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

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 ≥ 2 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 α-and β-adrenergic blocking agents, or treatment with an α-blocker. We considered the benefits of the treatment to outweigh the risks. 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, and the baseline characteristics of all 4 groups were similar. Compliance was excellent, and few losses to follow-up occurred through the 1-year study, and the patients were analyzed in the groups to which they were assigned (intention-to-treat analysis).

Terazosin reduced BPH symptoms and finasteride did not

Combination therapy was better than zidovudine alone for HIV infection

Drug treatment is an attractive alternative to surgery for patients with symptoms of BPH. Several clinical trials have shown that long-acting α1-adrenergic blockers and finasteride, a 5α-reductase inhibitor, 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, and the baseline characteristics of all 4 groups were similar. Compliance was excellent, and few losses to follow-up occurred through 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, both because 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 or increasing urinary-flow rates. 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 improvements in symptoms and urinary-flow rates seen among men receiving finasteride in the multicenter trial 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.

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References

Commentary
The results of the Delta and 2 similar studies on AIDS Clinical Trials Group (ACTG177) (1) and the Community Programs for Clinical Research on AIDS (CPRCA007) (2) support the superiority of combination therapy over zidovudine monotherapy in the treatment of HIV infection. In all 3 studies, the benefit of combination therapy on survival was most obvious in patients without previous zidovudine use, less benefit was seen in patients previously treated. In the Delta trial (3), the incidence of AIDS defining events was lower in the combination group than with the ddi combination alone. No serious side effects occurred in the Delta trial. It and the other studies of combination therapy had a high drug discontinuation rate for nonprotocol reasons.

Eleven antiretroviral agents are now available in the United States and Europe: nonnucleoside reverse transcriptase inhibitors (zidovudine, ddI, ddC, 3TC, d4T), reverse transcriptase inhibitors (nevirapine, delavirdine, and lopinavir-ritonavir), and protease inhibitors (saquinavir, ritonavir, and indinavir). Clinical studies of combination regimens with protease inhibitors in advanced HIV disease have shown significant survival benefits and marked improvements in CD4+ cell counts and disease progression occurred with the ddI combination than with the d4T combination alone. No serious side effects occurred in the Delta trial. It and the other studies of combination therapy had a high drug discontinuation rate for nonprotocol reasons. However, in the majority of cases, the reasons for discontinuation were related to the side effects of the drugs.

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