Finasteride: an update of its use in the management of symptomatic benign prostatic hyperplasia

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Authors' objectives
To overview the pharmacology of finasteride and provide an update of its clinical effects in patients with benign prostatic hyperplasia.

Searching
MEDLINE, EMBASE and AdisBase (a proprietary database of Adis International, Auckland, New Zealand) were searched for trials published in any language since 1966 until February 1999. Search terms included finasteride combined with either prostatic hypertrophy or benign prostatic hyperplasia. Bibliographic information, including contributory unpublished data was also requested from the company developing the drug.

Study selection
Study designs of evaluations included in the review
Inclusion of studies was mainly based on the methods section of the trials. When available, large well controlled trials with appropriate statistical methodology were preferred. Of the included trials, seven were double-blind randomised placebo controlled, multicentre trials; two were randomised, double-blind trials comparing different drugs; and three were non-comparative extensions of placebo-controlled trials.

Specific interventions included in the review
Finasteride. Studies included in the review compared it to placebo, terazosin, finesteride plus terazosin or serenoa repens. Dosages ranged from 1 mg-5 mg/day (most were 5mg/day) and duration of the treatment was between 6 months and 6 years.

Participants included in the review
People with benign prostatic hyperplasia. In all but one of the trials the inclusion criterion was mild to moderate uncomplicated symptomatic benign prostatic hyperplasia.

Outcomes assessed in the review
Symptomatic relief (as measured by the modified Boyarsky score or the International Prostate Symptom Score (IPSS)/American Urological Association (AUA) symptom score), reductions in prostate volume, risk of benign prostatic hypertrophy-related acute urinary retention, requirement for surgical intervention, increases in urinary flow rates, costs, quality of life, tolerability, adverse effects and adverse events.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the authors performed the selection.

Assessment of study quality
The authors do not state that they assessed validity.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the authors performed the data extraction.

Methods of synthesis
How were the studies combined?
Narrative summary.

How were differences between studies investigated?
The authors do not state how differences between the studies were investigated.

**Results of the review**

Eleven trials with a total of 13,822 participants (seven trials of finasteride versus placebo (n=11,005), two trials of finasteride versus other drugs (n=2,298) and three non-comparative follow-up studies (n=519)).

Reductions in prostate volume, increases in urinary flow rates and improvements in symptoms compared with placebo have been observed in trials of up to 4 years' duration and in noncomparative extensions (for up to 6 years). Results from the 4-year placebo-controlled PLESS trial show finasteride to significantly reduce the risk of benign prostatic hypertrophy-related acute urinary retention and the requirement for surgical intervention. Finasteride has significantly greater efficacy in patients with a large prostate (> or = 40 ml) than in patients with a small prostate. However, the predictive value of prostate size has been questioned. Results of an earlier comparative 1-year trial show terazosin monotherapy and terazosin plus finasteride therapy to be significantly more effective than both finasteride monotherapy and placebo in reducing symptom scores and improving maximum urinary flow rates. Prostatic volume was significantly reduced by finasteride monotherapy and combination therapy only. The overall efficacy of finasteride in patients with mild to moderate symptomatic benign prostatic hyperplasia tended to be greater than that of serenoa repens (Permixon) in a 6-month trial. Finasteride appears to improve overall quality of life to a similar extent to serenoa repens; patient satisfaction appears similar with finasteride and transurethral resection of the prostate (TURP). Finasteride is generally well tolerated. Most commonly reported adverse effects are sexually related (1 to 2.1 %). Gynaecomastia has been reported in 0.4% of patients.

**Cost information**

Yes. A US cost analysis model indicated that finasteride and terazosin are less expensive than TURP during the first 2 years of initiation. Canadian cost-effectiveness and cost-utility analyses using decision analysis modelling have shown primary intervention with finasteride to provide more quality-adjusted life years (QALYs) at lesser cost than watchful waiting or TURP in patients with moderate symptoms who receive the drug for < or = 3 years and < or = 14 years, respectively, but fewer QALYs at a higher cost in patients with severe symptoms needing therapy for > or = 4 years.

**Authors' conclusions**

Despite modest improvements in maximum urinary flow rates and symptom scores, finasteride is a first-line treatment option in those with moderate uncomplicated benign prostatic hyperplasia, especially in patients with a large prostate (> or = 40 ml). It is also an option in patients with more severe symptoms who are unable or unwilling to undergo surgery and in those awaiting surgery. Importantly, finasteride appears to reduce disease progression, significantly decreasing the incidence of acute urinary retention and the requirement for surgical intervention; to date, no other pharmacological agent has been shown to reduce these outcomes.

**CRD commentary**

Apart from the search strategy, no details are given about the methodology of the review, such as how the inclusion criteria were applied and how the data were extracted. In addition, no assessment of validity was undertaken. The review provides an update on a previous review (see Other Publications of Related Interest). The conclusions of this review should be interpreted with caution.

**Implications of the review for practice and research**

The authors state that prospective studies that carefully balance the costs of finasteride and alternative treatments taking into account treatment costs, outcome measures that are relevant for all treatment options, the percentage of patients likely to develop acute urinary retention or require surgery, the costs of treatment failure and the importance of choosing the right treatment for a particular patient are needed.

**Bibliographic details**


**PubMedID**

10235693
Other publications of related interest

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Subject indexing assigned by NLM

MeSH
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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.