

Saw palmetto and benign prostatic hyperplasia

Benign prostatic hyperplasia (BPH) is not uncommon among men, and its prevalence increases as men age. Men with BPH experience a range of lower urinary tract symptoms (LUTS) described as either obstructive or irritative in nature.

Obstructive symptoms include urinary hesitancy and the sensation of incomplete bladder emptying. Irritative symptoms include urinary urgency, frequency, and nocturia. The latter symptom may be particularly troubling for older men, as their risk of falling may be increased if they need to urinate during the night.

Although men may have only minor symptoms, BPH can have significant effects on quality of life. The American Urological Association Symptom Index (AUASI) for BPH is used to assess the severity of symptoms and the need for treatment. Mild LUTS secondary to BPH are defined by an AUASI score of less than 8, while moderate to severe LUTS is a score of 8 or greater.

Dietary supplements for LUTS

Drugs such as tamsulosin (Flomax—Boehringer Ingelheim) and finasteride are effective for some LUTS due to BPH, although many men prefer to use dietary supplements to maintain a healthy prostate. Many products contain multiple ingredients including saw palmetto (*Serenoa repens*), African plum (*Prunus africana*), beta sitosterol, stinging nettle (*Urtica dioica*), zinc, and copper. Of these ingredients, saw palmetto is the best studied and has been a first-line treatment of mild BPH symptoms in many European countries. An estimated 2 million Americans use saw palmetto, with estimated global sales of \$700 million

annually.

Saw palmetto may have alpha reductase inhibitor activity, as well as antiestrogenic and anti-inflammatory effects on the prostate. Unlike drugs such as finasteride, saw palmetto is not associated with decreased levels of prostate-specific antigen (PSA).

What the research says

A 2002 Cochrane Review of 21 studies ranging from 4 to 48 weeks in duration



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concluded that saw palmetto may provide mild improvement of some LUTS due to BPH. Some studies compared saw palmetto to finasteride; saw palmetto was reported to have some efficacy with fewer sexual adverse effects.

In 2006, a major study of 225 men 50 years or older compared saw palmetto and placebo in moderate to severe BPH. All participants had AUASI scores greater than 8 (mean 15.4), and the mean age was 63 years. The study evaluated saw palmetto 160 mg twice daily and adhered to strict quality control procedures to ensure the potency of saw palmetto and to maintain blinding in the study because of saw palmetto's odor. The study included men with moderate to severe disease. No significant difference in AUASI scores with saw palmetto and placebo was found.

A double-blind study published in September 2011 compared the effects on LUTS attributed to BPH of a high-quality saw palmetto product with those of placebo. Participants had AUASI

scores between 8 and 24, with a mean of 14.6; mean age was 61 years. The study used a standard dosage of 320 mg/d for 24 weeks, then increased the dosage to 640 mg/d for 24 weeks and to 960 mg/d for the third 24-week period. The change in AUASI score from baseline to 72 weeks was the primary outcome measure.

The authors evaluated secondary measures such as the BPH Impact Index, AUASI quality of life score, American Urological Association (AUA) nocturia score, peak flow rate, PSA level, and others. They reported that saw palmetto was similar to placebo on the primary and secondary outcome measures.

Increasing the dosage threefold did not decrease participant symptoms as measured by AUASI. One criticism of the study has been whether the symptoms were actually due to BPH or other conditions, such as prostatitis.

No natural product was recommended in the 2011 update of the AUA practice guidelines on the management of BPH. The lack of a recommendation was based on the inadequate long-term studies supporting the use of natural products.

What to tell patients

Counsel men to be evaluated by their primary care physician or urologist when the common symptoms of BPH develop or become more severe to ensure that they do not have prostate cancer or prostatitis. Most clinical trials of saw palmetto have been of high quality, although a potential issue with many studies is that participants had moderate to severe, not mild, disease.

Saw palmetto is considered safe and may help some individuals with mild symptoms, especially with nocturia. Other common elements of multi-ingredient prostate formulas, such as African plum and beta sitosterol, have less evidence to support their use.

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