Hypothesis

FSFS-DAO is a valid instrument to assess therapeutic response in women with FSD.

Methods

Study Subjects. All subjects were premenopausal women with a diagnosis of sexual distress and/or female sexual arousal disorder as defined by the FSFI, and a diagnostic interview. Each subject was in a stable relationship and was willing to be sexually active at least once a month.

Study Design. After a 4-week, no-treatment screening period to determine if FSD diagnosis, all subjects received a single subcutaneous placebo dose, followed by 4 weeks of single-blind, placebo-controlled self-dosing (by pre-filled syringe) ~45 minutes prior to anticipated sexual activity. Subjects were then randomized to double-blind placebo or BMT 0.75, 1.25, or 1.75 mg self-dosing (by pre-filled syringe) ~45 minutes prior to anticipated sexual activity for the preceding 4 days per week during a 4-week period. The study design is schematized in Figure 1.

Figure 1. Study Design

Results

Subject Disposition. Of 1,432 screened subjects, 307 were randomized and 237 completed the 12-month study. The objective of the current analysis was for the total scores at Visits 1, 5, and 12. The Spearman's ρ correlation coefficient was 0.6 (p<0.001), indicating acceptable test-retest reliability. All correlations of the FSDS-DAO total score were highly statistically significant except for discriminations between GAQ satisfaction with desire and the FSFI sexual desire subscale.

The FSDS-DAO total score correlated highly with previously validated self-report measures, such as the 20-item Generalized Anxiety Disorder scale (GAQ) and the linearly correlated with FSFI subscales and total score, was assessed by the Spearman's correlation coefficient (r): 0.85 (p<0.0001) for the total score at Visit 1 and 0.9 (p<0.0001) for the total score at Visit 5.

The ability of FSDS-DAO total scores to discriminate according to disease severity was assessed by ANOVA (Scheffe's test). The ability of the FSDS-DAO total score to discriminate according to disease severity was assessed by ANOVA (Scheffe's test). The ability of the FSDS-DAO total score to discriminate between the groups of patients with mixed HSDD/FSAD and solely HSDD, was assessed by ANOVA (Scheffe's test) (Table 3).

Conclusions

The FSFS-DAO demonstrates internal consistency, test-retest reliability, and construct and discriminant validity. The FSFS-DAO is a reliable and valid measure to assess sexual distress in women with FSD.

References


Support and Disclosures

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