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Original Contribution

Tolterodine and Tamsulosin for Treatment of Men With Lower Urinary Tract Symptoms and Overactive Bladder

A Randomized Controlled Trial

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Context Men with overactive bladder and other lower urinary tract symptoms may not respond to monotherapy with antimuscarinic agents or α-receptor antagonists.

Objective To evaluate the efficacy and safety of tolterodine extended release (ER), tamsulosin, or both in men who met research criteria for both overactive bladder and benign prostatic hyperplasia.

Design, Setting, and Participants Randomized, double-blind, placebo-controlled trial conducted at 95 urology clinics in the United States involving men 40 years or older who had a total International Prostate Symptom Score of 12 or higher and, an International Prostate Symptom Score quality-of-life (QOL) item score of 3 or higher, a self-rated bladder condition of at least moderate bother, and a bladder diary documenting micturition frequency (≥8 micturitions per 24 hours) and urgency (≥3 episodes per 24 hours), with or without urgency urinary incontinence. Patients were recruited between November 2004 and February 2006, and the study was completed May 2006.

Interventions Patients were randomly assigned to receive placebo (n = 222), 4 mg of tolterodine ER (n = 217), 0.4 mg of tamsulosin (n = 215), or both tolterodine ER plus tamsulosin (n = 225) for 12 weeks.

Main Outcome Measures Patient perception of treatment benefit, bladder diary variables, International Prostate Symptom Scores, and safety and tolerability were assessed.

Results A total of 172 men (80%) receiving tolterodine ER plus tamsulosin reported treatment benefit by week 12 compared with 132 patients (62%) receiving placebo (*P*<.001), 146 (71%) receiving tamsulosin (*P*=.06 vs placebo), or 135 (65%) receiving tolterodine ER (*P*=.48 vs placebo). Patients receiving tolterodine ER plus tamsulosin compared with placebo experienced significant reductions in urgency urinary incontinence (−0.88 vs −0.31, *P*=.005), urgency episodes without incontinence (−3.33 vs −2.54, *P*=.03), micturitions per 24 hours (−2.54 vs −1.41, *P*<.001), and micturitions per night (−0.59 vs −0.39, *P*.02). Patients receiving tolterodine ER plus tamsulosin demonstrated significant improvements on the total International Prostate Symptom Score (−8.02 vs placebo, −6.19, *P*=.003) and QOL item (−1.61 vs −1.17,

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P=.003). All interventions were well tolerated. The incidence of acute urinary retention requiring catheterization was low (tolterodine ER plus tamsulosin, 0.4%; tolterodine ER, 0.5%; tamsulosin, 0%; and placebo, 0%).

Conclusions These results suggest that treatment with tolterodine ER plus tamsulosin for 12 weeks provides benefit for men with moderate to severe lower urinary tract symptoms including overactive bladder.

Clinical Trials Registration clinicaltrials.gov Identifier: NCT00147654

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