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Randomized Controlled Trial Eur Urol. 2011 Nov;60(5):1105-13.
doi: 10.1016/j.eururo.2011.08.005. Epub 2011 Aug 12.

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 5mg (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 5mg 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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Comment in

Therapy: two birds, one stone: tadalafil is an effective treatment for men with both BPH-LUTS and ED.

Warde N.

Nat Rev Urol. 2011 Nov 15;8(12):643. doi: 10.1038/nrurol.2011.165.

PMID: 22083242 No abstract available.

Re: 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.

Seftel AD.

J Urol. 2012 Mar;187(3):990. doi: 10.1016/j.juro.2011.11.055. Epub 2012 Jan 20.

PMID: 22325528 No abstract available.

Re: Hartmut Porst, Edward D. Kim, Adolfo R. Casabé, et al., for the LVHJ study team. 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. Eur Urol 2011;60:1105-13.

Serefoglu EC, Mitchell GC, Hellstrom WJ.

Eur Urol. 2012 May;61(5):e45-6; author reply e47-8. doi: 10.1016/j.eururo.2012.02.016. Epub 2012 Feb 14.

PMID: 22342774 No abstract available.

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