Authors' objectives
To review the efficacy and safety of phytotherapeutic compounds used to treat men with symptomatic benign prostatic hyperplasia (BPH).

Searching
MEDLINE (1966 to 1997), EMBASE, Phytodok and the Cochrane Library were searched; the search terms and dates (for non-MEDLINE databases) were not reported. The bibliographies of identified trials and review articles were also checked, and relevant authors and drug companies were contacted.

Study selection
Study designs of evaluations included in the review
The authors stated that only randomised controlled trials (RCTs) were eligible for inclusion in the review. However, the sections on the efficacy and safety of Serenoa repens and Pygeum africanum were based on the results of earlier systematic reviews (see Other Publications of Related Interest nos.1-2), and so will not be reported further in this abstract.

Specific interventions included in the review
Studies of phytotherapeutic agents, alone or in combination with other phytotherapeutic agents, compared with placebo or other pharmacologic agents and administered for at least 30 days, were eligible for inclusion. The included studies assessed the following six phytotherapeutic agents: Serenoa repens (saw palmetto berry), Hypoxis rooperi (South African star grass), Secale cereale (rye pollen), Pygeum africanum (African plum tree), Urtica dioica (stinging nettle root) and Curcubita pepo (pumpkin seed).

Participants included in the review
Studies of men with symptomatic BPH were eligible for inclusion. No further details of the study participants were reported.

Outcomes assessed in the review
Inclusion criteria relating to the outcomes were not specified. The outcomes reported in the review included: urinary symptom scores, urinary flow measures, prostate size, adverse effects, withdrawal rates, urinary residual volume and nocturia.

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

Assessment of study quality
There was no formal validity assessment. However, the authors discussed factors such as the duration of treatment, standardisation and validation of outcome scales, and the level of reporting.

Data extraction
The authors stated that two reviewers extracted key data independently. For Hypoxis rooperi, means and standard deviations of symptom scores and peak urine flow for each group were extracted from studies that reported them and used to calculate weighted mean differences (WMDs).

Methods of synthesis
How were the studies combined?
Studies evaluating Hypoxis rooperi were combined in a random-effects meta-analysis. Studies of the other treatments were combined narratively, grouped by intervention.

How were differences between studies investigated?
Differences between the studies in terms of interventions and comparators were discussed. Heterogeneity in the meta-analysis was assessed using a chi-squared test.

Results of the review
Four RCTs (n=519) evaluated Hypoxis rooperi, four RCTs (n=444) evaluated Secale cereale, five RCTs (n=543 and n=41; participant numbers not reported for three trials) evaluated Urtica dioica and one RCT (n=55) evaluated Curcubita pepo.

Hypoxis rooperi (4 RCTs).
Two studies that reported urinary symptom scores showed statistically significant improvements (WMD -4.91, 95% confidence interval, CI: -6.29, -3.53). Heterogeneity was not present in this result (P=0.49).

Four studies that reported peak urine flow showed a statistically significant improvement when pooled (WMD 3.91 mL/second, 95% CI: 0.91, 6.90). Significant heterogeneity was present in this result (P=0.00).

One trial showed no reduction in prostate size, while another trial showed no improvement in urinary flow rates. Adverse events were reported to be infrequent and mild. The withdrawal rates were reported to be similar to placebo.

Secale cereale (4 RCTs).
The authors reported that the studies could not be combined in a meta-analysis, owing to differences in the comparators and reporting methods. Data from all studies were reported to show improvement in symptoms and urinary flow. The only adverse event reported was mild nausea. Some methodological limitations were noted in the included studies.

Urtica dioica (5 RCTs).
Three of the included studies evaluated Urtica dioica combined with other phytotherapeutic agents; the results of two of these were not reported. One RCT, which compared a combined preparation of Sabal and Urtica with finasteride, found no differences between the groups in symptom scores, peak urine flow, or residual urine volume. More adverse events were associated with finasteride. Symptom scores were improved compared with placebo.

A small trial (n=41) found improvement in symptom scores compared with placebo. Another placebo-controlled trial reported improvements in peak urine flow and total voided volume, but no improvement in symptoms. This trial had a withdrawal rate of 24% in the Urtica group, half due to adverse effects.

Curcubita pepo (1 RCT).
In this trial Curcubita was combined with Sabal serrulata and compared with placebo. The treatment group reported improved self-rating of urinary symptoms and nocturia, and a greater reduction in urine volume than the placebo group.

Cost information
The authors stated that phytotherapy cost less and was better tolerated in the short term than alpha-blockers or finasteride. It was unclear whether this came from studies included in the review or was the authors’ opinion.

Authors’ conclusions
Hypoxis rooperi and Secale cereale appeared to improve symptoms of BPH, although the evidence was not strong. There was no convincing evidence supporting the use of Urtica dioica or Curcubita pepo alone for the treatment of
BPH. Overall, phyotherapies were less expensive than alpha-blockers or finasteride, were well tolerated, and adverse events were mild and infrequent.

CRD commentary
Inclusion criteria for the study design, participants and interventions were clearly stated, whereas those for the outcomes were not explicitly stated. The search strategy appeared to include some attempt to locate unpublished material. However, it was not stated whether any language restrictions were applied, thus some relevant studies might have been missed. Validity was not formally assessed, so it was not always clear whether the results reported came from good- or poor-quality RCTs. Since details of the review process (how the studies were selected, validity assessed, and so on) were not reported, it was not clear whether bias could have occurred during the review process. The decision not to pool studies of Secale cereale seems appropriate given the diversity of the interventions and comparators. The authors’ conclusions seem appropriate.

Implications of the review for practice and research
Practice: The authors stated that if the primary goal was to reduce symptoms, alpha-blockers seem to be a better choice than finasteride and probably phyotherapy.

Reviewer’s comment: This statement does not seem to follow directly from the evidence presented in the review as there was no comparison of phyotherapy or finasteride with alpha-blockers.

Research: The authors stated that RCTs using standardised preparations of phyotherapeutic agents, and of longer study duration, are needed to determine their long-term effectiveness.

Bibliographic details

PubMedID
11276294

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Humans; MEDLINE; Male; Phytotherapy; Plant Extracts /therapeutic use; Plants, Medicinal /therapeutic use; Prostatic Hyperplasia /drug therapy /therapy; Randomized Controlled Trials as Topic; Treatment Outcome

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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.