Researchers | Daily Dosage (mg/b.i.d.) | Regime | # of Patients Saw palmetto group (SP) vs. Placebo | % Reduction in Urinary Frequency (at night) | % Increase in Peak Urinary Flow Rate | Tolerability of Therapy
--- | --- | --- | --- | --- | --- | ---
Tasca et al. (1985) | 160 x 1-3 mo | SP: 14 | Placebo: 13 | SP: 74% | SP: 26% | Excellent
Reece Smith et al. (1988) | 160 x 3 mo | SP: 33 | Placebo: 37 | SP: 36% | SP: 35% | Excellent
Emili et al. (1983) | Unclear x 1 mo | SP: 15 | Placebo: 15 | SP: 50% | SP: 33% | Excellent
Descotes et al. (1995) | 160 x 1 mo | SP: 82 | Placebo: 94 | SP: 33% | SP: 29% | Good
Cukier et al. (1985) | 160 x 2-3 mo | SP & Placebo: 146 | Placebo: 15% | SP: 33% | N/A | Good
Champault et al. (1984) | 160 x 1 mo | SP: 47 | Placebo: 41 | SP: 46% | SP: 50% | Excellent
Boccafoschi & Annoscia (1983) | 160 x 2 mo | SP: 11 | Placebo: 11 | SP: 55% | SP: 43% | Excellent

P <0.001 - < 0.05 vs. placebo

Finasteride vs. Saw Palmetto Extract
Carraro et al. completed the largest international comparative trial for the treatment of BPH. This double-blind study compared the therapeutic effects of finasteride versus saw palmetto extract in 1,098 patients with moderate BPH. The most critical observation of this comparative trial was that saw palmetto extract does not have a significant effect on serum PSA levels or prostate volume. With this knowledge, physicians do not need to be concerned that saw palmetto will affect PSA levels and mask prostate cancer. This clinical evidence also makes it clear that the primary action of saw palmetto is not its ability to inhibit 5-alpha reductase, since PSA levels remained relatively constant. Table 1.2 further highlights the results of this study.

Table 1.2 Double-Blind Trial Comparing the Therapeutic Effects of Saw Palmetto Extract with Finasteride in Patients with Moderate BPH

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Saw Palmetto Extract</th>
<th>Finasteride</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily Dosage</td>
<td>320 mg</td>
<td>5 mg</td>
</tr>
<tr>
<td>Quality of Life</td>
<td>38% improvement</td>
<td>41% improvement</td>
</tr>
<tr>
<td>Peak Flow Rate</td>
<td>25%</td>
<td>30% p&lt;0.05</td>
</tr>
<tr>
<td>Prostate Volume</td>
<td>-6%</td>
<td>-18% p&lt;0.001</td>
</tr>
<tr>
<td>PSA</td>
<td>No change</td>
<td>-41% p&lt;0.001</td>
</tr>
<tr>
<td>IPSS</td>
<td>-37%</td>
<td>-39%</td>
</tr>
</tbody>
</table>

- Patients reported more sexual dysfunction with finasteride and reported a significantly higher number of incidences of impotence and decreased libido p<0.001 on sexual function score
- IPSS= International Prostate Symptom Score
- PSA= prostate-specific antigen

Overview: Clinical Effects of Saw Palmetto (Serenoa repens)
- Decreases urinary urgency
- Decreases perineal pain
- Decreases nocturnal (nighttime) frequency
- Increases urinary flow rate
- Prevents infections due to residual urine
- Reduces residual urine
- Improves quality of life for BPH patients

Contraindications
- Pregnancy and lactation: it is possible that Saw palmetto may be unsafe for pregnant and lactating women due to its antiandrogen and estrogenic activity.

Side Effects
- Tolerability is generally excellent for Saw palmetto although it can in rare instances cause headache or mild gastrointestinal disturbances.