Saw Palmetto Gets Strong Public Boost:
USP Publishes Monograph and Consumer Reports Gives Thumbs Up, Recognizing Benefits for BPH

by Mark Blumenthal; photographs by Steven Foster

The native American herb saw palmetto has received some positive publicity in the past year. On April 28, 2000, the U.S. Pharmacopeia published a Dispensing Information (DI) monograph that supports the clinical benefits of saw palmetto (Serenoa repens (Bartram) Small, Arecales) (SP) to treat symptoms of benign prostatic hyperplasia (BPH) in older men. In September Consumer Reports published a three-page article discussing the benefits of SP and reviewing its analysis of 13 brands.

The USP Dispensing Information monograph deals with the therapeutic parameters of SP. Unlike the previous monograph published by the USP-National Formulary (NF) dealing with identity and quality control characteristics of SP, this monograph includes information for healthcare professionals on appropriate clinical uses and potential risks of SP. The USP-NF monograph setting a standard for SP (extract) and powdered SP fruit became official on January 1, 2000. These two monographs are in the new edition of USP24-NF19 published on July 1, 1999. The USPDI monograph notes that manufacturers are not required to meet the USP-NF standard, but if a manufacturer does so voluntarily and claims a USP-NF status on a product label, then the product must meet the USP-NF standard of not less than 7 percent lipophilic extract content and the sum of the percentages of all fatty acids must be not less than 9 percent.

According to the USP monograph in the "Modern Medical Use" section, the USP located 29 published clinical studies on SP for the treatment of lower urinary tract symptoms (LUTS) secondary to BPH in the international medical literature through August 1999. This search included seven placebo-controlled trials, one active-controlled trial vs. the conventional drug finasteride (Proscar), one active-controlled study vs. an alpha-adrenergic blocking drug (alfuzosin), and one meta-analysis — all meeting the USP quality standard for clinical trials at Level II or higher. (Level II refers to a "fairly stringent" level of evidence, although some of the trials may have methodological flaws, compared to the Level I status applied to conventional drugs.) The SP products tested in these studies were commercial liposterolic extracts of SP, standardized to 70–95 percent free fatty acids, at a dose of 160 mg twice daily. The duration of all the studies were from 21 days to 26 weeks.

The USP monograph includes mention that the German Commission E evaluated SP as safe and effective for urination problems in BPH stages I and II. However, lacking any formal system for evaluating benefits of herbs in the U.S., other than the formal new drug approval system, it is possible that the new USPDI monograph may be viewed by health professionals as tantamount to official recognition of the efficacy of SP for the first time in the U.S.

The USP notes that "These studies provide evidence of moderate scientific quality that commercial extracts of saw palmetto at a dose of 160 mg twice a day are more effective than a placebo in relieving lower urinary tract symptoms of benign prostatic hyperplasia including frequency, urgency, dysuria, nocturia (nighttime urination), and impaired urinary flow. These effects are reported to begin within 30 days of treatment and to continue through at least 6 months, the longest period studied to date. There is a large placebo effect in studies in this field. Saw palmetto extracts do not significantly affect prostate size or reduce PSA (prostate specific antigen) levels in the blood; nor do they appear to alter sexual function. Common side effects are mild and not consistently different from those reported in patients on placebo. No serious adverse events are known to be associated with saw palmetto."

The publication of the SP monograph represents a change in direction for USP. In the future, all USP resources will be applied to the development of standards for herbs and other dietary supplements, not information monographs. USP had almost completed information monographs on cranberry...
Saw Palmetto, Serenoa repens.

(Vaccinium macrocarpon) and ginkgo (Ginkgo biloba), but work on these monographs was terminated in July.

According to V. Srinivasan, Ph.D., Director of Dietary Supplements at USP: “USP has completed development work on the standards for raw plant materials for 18 botanicals and has already proposed standards for as many as 15 plant extracts and about 10 botanical dosage forms. The USP Committee of experts will continue to develop and establish public standards for the 20 botanicals identified earlier and may add three or four more important botanicals which are in wide use among the public.”

To date USP has published five information monographs on herbs — ginger (Zingiber officinale), valerian (Valeriana officinalis), comfrey (Symphytum officinale), feverfew (Tanacetum parthenium) and St. John’s wort (Hypericum perforatum) — however, using the same criteria as used for conventional drugs, all these monographs resulted in negative assessments of the potential efficacy (comfrey was rated negative for safety reasons). More at <www.usp.org>.

