

Serenoa repens for Benign Prostatic Hyperplasia

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As part of its efforts to disseminate the results of Cochrane reviews to a wider audience, the Cochrane CAM Field develops Summary of Findings (SoF) tables and then uses these tables as a basis for its consumer summaries. In each SoF table, the most important outcomes of the review, the effect of the intervention on each outcome, and the quality of the evidence for each outcome are presented. The process of developing the SoF table involves deciding which outcomes to present for which time points and evaluating the strength and quality of the evidence for the outcomes. The Cochrane CAM Field contacted the authors of this review to request clarification on any points that are not understood in the Cochrane review and also to request their review of the SoF.

SERENOA REPENS FOR BENIGN PROSTATIC HYPERPLASIA

A review of the effect of *Serenoa repens* for benign prostatic hyperplasia (BPH) was conducted by review authors in the Cochrane Collaboration. After searching for all relevant studies, they found 30 studies done by other researchers that fulfilled their inclusion criteria. Fourteen of the studies reported outcomes for *Serenoa repens* alone vs placebo. Their findings are summarized below.

WHAT IS BENIGN PROSTATIC HYPERPLASIA, AND WHY SERENOA REPENS?

With age, the prostatic gland may begin to grow. The growth in itself is harmless, and therefore the condition is called benign prostatic hyperplasia (BPH). It may compress the urethra, which in turn can impede the flow of urine.

BPH is characterized by lower urinary tract symptoms, including the need to urinate frequently during the day and night, a slow flow of urine, the need to urinate urgently, difficulty starting the urinary stream, and pain during urination. More serious problems include stones in the bladder, urinary tract

infections, and complete blockage of the urethra, which may be a medical emergency.

BPH generally begins in a man's 30s, evolves slowly, and most commonly only causes symptoms after age 50. BPH is found in more than 40% of men in their 50s and nearly 90% of men in their 80s.

One way to evaluate the severity of the symptoms of BPH is by using the International Prostate Symptom Score questionnaire. This questionnaire covers the different problems related to urination mentioned above. The more severe the symptoms are, the higher the total score will be.

The scale of the questionnaire ranges from 0 to 35. A total score below 8 implies mild severity of symptoms. A total score between 8 and 19 implies moderate severity and above 19, high severity of symptoms.

Medication is often prescribed as the first treatment option. Other options are minimally invasive therapies through a urethral catheter or surgery.

The most widely used plant extract available for the treatment of BPH is an extract from the berry of the dwarf palm plant, *Serenoa repens*. The berries of the plant are dried and used in tablets or in fluid extracts. Despite widespread use, the clinical efficacy of *Serenoa repens* to improve BPH symptoms remains unclear.

WHAT DOES THE RESEARCH SAY?

Not all research provides the same quality of evidence. The higher the quality, the more certain we are about what the research says about an effect. The words *will* (high-quality evidence), *probably* (moderate-quality evidence), or *may* (low-quality evidence) describe how certain we are about the effect.

- The studies showed that giving men with BPH *Serenoa repens*
- probably makes little or no difference in the severity of prostate symptoms,
 - may decrease the number of urination incidents at night,
 - may make little or no difference to peak urine flow,
 - may increase the number of patients rating improvement of their symptoms, and
 - may make little or no difference to adverse events.

WHERE DOES THIS INFORMATION COME FROM?

The Cochrane Collaboration is an independent global network of volunteers dedicated to summarizing research about health care.

TABLE Summary of Findings: *Serenoa repens* Compared to Placebo for BPH

Patient or Population: Patients with BPH

Settings: The trials were conducted in Australia (1), Belgium (1), Denmark and Sweden (1), France (3), Italy (5), United States (2) and United Kingdom (1).

Intervention: *Serenoa repens*

Comparison: Placebo

Outcomes	Illustrative Comparative Risks* (95% CI)		Relative Effect (95% CI)	No. of Participants (Studies)	Quality of the Evidence (GRADE)
	Assumed risk Placebo	Corresponding risk <i>Serenoa repens</i>			
International Prostate Symptom Score (IPSS) Scale from: 0 to 35 Follow-up: 6 to 12 mo	The mean change in IPSS in the control groups was -1.4	The mean change in IPSS in the intervention groups was 0.77 lower (2.88 lower to 1.34 higher)		304 (2 studies)	⊕⊕⊕O moderate ^{1,2}
Times of urination at night at end of treatment Nocturia (times/evening) Follow-up: 4 to 13 wk	The mean times of urination at night at end of treatment in the control groups was 2.5	The mean times of urination at night at end of treatment in the intervention groups was 0.78 lower (1.34 to 0.22 lower)		581 (9 studies)	⊕⊕OO low ^{3,4,6}
Peak urine flow mL/s at end of treatment Follow-up: 4 wk to 12 mo	The mean peak urine flow mL/s at end of treatment in the control groups was 12	The mean peak urine flow mL/s at end of treatment in the intervention groups was 1.02 higher (0.14 lower to 2.19 higher)		1019 (10 studies)	⊕⊕OO low ^{2,4}
Patient rated improved symptoms Follow-up: 4 to 12 wk	54 per 100	82 per 100 (59 to 100)	RR 1.54 (1.11 to 2.14)	619 (5 studies)	⊕⊕OO low ^{4,5}
Any adverse events Follow-up: 8 wk to 6 mo	15 per 100	16 per 100 (11 to 23)	RR 1.07 (0.76 to 1.51)	618 (5 studies)	⊕⊕OO low ^{2,4}

*The assumed risk is calculated based on the median control group risk across studies. The corresponding risk (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
Abbreviations: CI, confidence interval; RR, risk ratio.

GRADE Working Group grades of evidence

High-quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate-quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low-quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low-quality: We are very uncertain about the estimate.

¹ Although the results of these 2 studies were heterogeneous (ie, I-squared=63%), we decided not to downgrade the quality of the evidence for this outcome based on the heterogeneity.

² Wide CI.

³ Unclear randomization procedure, allocation concealment, and high losses to follow-up.

⁴ Unclear randomization procedure and allocation concealment.

⁵ High heterogeneity (ie, I-squared=81%).

⁶ There was significant heterogeneity in the results of these trials (I-squared=66%), and a sensitivity analysis, utilizing only the higher quality, larger trials (≥40 subjects), reduced the heterogeneity and showed no significant difference.

This information is taken from this Cochrane Review: Tacklind J, MacDonald R, Rutks I, Wilt TJ. *Serenoa repens* for benign prostatic hyperplasia. *Cochrane Database Syst Rev*. 2009;(2):CD001423.

Acknowledgments

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