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FILE: ▪ Saw Palmetto (*Serenoa repens*)
▪ Benign Prostatic Hyperplasia
▪ Tamsulosin

HC 030172-335

Date: August 31, 2007

RE: Efficacy of Saw Palmetto and Tamsulosin, Alone or in Combination, for the Treatment of Benign Prostatic Hyperplasia

Hizli F, Uygur MC. A prospective study of the efficacy of *Serenoa repens*, tamsulosin, and *Serenoa repens* plus tamsulosin treatment for patients with benign prostate hyperplasia. *Int Urol Nephrol.* 2007; Jan 4 [Epub ahead of print].

Lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH), a non-malignant enlargement of the prostate, are common in men older than 60 years worldwide. The availability of 5-alpha-reductase inhibitors, alpha-blockers, and phytotherapeutic agents to treat the symptoms associated with this condition has reduced the need for surgery in these patients; however, the use of many of these drugs is associated with adverse effects, including postural hypotension and sexual dysfunction. Thus, increasing attention has focused on the use of phytotherapeutic agents to ameliorate the symptoms associated with BPH. The objective of this study was to assess the safety and efficacy of saw palmetto (*Serenoa repens*) and tamsulosin (Flomax®; Boehringer Ingelheim Pharmaceuticals, Ridgefield, CT), alone or in combination, for the treatment of LUTS secondary to BPH.

Sixty men aged 43–73 years with symptomatic BPH were enrolled between May and November 2005 in this 6-month prospective, open-label, randomized study, the location of which was not identified. The subjects were randomly assigned to 1 of 3 groups (n = 20 per group): 320 mg saw palmetto/day (referred to in this study as the SR group), 0.4 mg tamsulosin/d (TAM group), or 320 mg SR/d + 0.4 mg TAM/d (SR + TAM group). No placebo group was included. There was no mention in the article of the type of saw palmetto product used in this study. The International Prostate Symptom Score (I-PSS), the maximal urinary flow rate (Q_{max}), prostate volume, prostate-specific antigen (PSA) concentrations, quality-of-life scores, and postvoiding residual volume (PVR) were determined at baseline and at months 2, 4, and 6 of the study.

The I-PSS decreased significantly ($P < 0.05$) from baseline to 6 months by 6.1, 4.6, and 4.9 points in the SR, TAM, and SR + TAM groups, respectively. Q_{max} increased significantly ($P < 0.05$) from baseline to 6 months by 3.2, 3.7, and 4.3 mL/second in the SR, TAM, and SR + TAM groups, respectively; however, the differences between groups were not significant. Prostate volume, PSA concentrations, quality-of-life scores, and PVR decreased in all 3 groups by 6 months, but not significantly so in any of the groups. No adverse effects were observed in the SR group, and those that were observed in the 2 other groups (e.g., postural hypotension, dizziness, decrease in libido, dry mouth, and fatigue) were not serious enough to require withdrawal from the study.

Treatment of BPH with SR or TAM alone was equally effective, and treatment with a combination of SR and TAM conferred no extra benefit. The authors conclude that "SR is a well-tolerated agent that can be used alternatively in the treatment of LUTS due to BPH." Larger, prospective, randomized studies with longer follow-up periods should be conducted to determine the efficacy of SR in the treatment of BPH.

—Brenda Milot, ELS