Saw palmetto and prostatic hypertrophy

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An extract of the fruit from the American saw palmetto plant has been used by native American Indians for hundreds of years to treat a variety of men's problems, and prostate gland swelling since the 1800s. Does it work? Systematic reviews [1,2] say that it does.

Search

The search for randomised controlled studies of Saw palmetto (using all those peculiar botanical names that plants have) against placebo or other treatments was thorough. It found 24 studies, 18 of which met the inclusion criteria. The mean age of men involved was 65 years and the mean duration of the studies was nine weeks.

Results

Compared with placebo, Saw palmetto improved peak urinary flow rate by an average of 1.9 mL/second and mean urinary flow rate by 2.2 mL/second (Figure 1). Saw palmetto did not decrease prostate size.

Figure 1: Peak urinary flow
Patient rating of prostate-related symptoms showed significant benefits for Saw palmetto over placebo. In six studies (Figure 2) 242/329 (74%) men had symptom improvement with Saw palmetto compared with 168/330 (51%) with placebo. This means that for every 4.4 men treated with Saw palmetto (95% CI 3.4 to 6.5) one will have symptoms improved who would not have done with placebo.

Figure 2: Symptom improvement
The problems

One problem was the short duration of studies, with a mean of nine weeks, and that half the men had symptom improvement with placebo. The largest and longest randomised trial ever done (3,040 men over four years, [3], Bandolier 50) clearly demonstrated that with placebo symptom improvement continued over about six months before levelling off or starting to rise. So measuring changes over a few weeks, and with relatively few men (660 for palmetto) means that we cannot be certain of the benefits.

The other problem is that of outcomes. For conventional treatments we look for hard outcomes, like the number of patients needing surgery or being admitted to hospital with acute urinary retention. This is missing from the placebo comparison data for Saw palmetto.

The answer

This comes from two large high-quality randomised, double-dummy, comparisons of Saw palmetto and finasteride for, respectively, 26 weeks [4] and 48 weeks [5].

The first [4] study had very similar outcomes for Saw palmetto (536 patients) and those treated with finasteride 5 mg (533 patients) (Table). Similar proportions of men had reductions and increases in symptom severity and urine flow. Finasteride produced a larger decrease in mean prostate volume, fewer study withdrawals, urinary retention, and men needing surgery. In this study the mean prostate volume was about 43 mL, and previous research shows finasteride to be effective in men with prostate volumes greater than 40 mL. While this study showed equivalence between Saw palmetto and finasteride, it probably underestimated finasteride efficacy.
<table>
<thead>
<tr>
<th>Outcome at 26 weeks</th>
<th>Saw palmetto</th>
<th>Finasteride 5 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-point decrease in IPSS (%)</td>
<td>63</td>
<td>67</td>
</tr>
<tr>
<td>2-point increase in IPSS (%)</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Increase in max flow by &gt;3 mL/sec (%)</td>
<td>36</td>
<td>39</td>
</tr>
<tr>
<td>Mean reduction in prostate volume (%)</td>
<td>7</td>
<td>16</td>
</tr>
<tr>
<td>Study withdrawals (%)</td>
<td>16</td>
<td>11</td>
</tr>
<tr>
<td>Impotence (%)</td>
<td>1.5</td>
<td>2.8</td>
</tr>
<tr>
<td>Urinary retention (%)</td>
<td>1.3</td>
<td>0.6</td>
</tr>
<tr>
<td>Needing surgery (n)</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

Main results from Carraro et al [4]. IPSS = International Prostate Symptom Score (Bandolier 11)
The second study [5] examined outcomes over 48 weeks in 543 randomised men. The IPSS symptom score continued to decrease over the 48 weeks in men treated with Saw palmetto and finasteride (Figure 3).

Figure 3: Change in symptom score over 48 weeks in RCT comparison in 543 men

Comment

There is good evidence that Saw palmetto is effective in men with symptoms of benign prostatic hyperplasia. Finasteride is now considered to be best used in men with larger prostate volumes (Bandolier 46) and, consequently, disease that may be considered more severe. We also have excellent efficacy and adverse effect information from a very large randomised trial (Bandolier 50, [3]). We don't quite have the same extent of information for Saw palmetto. The evidence on Saw palmetto is sufficient, though, to make it worth considering for men with milder symptoms.
Reference:


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