual cycle, androgens contribute to the overall hormonal balance necessary for optimal reproductive health. Testosterone plays a role in regulating ovarian activity, ovulation, and the menstrual cycle. When androgen levels are insufficient, women may experience menstrual irregularities, anovulation (lack of ovulation), and fertility problems.

2. **Metabolism and Body Composition**
   Testosterone influences the development and maintenance of muscle mass, bone density, and the distribution of body fat. Low testosterone levels in women are associated with an increase in abdominal fat and a decrease in muscle mass, particularly as women age. This hormonal decline is most evident after menopause, contributing to an increased risk of sarcopenia (loss of muscle mass) and metabolic changes such as obesity. [5]

3. **Cardiovascular Health**
   Although testosterone is present in much lower amounts in women than men, it plays a critical role in cardiovascular health. Testosterone is known to improve endothelial function, reduce oxidative stress, and decrease inflammation, all of which contribute to vascular health. Reduced testosterone levels are linked to accelerated aging of blood vessels, which increases the risk of cardiovascular diseases in postmenopausal women.[6]

4. **Psychological Well-being**
   Testosterone has a profound effect on mood, energy levels, and behavior in women. Low testosterone levels are associated with symptoms of depression, fatigue, and a decrease in overall psychological well-being. Women with low testosterone may experience reduced motivation, diminished sexual desire, and difficulty focusing. These symptoms may significantly affect their quality of life.[7, 8]

Hypoactive sexual desire disorder (HSDD)- diagnosis and classification

Hypoactive sexual desire disorder (HSDD) is defined as a persistent or recurrent lack or decrease in sexual fantasies and desire for sexual activity, causing significant distress or interpersonal difficulties. In the DSM-IV-TR classification, HSDD was recognized as a separate disorder. However, in DSM-5, it was combined with female sexual arousal disorder, creating a new diagnosis: female sexual interest/arousal disorder (FSIAD). This change reflects the understanding that, in women, issues with sexual desire and arousal often overlap. In DSM-5, the diagnostic criteria for FSIAD include a lack of significant reduction in interest in sexual activity, absence of sexual fantasies, lack of sexual initiation, and a lack of pleasure during sexual activity. These symptoms must persist for at least six months and cause significant distress for the affected individual. [9]

In the ICD-11 classification by the World Health Organization (WHO), disorders related to sexual desire have been included in a new chapter on sexual health. Categories such as hypoactive sexual desire dysfunction and sexual arousal dysfunction have been introduced, reflecting a more integrated approach to sexual health that considers both physical and psychological factors.

The diagnosis of HSDD is based on a thorough medical and psychological history, an assessment of interpersonal relationships, and the exclusion of other potential causes of reduced sexual desire, such as hormonal disorders, chronic illnesses, or side effects of medications. It is also important to consider cultural context and individual differences in sexual norms. It is worth noting that the introduction of new diagnostic criteria in DSM-5 has been met with some controversy. Some researchers suggest that the new criteria may raise the "threshold" for diagnosis, potentially leading to underdiagnosis in some cases. However, empirical studies have shown that most women diagnosed with HSDD under the previous criteria also meet the criteria for FSIAD, suggesting that these changes do not significantly restrict the diagnosis. [9, 10]

In summary, the classification and diagnosis of sexual desire disorders have evolved in recent years, reflecting a better understanding of the complexity of female sexual response and the need for a more integrated approach that considers both physical and psychological aspects.

