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HerbClip™

FILE: ▪ Saw Palmetto (*Serenoa repens*)
▪ Benign Prostatic Hyperplasia
▪ Urinary Tract Disorders

HC 020185-354

Date: June 13, 2008

RE: Herbal Prostate Formula Containing Saw Palmetto May Improve Symptoms Associated with Benign Prostatic Hyperplasia

Shi R, Xie Q, Gang X, et al. Effect of saw palmetto soft gel capsule on lower urinary tract symptoms associated with benign prostatic hyperplasia: a randomized trial in Shanghai, China. *J Urol.* 2008;179:610–615.

Lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH), including voiding symptoms (e.g., urinary hesitancy, decreased urinary stream, straining, and incomplete emptying of the bladder) and filling symptoms (e.g., urinary urgency, frequency of urination, and nocturia), are common in aging men worldwide. Traditional therapeutic approaches for BPH symptoms include surgery, watchful waiting, and pharmacotherapy. More recently, phytotherapeutic options have gained popularity. Saw palmetto (*Serenoa repens*) extract is the most commonly used phytotherapeutic agent, and many studies have shown some beneficial effects of this agent in the treatment of LUTS associated with BPH. However, limitations associated with this agent include a potential placebo effect and batch-to-batch variations in potency. The objective of this study was to evaluate the short-term effect of an herbal formulation containing saw palmetto, as well as several other herbs and vitamins, in ameliorating LUTS associated with BPH in men.

Men aged 49-75 years with newly diagnosed LUTS associated with BPH were recruited from 2 health care centers in China into this randomized, double-blind, placebo-controlled trial. All of the subjects had refused conventional treatment or had opted for watchful waiting. Exclusion criteria included a history of prostate cancer and the use of any drugs or herbs for the treatment of LUTS associated with BPH in the previous 4 weeks. The subjects were randomly assigned to receive either 2 placebo (n = 48) or 2 multi-supplement formula (n = 46) soft gels (Prostaplex™; LifeSource Nutrition; Beaverton, OR) daily for 12 weeks. The study consisted of a 2-week recruitment period, a 2-week washout period, and a 12-week follow-up. The subjects underwent testing to determine prostate-specific antigen (PSA) concentration, maximal urinary flow rate (MFR), relative urinary resistance (RUR),

prostate volume, and the International Prostate Symptom Score (I-PSS) at baseline and after the intervention. Compliance was monitored, and a decrease of 3.0 or greater in the I-PSS was considered a significant improvement.

Two subjects in the placebo group did not complete the study. No significant differences in the variables measured at baseline were found between groups, except for a greater I-PSS in the multi-supplement group than in the placebo group ($P = 0.043$). After 12 weeks, the mean ($\pm$ SD) MFR was significantly greater ($P < 0.001$) in the multi-supplement group (14.07 ± 2.56 mL/sec) than in the placebo group (11.74 ± 1.23 mL/sec); RUR was significantly lower ($P = 0.02$) in the multi-supplement group (2.35 ± 0.83) than in the control group (3.02 ± 1.18). No significant between-group differences in I-PSS, PSA concentration, or prostate volume were observed after the 12-week intervention. However, the I-PSS decreased significantly ($P < 0.001$) from 16.85 ± 6.48 at baseline to 14.83 ± 6.42 after the intervention in the multi-supplement group. The I-PSS decreased by 3.0 or greater in 18 (39.1%) patients in the multi-supplement group, but in only 1 (2.2%) patient in the placebo group. Compliance was greater than 95% in both groups

The results indicate that "Prostaplex demonstrated some short-term beneficial effects in Chinese men with LUTS associated with BPH." The present finding of an improvement in I-PSS of 3.0 or greater in 39.1% of the patients treated with multi-supplement containing saw palmetto is consistent with the findings of the TransEurope Research into the use of Management of Policies for LUTS Suggestive of BPH in Primary Healthcare, which found improvement of I-PSS in 43% of patients studied. The study had some limitations worthy of mention: a relatively small sample size, a relatively short duration (12 weeks), and no placebo run-in period. The authors of the present study suggest that "larger studies may be warranted to achieve a more definitive evaluation of the supplement in this patient population." Another limitation is that no information regarding Prostaplex (e.g., standardization, manufacturer) was provided.

—Brenda Milot, ELS