



Tips from Other Journals

Adult Medicine

1202 Saw Palmetto Extract Ineffective for BPH Symptoms

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Saw Palmetto Extract Ineffective for BPH Symptoms

Background: Benign prostatic hyperplasia (BPH) commonly causes lower urinary tract symptoms in older men. BPH typically is treated with medications, minimally invasive therapies, or surgery. Early studies suggested that extracts from the fruit of the saw palmetto dwarf palm tree were effective in reducing lower urinary tract symptoms caused by BPH; however, a 2009 Cochrane review did not find any benefit for saw palmetto extract over placebo. Barry and colleagues studied increasing doses of saw palmetto extract to determine whether higher doses would improve lower urinary tract symptoms in men with BPH.

The Study: This multicenter, double-blind, placebo-controlled randomized trial enrolled men 45 years or older who had a peak uroflow rate of at least 4 mL per second and a score between 8 and 24 on the American Urological Association Symptom Index (AUASI). This self-administered, seven-item questionnaire assesses frequency of lower urinary tract symptoms with scores ranging from 0 to 35. Men were excluded from the study if they had undergone invasive treatment for BPH or genitourinary instrumentation, had recently taken any medications that could affect urination, or had underlying kidney or liver disease. Participants

were randomly assigned to receive placebo or increasing doses of saw palmetto extract; the initial dosage of 320 mg per day was doubled at 24 weeks and tripled at 48 weeks. Treatment was completed after 72 weeks. The primary outcome was a decrease in AUASI score. Secondary outcomes included improvements on 11 other assessments, including quality-of-life scores and prostate-specific antigen levels.

Results: A sample size of 157 participants per group was estimated to detect a two-point difference on the AUASI with 90 percent power. Of the 369 men who were randomized, 183 men were assigned to the treatment group and 186 were assigned to the placebo group. The mean age of participants was 61 years, and the mean AUASI score was 14.6 points. Adherence to study protocol was high; 97 percent of participants completed their visits, and pill counts were appropriate in 98 percent of visits. All participants who completed the 72 weeks of treatment tolerated the maximal dosing. At the conclusion of the study, the treatment and placebo groups had similarly decreased mean AUASI scores (2.20 and 2.99 points, respectively; $P = .91$). The analysis of dose response confirmed no difference between saw palmetto extract and placebo at any dose level, and none of the secondary outcome measures showed a benefit with saw palmetto extract.

Conclusion: Even at three times the standard dosing, saw palmetto extract had no greater effect than placebo on improving lower urinary tract symptoms associated with BPH.

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Source: Barry MJ, et al. Effect of increasing doses of saw palmetto extract on lower urinary tract symptoms: a randomized trial. *JAMA*. September 28, 2011;306(12):1344-1351. ■