Testosterone Therapy for Women

Indications for Therapy

Testosterone therapy is typically considered for women with low libido or hypoactive sexual desire disorder (HSDD) who do not respond to conventional treatments such as estrogen therapy or counseling. Women who have undergone oophorectomy or surgical castration may experience a significant decline in their natural testosterone production, leading to a marked reduction in sexual desire. Additionally, women who experience early menopause are at an elevated risk for various health complications, including osteoporosis, cardiovascular diseases, and cognitive decline. These risks may be mitigated by estrogen therapy, but testosterone supplementation may be necessary to address low libido. [11, 12]

Forms of Testosterone Therapy

Testosterone can be administered in a variety of forms, including transdermal patches, topical gels, creams, and intramuscular injections. Among these, transdermal patches and topical gels are preferred for their ease of use and consistent release of testosterone, reducing fluctuations in hormone levels that can lead to side effects. Transdermal applications are particularly beneficial because they minimize the risk of liver metabolism, which can occur with oral testosterone formulations. [13]

Efficacy

Several clinical studies have shown that testosterone therapy can significantly improve sexual desire, arousal, and satisfaction in women with low libido. Women receiving testosterone therapy often report increased sexual frequency, better arousal, and enhanced sexual satisfaction. These improvements are particularly evident when testosterone therapy is combined with estrogen replacement therapy in postmenopausal women. Although estrogen therapy alleviates menopausal symptoms such as vaginal dryness and hot flashes, it does not directly address libido, whereas testosterone supplementation has a direct effect on sexual desire. Combined estrogen and testosterone therapy may offer a more comprehensive approach to improving sexual health in women, particularly those who are postmenopausal. [12, 14]

Safety and Risks

Testosterone therapy for postmenopausal women has shown potential benefits, but its use is not without risks. Common side effects of testosterone treatment include acne, hirsutism (excessive hair growth), voice deepening, and clitoral enlargement. While most side effects in studies were modest and significant only in a few cases, long-term safety data is limited, typically covering up to 2 years of treatment. Testosterone levels in treated women mostly remain below the upper limit for premenopausal women, with no significant increase in cardiovascular risk factors, such as blood lipids, blood pressure, or insulin resistance, in healthy women.

Additionally, testosterone treatment does not appear to increase breast cancer risk or mammographic breast density in short-term studies and may counteract breast cell proliferation when combined with menopausal hormone therapy. [15] A study involving postmenopausal women with previous breast cancer showed that a combination of testosterone and an aromatase inhibitor significantly improved symptoms, with no cancer recurrence during up to 9.4 years of follow-up. [16]

However, long-term safety data regarding breast, endometrial, and liver health is lacking, and potential risks such as cardiovascular diseases and liver abnormalities must be considered. Women with BRCA mutations or those at higher risk of breast cancer may also be candidates for treatment, but more research is needed to ensure safety in these populations. Despite the benefits, healthcare providers must monitor testosterone therapy closely, adjusting dosages as necessary to minimize side effects and ensuring regular follow-up visits for continued safety and efficacy. A 2019 meta-analysis of 36 randomized controlled trials found no increased risks of serious events, but ongoing monitoring remains essential for women receiving this treatment. [15, 16, 17]

Guidelines of testosterone treatment

A global consensus on testosterone treatment for women was recently published by Davis et al., although Nordic countries did not participate in the collaboration. Norwegian guidelines align largely with this consensus, while British and Australasian guidelines provide more detailed recommendations. These guidelines suggest optimizing estrogen treatment first for postmenopausal women with sexual desire issues, with transdermal testosterone preferred to minimize sex hormone-binding globulin (SHBG). If sexual function does not improve, testosterone therapy is considered. Women with androgen deficiency due to conditions like premature ovarian insufficiency, pituitary failure, or adrenal deficiency may also benefit from testosterone treatment. However, no transdermal testosterone preparations are available for women in Nordic countries, and most prescriptions are for male testosterone products (gel, cream, or spray), which are not ideal for women due to their high concentrations and lack of studies on their efficacy and safety in women. The British Menopause Society suggests that 5 mg/day of male gel or cream may be an equivalent dose, though some women may require a lower dose. In Norway, over 2000 women received testosterone prescriptions in 2018, highlighting the need for female-specific testosterone treatments. [18, 19]

In the United States, there are currently no FDA-approved testosterone products specifically for women. However, compounded testosterone formulations are available, though their safety and efficacy remain poorly established. In Australia, testosterone therapy for women has been approved and is accessible, offering an option for women with low libido. Due to the lack of FDA-approved testosterone products, healthcare providers in the U.S. may consider the off-label use of testosterone therapy but must inform patients about potential benefits and risks.

