

Serenoa repens for benign prostatic hyperplasia.

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BACKGROUND: Benign prostatic hyperplasia (BPH), nonmalignant enlargement of the prostate, 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 has been growing steadily. The extract of the American saw palmetto or dwarf palm plant, *Serenoa repens* (also known by its botanical name of *Sabal serrulatum*), is one of the several phytotherapeutic agents available for the treatment of BPH. **OBJECTIVES:** This systematic review aimed to assess the effects of *Serenoa repens* in the treatment of LUTS consistent with BPH. **SEARCH STRATEGY:** Trials were searched in computerized general and specialized databases (MEDLINE, EMBASE, Cochrane Library, Phytodok), by checking bibliographies, and by contacting manufacturers and researchers. **SELECTION CRITERIA:** Trials were eligible if they (1) randomized men with BPH to receive preparations of *Serenoa repens* (alone or in combination) in comparison with placebo or other BPH medications, and (2) included clinical outcomes such as urologic symptom scales, symptoms, or urodynamic measurements. Eligibility was assessed by at least two independent observers. **DATA COLLECTION AND ANALYSIS:** Information on patients, interventions, and outcomes was extracted by at least two independent reviewers using a standard form. The main outcome measure for comparing the effectiveness of *Serenoa repens* with placebo or other BPH medications was the change in urologic symptom scale scores. Secondary outcomes included changes in nocturia and urodynamic measures. The main outcome measure for side effects was the number of men reporting side effects. **MAIN RESULTS:** In this update, 3 new trials involving 230 additional men (7.8%) have been included. 3139 men from 21 randomized trials lasting 4 to 48 weeks were assessed. 18 trials were double-blinded and treatment allocation concealment was adequate in 11 studies. Compared with placebo, *Serenoa repens* improved urinary symptom scores, symptoms, and flow measures. The weighted mean difference (WMD) for the urinary symptom score was -1.41 points (scale range 0-19), (95%CI = -2.52, -0.30, n = 1 study) and the risk ratio (RR) for self rated improvement was 1.76 (95%CI = 1.21, 2.54, n = 6 studies). The WMD for nocturia was -0.76 times per evening (95%CI = -1.22, -0.32; n = 10 studies). The WMD for peak urine flow was 1.86 ml/sec (95%CI = 0.60, 3.12, n = 9 studies). Compared with finasteride, *Serenoa repens* produced similar improvements in urinary symptom scores (WMD = 0.37 IPSS points (scale range 0-35), 95%CI = -0.45, 1.19, n = 2 studies) and peak urine flow (WMD = -0.74 ml/sec, 95%CI = -1.66, 0.18, n = 2 studies). Adverse effects due to *Serenoa repens* were mild and

infrequent. Withdrawal rates in men assigned to placebo, Serenoa repens or finasteride were 7%, 9%, and 11%, respectively. REVIEWER'S CONCLUSIONS: The evidence suggests that Serenoa repens provides mild to moderate improvement in urinary symptoms and flow measures. Serenoa repens produced similar improvement in urinary symptoms and flow compared to finasteride and is associated with fewer adverse treatment events. The long term effectiveness, safety and ability to prevent BPH complications are not known. The results of this update are in agreement with our initial review.

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