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Benign Prostatic Hyperplasia

Efficacy and Safety of Tadalafil Once Daily in the Treatment of Men With Lower Urinary Tract Symptoms Suggestive of Benign Prostatic Hyperplasia: Results of an International Randomized, Double-Blind, Placebo-Controlled Trial

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Abstract

Background: Tadalafil is being investigated for the treatment of lower urinary tract symptoms (LUTS) suggestive of benign prostatic hyperplasia (BPH-LUTS).
Objective: To assess efficacy, including onset, and safety of tadalafil on BPH-LUTS and the subject's and clinician's perception of changes in urinary symptoms.
Design, setting, and participants: This randomized, double-blind, placebo-controlled, 12-week trial enrolled men ≥45 yr of age with BPH-LUTS for >6 mo, International Prostate Symptom Score (IPSS) ≥13, and maximum urine flow rate (Q_{max}) ≥4 to ≤15 ml/s.
Intervention: Tadalafil 5 mg (n = 161) or placebo (n = 164), once daily.
Measurements: Analysis of covariance (ANCOVA) modeling evaluated change from baseline in continuous efficacy variables. Categoric efficacy variables were analyzed with the Cochran-Mantel-Haenszel test, and between-group differences in treatment-emergent adverse events (TEAEs) were assessed using the Fisher exact test.
Results and limitation: Tadalafil significantly improved IPSS results, from baseline to endpoint, compared to placebo (−5.6 vs −3.6; p = 0.004). Reduction in IPSS results was apparent after 1 wk and significant after 4 wk (tadalafil −5.3 vs placebo −3.5; p = 0.003). The BPH Impact Index (BII) was not assessed at week 1; however, BII improvement was apparent at 4 wk (tadalafil −1.8 vs placebo −1.2; p = 0.029) and continued at 12 wk (tadalafil −1.8 vs placebo −1.3; p = 0.057). Tadalafil significantly improved the International Index of Erectile Function–Erectile Function score in sexually active men with erectile dysfunction (ED; 6.7 vs 2.0; $p < 0.001$) at 12 wk (not assessed at week 1). Few subjects reported one TEAE or more (p = 0.44). For tadalafil, the most common TEAEs were headache (3.7%) and back pain (3.1%). Tadalafil did not significantly improve Q_{max} or reduce postvoid residual volume.
Conclusions: Tadalafil 5 mg once daily for 12 wk resulted in a clinically meaningful reduction in total IPSS results as early as 1 wk and achieved statistical significance at 4 wk in men with BPH-LUTS. The adverse event profile was consistent with that previously reported in men with ED.
Trial registration: This clinical trial is registered on the clinicaltrials.gov website (http://www.clinicaltrials.gov). The registration number is NCT00827242.

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