

Treatment of Benign Prostatic Hyperplasia: A Synthesis of the Evidence

Benign prostatic hyperplasia (BPH) causes urinary hesitancy and intermittency, weak urine stream, nocturia (urinating at night), frequency, urgency, and the sensation of incomplete bladder emptying. These symptoms, collectively called “lower urinary tract symptoms,” or LUTS, can significantly reduce quality of life. Men with no symptoms or mild symptoms and those who tolerate moderate symptoms well, may be managed without pharmacotherapy (“watchful waiting”). For those who have moderate or severe symptoms, medical treatments include alpha-1-selective adrenergic receptor (α-1-AR) antagonists, 5-alpha-reductase inhibitors (5-αRIs), or a combination therapy with one drug from each of these classes.

Investigators at the Portland VA Medical Center, and part of HSR&D’s Evidence Synthesis Pilot Program, conducted a comprehensive literature review of studies (conducted from 1966 through July 2006) on the treatment of BPH to assess the evidence regarding effective treatment. Following is a summary of their findings, submitted as part of a Final Report to HSR&D’s Central Office.

Report Results

Combination therapy versus an alpha blocker or 5-ARI alone

In the first year of treatment, alpha blockers are more effective than finasteride in improving symptoms. Combination therapy and an alpha blocker alone have similar effects on quality of life in the first year and a half of treatment.

For men who have BPH and a large prostate, or a high PSA at baseline, combination therapy can prevent about two episodes of clinical progression per 100 men, per year over 4 years of treatment. There is

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no additional benefit within the first year of treatment. Most men who take combination therapy will have no additional benefit, and about 4 additional patients per 100 will become impotent, who would not have taken an alpha blocker alone. Combination therapy also can be instituted after clinical progression occurs, but this strategy, while used widely, has not been studied.

There is considerable uncertainty about how best to monitor PSA in those who choose to take finasteride or combination therapy, and who are otherwise candidates for PSA screening. Candidates for combination therapy—patients who have large prostates and at least moderate symptoms—tend to have higher PSA levels than other patients who have BPH. Finasteride reduces prostate size and PSA levels, making detection of prostate cancer more difficult. Alpha-blockers do not affect PSA levels. Expanding access to combination therapy as an initial option would require higher utilization of ultrasound and PSA testing in BPH patients to assess the risk of progression. The consequences of such a program in a primary care setting have not been studied.

Choice of Alpha-Blocker

Previous, good-quality systematic reviews found that the alpha blockers, including alfuzosin prolonged-release and doxazosin GITS, have similar efficacy in improving symptoms related to urinary flow rate. Observational studies of doxazosin, terazosin, and tamsulosin in selected patients indicate that in most patients who respond to an alpha blocker and tolerate it well initially, the drug continues to work and to be well-tolerated for many years.

Head-to-head trials of alpha-blockers are few, small and have serious limitations. They do not adequately test commonly held beliefs about differences in the side-effect profiles of the alpha-blockers. Specifically, they do not prove that tamsulosin causes fewer cardiovascular adverse effects than other alpha-blockers because it does not reduce blood pressure. In placebo-controlled trials, tamsulosin caused higher rates of sexual ejaculation abnormalities than other alpha blockers. The placebo-controlled trials do not adequately test the hypothesis that use of tamsulosin as an initial therapy reduces the risk of symptomatic hypotension.

For combination therapy, doxazosin is the best-studied alpha blocker.

Treatment of BPH in subgroups of patients

Long-term observational studies establish that BPH can be treated

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safely with alpha blockers in patients taking other medications for hypertension. Alpha-blockers should not be used as initial treatment for patients with hypertension, even those with BPH, because they are associated with poorer long-term outcomes than other choices. Data on the safety of alpha-blockers in patients taking erectile dysfunction drugs are sparse.

Recently, the FDA issued a notice that intra-operative Floppy Iris Syndrome (IFIS) has been observed during phacoemulsification cataract surgery in some patients currently or recently treated with tamsulosin.

Hefland M and Muzyk T. [Comparative effectiveness review on benign prostatic hyperplasia \(BPH\) management in primary care – Screening and therapy](#). Final Report, September, 2006.

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NOTE: This Report does not represent a medication usage guideline, nor should it be read as an endorsement of, or recommendation for any particular drug, use or approach. Moreover, the Portland VA Medical Center does not recommend or endorse any guideline or recommendation developed by users of these reports.