Terazosin reduced BPH symptoms and finasteride did not


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

Design
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 y) 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 any medications, including the study drugs, α-blockers, β-blockers, and antiandrogen drugs, or multiple 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 (n = 165) or both (n = 309). The terazosin dose was titrated from 1 mg/day at 1 to 15 mg/day by day 15. Follow-up was 87%.

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 combination groups compared with the placebo group (P < 0.001 for all comparisons except terazosin vs combination, P = 0.15, and finasteride vs placebo, P = 0.07). The intervention group improved by week 4, and the rates stayed stable thereafter. Dizziness and postural hypotension were increased in the terazosin and combination groups (P = 0.001). Improvement was increased in the combination groups (P = 0.001), 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. Terazosin and combination. The combination of terazosin and finasteride was no more effective than terazosin alone.

Combination therapy was better than zidovudine alone for HIV infection


Objective
To determine whether zidovudine combined with didanosine (ddI) or zalcitabine (ddC) is more effective than zidovudine alone for reducing mortality and disease progression in patients with HIV infection.

Design
Randomized, double-blind, controlled trial with interim analyses.

Setting
175 centers in Europe and Australia.

Patients
2307 adults (mean age 36.5 y, 85% men) with confirmed HIV infection were included if they had never taken zidovudine (n = 2129) or had taken it for ≥ 3 months (n = 1083). Exclusion criteria were AIDS with a CD4⁺ count < 500/µL or minimal symptoms with CD4⁺ counts < 250/µL/mm³, history of pancreatitis or peripheral neuropathy, combination chemotherapy.

Conclusions
The improvements seen with terazosin alone were modest, but finasteride was no better than placebo in relieving symptoms. Terazosin and combination are modestly effective in relieving the symptoms of BPH. In this randomized controlled trial, Lepor and colleagues compared the α₁-adrenergic blocking agent terazosin with finasteride alone, a terazosin-finasteride combination, and placebo. The study appears to be valid. Patients and providers were blinded to treatment allocations, the baseline characteristics of all 4 groups were similar, compliance was excellent, fewer losses to follow-up occurred throughout the 1-year study, and the patients were analyzed in the groups to which they were assigned (intention-to-treat analysis). The outcomes (symptom scores and urinary-flow rates) are clinically relevant, but it would have been helpful if the authors had included information on improvement in residual volumes after voiding, which can be easily ascertained in an office practice. The improvements seen with terazosin alone were modest, but finasteride was no better than placebo in relieving symptoms. With the exception of dizziness and postural hypotension, the side effects of terazosin were mild. Men receiving finasteride were more likely to report sexual dysfunction. A global assessment would have been helpful in showing whether patients considered the benefits of the treatment to outweigh the side effects.

Random variation could easily explain the apparent discrepancy between the lack of benefit from finasteride in this study and the small improvement in symptoms and urinary-flow rates seen among men receiving finasteride in the multicenter study reported in 1992 (1). Our approach is to start men with symptomatic BPH therapy with an α₁-blocker. We recommend surgery instead of adding finasteride if our patients’ symptoms and residual volumes after voiding are not sufficiently alleviated by single-agent therapy.

Peter S. Millard, MD, PM Williams, J. Mitten Jr, MD Eastern Maine Medical Center, Bangor, Maine, USA

Reference

Evidence-Based Medicine January/February 1997

Therapeutics

Combination therapy was better than zidovudine alone for HIV infection

Timming of initiation of therapy, optimal drug combinations, duration of benefit, and when and how to switch drugs need further study. The clinical message, however, is clear: When a drug regimen is no longer effective, the combination therapy should be started.

Philipp J. Easterbrook, MD Chelsea and Westminster Hospital London, England, UK

References