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Acute Effects of Combined Sublingual Testosterone and Sildenafil on Clitoral Blood Flow in Premenopausal Women with Acquired Generalized FSIAD: A Randomized Open-Label Dose-Response Study

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Introduction:
Female Sexual Interest and Arousal Disorder (FSIAD) is among the most common sexual dysfunctions in women, yet its physiological mechanisms remain poorly understood. Simultaneous pharmacological modulation of central and peripheral arousal pathways represents a potentially valuable therapeutic approach.

Objective:
To assess the acute hemodynamic effects of two dose combinations of sublingual testosterone and oral sildenafil on clitoral arterial blood flow in premenopausal women with acquired generalized FSIAD, using clitoral Doppler duplex ultrasonography (CDU) as an objective physiological endpoint.

Methods:
Sixteen premenopausal women with DSM-5-confirmed acquired generalized FSIAD were randomly assigned to a standard-dose group (testosterone 0.5 mg sublingually plus sildenafil 50 mg orally; n = 8) or a high-dose group (testosterone 1.0 mg sublingually plus sildenafil 100 mg orally; n = 8). Sildenafil was administered three hours after testosterone during a single study visit. CDU was performed before and after treatment to obtain peak systolic velocity (PSV), end-diastolic velocity (EDV), and resistance index (RI). Standardized erotic visual stimulation was applied immediately before each assessment to ensure comparable arousal conditions.

Results:
Both dose combinations produced a meaningful increase in clitoral PSV. The mean change across the full cohort was +5.22 cm/s (SD 5.95; Wilcoxon signed-rank p = 0.0008). The high-dose group reached within-group statistical significance (mean ΔPSV +5.29 cm/s, SD 4.82; p = 0.008), while the standard-dose group showed a comparable absolute increase (mean ΔPSV +5.15 cm/s, SD 7.26; p = 0.055). EDV did not change significantly (p = 0.632), whereas RI increased significantly overall (mean change +0.121, SD 0.160; p = 0.009). No between-group differences were observed for any hemodynamic parameter.

Conclusions:
The significant rises in PSV and RI without a proportional increase in EDV is

consistent with progressive clitoral vascular filling. Combined sublingual testosterone and oral sildenafil produced a significant increase in clitoral arterial blood flow in premenopausal women with acquired generalized FSIAD. Placebo-controlled trials incorporating patient-reported outcomes are warranted to establish the clinical efficacy and therapeutic profile of this combination.

Disclosure:
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Clarification: Industry funding only - investigator initiated and executed study