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FPIN's Clinical Inquiries

Medical Treatment of Benign Prostatic Hyperplasia

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Clinical Question

What is the best medical therapy for benign prostatic hyperplasia (BPH)?

Evidence-Based Answer

Although alpha blockers and 5-alpha reductase inhibitors each reduce BPH symptoms more than placebo (Strength of Recommendation [SOR]: A), alpha blockers are more effective than 5-alpha reductase inhibitors. (SOR: B). Phytotherapy (herbal treatment) has potential but unproven benefit in BPH. (SOR: B).

Evidence Summary

In a Cochrane systematic review of 14 randomized controlled trials (RCTs) with 4,122 patients, the alpha blocker tamsulosin (Flomax) demonstrated dose-dependent superiority in symptom relief over placebo. There was a 12 percent improvement in the American Urologic Association (AUA) symptom index (a 35-point symptom score) for 0.4 mg and 16 percent improvement for 0.8 mg. In general, a 10 to 20 percent improvement in symptom score is the minimum that is considered to be clinically significant. There were no significant differences in symptom relief between tamsulosin and other alpha blockers.¹

Another Cochrane systematic review of 17 RCTs with 5,151 patients found that the alpha blocker terazosin (Hytrin) was more effective than placebo in reducing symptoms. Using a 27-point symptom score, the pooled mean improvement was 37 percent for terazosin versus 15 percent for placebo.² A single RCT of 1,229 patients favored terazosin over the 5-alpha reductase inhibitor finasteride (Proscar) and placebo in symptom reduction at one-year follow-up (17, 9, and 7 percent improvement in AUA symptom score, respectively).³

Another review found that finasteride and dutasteride (Avodart) were slightly more effective than placebo at symptom reduction (4 and 6 percent improvement in AUA symptom score, respectively). In head-to-head trials, alpha blockers were slightly more effective than 5-alpha reductase inhibitors in symptom score reduction and improving urinary flow rates.⁴ One RCT of 3,047 men, which examined duration of benefit, showed that doxazosin (Cardura) had improved symptom control at one year (6 percent improvement in AUA symptom score; $P < .001$) and four years (3 percent improvement, $P = .002$)

compared with finasteride. However, these small improvements (less than 10 percent) in symptom scores are unlikely to be clinically meaningful. This trial also examined combinations of therapy. Although doxazosin and finasteride were each more effective than placebo in preventing the progression of BPH (defined as an 11 percent improvement in symptom score) at four years, the combination of doxazosin and finasteride was superior to either alone (number needed to treat [NNT] = 14 for doxazosin or finasteride alone; NNT = 9 for the combination).⁵

Research evaluating the effectiveness of herbal treatment is limited in quality (e.g., small trials, short study duration, unclear quality control of preparations used, variable methodologic quality). Saw palmetto (*Serenoa repens*) has the best data quality, but the data are conflicting regarding effectiveness. A Cochrane systematic review of 21 RCTs with 3,139 patients demonstrated that saw palmetto was comparable to finasteride and superior to placebo in terms of self-reported symptom improvement.⁶ However, a subsequent high-quality RCT with 225 patients comparing saw palmetto with placebo found no significant difference in AUA symptom scores.⁷ A Cochrane systematic review of four RCTs with 519 patients demonstrated that beta-sitosterols (South African star grass) improved symptom scores compared with placebo (14 percent weighted mean difference in AUA symptom score).⁸ Two additional Cochrane systematic reviews demonstrated modest symptom improvements with cernilton (ryegrass pollen) and *Pygeum africanum* (bark of African prune tree).^{9,10}

Recommendations from Others

The AUA recommends treatment of BPH based on the severity of lower urinary tract symptoms using the AUA symptom index.¹¹ Men with mild symptoms (score of 7 or less) or with moderate to severe symptoms (score of 8 or greater) without bother (i.e., symptoms do not impair lifestyle, or patient can live with the symptoms) can be managed with watchful waiting and yearly follow-up. Men with moderate to severe symptoms and with bother can be treated with medication; those who do not have complications of BPH (e.g., renal failure, urinary retention, recurrent urinary tract infections) can be treated with watchful waiting.

Alpha blockers are recommended as first-line treatment for BPH, except for prazosin (Minipress) and phenoxybenzamine (Dibenzylin), which lack data to support their use and, therefore, are not recommended. The 5-alpha reductase inhibitors are only recommended in men with documented prostate enlargement. There is panel consensus that combination treatment with alpha blockers and 5-alpha reductase inhibitors is also appropriate for BPH.

Clinical Commentary

Patient preference should guide BPH treatment. Men who are not inconvenienced by symptoms of BPH often accept no treatment. Because of the increasing popularity of "natural" treatment, many men will opt for phytotherapy because of its perceived potential benefit and little risk of harm. Saw palmetto is sold over-the-counter and, thus, is very accessible.

Among prescription medications, alpha blockers can be used to treat coexisting hypertension. The generic formulations of alpha blockers cost significantly less than their name brand counterparts, making them the most cost-effective treatment option. However, alpha blockers also have the most symptomatic side effects, which limits their use. From a clinical and practical standpoint, 5-alpha reductase inhibitors appear to be a second or third choice because they are less effective than alpha blockers, cost more, are not available in generic formulations, and require the additional expense and time of monitoring prostate-specific antigen.

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