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


**Clinical impact ratings:** GIM/TP/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 stricture, 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; 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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For correspondence: Dr. S. Bent, San Francisco VAMC, San Francisco, CA, USA. E-mail bent@itsa.ucsf.edu.

*See Glossary.
†Information provided by author.

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

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Mean change from baseline</th>
<th>Difference in change between groups (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Urological Association Symptom Index score</td>
<td>−0.68</td>
<td>−0.72</td>
</tr>
<tr>
<td>Maximum urine flow rate (mL/s)</td>
<td>0.42</td>
<td>−0.01</td>
</tr>
<tr>
<td>Prostate volume (mL)</td>
<td>3.8</td>
<td>5.0</td>
</tr>
<tr>
<td>Residual volume after voiding (mL)</td>
<td>14</td>
<td>19</td>
</tr>
<tr>
<td>Prostate-specific antigen level (ng/dL)</td>
<td>−0.005</td>
<td>0.15</td>
</tr>
<tr>
<td>Creatinine level (mg/dL/μmol/L)</td>
<td>0.002 (0.18)</td>
<td>−0.004 (−0.35)</td>
</tr>
<tr>
<td>Testosterone level (ng/dL)</td>
<td>−17</td>
<td>−1.4</td>
</tr>
</tbody>
</table>

‡Information provided by author.

**Commentary**
Enthusiasm for herbal therapies for lower urinary tract symptoms has been prompted by several reviews concluding that several herbal therapies moderately improve urologic symptoms and flow measures (1). However, our review of one of the most widely used and studied herbal therapies, saw palmetto, emphasized that such results should be viewed with caution (2). The literature on herbal extracts is limited by many sources and speculation on why findings from the saw palmetto studies differ 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 conflicting 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.

Timothy J. Wilt, MD, MPH
Minneapolis VA Center for Chronic Disease Outcomes Research
Minneapolis, Minnesota, USA

**References**