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[Intervention Review]

Serenoa repens for benign prostatic hyperplasia

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ABSTRACT

Background

Benign prostatic hyperplasia (BPH) is a nonmalignant enlargement of the prostate, which can lead to obstructive and irritative lower urinary tract symptoms (LUTS). The pharmacologic use of plants and herbs (phytotherapy) for the treatment of LUTS associated with BPH is common. The extract of the berry of the American saw palmetto, or dwarf palm plant, *Serenoa repens* (SR), which is also known by its botanical name of *Sabal serrulatum*, is one of several phytotherapeutic agents available for the treatment of BPH.

Objectives

This systematic review aimed to assess the effects and harms of *Serenoa repens* in the treatment of men with LUTS consistent with BPH.

Search methods

We searched for trials in general and in specialized databases, including the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE®, EMBASE, CINAHL®, Web of Science, SCOPUS, BIOSIS Previews®, LILACS, ClinicalTrials.gov, Controlled-Trials.com, World Health Organization (WHO), and Google Scholar. We also handsearched systematic reviews, references, and clinical practice guidelines. There were no language restrictions.

Selection criteria

Trials were eligible if they randomized men with symptomatic BPH to receive preparations of SR (alone or in combination) for at least four weeks in comparison with placebo or other interventions, and included clinical outcomes, such as urologic symptom scales, symptoms, and urodynamic measurements. Eligibility was assessed by at least two independent observers (JT, RM).

Data collection and analysis

One review author (JT) extracted Information on patients, interventions, and outcomes which was then checked by another review author (RM). The main outcome measure for comparing the effectiveness of SR with active or inert controls was change in urologic symptom-scale scores, with validated scores taking precedence over non validated ones. Secondary outcomes included changes in nocturia and urodynamic measures. The main outcome measure for harms was the number of men reporting side effects.

Main results

In a meta-analysis of two high quality long-term trials (n = 582), *Serenoa repens* therapy was not superior to placebo in reducing LUTS based on the AUA (mean difference (MD) 0.25 points, 95% confidence interval (CI) -0.58 to 1.07). A 72 week trial with high quality evidence, using the American Urological Association Symptom Score Index, reported that SR was not superior to placebo at double and triple doses. In the

same trial the proportions of clinical responders (≥ three-point improvement) were nearly identical (42.6% and 44.2% for SR and placebo, respectively), and not significant (RR 0.96, 95% CI 0.76 to 1.22).

This update, which did not change our previous conclusions, included two new trials with 444 additional men, an 8.5% (5666/5222) increase from our 2009 updated review, and a 28.8% (1988/1544) increase for our main comparison, SR monotherapy versus placebo control (17 trials). Overall, 5666 men were assessed from 32 randomized, controlled trials, with trial lengths from four to 72 weeks. Twenty-seven trials were double blinded and treatment allocation concealment was adequate in 14.

In a trial of high quality evidence (N = 369), versus placebo, SR did not significantly decrease nightly urination on the AUA Nocturia scale (range zero to five) at 72 weeks follow-up (one-sided P = 0.19).

The three high quality, moderate-to-long term trials found peak urine flow was not improved with *Serenoa repens* compared with placebo (MD 0.40 mL/s, 95% CI -0.30 to 1.09).

Comparing prostate size (mean change from baseline), one high quality 12-month trial (N = 225) reported no significant difference between SR and placebo (MD -1.22 cc, 95% CI -3.91 to 1.47).

Authors' conclusions

Serenoa repens, at double and triple doses, did not improve urinary flow measures or prostate size in men with lower urinary tract symptoms consistent with BPH.

PLAIN LANGUAGE SUMMARY

Serenoa repens for benign prostatic hyperplasia

Benign prostatic hyperplasia (BPH) is the nonmalignant enlargement of the prostate gland that is caused by an increase in volume of epithelial (top layer of tissue that line cavities and surfaces of the body) and stromal (connective tissue) cells. This increase in cells can, over time, create fairly large, discrete nodules in the periurethral region of the prostate, and in turn can restrict the urethral canal causing partial or complete blockage.

The use of plants and herbs (phytotherapy) for the treatment of lower urinary tract symptoms associated with BPH is common and has been growing steadily in most Western countries. The extract of the berry of the American saw palmetto, or dwarf palm plant, *Serenoa repens* (SR), which is also known by its botanical name of *Sabal serrulatum*, is one of several phytotherapeutic agents available for the treatment of BPH.

The update of this review included 32 randomized controlled trials involving 5666 men.

Compared with placebo, *Serenoa repens*, at double and triple the usual dose, provides no improvement for nocturia, peak urine flow, and symptom scores for men with benign prostatic hyperplasia.