P.O. Box 144345 Austin, TX 78714-4345 ▪ 512.926.4900 ▪ Fax: 512.926.2345 ▪ www.herbalgram.org

HerbClip™

Mariann Garner-Wizard Shari Henson Sandy Jean
Heather S Oliff, PhD Samaara Robbins

Executive Editor – Mark Blumenthal *Managing Editor* – Lori Glenn

Consulting Editors – Wendy Applequist, PhD, Thomas Brendler, Philip Gregory, PharmD, Allison McCutcheon, PhD, Carrie Waterman, PhD

File: ■ Saw Palmetto (*Serenoa repens*, Arecaceae)
■ Prostatic Inflammation

HC 111832-619

Date: June 14, 2019

RE: Saw Palmetto Extract Reduces Markers of Prostatic Inflammation

Gravas S, Samarinas M, Zacharouli K, et al. The effect of hexanic extract of *Serenoa repens* on prostatic inflammation: results from a randomized biopsy study. *World J Urol*. March 2019;37(3):539-544. doi: 10.1007/s00345-018-2409-1.

Many men with lower urinary tract symptoms (LUTS) and benign prostatic hyperplasia (BPH) have chronic prostatic inflammation after a prostate biopsy. Managing male LUTS includes the treatment of prostatic inflammation. The hexane extract of saw palmetto (*Serenoa repens*, Arecaceae), or HESr, has been studied for its anti-inflammatory, antiandrogenic, and antiproliferative effects; however, say the authors, clinical studies investigating its effects on prostatic inflammation are scarce. These authors conducted a randomized, double-blind study to evaluate the effect of HESr in patients diagnosed with prostatic inflammation. No standardization information of the HESr was provided.

The study was conducted at the University Hospital of Larissa, Greece. The primary endpoint was the change in inflammation from baseline, at a six month follow-up. Of the 110 men with prostatic inflammation confirmed by transrectal ultrasound-guided biopsy and enrolled in the study, 13 were excluded from the final analysis because they developed prostate cancer during the study. All patients had undergone biopsy because of an elevated prostate-specific antigen (PSA) level or a positive digital rectal examination (DRE), or both. The patients were randomized to receive 320 mg of HESr daily for six months (n = 49) or to receive no therapy (control group, n = 48). The patients underwent a second biopsy at the six-month study end.

The primary endpoint was assessed by total Irani's score, a prostatic inflammation scoring system, and immunohistochemical staining. The extent of inflammation was graded from 0 to 3 on the basis of the degree of invasion of inflammatory cells in prostatic tissue. The aggressiveness of inflammation was graded from 0 to 3 based on the degree of contact or disruption of prostatic glandular epithelium by inflammatory cells. Secondary endpoints were changes in immunohistochemical staining for prostatic inflammation using the following antibodies specific for inflammatory cells: CD3, CD4, CD8, CD20, and CD163. The expression of each antibody in prostate tissue was graded from 0 to 3 based on the intensity of tissue involvement.

At baseline, the mean inflammation grading score for the HESr group was 1.55; this score significantly decreased to 0.79 after the 6-month treatment (P = 0.001) period. The mean aggressiveness grading score decreased from 1.55 to 0.87 during the study (P = 0.001). In the control group, the mean inflammation grading score decreased from 1.44 to 1.23 (P = 0.09), and the mean aggressiveness grading score decreased from 1.09 to 0.89 (P = 0.74) from baseline to the end of the study, after six months.

The total Irani's score mean decreased significantly in the HESr group (P = 0.001) and slightly but not significantly in the control group (P = 0.52) during the study.

Comparing the two groups revealed significantly greater decreases in inflammation grading scores (P = 0.001); aggressiveness grading scores (P = 0.009); and total Irani's score (P = 0.001) in the HESr group compared with the control group.

Immunohistochemical staining revealed a significant decrease in the expression of CD3, CD4, and CD8 (for T-leucocytes), CD20 (for B-leucocytes), and CD 163 (for macrophages) antibodies in the HESr group at the second biopsy after six months of treatment, compared with the baseline biopsy (P < 0.001 for all) results. No significant changes were reported in the control group. The changes in expression of antibodies were significantly greater in the HESr group compared with the control group (P < 0.001 for CD3, CD8, CD20, and CD 163, and P = 0.002 for CD4).

The intensity of the antibodies increased in the control group patients; however, only one patient in the HESr group had an increase in CD3 expression at the end of the study. "These results suggest that inflammation seems to progress over time and confirm the anti-inflammatory properties of HESr," write the authors.

These study results are limited by the fact that only patients with elevated serum PSA or positive DRE, or both, were eligible for a prostate biopsy, and only those with confirmed inflammation on baseline biopsy were included in the study. The authors suggest that a larger trial should investigate if and how the improvement in prostatic inflammation reported here can be translated into clinical practice and if patients with higher decreases in prostatic inflammation who are treated with HESr experience LUTS relief.

The authors conclude that "HESr seems to reduce prostatic inflammation in terms of histological and immunohistochemical parameters in patients who underwent two biopsies due to elevated PSA and/or suspicious DRE."

Author S. Gravas disclosed the receipt of speaker honoraria from Astellas Pharma and Pierre Fabre Medicament and consultancy honoraria from Astellas Pharma and GlaxoSmithKline.

—Shari Henson

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.