

FPIN's Help Desk Answers

Tadalafil for the Treatment of Lower Urinary Tract Symptoms in Men With Benign Prostatic Hyperplasia

C. R. Rohrbough, MD; Bridget Colgan, MD, MM; and Ollie Gasser, MD

Tripler Army Medical Center, Honolulu, Hawaii

Clinical Question

Is tadalafil effective in treating lower urinary tract symptoms in men with benign prostatic hyperplasia?

Evidence-Based Answer

Tadalafil may be useful in improving symptoms and quality of life in patients with lower urinary tract symptoms associated with benign prostatic hyperplasia. (Strength of Recommendation [SOR]: A, meta-analysis of randomized controlled trials [RCTs].) Tadalafil is superior to tamsulosin (Flomax) when lower urinary tract symptoms are also associated with erectile dysfunction. (SOR: A, systematic review of RCTs.)

Evidence Summary

A 2021 meta-analysis of 15 RCTs (n = 9,525) evaluated the effectiveness and safety of tadalafil for lower urinary tract symptoms associated with benign prostatic hyperplasia.¹ Trials included men

with benign prostatic hyperplasia treated with 5 mg of tadalafil or placebo once daily for 12 weeks. The primary outcome was the change in the total International Prostate Symptom Score, which ranges from 0 to 35; higher scores indicate worse symptoms. Subscores for storage or irritative symptoms (0 to 15); voiding or obstructive symptoms (0 to 20); benign prostatic hyperplasia impact index (0 to 13); quality-of-life symptoms (0 to 6); adverse events; serious adverse events; maximum flow rate; and postvoid residual volume over 12 weeks were measured at baseline and posttreatment. Compared with placebo, tadalafil improved the total International Prostate Symptom Score (15 trials; n = 9,525; mean difference [MD] = -1.97; 95% CI, -2.24 to -1.70). Tadalafil also improved subscores of voiding (15 trials; n = 9,525; MD = -1.30; 95% CI, -1.48 to -1.11), storage (MD = -0.70; 95% CI, -0.82 to -0.58), quality of life (14 trials; n = 9,423; MD = -0.29; 95% CI, -0.35 to -0.22), and benign prostatic hyperplasia impact index (eight trials; n = 3,682; MD = -0.58; 95% CI, -0.76 to -0.40). No improvement was noted in the maximum flow rate or postvoid residual scores. Tadalafil and placebo were similar in the incidence of serious adverse events, although adverse events such as headache, dyspepsia, and back pain occurred more often in the tadalafil group (risk ratio = 1.27; 95% CI, 1.19 to 1.36). Limitations included incomplete outcomes data in four studies that may have led to attrition bias.

A 2020 meta-analysis of seven RCTs (n = 1,601) evaluated the effectiveness of tadalafil compared with tamsulosin in the treatment of lower urinary tract symptoms associated with benign prostatic hyperplasia.² The trials included men treated with 5 mg of tadalafil or 0.2 mg or 0.4 mg of tamsulosin once daily for 12 weeks. The primary outcomes were similar to those of the previous meta-analysis, with the addition of the International Index of Erectile Function, which is a 15-item questionnaire

Help Desk Answers provides answers to questions submitted by practicing family physicians to the Family Physicians Inquiries Network (FPIN). Members of the network select questions based on their relevance to family medicine. Answers are drawn from an approved set of evidence-based resources and undergo peer review. The strength of recommendations and the level of evidence for individual studies are rated using criteria developed by the Evidence-Based Medicine Working Group (<https://www.cebm.net>).

The complete database of evidence-based questions and answers is copyrighted by FPIN. If interested in submitting questions or writing answers for this series, go to <https://www.fpin.org> or email: questions@fpin.org.

This series is coordinated by John E. Delzell Jr., MD, MSPH, associate medical editor.

A collection of FPIN's Help Desk Answers published in *AFP* is available at <https://www.aafp.org/afp/hda>.

Author disclosure: No relevant financial relationships.

HELP DESK ANSWERS

for the assessment of erectile function across five domains (i.e., erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction); lower scores indicate more severe dysfunction. Compared with tamsulosin, tadalafil improved the International Index of Erectile Function scores (two trials; $n = 208$; weighted MD = 5.02; 95% CI, 3.78 to 6.27). The total International Prostate Symptom Score, voiding or storage scores, quality-of-life scores, or postvoid residual volume scores did not differ between the treatment groups. Limitations included increased heterogeneity in the men with lower urinary tract symptoms treated with tadalafil and tamsulosin.

A 2022 prospective RCT ($n = 92$) compared the effectiveness of tadalafil to tamsulosin in men older than 40 years with symptomatic benign prostatic hyperplasia.³ The trial excluded patients with hematuria, chronic kidney disease, bilateral hydronephrosis, bladder calculi, or bladder diverticula and those taking alpha blockers. Patients were randomly assigned to receive 0.4 mg of tamsulosin or 5 mg of tadalafil daily. Primary outcomes included changes in postvoid residual volume, maximum flow rate, the total International Prostate Symptom Score, and the Sexual Health Inventory for Men questionnaire. The Sexual Health Inventory for Men asks patients five questions, and each question carries a score of 1 to 5 (a total score of 22 to 25 = no erectile dysfunction; 17 to 21 = mild erectile dysfunction; 12 to 16 = mild to moderate erectile dysfunction; 8 to 11 = moderate erectile dysfunction; 5 to 7 = severe erectile dysfunction). Patients were assessed at baseline and again at three and six months posttreatment. Compared with tamsulosin, tadalafil resulted in similar improvements in maximum flow rate, postvoid

residual urine, and the International Prostate Symptom Score, but a greater improvement in the Sexual Health Inventory for Men (mean three-month follow-up score = 16.2 for tamsulosin vs. 21.9 for tadalafil; $P < .005$; mean six-month follow-up score = 16.3 vs. 22.1; $P < .001$).

The 2021 American Urological Association practice guidelines for the management of lower urinary tract symptoms recommend that patients with lower urinary tract symptoms from benign prostatic hyperplasia, irrespective of comorbid erectile dysfunction, may consider taking 5 mg of tadalafil daily.⁴

Copyright © Family Physicians Inquiries Network. Used with permission.

The opinions and assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the U.S. Army, the U.S. Department of Defense, or the U.S. government.

Address correspondence to Christopher Rohrbough, MD, at christopher.r.rohrbough.mil@health.mil. Reprints are not available from the authors.

References

1. Cui J, Cao D, Bai Y, et al. Efficacy and safety of 12-week monotherapy with once daily 5 mg tadalafil for lower urinary tract symptoms of benign prostatic hyperplasia. *Front Med (Lausanne)*. 2021;8:744012.
2. Guo B, Chen X, Wang M, et al. Comparative effectiveness of tadalafil versus tamsulosin in treating lower urinary tract symptoms suggestive of benign prostate hyperplasia. *Med Sci Monit*. 2020;26:e923179.
3. Ahmad MS, Dar YA, Khawaja AR, et al. Comparative study of tamsulosin versus tadalafil in benign prostatic hyperplasia patients with lower urinary tract symptoms. A prospective randomized study. *Urol Ann*. 2022;14(3):236-240.
4. Lerner LB, McVary KT, Barry MJ, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA guideline part I—initial work-up and medical management [published correction appears in *J Urol*. 2021;206(5):1339]. *J Urol*. 2021;206(4):806-817. ■