

Saw palmetto extracts for treatment of benign prostatic hyperplasia: a systematic review.

Wilt TJ, Ishani A, Stark G, MacDonald R, Lau J, Mulrow C.

Department of Veterans Affairs Coordinating Center of the Cochrane Collaborative Review Group in Prostatic Diseases and Urologic Malignancies, Minneapolis Veterans Affairs Medical Center, Minn 55417, USA. wilt.timothy@minneapolis.va.gov

OBJECTIVE: To conduct a systematic review and, where possible, quantitative meta-analysis of the existing evidence regarding the therapeutic efficacy and safety of the saw palmetto plant extract, *Serenoa repens*, in men with symptomatic benign prostatic hyperplasia (BPH). **DATA SOURCES:** Studies were identified through the search of MEDLINE (1966-1997), EMBASE, Phytodok, the Cochrane Library, bibliographies of identified trials and review articles, and contact with relevant authors and drug companies. **STUDY SELECTION:** Randomized trials were included if participants had symptomatic BPH, the intervention was a preparation of *S repens* alone or in combination with other phytotherapeutic agents, a control group received placebo or other pharmacological therapies for BPH, and the treatment duration was at least 30 days. **DATA EXTRACTION:** Two investigators for each article (T.J.W., A.I., G.S., and R.M.) independently extracted key data on design features, subject characteristics, therapy allocation, and outcomes of the studies. **DATA SYNTHESIS:** A total of 18 randomized controlled trials involving 2939 men met inclusion criteria and were analyzed. Many studies did not report results in a method that permitted meta-analysis. Treatment allocation concealment was adequate in 9 studies; 16 were double-blinded. The mean study duration was 9 weeks (range, 4-48 weeks). As compared with men receiving placebo, men treated with *S repens* had decreased urinary tract symptom scores (weighted mean difference [WMD], -1.41 points [scale range, 0-19] [95% confidence interval (CI), -2.52 to -0.30] [n = 1 study]), nocturia (WMD, -0.76 times per evening [95% CI, -1.22 to -0.32] [n = 10 studies]), and improvement in self-rating of urinary tract symptoms; risk ratio for improvement (1.72 [95% CI, 1.21-2.44] [n = 6 studies]), and peak urine flow (WMD, 1.93 mL/s [95% CI, 0.72-3.14] [n = 8 studies]). Compared with men receiving finasteride, men treated with *S repens* had similar improvements in urinary tract symptom scores (WMD, 0.37 International Prostate Symptom Score points [scale range, 0-35] [95% CI, -0.45 to 1.19] [n = 2 studies]) and peak urine flow (WMD, -0.74 mL/s [95% CI, -1.66 to 0.18] [n = 2 studies]). Adverse effects due to *S repens* were mild and infrequent; erectile dysfunction was more frequent with finasteride (4.9%) than with *S repens* (1.1%; $P < .001$). Withdrawal rates in men assigned to placebo, *S repens*, or finasteride were 7%, 9%, and 11%, respectively. **CONCLUSIONS:** The existing literature on *S repens* for treatment of BPH is limited in terms of the short duration of studies and variability in study design, use of phytotherapeutic preparations, and reports of outcomes. However, the evidence suggests that *S repens* improves urologic symptoms and flow measures. Compared with finasteride, *S repens* produces similar improvement in urinary tract symptoms and urinary flow and was associated with fewer adverse

treatment events. Further research is needed using standardized preparations of *S repens* to determine its long-term effectiveness and ability to prevent BPH complications.