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Commission E](#)[HerbMedPro™](#)[Healthy Ingredients](#)[Herbal Body Care](#)[Event Calendar](#)[Content Licensing](#)[Sponsors](#)[American Botanical Council](#) > **New Clinical Trial on Saw Palmetto Inconsistent with Positive Results in Previous Studies****New Clinical Trial on Saw Palmetto Inconsistent with Positive Results in Previous Studies****Clinical Evidence Supports Use of Saw Palmetto for Mild to Moderate Prostate Problems**

(Austin, TX, February 8, 2006) The results of a new clinical trial on the popular herb saw palmetto may confuse the public, especially men with prostate problems, according to the American Botanical Council, a nonprofit herb research and education group. The trial, published this week in the *New England Journal of Medicine* (NEJM), found no significant differences between a saw palmetto pill and a placebo in men with moderate to advanced prostate problems. ¹

Saw palmetto is an herbal dietary supplement that is widely recognized for its safety and efficacy in treating *mild to moderate* symptoms associated with benign prostatic hyperplasia (BPH). BPH is a non-cancerous swelling of the prostate gland in older men, resulting in various symptoms associated with the interruption of normal urinary flow.

“Our primary concern with this trial is the relatively *advanced condition* of the prostate problems in many of the men who were tested,” said Mark Blumenthal, Founder and Executive Director of ABC.

Blumenthal emphasized that the men in this trial experienced *moderate to severe symptoms* of BPH, although most of the previous controlled trials showing positive results and efficacy for saw palmetto were conducted on men with *mild to moderate* symptoms of BPH. The men in the trial had scores between 8-35, i.e., moderate to severe BPH, according to the American Urological Association Symptom Inventory (AUASI).

“Most of the official international monographs that recognize the benefits of saw palmetto do so for stage 1 and 2 of BPH, i.e., the mild to moderate range of BPH symptoms,” said Blumenthal. “These include monographs from the German government and the World Health Organization.”

“The results of this trial need to be seen in the perspective of the preponderance of the existing evidence, including at least 21 controlled trials showing positive outcomes with saw palmetto preparations,” he added.

In the new trial reported in NEJM, conducted at the University of California at San Francisco, 225 men (112 in saw palmetto group; 113 placebo) 49 years of age or older with moderate to severe BPH were randomly assigned to groups who took a leading saw palmetto extract (160mg twice daily, the normal dose shown effective in over 21 clinical trials) or a matching placebo capsule. The patients made 8 study visits over a one-year period to assess changes in the AUASI scores (this is the primary outcome of the trial), maximal urine flow, post-void residual urine volume, prostate size, and other health-related outcomes. On average, participants in both the saw palmetto and the placebo groups improved over the one-year duration of the trial, but there were no significant differences in the rates of improvement overall between the two groups as measured by the AUASI.

While ABC believes that this trial employed a good design and used a high quality saw palmetto extract, the group pointed to an anomaly of the trial — the significantly higher adverse effect profile in the placebo group. Saw palmetto preparations are known to be safe and very well tolerated, producing few adverse effects. In this trial, minor adverse effects in the saw palmetto and placebo groups were nearly equal (saw palmetto, 39; placebo, 34) — evidence of the safety of saw palmetto. However, there were almost *twice as many serious adverse effects in the placebo group* (11) as in the saw palmetto group (6), suggesting that the patient population may have had other serious illnesses, possibly interfering in the attempt to treat the moderate-to-severe BPH symptoms.

The study was funded primarily by the National Institute of Diabetes and Digestive and Kidney Diseases, with additional funding from the National Center for Complementary and Alternative Medicine.

About Saw Palmetto

Saw palmetto (*Serenoa repens*) preparations are made from the fruit of a small palm tree which is native to Florida and was a former staple food of Seminole Indians. Saw palmetto berries were widely used by Eclectic physicians of the late 19th and early 20th centuries for a variety of indications, including treating the male reproductive system.

Saw palmetto extracts are widely used in Europe and in the past decade in the United States as a natural therapy to help maintain normal prostate and urinary function, particularly by treating the symptoms of BPH in men with mild to moderate cases of BPH.

A meta-analysis (statistical analysis of a group of studies) of 18 clinical trials published in the *Journal of the American Medical Association*² and another on 21 clinical trials carried out on over 3000 men as reviewed by the Cochrane Collaboration³ have confirmed the safety and efficacy of saw palmetto extract preparations in treating symptoms of BPH, usually of stage 1 and 2. The latest meta-analysis³ concludes that the clinical literature supports the use of saw palmetto preparations in treating symptoms of BPH in stages 1 and 2, and that saw palmetto preparations have shown efficacy and greater safety when compared to conventional pharmaceutical drugs (e.g., finasteride, aka Proscar®).

