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The efficacy of terazosin in the treatment of benign prostatic hyperplasia (BPH) and finasteride in the treatment of prostatic hyperplasia was evaluated. Terazosin reduced BPH symptoms and finasteride did not. Combination therapy was better than treatment with either drug alone.

Objective
To determine whether terazosin, finasteride, or both are safe and effective for men with benign prostatic hyperplasia (BPH).

Design
A 1-year, randomized, double-blind, placebo-controlled trial.

Setting
U.S. Veterans Affairs medical centers.

Patients
1229 men who were 40 to 80 years old (mean age 65 ± 5 years) and had symptomatic BPH. Inclusion criteria were scores of ≥ 8 on the American Urological Association (AUA) Symptom Index, a mean peak urinary-flow rate of ≤ 15 mL/s, and a minimal residual volume after voiding of ≥ 125 mL. Exclusion criteria were use of many medications, including the study drugs, α-blockers, β-blockers, and antiandrogen drugs, or numerous medical conditions.

Intervention
After a 4-week run-in period, men were allocated to placebo (n = 305), finasteride, 5 mg/d at bedtime (n = 110), terazosin, 15 mg/d at bedtime (n = 165) or both (n = 309). The terazosin dose was titrated from 1 mg at day 1 to 15 mg by day 15. Follow-up was 82%.

Main outcome measures
AUA symptom scores and peak urinary-flow rates.

Main results
Analysis was by intention to treat. Compliance ranged from 94% to 98% at 1 year, and symptom scores were lower (improved) in the terazosin and the combination groups compared with the finasteride and placebo groups (P < 0.001 for all comparisons except terazosin vs combination, P = 0.15, and finasteride vs placebo, P = 0.07). The increases in peak urinary-flow rates were 2.7 mL/s occurred by week 4, and the rates stayed stable thereafter. Dizziness and postural hypotension were increased in the terazosin and combination groups (P = 0.001), impotence increased was more effective than placebo, and decreased libido occurred in the finasteride and combination groups (P = 0.05).

Conclusions
Terazosin was more effective than placebo for reducing symptoms and increasing peak urinary-flow rates in men with benign prostatic hyperplasia (BPH). Drug treatment was an attractive alternative to surgery for patients with symptoms considered the benefits of the treatment to most obvious in patients without previous zidovudine use, less benefit was seen in patients previously treated. In the Delta Coordinating Committee. Delta: randomised double-blind controlled trial comparing combination regimens with nucleoside reverse transcriptase inhibitors (zidovudine, ddI, ddC, 3TC, d4T), nonnucleoside reverse transcriptase inhibitors (nevirapine, delavirdine, and efavirenz), and protease inhibitors (saquinavir, ritonavir, and indinavir).

Combination therapy was better than zidovudine alone for infection with HIV infection.


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