Doxazosin plus finasteride reduced clinical progression of benign prostatic hyperplasia more than either drug used alone


**Question**
In men with benign prostatic hyperplasia (BPH), what is the long-term effect of doxazosin or finasteride, alone or in combination, on measures of clinical progression?

**Design**
Randomized (unclear allocation concealment*), blinded (patients and investigators)*, placebo-controlled trial with mean follow-up of 4.5 years (Medical Therapy of Prostatic Symptoms [MTOPS] Study).

**Setting**
17 clinical centers in the United States.

**Patients**
3047 men ≥ 50 years of age (mean age 63 y) who had an American Urological Association (AUA) symptom score of 8 to 35 in the pilot phase (changed to 8 to 30 in the full study) and a maximum urine flow rate between 4 and 15 mL/s with a voided volume ≥ 125 mL. Exclusion criteria were previous medical or surgical intervention for BPH, blood pressure < 90/70 mm Hg in the supine position, or serum prostate-specific antigen level > 10 ng/mL. Follow-up was 100%.

**Intervention**
Patients were allocated to doxazosin, beginning at 1 mg/d and increased to 8 mg/d (n = 756); finasteride, 5 mg/d (n = 768); doxazosin (beginning at 1 mg/d and increased to 8 mg/d; same as for monotherapy) plus finasteride, 5 mg/d (n = 786); or placebo (n = 737), once daily.

**Main outcome measure**
Overall clinical progression of BPH, defined as the first occurrence of an increase from baseline ≥ 4 points in the AUA symptom score, acute urine retention, renal insufficiency, recurrent urinary tract infection, or urinary incontinence.

**Main results**
Analysis was by intention to treat. Overall clinical progression of BPH was reduced with doxazosin alone, finasteride alone, and their combination more than with placebo (Table).

**Combination therapy was better than either drug alone (Table).**

**Conclusions**
In men with benign prostatic hyperplasia, long-term doxazosin plus finasteride combination therapy reduced the risk for overall clinical progression of benign prostatic hyperplasia more than either drug used alone. Both drugs used alone were more effective than placebo.

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*See Glossary.

**Table**
Doxazosin, finasteride, doxazosin plus finasteride (combination), and placebo for clinical progression of benign prostatic hyperplasia at mean 4.5 years†

<table>
<thead>
<tr>
<th>Comparisons</th>
<th>Event rates</th>
<th>RRR (95% CI)</th>
<th>NNT (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doxazosin vs placebo</td>
<td>11% vs 17%</td>
<td>35% (17 to 50)</td>
<td>17 (11 to 39)</td>
</tr>
<tr>
<td>Finasteride vs placebo</td>
<td>12% vs 17%</td>
<td>33% (14 to 48)</td>
<td>18 (11 to 45)</td>
</tr>
<tr>
<td>Combination vs placebo</td>
<td>6% vs 17%</td>
<td>64% (51 to 74)</td>
<td>9 (7 to 13)</td>
</tr>
<tr>
<td>Combination vs doxazosin</td>
<td>6% vs 11%</td>
<td>45% (23 to 60)</td>
<td>20 (13 to 46)</td>
</tr>
<tr>
<td>Combination vs finasteride</td>
<td>6% vs 12%</td>
<td>46% (25 to 61)</td>
<td>19 (13 to 40)</td>
</tr>
</tbody>
</table>

†Abbreviations defined in Glossary; RRR, NNT, and CI calculated from data in article.