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File: ■ Saw Palmetto (*Serenoa repens*)
■ Lower Urinary Tract Symptoms
■ Benign Prostatic Hyperplasia
■ Tamsulosin

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RE: Saw Palmetto Berry Extract Alone Is as Effective in Treating Benign Prostatic Hyperplasia as Tamsulosin

Argirović A, Argirović D. Does the addition of *Serenoa repens* to tamsulosin improve its therapeutical efficacy in benign prostatic hyperplasia? *Vojnosanit Pregl*. December 2013;70(12):1091-1096.

Lower urinary tract symptoms (LUTS) are associated with benign prostatic hyperplasia (BPH), and the incidence of both LUTS and BPH increase in men over the age of 50. The severity of LUTS is, in part, determined by smooth muscle tone of the prostate and bladder neck. Alpha-blockers (ABs) and α -reductase inhibitors (5-ARIs) are thought to improve the functioning of the smooth muscles and both have been used to treat LUTS/BPH. Tamsulosin is an AB that seems to be more effective at targeting the smooth muscle of the prostate and bladder neck than other ABs, and thus, is commonly used to treat LUTS/BPH. Saw palmetto (*Serenoa repens*) has been used as an alternative treatment for LUTS/BPH. The goal of this 3-armed, randomized study was to compare the effectiveness of tamsulosin and saw palmetto alone versus a combination of tamsulosin and saw palmetto in treating men with BPH.

Two hundred ninety-seven men with BPH who were between the ages of 50 and 87 years old were recruited for this 6-month study conducted in Belgrade, Serbia. Patients had to be at least 50 years old, have a total International Prostate Symptom Score (IPSS) between 7 and 18 points, a Quality of Life score (QoLs) greater than 3, a maximal urine flow (Qmax) between 5 and 15 ml/s, a post-voiding residual volume (PVR) < 150 ml, a prostate volume (PV) of < 50 ml, and serum prostate-specific antigen (PSA) between 1.5 and 4 ng/ml. Patients were excluded if they had bladder or prostate cancer, bladder stones, a history of bladder disease or infection, neurogenic lower urinary tract dysfunction, or other diseases which can cause urinary problems. Patients were randomly divided into 1 of 3 treatment groups: a group that took tamsulosin (0.4 mg/day) alone; a group that took saw palmetto (Prostamol® Uno, 320 mg/day berry; Berlin-Chemie Menarini; Berlin, Germany) alone; or a group that took both tamsulosin (0.4 mg/day) and saw palmetto (320 mg/day). Prostamol Uno contains 320 mg of saw palmetto berry extract (no standardization information) plus succinylated gelatin,

glycerol, purified water, titanium dioxide (E171), black iron oxide (E172), and cochineal red (E124). The study did not cite the randomization technique, and did not include information about blinding. The following information was collected prior to treatment: a complete medical history, a list of current medications, a physical exam, urine analysis, urine culture, creatinine, PSA, total IPSS, QoLs, PV, Qmax, and PVR. IPSS, QoLs, Qmax, and PVR were measured again at 3 and 6 months. PV and PSA were re-measured at 6 months. Patients who showed no improvement at 3 months were removed from the study. Data were analyzed with the Kruskal-Wallis test and Wilcoxon signed-rank test.

The average age of patients was 64.9 years old, and there were no differences among treatment groups at pretreatment, although differences among treatment groups for PV approached significance ($P = 0.07$). There were 87 patients in the tamsulosin treatment group, 97 patients in the saw palmetto treatment group, and 81 patients in the tamsulosin/saw palmetto treatment group. Patients were lost in each group due to voluntary withdrawal, protocol violations, lack of efficacy, and loss to follow-up. IPSS decreased significantly in all groups ($P < 0.05$), with no significant differences among groups. The greatest improvement in IPSS was seen in men with pronounced ejaculation disorders. Qmax increased significantly in all groups over the 6 months of the study ($P < 0.005$). The percentage of patients affected by urinary symptoms decreased by over 50% over the course of the study ($P < 0.001$). QoLs, PV, and PSA all decreased in the treatment groups, but none of these decreases were significant. The most common adverse effects were decreased or absent ejaculation and headache. These effects were found only in the groups that took tamsulosin and tamsulosin plus saw palmetto.

This study provides evidence that saw palmetto is as effective as tamsulosin in reducing LUTS/BPH, and that the combination of saw palmetto and tamsulosin is no more effective than either treatment alone for LUTS/BPH. In addition, both tamsulosin treatment groups had adverse effects, while no adverse events were found in patients receiving only saw palmetto extract. Based on this study, it would seem reasonable to treat patients with LUTS/BPH with saw palmetto alone because of its similar efficacy to tamsulosin and the lack of adverse side effects. This study lacked a placebo group, and it is therefore impossible to subtract a placebo effect from the treatment effects. Other limitations of this study are the relatively short follow-up and lack of description of treatment blinding.

–Cheryl McCutchan, PhD

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