CONSUMER REPORTS: SAW PALMETTO “MIGHT BE WORTH TRYING”

The Consumer Reports (CR) article included two pages of discussion of BPH and the role SP can play in treating symptoms. It says that in the herbal world where research is “usually scanty, that evidence is rather impressive.” It noted that there is currently an NIH-funded one-year clinical trial on SP and that the longest previous SP study is six months, compared to those on conventional drugs for BPH which last up to six years. CR says the American Urological Association is keeping “an open mind while awaiting the outcome of longer clinical trials.”

CR also noted that in a study where SP was compared to the conventional drug finasteride (Proscar®), the drug increased urinary flow by 30 percent while SP came close at 25 percent. However, regarding adverse effects, men taking SP did not report erectile dysfunction while nine percent of the men taking finasteride did. CR also compared the prices of SP compared to the drug: $15 to $45 per month for the herbal product (not covered by health insurance) compared to about $85 for finasteride.

CR concluded its assessment of SP’s efficacy with a somewhat modest approval: “Although the long-term safety and efficacy of saw palmetto remain unclear, Consumers Union’s medical consultants say there’s enough evidence to conclude that supplements containing at least 320 milligrams per day of saw-palmetto extract, the amount that worked in clinical trials, might be worth trying for some men with mild symptoms; they should discuss this option with their doctor.”

CR tested 13 products, concluding that eight contained adequate levels (320 mg per day of the standardized extract, presumably calculated at 85–95 percent of the free fatty acids) that were deemed necessary to provide efficacy for symptoms of BPH, as determined in clinical studies. This is also the dosage recommendation of the German Commission E monograph. The table of test results also shows the daily cost of each brand required to consume this effective level varied from $.44 to $1.44.

MARKET POSITION

Saw palmetto is the only herb in the mainstream domestic American herb market that has increased in sales in the past year. According to statistics gathered by Information Resources Inc. of Chicago, sales of SP in food, drug, and mass market retail stores increased 8.4 percent in the 52-week period ending July 23, 2000 compared to the same period ending the previous year. Sales for other top-selling herbs — ginkgo (Ginkgo
Saw Palmetto Harvesting

Roadside billboard in central Florida advertising purchase of saw palmetto berries.

Laborer harvesting saw palmetto berries in the sweltering Florida sun.

Saw palmetto gets its name from the blades of the plant that look like miniature saws.

A day's intake of fresh saw palmetto berries at Plantation Medicinals, Inc., Felda, Florida, to be transferred to dryers before day's end.
Andrian Herrera, picking crew leader and broker with freshly picked berries, before drying.

A worker stirs saw palmetto berries in dryer, prior to being transferred to a cleaning facility.

Full buckets of berries sit in the sun.

Independent saw palmetto berry pickers unloading a day's harvest to a loading dock.
Saw Palmetto Up Close

Top Left and Right, Bottom Right: Ripe saw palmetto berries. Bottom Left: Saw palmetto in bloom.
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billoba), St. John’s wort, ginseng (Panax spp.), garlic (Allium sativum) etc. — were down in the same period. SP ranked sixth in total mainstream sales for all herbs in 1999, with sales of $45,063,652, reflecting an increase of 34 percent from the 1998 sales of $33,748,984.16

The herb received strong public recognition for its benefits in treating symptoms of BPH in a meta-analysis of 18 European clinical studies published in the Journal of the American Medical Association,13 which concluded that SP was significantly more effective than placebo. It is quite probable that the new USP monograph will have a positive impact on health professionals and this, coupled with the increasing market demand for prostate medications by aging baby boomers, will continue to stimulate SP’s increased growth in sales in the U.S.1

REFERENCES

LABEL GUIDELINES FOR SAW PALMETTO

The American Herbal Products Association recently endorsed the following language on the labels of dietary supplements containing saw palmetto (SP) intended for use in dealing with symptoms associated with benign prostatic hyperplasia (BPH):

“Notice: The National Institute on Aging recommends that men get regular medical checkups with a thorough prostate exam. You should inform your health care practitioner that you are using this product.”

According to the German Commission E, the following notice is required with the labeling of all saw palmetto products marketed as nonprescription drugs in Germany: “This medication relieves only the symptoms associated with an enlarged prostate without reducing the enlargement. Please consult a physician at regular intervals.”

The Commission E approves use of SP for “urination problems in BPH stages I and II. Stage I is characterized by increase in frequency of urination, pollakiuria (abnormally frequent urination), nocturia (urination at night, usually disrupting sleep), delayed onset of urination, and weak urinary stream. Stage II is characterized by the beginning of the decomposition of the bladder function accompanied by formation of residual urine and urge to urinate.”

REFERENCES