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CHARACTERIZATION OF SEXUAL FUNCTION IN WOMEN WITH OVERACTIVE BLADDER AND URGENCY URINARY INCONTINENCE AT BASELINE AND AFTER TREATMENT WITH TOLTERODINE EXTENDED RELEASE

Hypothesis / aims of study
Baseline sexual function has not been well described in previous clinical studies of women with overactive bladder (OAB) and urgency urinary incontinence (UUI). The aim of this study was to evaluate sexual function in these women at baseline and after treatment with tolterodine extended release (TER) versus placebo (PBO). In this post hoc analysis, we evaluated the effects of treatment on specific aspects of sexual activity and function using the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ), a validated, condition-specific sexual function questionnaire.

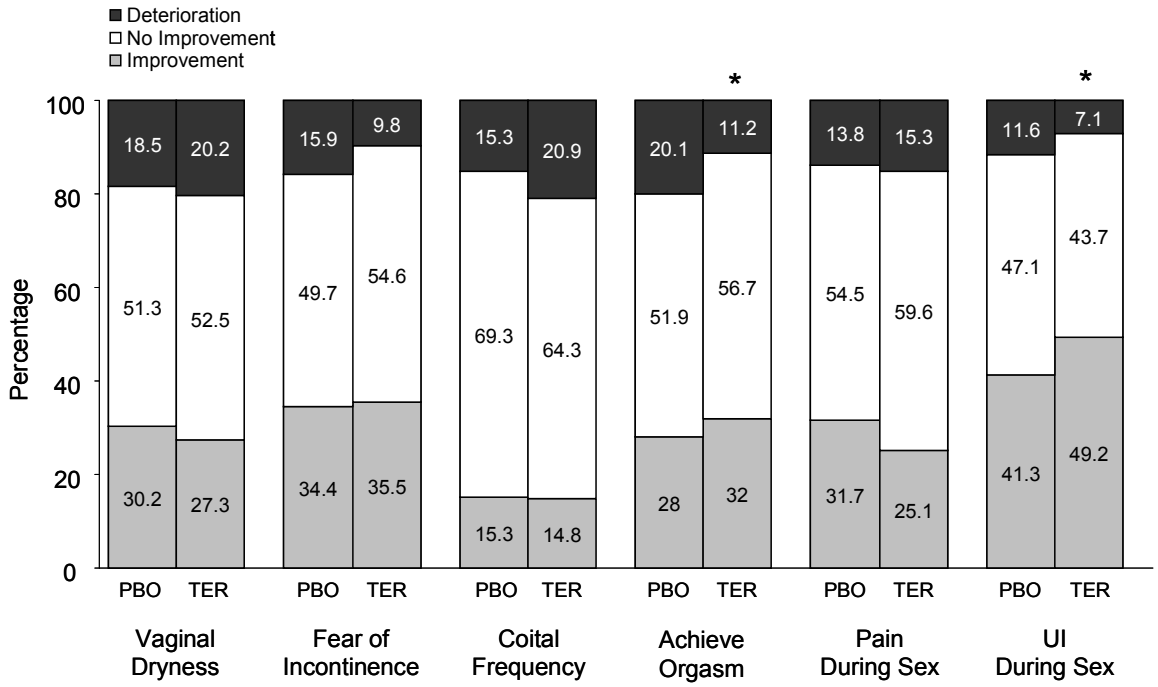
Study design, materials and methods
This was a multicenter, 12-week, double-blind, randomized, PBO-controlled trial. Eligible female outpatients (aged ≥18 y) had self-reported OAB (≥8 voids per 24 h, ≥3 urgency-related micturitions per 24 h) and UUI (mean of ≥0.6 episodes per 24 h) for ≥3 months and rated their bladder condition as causing at least "some moderate problems." Patients described themselves as being sexually active and in a stable relationship with a male partner for ≥6 months. Patients were randomized to once-daily TER (4 mg; n=202) or PBO (n=211). Patients completed the PISQ at baseline and week 12. The PISQ is a 31-item, self-administered questionnaire; we report an item analysis for 6 questions particularly relevant to OAB symptoms. PISQ responses were scored on a 5-point scale: 0 = always, 1 = usually, 2 = sometimes, 3 = seldom, and 4 = never. Coital frequency and orgasm questions were reverse scored so that higher scores represented more favorable responses for all 6 items. Between-group differences were analyzed using a 3-category approach: improvement (ie, ≥1-point increase in score), no improvement (no change in score), and deterioration (≥1-point decrease in score). A Cochran-Mantel-Haenszel test (stratified by method of delivery) was used to calculate *P* values.

Results
At baseline, 58% of women reported lower rates of orgasm; nearly half experienced coital incontinence, vaginal dryness, and lower rates of sexual activity. Thirty percent of women reported restricting sexual activity because of fear of incontinence **(Table)**. Compared with PBO, TER treatment was associated with less deterioration for the orgasm question (11% vs 20%; *P*=0.0395) and greater improvement for the coital incontinence question (49% vs 41%; *P*=0.0347). There were no increases in vaginal dryness or dyspareunia **(Figure)**.

Table. Baseline PISQ Question Characteristics

	PBO (n=189)	TER (n=183)	Total (N=372)
Item (Responses)	**n (%)**	**n (%)**	**n (%)**
Achievement of orgasm (seldom or never)	110 (58)	107 (58)	217 (58)
UI during sex (sometimes–always)	88 (47)	84 (46)	172 (46)
Vaginal dryness (somewhat–extremely)	91 (48)	78 (43)	169 (45)
Coital frequency (<1 time/mo or never)	83 (44)	85 (47)	168 (45)
Pain during intercourse (sometimes–always)	80 (42)	74 (40)	154 (41)
Fear of incontinence restricts sex (sometimes–always)	53 (28)	57 (31)	110 (30)

Figure. Percentage Change From Baseline to Week 12 on PISQ Items



Interpretation of results

After 12 weeks of treatment, women taking TER reported improvements in orgasm and coital incontinence. Importantly, there were no changes in vaginal dryness or pain with intercourse after TER treatment. These findings may not be applicable to women who choose not to be sexually active owing to their OAB symptoms.

Concluding message

Many women with OAB and UUI report impaired sexual quality of life. Treatment with TER improved 2 important aspects of sexual function in symptomatic patients.

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CLINICAL TRIAL REGISTRATION: **Clinical Trials Registry - #NCT00143481**

HUMAN SUBJECTS: **This study was approved by the Schulman Associates and followed the Declaration of Helsinki Informed consent was obtained from the patients.**