The global consensus recommends measuring baseline testosterone levels before initiating treatment, followed by a 3-6 week trial with monitoring for side effects such as hair growth and acne. If serum testosterone remains within normal premenopausal reference ranges, there is no risk of virilization. Treatment effects are typically seen within 3 months, and patients should be monitored every 6 months. If there is no improvement in sexual function after 6 months, discontinuation of treatment is recommended. [18, 20]

Trials of testosterone treatment for postmenopausal women with hypoactive sexual desire disorder

Testosterone treatment refers to the administration of testosterone as a supplement. While there are no officially approved indications for its use in women, research has primarily focused on postmenopausal women with hypoactive sexual desire disorder (HSDD).

Earlier studies investigated oral and intramuscular testosterone in women with HSDD, demonstrating some efficacy but often leading to supra-physiological testosterone levels and negative metabolic effects, such as lipid profile disturbances. Later trials introduced transdermal testosterone patches, which bypass liver metabolism, thereby avoiding adverse effects on lipids while maintaining stable testosterone levels comparable to premenopausal production. [11, 15]

Seven randomized controlled trials (RCTs) assessed the effectiveness of testosterone patches in postmenopausal women with HSDD, measuring outcomes such as satisfying sexual episodes, sexual desire, distress, adverse effects, and hormone levels. Women receiving 300 µg/day testosterone patches consistently reported significant improvements in sexual desire and satisfaction compared to placebo. Notably, increasing the dose beyond 300 µg/day did not enhance the response, suggesting a dose-response plateau. Across studies, testosterone therapy led to an increase of 0.7 to 2.5 additional satisfying sexual episodes per month, compared to 0.5 to 1 in placebo groups. A subgroup of participants confirmed that an increase of 0.8–1 additional satisfying episode per month was clinically meaningful for their sexual well-being.[11, 15, 20]

Testosterone therapy for premenopausal women with HSDD

Testosterone therapy has been increasingly explored as a potential treatment option for women with hypoactive sexual desire disorder (HSDD), particularly for those who are premenopausal. While much of the research has traditionally focused on postmenopausal women, emerging studies suggest that testosterone therapy might offer benefits for premenopausal women as well. HSDD is a condition characterized by a persistent or recurrent lack of sexual desire, which can significantly affect a woman's quality of life, emotional well-being, and interpersonal relationships. As testosterone plays a critical role in sexual arousal and desire, supplementation with this hormone has been considered as a way to address the issue.

Despite these promising possibilities, the evidence supporting the use of testosterone therapy for premenopausal women with HSDD is still evolving. Most studies examining this treatment have been small-scale, and many of the results are inconclusive. While some clinical trials indicate that testosterone therapy may improve sexual desire and overall sexual functioning in premenopausal women with HSDD, the research is not sufficiently robust to make testosterone therapy a routine or first-line treatment for this condition.

The therapy's potential benefits must therefore be weighed against the potential risks, and further well-designed clinical trials are essential to determine its long-term efficacy and safety profile for premenopausal women.

In clinical practice, healthcare providers must approach testosterone therapy cautiously and consider the unique circumstances of each patient. Comprehensive discussions should take place between healthcare providers and patients, addressing the potential risks and benefits of testosterone therapy. Additionally, close monitoring for any side effects is necessary throughout the treatment process. In cases where testosterone therapy is considered, it is essential for healthcare professionals to ensure that patients are fully informed about the potential risks and implications, empowering them to make decisions that align with their personal health goals and values. [21]

Clinical Trials:

