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**File: ■ Saw Palmetto (*Serenoa repens*)  
■ Prulifloxacin  
■ Chronic Bacterial Prostatitis**

**HC 061436-507**

**Date: October 31, 2014**

**RE: Saw Palmetto Extract Helps Manage Symptoms of Chronic Prostatitis**

Stamatiou K, Pierris N. *Serenoa repens* extract additionally to quinolones in the treatment of chronic bacterial prostatitis. The preliminary results of a long term observational study. *Arch Ital Urol Androl.* 2013;85(4):190-196.

Prostatitis is diagnosed often in men older than 65 years. Its symptoms, which include pelvic pain, urinary symptoms, and erectile and sexual dysfunction, are similar to those of benign prostatic hyperplasia. [Editor's Note: The authors used the term hypertrophy incorrectly. Hyperplasia is different from hypertrophy in that the adaptive cell change in hypertrophy is an increase in the *size* of cells, whereas hyperplasia involves an increase in the *number* of cells.] It would seem that phytotherapy used for symptoms of benign prostatic hyperplasia could be used to treat chronic prostatitis. One such phytotherapeutic agent is saw palmetto (*Serenoa repens*), which contains fatty acids, phytosterols, and vitamins. Although its mechanism of action is not fully understood, it is attributed to hormonally and nonhormonally mediated anti-inflammatory activity.<sup>1</sup> These authors conducted a prospective, randomized study to assess the effectiveness of phytotherapeutics in managing the symptoms of prostatitis.

Conducted at Tzaneio General Hospital in Piraeus, Greece, the study enrolled patients with symptoms and signs of chronic prostatitis who visited the specialist clinic between May 1, 2011 and May 30, 2012.

Of the 72 patients who enrolled in the study, 16 were excluded because of absence of pathogenic bacteria. The remaining 56 patients were randomly assigned to 1 of 2 groups depending on visit date (odd or even day of the month). Patients in Group A (n=28) received prulifloxacin 600 mg for 15 days and patients in Group B (n=28) received prulifloxacin 600 mg for 15 days and saw palmetto extract for 8 weeks. Prulifloxacin is a fluoroquinolone antibiotic. No information about the saw palmetto extract or the dosage is given in the original article.

Patients in both groups were similar in age and history of prostatitis. The primary symptom for all patients was pain; also reported were urinary disturbances and erectile dysfunction. A questionnaire completed at baseline by all patients revealed moderate-to-severe urinary symptoms in more than half of the patients in both groups and erectile or sexual dysfunction in less than 30% of patients in both groups.

Urine specimens were collected and cultured, and all patients completed questionnaires about chronic prostatitis (National Institutes of Health Chronic Prostatitis Symptom Index [NIH-CPSI]), urinary symptoms (International Prostate Symptom Score [IPSS]), and sexual function (International Index of Erectile Function [IIEF-5]) after 4 weeks (visit 1) and 8 weeks (visit 2). The final outcome was assessed 3 to 6 months later (visit 3).

At visit 1, 16 patients in Group A and 10 in Group B reported persistence of symptoms. Four patients in Group A and 3 in Group B had positive cultures (presence of pathogenic bacteria). Bacterial eradication was reported in all other patients. Analysis of the symptoms questionnaire revealed a statistically significant difference between the 2 groups regarding symptom regression, with better results reported for Group B ( $P=0.022$ ).

At visit 2, 7 patients in Group A and 1 in Group B reported persistence of symptoms (5 patients did not attend the visit). Only 1 patient from each group had a positive culture. Again, the symptoms questionnaire analysis revealed statistically significant differences between the 2 groups regarding symptom regression ( $P=0.025$ ).

At visit 3, 5 patients in Group A and 1 in Group B reported persistence of symptoms (5 patients in Group A and 6 in Group B did not attend this visit). Only 1 patient from Group A had a positive culture. As at visits 1 and 2, significant differences were reported between the 2 groups regarding symptom regression ( $P=0.046$ ). Comparing IPSS and IIEF-5 scores revealed greater improvement in urinary symptoms in Group B compared with Group A ( $P<0.05$ ), but no statistically significant differences regarding erectile or sexual dysfunction. The occurrence of adverse events was not discussed by the authors.

In a number of earlier studies, saw palmetto has been used as a sole agent; in combination or in comparison with other phytotherapeutics; and in combinations with antibiotics, alpha-blockers, anti-inflammatory agents, and 5-alpha reductase inhibitors to treat benign prostatic hyperplasia. Results from those studies are conflicting. "We expect the effectiveness of *Serenoa repens* in an array of symptoms related to prostatitis to depend on the type of prostatitis, the presence of prostatic hypertrophy [*sic*], any preexisting obstruction, co-administered treatments and the duration of treatment," the authors explain.

In this study, saw palmetto extract was effective in treating pain associated with chronic bacterial prostatitis. The 8-week intake of saw palmetto seemed to improve the effect of antibacterial therapy on pain; a longer duration could possibly alleviate any remaining symptoms.

—Shari Henson

#### Reference

<sup>1</sup>Levin RM, Das AK. A scientific basis for the therapeutic effects of *Pygeum africanum* and *Serenoa repens*. *Urol Res*. 2000;28(3):201-209.

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

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