Saw Palmetto Extract Effectively Manages Lower Urinary Tract Symptoms in Men


**Summary:** In a randomized, double-blind, placebo-controlled clinical trial, the efficacy of a saw palmetto (*Serenoa repens* (W. Bartram) Small, syn. *Chamaerops serrulata* Michx., *Corypha repens* W. Bartram [basionym], *Sabal dealbata* hort. ex L.H. Bailey, *Sabal serrulata* (Michx.) Nutt. ex Schult. & Schult. f., *Serenoa serrulata* (Michx.) G. Nicholson, Arecales) berry extract was tested on urinary symptoms, sexual function, and urinary flow in men with lower urinary tract symptoms (LUTS). Following a 1-month placebo run-in period, 85 men, 45 years of age and older with an International Prostate Symptom Score (IPSS)* of 8 or greater, were randomized to receive 160 mg of saw palmetto berry extract (SPBE), standardized to 85-95 percent fatty acids and sterols (Nutraceutical Corp., Ogden, Utah), or placebo two times per day for 6 months. Patients were evaluated using the IPSS, a quality-of-life questionnaire, a sexual function questionnaire, and by measurement of urinary flow rate. Serum prostate-specific antigen (PSA) was also measured. These measures were completed prior to the placebo run-in period, at baseline and at months 2, 4, and 6. The mean ages of the men completing the 6-month trial were 64.6 (± 9.9) years for the SPBE group (n = 41) and 65.3 (± 9.7) years for the placebo group (n = 44).

The mean IPSS symptom score decreased from 16.7 to 12.3 in the saw palmetto group compared with 15.8 to 13.6 in the placebo group (p = 0.038). The quality of life score improved to a greater degree in the SPBE group compared to placebo (0.7 versus 0.3), but was not statistically significant. There was no improvement in the sexual function questionnaire in either group. The peak urinary flow rate increased by 1.0 mL/s in the SPBE group compared to 1.4 mL/s in the placebo group (p = 0.73) [Note: While the increase was slightly higher in the placebo group, this difference was not significant. Neither group had a notable increase compared to baseline]. There was no significant change in PSA levels in either the SPBE or placebo groups. Only one adverse event was reported -- mild gastric distress in one patient in the SPBE group.

**Comments/Opinions:** This is the second saw palmetto study to be completed by Glenn Gerber, M.D., and colleagues at the University of Chicago Pritzker School of Medicine in Chicago. The first, a 6-month, open-label, nonrandomized study using the same preparation and dose of SPBE, found results similar to the placebo-controlled trial summarized above -- an improvement on the mean IPSS (7 points) but no improvement in peak urinary flow.† Interestingly, the earlier trial also found no change in mean serum levels of prostate specific antigen (PSA) in those men taking saw palmetto.

Gerber and colleagues have taken a novel approach to their studies of saw palmetto. While the majority of clinical trials published to date have focused primarily on men with urinary tract symptoms secondary to clinically confirmed benign prostatic hyperplasia (BPH), Gerber's studies have focused primarily on men with a diagnosis of LUTS who may or may not have...
accompanying BPH. This strategy presents a bit of a paradox -- while looking at men with LUTS may approximate the larger population choosing to self-medicate with saw palmetto, it creates a more diverse study population, making evaluation of the outcome more difficult. This is particularly the case when peak urinary flow is used as one of the primary outcome measures as many of the men included in his studies had peak urinary flow of 15 mL/s or greater -- essentially in the normal range.

During the 1990s, considerable debate began to arise among urologists as to how to categorize those men with urinary tract symptoms and clinically identified BPH (e.g., an enlarged prostate) versus those men with urinary tract symptoms in the absence of BPH. The consensus was to use the terminology lower urinary tract symptoms or LUTS to describe the collection of symptoms listed on the IPSS. While the consensus regarding classification has become largely accepted, the etiology of LUTS or BPH remains cloudy.

It's interesting to note that the class of drug that has most successfully treated LUTS has been the alpha-adrenergic receptor blockers (e.g., Cardura, Flomax, and Hytrin) and not the 5-alpha-reductase inhibitor finasteride (Proscar). While studies have favorably compared SPBE, either alone or in combination with stinging nettle root (Urtica dioica L. ssp. dioica, Urticaceae), with finasteride in the treatment of urinary tract symptoms associated with BPH, the results of Gerber's trials suggest that the more interesting comparison should be with alpha-adrenergic receptor blockers.

It's important to note that although debate continues about the quality of some clinical trials examining the efficacy of SPBE for BPH, the consensus of at least two meta-analyses indicate that the herbal extract does improve both peak urinary flow as well as urinary tract symptoms in men with BPH. It is unclear from this study how many men actually had BPH versus those with LUTS in the absence of BPH.

Hopefully, future clinical trials will focus on the use of SPBE for LUTS over a more extended period and, as mentioned above, add a comparison with the more commonly used alpha-blockers. These trials will hopefully expand the clinical understanding of where SPBE may lie in the spectrum of available treatments for LUTS.

**Practice Implications:** This U.S. clinical trial suggests that a liposterolic extract of saw palmetto berries may be a safe and efficacious treatment option for the management of LUTS in men over 45 years of age. While successful trials with SPBE for BPH have found an improvement in peak urinary flow, this trial failed to find any effect. This may be partly explained by the fact that many of the men entered in this trial had normal flow rates (> 15 mL/s) while other trials have typically studied men with abnormal flow rates (<15 mL/s) typically seen in BPH.

**References**


*Note: The International Prostate Symptom Score (IPSS) is based on seven questions regarding urinary tract symptoms associated with benign prostatic hyperplasia. These symptoms include urgency, daytime and nighttime urinary frequency, hesitancy, intermittency, sensation of incomplete voiding, and force of urine stream.*