The safety and efficacy of saw palmetto preparations have gained international recognition by various governments and professional health groups. Saw palmetto has been approved by the German government's respected Commission E⁴ and the Canadian government's Natural Health Products Directorate.⁵ It is also recognized by leading scientists and physicians in Western Europe through a positive monograph by the European Scientific Cooperative on Phytotherapy (ESCOP), which acknowledges its efficacy for symptomatic treatment of micturition (urinary) disorders in *mild to moderate* BPH.⁶ The World Health Organization also recognizes the efficacy of saw palmetto for treating lower urinary tract symptoms secondary to BPH stages I and 2.⁷ Additional recent reviews of the medical and scientific literature have concluded that saw palmetto extract preparations are safe and effective for treating symptoms of BPH. These include *The ABC Clinical Guide to Herbs*⁸ and others.⁹ The American Botanical Council has made the complete saw palmetto chapter from *ABC Clinical Guide to Herbs* available online in PDF format, including Clinical Overview, Patient Information Sheet, and complete monograph which reviews 19 clinical studies. You may access this resource by clicking the following link: http://www.herbalgram.org/files/pdfs/Saw_Palmetto.pdf.

Saw palmetto is frequently combined with other herbs that have shown benefit for prostate function to produce safe and effective preparations that have been clinically documented. For example, a leading European saw palmetto preparation also contains the root of nettle (*Urtica dioica*), for which several recent randomized controlled clinical trials have shown safety and efficacy, the most recent, conducted on 257 men in Russia, was published in July 2005.¹⁰

The large success of most saw palmetto trials has driven preparations of this traditional herb to large consumer acceptance, not only among natural health enthusiasts, but also in the mainstream market. In 2004 and 2005 retail sales of saw palmetto preparations ranked third (behind only garlic and echinacea), according to market report articles in the ABC's quarterly, peer-reviewed article *HerbalGram*.^{11,12} The NEJM article cited a 2002 survey showing that about 2.5 million men were estimated to have been using saw palmetto preparations. ABC estimates that saw palmetto retail sales in all channels of trade in the U.S. may be as high as \$100-120 million or possibly more.

About the American Botanical Council

Established in 1988, the American Botanical Council (ABC) is the leading nonprofit, member-based international organization working to educate consumers, healthcare professionals, researchers, educators, industry, and the media on the safe and effective use of herbs and medicinal plants products. ABC is located on a 2.5 acre site in Austin, Texas where it publishes *HerbalGram*, a peer-reviewed quarterly journal. ABC is also the publisher of *The ABC Clinical Guide to Herbs*, a continuing education and reference book, which contains extensive monographs on the safety and efficacy of 29 popular herbs. More information is available at

<http://www.herbalgram.org/>.

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EDITOR'S NOTE:

The American Botanical Council has made the complete saw palmetto chapter from *ABC Clinical Guide to Herbs* available online in PDF format, including Clinical Overview, Patient Information Sheet, and complete monograph which reviews 19 clinical studies. You may access this resource by clicking the following link: http://www.herbalgram.org/files/pdfs/Saw_Palmetto.pdf.

ABC has additional saw palmetto research in its online resources. Please use your member login for any studies that are protected or contact ABC to get your login information.

A search of HerbClip™ Online, one of ABC's six databases (available at select membership levels), revealed the following results on saw palmetto.

<http://www.herbalgram.org/herbclip/search.asp?s=saw+palmetto&m=E>.

A search on *HerbalGram* Online, another of ABC's databases, turned up these additional articles of interest on saw palmetto:

Anon. [SAW PALMETTO EXTRACT IN THE TREATMENT OF BPH](#). *HerbalGram*. 1995;34:12.

Blumenthal M, Milot B. [Long-Term Use of Saw Palmetto and Nettle Root Combination Shown Effective for BPH in Clinical Trial](#). *HerbalGram*. 2005;68:24.

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11. Blumenthal M. Herb Sales Down 7.4 Percent in Mainstream Market; Garlic Is Top-Selling Herb; Herb Combinations See Increase. *HerbalGram* 2005;66:63.

12. Blumenthal M. Herb Market Review—2005. *HerbalGram* 2006;70 (in press).

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