Prostate volume predicts outcome of treatment of benign prostatic hyperplasia with finasteride: meta-analysis of randomized clinical trials

Boyle P, Gould A L, Roehrborn C G

Authors' objectives
To examine whether prostate size could predict the outcome of finasteride treatment, and therefore, indicate which men should be the best candidates for finasteride therapy.

Searching
The authors do not provide details of the sources searched or the strategies employed.

Study selection
Study designs of evaluations included in the review
Randomised, multicentre, placebo-controlled clinical trials of at least 12 months’ duration were included.

Specific interventions included in the review
Terazosin, finasteride (5 mg) or a combination of these two drugs used for at least 12 months.

Participants included in the review
Men (n=2,741) with clinical benign prostatic hyperplasia (BPH) (size greater than 30 mL by palpation required), and within the age range 40 to 83 years. There is a wide range of variation between studies for baseline prostate volume, baseline peak urinary flow rate and baseline symptom severity score, due to the difference in entry criteria. The mean prostate volume varies by more than 50% (or 22 mL) between the Veteran Affairs (VA) and the North American studies.

Outcomes assessed in the review
The outcomes were peak urinary flow rate, symptom score and prostate volume.

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?
The statistical analysis employed used a maximum likelihood Empirical Bayes method, which relates the between-treatment differences in change from baseline in each study to measures of disease severity at baseline, and explicitly allows for random variation among studies and sampling variation within studies. Since the data for each patient were available for each study, additional analyses were carried out using a random-effects model with specific effects for the finasteride-placebo differences. In addition, simple linear models were fitted to relate the changes from baseline in peak urinary flow rate, and Quasi-International Prostate Symptom Score Index, to the baseline prostate volume. Models
relating the symptom score changes to the baseline peak flow rate were also considered.

**How were differences between studies investigated?**
The authors do not state how differences between the studies were investigated, though there was a wide range of variation between studies for baseline prostate volume, baseline peak urinary flow rate, and baseline symptom severity score; in particular, the mean prostate volume varied by greater than 50% (or 22 mL) between the VA and North American studies.

**Results of the review**
Six RCTs with 2,601 men in total were included.

The effect of finasteride treatment on improvements in total symptom severity, frequency score, and peak urinary flow rate was consistent across all 6 trials, and similar among men with similar prostate volumes at baseline. Symptom severity improved by 1.8 points (95% confidence interval, CI: 0.7, 2.9) in men with prostate volumes less than 20 mL (n=72), while the improvement was 2.8 points (95% CI: 2.1, 3.5) for men with volumes greater than 60 mL (n=272). Improvements in peak urinary flow rate ranged from 0.89 mL/second (95% CI: -0.05, 1.83) to 1.84 mL/second (95% CI: 1.37, 2.30) for men with prostate volumes less than 20 mL and greater than 60 mL, respectively. Baseline prostate volume is a key predictor of treatment outcomes: approximately 80% of the variation in the treatment effects noted between studies could be attributed to differences in mean prostate volumes at baseline.

**Authors’ conclusions**
This meta-analysis suggests that finasteride is most effective in men with large prostates. Men with small prostates may not be suitable candidates for finasteride therapy for BPH. The need for a careful reevaluation of the definitions and terminology used when discussing urination problems is apparent.

**CRD commentary**
This is a methodologically-sound review examining the predictability of prostate size on the outcome of finasteride treatment, but there are some shortfalls. No details are provided of the search strategy for locating trials, and it is unclear whether a thorough search would have uncovered other studies. This and the lack of a validity assessment suggest caution may be required when interpreting the results of this meta-analysis. The validity, quality and relevance of the primary studies included cannot be commented on, as none of these issues were assessed or described in the paper.

**Funding**
Merck and Co.

**Bibliographic details**

**PubMedID**
8804493

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Enzyme Inhibitors /therapeutic use; Finasteride /therapeutic use; Humans; Male; Predictive Value of Tests; Prostate /pathology; Prostatic Hyperplasia /drug therapy /pathology; Randomized Controlled Trials as Topic
Record Status
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.