

## **HerbClip**<sup>TM</sup>

Mariann Garner-Wizard Jennifer Minigh, PhD Densie Webb, PhD

Shari Henson Heather S Oliff, PhD Brenda Milot, ELS Marissa Oppel, MS

Executive Editor - Mark Blumenthal

Managing Editor – Lori Glenn

Consulting Editors – Dennis Awang, PhD, Steven Foster, Roberta Lee, MD Funding/Administration – Wayne Silverman, PhD Production – George Solis

FILE: Saw Palmetto (Serenoa repens)
Lower Urinary Tract Symptoms

HC 110362-326

Date: April 13, 2007

## **RE:** Effect of Saw Palmetto on Lower Urinary Tract Symptoms

Avins AL, Bent S. Saw palmetto and lower urinary tract symptoms: what is the latest evidence? *Current Urology Reports*. 2006:7:260-265.

Almost 20% of Americans took a dietary supplement in 2002. Men often use dietary supplements for sexual dysfunction and prostate disease, particularly lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). One of the most commonly used supplements for LUTS is saw palmetto (*Serenoa repens*). More than 350 different saw palmetto-containing products are marketed in the United States, although many of these products use extracts obtained from a much smaller group of suppliers. The authors review the prior research on the clinical efficacy of saw palmetto, describe the latest published evidence since the major reviews, and examine the most recent research on potential biologic actions of saw palmetto extracts.

An extensive systematic review of all of the prior randomized, controlled trials of saw palmetto (alone or in combination) compared with placebo or a medication for treatment of BPH was conducted by Wilt et al.<sup>3,4</sup> Twenty-one studies involving 3,139 participants were identified. Despite methodologic weaknesses, say the authors, all of the studies suggested mild to moderate improvements in urinary symptoms and urine flow measures with the use of saw palmetto.

The authors express concern that none of the 21 studies described a process for assessing the adequacy of blinding and that a lack of adequate blinding could have biased some of the studies. Because of the distinctive, pungent odor and bitter taste of saw palmetto, they say, developing an adequately blinded placebo capsule is difficult.

Since 2000, four controlled clinical trials have been reported. According to the authors, the new studies complicate the assessment of the efficacy of saw palmetto and provide "important but provocative insights" into its possible clinical effects. In one study, 44 men with at least moderate BPH symptoms were treated with an herbal blend containing saw palmetto or with placebo. No between-group differences were observed in any clinical parameter, although this study was not intended to identify such differences. Another study of men with at least moderate LUTS reported a significantly greater decrease in the IPSS scores among the participants randomized to the active herbal therapy arm (P=0.04); however, no significant change in urinary flow rates was reported between the two study groups and no other significant differences were seen in other outcome measurements. An Australian study reported no significant differences between those treated with

saw palmetto extract and those treated with placebo. In the fourth study, 704 men with at least moderate BPH symptoms and impaired urine flow were randomized to saw palmetto or tamsulosin (an alpha-blocking medication) for 1 year. Men in both groups showed progressive declines in symptoms during the first 3 months. No significant differences were noted between the two groups, and the confidence intervals around the different measures excluded clinical meaningful effects. The men taking the saw palmetto showed a modest but statistically significant reduction in prostate size compared with those taking tamsulosin. Fortunately, say the authors, larger and longer studies are being funded by the National Institutes of Health to provide important information about the appropriate role of saw palmetto in the treatment of BPH.

Regarding safety, the authors note that in the published reviews, no substantial adverse effects of saw palmetto extracts were reported. Interactions between saw palmetto and prescription drugs are only a theoretical concern, say the authors, although little directed research into potential interactions has been conducted. The authors report that the most worrisome aspect is the potential for prolongation of the bleeding time among patients undergoing oral anticoagulant therapy.<sup>2,5</sup>

Several investigators have examined the physiologic effects of saw palmetto to try to understand its possible mechanism of action. Among its most important biologic effects, as shown in several in vitro and in vivo studies cited by the authors, are its antiandrogenic, anti-inflammatory, and antiproliferative properties.

In conclusion, the authors caution that current data are insufficient to recommend saw palmetto as an established therapeutic complement to prescription medicine. "Whereas older data suggest a more consistent benefit of saw palmetto, newer data raise more questions, precluding a coherent conclusion regarding the clinical effects of saw palmetto extracts." Because better and larger studies are being performed, "we soon will be able to provide patients with more objective and comprehensive information for making rational decisions about the use of phytotherapeutic agents in the treatment of LUTS," say the authors.

—Shari Henson

## References

<sup>1</sup>Barnes P, Powell-Griner E, McFann K, Nahin R. CDC Advanced ata Report #343. Complementary and alternative medicine among adults: United States, 2002. May 27, 2004.

<sup>2</sup>Jellin JM. Saw palmetto monograph. In: Jellin JM, ed. *Natural Medicines Comprehensive Database*. Stockton, Calif: Therapeutic Research Faculty; 2005.

<sup>3</sup>Wilt T, Ishani A, MacDonald R. *Serenoa repens* for benign prostatic hyperplasia. *Cochrane Database Syst Rev.* 2002;3:CD001423.

<sup>4</sup>Wilt TJ, Ishani A, Stark G, MacDonald R, et al. Saw palmetto extracts for treatment of benign prostatic hyperplasia: a systematic review. *JAMA*. 1998;280:1604-1609.

<sup>5</sup>Cheema P, El-Mefty O, Jazieh AR. Intraoperative haemorrhage associated with the use of extract of saw palmetto herb: a case report and review of literature. *J Intern Med.* 2001;250:167-169.

The American Botanical Council has chosen not to reprint the original article.

The American Botanical Council provides this review as an educational service. By providing this service, ABC does not warrant that the data is accurate and correct, nor does distribution of the article constitute any endorsement of the information contained or of the views of the authors.

ABC does not authorize the copying or use of the original articles. Reproduction of the reviews is allowed on a limited basis for students, colleagues, employees and/or members. Other uses and distribution require prior approval from ABC.