Efficacy and safety of tamsulosin for the treatment of benign prostatic hyperplasia: a meta analysis

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CRD summary
This review concluded that in comparison with placebo, tamsulosin improved international prostate symptom scores and maximum flow rates for patients with benign prostatic hyperplasia with no significant difference in adverse events. A risk of missing data, paucity of evidence and a lack of information regarding study quality suggest that the findings should be interpreted with caution.

Authors' objectives
To determine the safety and efficacy of tamsulosin compared with placebo for the treatment of benign prostatic hyperplasia (BPH).

Searching
PubMed, EBSCO, CBM and CNKI were searched up to 2008. Search terms were reported. Science Direct and four relevant journals were searched up to April 2008 (see review for details). Reference lists of retrieved studies were checked for additional studies. Only studies published in English or Chinese were eligible for inclusion in the review.

Study selection
Double-blind randomised controlled trials (RCTs) that compared oral tamsulosin with placebo for treatment of patients diagnosed with BPH according to defined criteria (see review for further details) were eligible for inclusion in the review. Eligible outcomes included International Prostate Symptom Score (IPSS), Boyarsky symptom score, maximum flow rate, quality of life and adverse events. Short-term studies (two weeks) were excluded from the review.

It appeared that only studies of 0.2 or 0.4mg/day oral tamsulosin were included in the review. Treatment duration ranged from four to 13 weeks; most studies continued treatment for 12 or 13 weeks. All except one of the included studies assessed maximum flow rate and adverse events. All studies assessed reported either IPSS or Boyarsky scores. Publication dates covered a 11-year period from 1995.

Studies were assessed for inclusion by two independent reviewers. Discrepancies were resolved through discussion.

Assessment of study quality
Validity of the included studies was assessed by two independent reviewers who used the Jadad scale of randomisation, blinding and study withdrawal. Allocation concealment was assessed. Each study was awarded a Jadad score up to a maximum of 5 points. Discrepancies were resolved through discussion.

Data extraction
Two reviewers independently extracted the difference from baseline in symptom and quality of life scores for both the intervention and placebo treatment groups. Standardised mean differences (SMDs) with 95% confidence intervals (CIs) were calculated. The number of participants who experienced an adverse event was extracted and used to calculate an odds ratio (OR) with 95% CIs. Discrepancies between reviewers were resolved through discussion.

Methods of synthesis
Studies were grouped according to outcome and pooled SMD/weighted mean differences (WMD) with 95% CIs calculated for continuous outcomes and odds ratios with 95% CIs for dichotomous outcomes. Heterogeneity was assessed using X^2 and I^2 statistics and findings from these assessments were used to determine whether fixed-effect or random-effects methods were used to pool the studies. Publication bias was assessed with funnel plots and by calculating the fail-safe number.

Results of the review
Seven RCTs (n=2,455) were included in the review. None of the included studies reported the method of randomisation or allocation concealment, but all were double-blinded and reported the number of patients who withdrew. All studies scored 3 for study quality.

Differences in pooled symptom scores (SMD -1.17, 95% CI -1.50 to -0.84; five RCTs) and maximum flow rate (WMD 1.02, 95% CI 0.71 to 1.34; five RCTs) favoured tamsulosin in comparison with placebo (figures in the text and forest plot differed; these were from the forest plot). Only one RCT assessed quality of life and this did not report a significant difference between tamsulosin and placebo. There was no evidence of statistical heterogeneity for any analyses. There was no significant difference in the incidence of adverse events between tamsulosin and placebo (three RCTs). Reported events included fatigue, pharyngitis, dizziness, rhinitis, postural hypotension, headache and abnormal erection.

A funnel plot of symptom scores suggested that there was a risk of publication bias.

**Authors’ conclusions**
In comparison with placebo, tamsulosin improved international prostate symptom scores and maximum flow rates, with no significant difference in adverse events.

**CRD commentary**
This review assessed a clearly defined question and searched a number of different sources for relevant data. Only published studies written in Chinese or English were eligible for inclusion in the review, which suggested that there were risks of publication and language biases. The authors’ assessment for the presence of publication bias confirmed this risk. The risk of reviewer error and bias was low. All stages of the review process were performed in duplicate. Study quality was assessed, although the reliability of data was unclear as the study methods were often not reported by the primary study authors, particularly with respect to randomisation and allocation concealment. The studies were pooled appropriately and attempts were made to assess the level of heterogeneity between studies. However, few details of the participants were reported, so it was difficult to assess the generalisability of the findings to other populations.

Overall, the authors’ conclusions appear reasonable, but the paucity of studies, risk of missing data and lack of information on study quality suggest that the findings should be interpreted with caution.

**Implications of the review for practice and research**
**Practice:** The authors did not state any implications for practice.

**Research:** The authors stated that further randomised controlled trials with long-term follow-up over multiple time points were required to assess the safety and efficacy of tamsulosin in comparison with placebo for treatment of benign prostatic hyperplasia. Relevant outcomes such as average flow rate, residual urine, quality of life and prostate volume should be included. Different doses of tamsulosin (such as 0.6 and 0.8mg/day) should be assessed.

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