A systematic review of 13 studies investigating testosterone therapy for premenopausal women with HSDD highlighted the mixed results and the need for more comprehensive data. While certain research indicates that testosterone therapy can have a positive effect on sexual desire and function, these findings are not universally consistent. The review concluded that, although testosterone may offer some benefits, the evidence is not definitive enough to recommend it as a standard treatment option for low libido in premenopausal women. Many of the studies involved small sample sizes or lacked long-term follow-up, further complicating efforts to draw firm conclusions regarding the therapy's effectiveness. [21]

Side Effects:

Reported side effects include acne, hirsutism (excessive hair growth), voice deepening, and clitoral enlargement. These effects are generally mild and reversible upon discontinuation of therapy.

Clinical Guidelines:

The International Society for the Study of Women's Sexual Health (ISSWSH) has developed clinical practice guidelines for the use of systemic testosterone in women with HSDD. These guidelines recommend considering testosterone therapy for premenopausal women with HSDD who have low circulating testosterone levels and have not responded to other interventions. The guidelines emphasize the importance of informed consent, shared decision-making, and monitoring for potential side effects. [21]

Considerations:

Off-Label Use: In many countries, including the United States, testosterone therapy is not FDA-approved for use in women. Therefore, its use in premenopausal women with HSDD is considered off-label and should be approached with caution. [21]

Monitoring testosterone levels in women

Monitoring testosterone levels in women with hypoactive sexual desire disorder (HSDD) during hormonal treatment is essential to ensure therapeutic efficacy and minimize potential adverse effects. Testosterone therapy has been shown to improve sexual function in postmenopausal women with HSDD, but its long-term safety remains uncertain. [17, 20]

Monitoring Recommendations:

1. Baseline Assessment:
    - Measure total testosterone levels before initiating therapy to establish a reference point.
2. During Treatment:
    - Regularly assess for clinical signs of androgen excess, such as acne, hirsutism, voice deepening, and clitoral enlargement.
    - Monitor total testosterone levels to maintain concentrations within the physiologic premenopausal range.
3. Long-Term Monitoring:
    - Given the limited data on long-term safety, especially concerning cardiovascular risk and breast cancer incidence, continuous monitoring is recommended.

Clinical Considerations:

- Individualized Treatment: Tailor therapy based on the patient's specific needs and response to treatment.
- Informed Consent: Discuss potential benefits and risks with the patient, emphasizing the off-label use of testosterone therapy.
- Alternative Therapies: Consider other treatment options if testosterone therapy is not suitable or if adverse effects occur.

In summary, while testosterone therapy can be beneficial for women with HSDD, vigilant monitoring of testosterone levels and clinical signs is crucial to ensure safety and effectiveness.

Conclusion

Testosterone plays a crucial yet often underappreciated role in female sexual health, contributing significantly to sexual desire, arousal, and overall well-being. As women age or undergo medical procedures such as menopause or oophorectomy, the natural decline in testosterone levels can lead to sexual dysfunction, including hypoactive sexual desire disorder (HSDD). Testosterone replacement therapy (TRT) has emerged as a promising treatment for these women, demonstrating effectiveness in improving libido and sexual satisfaction.

However, the use of testosterone therapy requires careful management, as there are potential side effects, including acne, hair growth, and voice changes. Monitoring for these side effects, as well as ensuring that testosterone levels remain within the physiologic premenopausal range, is essential to minimize risks.

Furthermore, while the evidence for testosterone therapy in premenopausal women is still evolving, its potential benefits for managing HSDD in this population should not be overlooked. Ongoing research is necessary to fully understand the long-term safety and efficacy of testosterone therapy in women, particularly concerning cardiovascular health and cancer risks. Healthcare providers should approach testosterone treatment with caution, offering it as part of a comprehensive care plan that includes thorough patient education, individualized treatment strategies, and regular monitoring. As our understanding of female sexual health continues to evolve, testosterone therapy offers hope for many women struggling with the effects of declining hormone levels, potentially improving their quality of life and sexual well-being.

Disclosures

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