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File: ■ Saw Palmetto (*Serenoa repens*)
■ Benign Prostatic Hyperplasia (BPH)
■ Sexual Dysfunction

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RE: Saw Palmetto Improves Sexual Dysfunction and Benign Prostatic Hyperplasia

Suter A, Saller R, Riedi E, Heinrich M. Improving BPH symptoms and sexual dysfunctions with a saw palmetto preparation? Results from a pilot trial. *Phytother Res*. April 23, 2012;[epub ahead of print]. doi: 10.1002/ptr.4696.

Benign prostatic hyperplasia (BPH) is a common cause of lower urinary tract symptoms (LUTS) in older males. LUTS are divided into irritative and obstructive symptoms and include increased frequency, urgency, and nocturia (nighttime urination), as well as reduced urine stream and incomplete bladder emptying. BPH is also a leading risk factor in the development of sexual dysfunction (SDys), such as erectile and ejaculatory disorders. Current pharmaceutical BPH treatments are alpha-blockers and 5-alpha-reductase inhibitors; however, an adverse side effect of both of these classes of compounds is interference with sexual performance. Saw palmetto (*Serenoa repens*) berry extract has an established use for BPH, with concurrent good tolerability and efficacy.[1,2] There is also historical use of the berry for SDys. This open clinical trial investigated whether saw palmetto supplementation could have positive effects on the sexual function of men with BPH and concomitant SDys.

This study, funded by Bioforce AG (Roggwil, Switzerland), took place in 6 centers in Switzerland and utilized the International Prostate Symptom Score (IPSS) to assess the severity of 7 BPH symptoms. Men aged 18-80 years with an IPSS score of >7, diagnosed with both BPH and SDys for >2 months, who had the desire and possibility of sexual activity with no physical impairment, were included. SDys was defined as a score <7 using the Brief Sexual Function Inventory (bSFI), a questionnaire assessing 12 aspects of sexual function.

Patients were excluded if they had SDys related to psychiatric disorders, decreased libido for <2 months, severe vascular pathologies or diabetes, stably treated hypertension for <2 months, neuropathies, a history of poor compliance, recently participated in another clinical trial, a history of substance abuse, or scheduled surgery. Unless taken as a stable medication for at least 3 months prior, patients using alpha-antagonists or 5-alpha-reductase inhibitors, nonsteroidal anti-inflammatory drugs (NSAIDs), or pharmaceutical antidepressants were also excluded. Four days prior to the

first visit and throughout the study, patients were not to take the erectile dysfunction (ED) medication, phosphodiesterase-5 (PDE-5) inhibitor.

The 9-week pilot study consisted of a 1-week pre-treatment run-in period, and an 8-week treatment phase during which patients took a daily capsule containing 320 mg of saw palmetto berry 9-12:1 ethanol extract (Prostasan®; A. Vogel Bioforce AG; Roggwil, Switzerland). The extract was standardized to contain 85% fatty acids, providing 275 mg of fatty acids per capsule. The principle fatty acid components were lauric acid (29.5%), oleic and linoleic acids (39.2%), myristic acid (13.5%), and palmitic acid (19%).

At each of the 3 study visits, patients completed the IPSS, bSFI, and a 3-question visual analog scale, the Urolife BPH Quality of Life-9 (Urolife QoL-9). At the end of the study, both patients and investigators completed global assessments of efficacy, safety, and treatment preferences. Compliance was measured by pill count at the end of the study.

From a total of 82 patients in the intention-to-treat (ITT) group, 13 did not conform to the study protocol and were excluded from the final analysis. Protocol deviances included: questionnaire scores outside the specified ranges (n=2), prohibited medications (n=4), and voluntary withdrawal (n=7) for reasons such as the death of a family member (n=1), adverse side effects (n=2), and unknown factors (n=4). The remaining 69 conforming patients had a mean age of 57.3 ± 11.1 years, mean body weight of 80.3 ± 13.0 kg, mean heart rate of 71.4 ± 11.2 bpm, mean systolic blood pressure of 132.5 ± 14.8 mmHg, and mean diastolic blood pressure of 84.3 ± 8.3 mmHg; of the total subjects, 54 patients were recruited at a single center, and 15 patients recruited at the other 5 centers. The pre-determined endpoint for good compliance was 80-120% consumption of the medication; 78.6% met this criterion, and only 7.1% were below (the remainder were lost to follow-up).

After treatment, total IPSS scores were significantly decreased compared to baseline ($P<0.0001$). The percentage of patients with severe BPH symptoms was reduced from 18.8% to 4.3%, and all individual IPSS scores were significantly improved.

Total bSFI scores significantly increased as compared to baseline ($P<0.0001$), as did individual components of the bSFI, most notably "getting and keeping an erection" (64%), problems with lack of drive (54%), ejaculation (54%), improved sexual drive within the last 30 days (47%), and erection firm enough to have sexual intercourse (42%) ($P<0.0001$). On the inversely scaled Urolife QoL-9, total scores also significantly improved ($P<0.0001$), as did all 3 individual question scores ($P<0.0001$). Statistical analyses of the IPSS, bSFI, and Urolife QoL-9 score data confirmed a significant correlation between decreases in LUTS and increases in sexual function.

A center effect was observed: patients enrolled at the main study center (n=54) had significantly improved bSFI scores, while patients enrolled at the other locations (n=15) only showed a trend towards improvement. The authors note that most patients could not complete the bSFI without the assistance of a physician, but they could easily fill out the Urolife QoL-9 independently. Also, patients at the main study center may have had access to more assistance with completing the questionnaires than those at the other centers.

In the post-study global assessments, 76% of patients and 82% of investigators indicated that the efficacy of the saw palmetto berry extract was very good or good.

Patients deemed that the treatment was most effective on erectile function and libido combined (66%). Sixty-two patients said that they would use the treatment again, and investigators would prescribe the medication again in 91% of cases.

Tolerability was rated as very good or good by 97.1% of patients and by 96.1% of investigators. Reported adverse side effects considered related to the treatment included nausea, eructation, and acid regurgitation. Given the choice between an herbal medication and a drug, 61% of patients thought it was very important the treatment was herbal; given equal efficacy and safety, 97% preferred the herbal option. From the investigator's perspective, the most important reasons for prescribing saw palmetto were its good safety (95%) and its efficacy (93%).

Based upon the results of this comparatively small study and comparisons to previously published data, the authors conclude that saw palmetto is the treatment of choice for mild-to-moderate BPH, as it is efficacious, has good tolerability, is cost effective, and may also improve SDys (although data from other studies suggest it is not as effective as PDE-5 inhibitors in treating ED specifically). Larger studies focusing more on SDys are needed to support their conclusion.

—Amy C. Keller, PhD

Reference

[1]Blumenthal M, Goldberg A, Brinckmann J, eds. *Herbal Medicine: Expanded Commission E Monographs*. Austin, TX: American Botanical Council; Newton, MA: Integrative Medicine Communications; 2000.

[2]Bennett BC, Hicklin J. Uses of saw palmetto (*Serenoa repens*, Arecaceae) in Florida. *Econ Bot*. 1998;52(4):381-393.

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