Saw palmetto did not differ from placebo for benign prostatic hyperplasia in men

Bent S, Kane C, Shinohara K, et al. **Saw palmetto for benign prostatic hyperplasia.** N Engl J Med. 2006;354:557-66.

Clinical impact ratings: GIM/FP/GP ★★★★★★☆ Nephrology ★★★★☆☆☆

QUESTION

In men with moderate-to-severe symptoms, is saw palmetto more effective than placebo for benign prostatic hyperplasia?

METHODS

Design: Randomized placebo-controlled trial.

Allocation: Concealed.*

Blinding: Blinded {patients, health care providers, outcome assessors, data collectors, and data analysts}†.*

Follow-up period: 1 year.

Setting: San Francisco Veterans Affairs Medical Center, Kaiser Permanente Northern California, and the surrounding community, California, USA.

Patients: 225 men > 49 years of age (mean age 63 y, 82% white) with moderate-to-severe symptoms of benign prostatic hyperplasia defined by the American Urological Association Symptom Index (AUASI) score ≥ 8, and a peak urine flow rate < 15 mL/s. Exclusion criteria were high risk for urine retention, peak urine flow rate < 4 mL/s, residual volume > 250 mL after voiding, history of prostate cancer, surgery for benign prostatic hyperplasia, urethral structure, neurogenic bladder, creatinine level > 2 mg/dL (> 176.8 µmol/L), prostate-specific antigen (PSA) > 4 ng/dL, use of medications that affect urination, or severe concomitant disease.

Intervention: Saw palmetto, 320 mg/d (n = 112), or matching placebo (n = 113).

Outcomes: Changes from baseline in AUASI score and maximum urine flow rate. Secondary outcomes were prostate size; residual urine volume after voiding; levels of PSA, creatinine, and testosterone; serious and nonserious adverse events; self-reported side effects; and quality of life. The study had 90% power to detect a 3-point difference between groups on the AUASI score.

Patient follow-up: 216 patients (96%) (intention-to-treat analysis).

MAIN RESULTS

Groups did not differ for changes in AUASI score; maximum urine flow rate; prostate size; residual urine volume after voiding; or levels of PSA, creatinine, and testosterone (Table). Groups did not differ for the occurrence of ≥ 1 serious adverse events (6 vs 11, P = 0.31) or the mean number of nonserious adverse events (0.51 vs 0.47, P = 0.72), self-reported side effects, or quality of life.

CONCLUSION

In men with moderate-to-severe symptoms, saw palmetto was no more effective than placebo for benign prostatic hyperplasia.

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*See Glossary.

†Information provided by author.

Saw palmetto vs placebo for benign prostatic hyperplasia at 1 year‡

Outcomes	Mean change from baseline		Difference in change between groups (95% CI)
	Saw palmetto	Placebo	
American Urological Association Symptom Index score	–0.68	–0.72	–0.04 (–1.0 to 0.9)
Maximum urine flow rate (mL/s)	0.42	–0.01	0.43 (–0.5 to 1.4)
Prostate volume (mL)	3.8	5.0	–1.2 (–3.9 to 1.5)
Residual volume after voiding (mL)	14	19	–4.5 (–24 to 15)
Prostate-specific antigen level (ng/dL)	–0.005	0.15	0.16 (–0.04 to 0.4)
Creatinine level (mg/dL [µmol/L])	0.002 [0.18]	–0.004 [–0.35]	–0.006 (–0.03 to 0.02) [–0.53 (–2.65 to 1.77)]
Testosterone level (ng/dL)	–17	–1.4	–15 (–39 to 8.7)

‡CI defined in Glossary. All comparisons were not significant.

COMMENTARY

Enthusiasm for herbal therapies for lower urinary tract symptoms has been prompted by previous reviews concluding that several herbal therapies moderately improved urologic symptoms and flow measures (1). However, our review of one of the most widely used and studied herbal preparations, saw palmetto, emphasized that such results should be viewed with caution (2). The literature on herbal extracts is limited by short study durations, variability in study designs and reporting of outcomes, and use of nonstandardized phytotherapeutic preparations (1).

Therefore, the results by Bent and colleagues are not entirely surprising. Concerns regarding the effectiveness and safety of many herbal products and speculation on why findings from the saw palmetto systematic review differed from those of Bent and colleagues have been reported (3). The Bent trial was well-powered, lasted 52 weeks, and tested a widely used dose (320 mg/d) and standardized preparation of saw palmetto. The participants and investigators were adequately blinded to the distinctive pungent odor of saw palmetto, and validated symptom scale scores showed that groups did not differ for baseline symptom severity, PSA level, prostate size, or urine flow rates. The upcoming CAMUS trial will assess the effectiveness and safety of 320 to 960 mg/d of standardized saw palmetto extracts in men with moderate symptoms (4). Unless CAMUS and other trials provide contradicting evidence, the findings by Bent and colleagues indicate that saw palmetto does not improve symptoms or objective measures of benign prostatic hyperplasia. There is also no evidence that saw palmetto maintains prostate health or prevents development of urinary symptoms or prostate cancer. Its use should not currently be recommended.

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References

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