Cochrane for Clinicians

Putting Evidence Into Practice

Saw Palmetto for the Treatment of Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia

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Author disclosure: No relevant financial relationships.

Clinical Question

Does saw palmetto (*Serenoa repens*) reduce symptoms associated with benign prostatic hyperplasia (BPH)?

Evidence-Based Answer

Saw palmetto, alone or in combination with other phytotherapeutic agents, does not improve urologic symptoms or quality of life in the short term (3 to 6 months) or long term (12 to 17 months). Also, it does not cause significant adverse events.[1] (Strength of Recommendation: A, consistent, good-quality patient-oriented evidence.)

Practice Pointers

BPH-related symptoms of urologic obstruction and irritation affect about one-fourth of men in their 50s, one-third of men in their 60s, and one-half of men 80 years or older.[2] Using plants and herbs (phytotherapy) for this condition is common worldwide. Saw palmetto is one of the most commonly used phytotherapeutic agents. The authors of this Cochrane review sought to determine whether saw palmetto, alone or in combination with other phytotherapeutic agents, improves urologic symptoms due to BPH.

This Cochrane review included 27 randomized controlled trials with 4,656 participants.[1] In the review, 19 trials compared saw palmetto to placebo, and eight trials compared the combination of saw palmetto and other phytotherapeutic agents to placebo. Almost all studies used a saw palmetto dosage of 320 mg per day. Other agents used in combination with saw palmetto included pumpkin seed oil, lycopene, and sabal and urtica extract. Most studies included participants who were older than 50 years (mean age = 52 to 68 years) with moderate urologic symptoms (International Prostate Symptom Score [IPSS] = 8 to 19). For urologic symptoms, the authors considered an improvement of 3 points on the IPSS as the minimal clinically important difference to determine effectiveness. The authors used the final question on the IPSS to analyze quality of life and considered an improvement of 0.5 as the minimal clinically important difference to determine effectiveness.

At short-term follow-up (3 to 6 months), when compared with use of placebo, saw palmetto treatment alone did not improve urologic symptoms (IPSS range = 0 to 35; mean difference [MD] = −0.90; 95% CI, −1.74 to −0.07) or quality of life (IPSS range = 0 to 6; MD = −0.20; 95% CI, −0.40 to −0.00). Similarly, at longer-term follow-up (12 to 17 months), no significant improvements in urologic symptoms or quality of life were noted. Saw palmetto did not cause more adverse events throughout the studies (risk ratio = 1.01; 95% CI, 0.77 to 1.31). In combination with other therapeutic agents, saw palmetto resulted in little to no difference in urologic symptoms, quality of life, or adverse events. Findings were consistent across most studies. The few studies that indicated some improvement in urologic symptoms and quality of life were industry funded, used a very small sample size, or did not demonstrate a clinically relevant improvement based on the predefined minimal clinically important difference.

When treating patients with symptoms of BPH, the National Institute for Health and Care Excellence recommends not offering phytotherapy.[3] The 2021 American Urological Association guideline does not include phytotherapy in its treatment algorithm, and the previous version recommended against phytotherapeutic agents.[4] The 2023 European Association of Urology guidelines recommend using saw palmetto in patients who want to avoid potential adverse events associated with more effective medicines (weak recommendation) while informing the patient that the magnitude of effectiveness may be modest (strong recommendation). These guidelines did not include findings from this Cochrane review.[5]

The practice recommendations in this activity are available at https://www.cochrane.org/CD001423.

The views expressed in this article are those of the authors and do not necessarily reflect the official policy or position of the U.S. Department of the Navy, the U.S. Department of Defense, or the U.S. government.

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CME This clinical content conforms to AAFP criteria for CME. See CME Quiz on page 393.

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Antidepressants to Aid in Smoking Cessation

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Clinical Question

Are antidepressants safe and effective for tobacco smoking cessation?

Evidence-Based Answer

Bupropion facilitates tobacco cessation reported at 6 months of follow-up compared with placebo or no pharmacological treatment (number needed to treat [NNT] with 150 to 300 mg of bupropion per day to yield one patient who stops smoking = 14; 95% CI, 13 to 17).[1] (Strength of Recommendation: A, consistent, good-quality patient-oriented evidence.) More people discontinue using bupropion due to adverse effects than those using placebo or no pharmacological treatment (number needed to harm [NNH] with 150 to 300 mg of bupropion daily to result in one patient quitting = 33; 95% CI, 33 to 100). Nortriptyline might also be effective compared with placebo, but the evidence is not as strong as for bupropion. Bupropion is not as effective as varenicline (Chantix) alone or combination nicotine replacement therapy (e.g., nicotine patch plus nicotine gum or lozenges) at helping patients stay smoke-free 6 months after starting therapy.[1]

Practice Pointers

Cigarette smoking is the leading cause of preventable disease, disability, and death in the United States.[2] Antidepressants offer an alternative to first-line smoking cessation medications. Further insight into the effectiveness and potential harms of antidepressants for smoking cessation is valuable because of the significant worldwide morbidity and mortality caused by tobacco smoking.

This Cochrane review included 124 randomized controlled trials (RCTs) and cluster RCTs in a meta-analysis of 48,832 participants.[1] Only studies that tracked at least 6 months of smoking cessation rates after follow-up were included. Trials with additional, uncontrolled nonantidepressant interventions in only one study arm were excluded. Trials assessed different dosages, durations, and schedules of antidepressants, including 150 to 300 mg per day of bupropion and 75 to 100 mg per day of nortriptyline. Studies that included pregnant women and those that focused on smoking harm reduction or relapse prevention were excluded. Most participants were adults recruited from community settings in Asia, Australia, Europe, and North America.

High-certainty evidence found that 19% of participants taking bupropion were not smoking at 6 months of therapy compared with 12% of participants receiving placebo or nonpharmacological treatment (NNT = 15; 95% CI, 13 to 17; 50 studies; n = 18,577). There was no evidence that the effect depended on behavioral therapy or the presence of a psychiatric disorder. High-certainty evidence showed that 9% of participants dropped out due to bupropion therapy vs. 6% of those receiving placebo or nonpharmacological therapy (NNH = 33; 95% CI, 33 to 100; 25 studies; n = 12,346). Patients taking bupropion were not at increased risk of serious adverse effects.

Twice as many participants were not smoking at 6 months of follow-up with nortriptyline vs. placebo (20% vs. 10%, respectively; relative risk [RR] = 2.03; 95% CI, 1.48 to 2.78; six studies; n = 975). A smaller proportion of participants taking bupropion were not smoking at 6 months vs. those taking varenicline (18% vs. 24%; RR = 0.73; 95% CI, 0.67 to 0.80; nine studies; n = 7,564). Compared with patients taking bupropion, those receiving combination nicotine replacement therapy were more likely to be not smoking at 6 months (33% vs. 25%; RR = 0.74; 95% CI, 0.55 to 0.98; two studies; n = 720).

The U.S. Preventive Services Task Force recommendations include U.S. Food and Drug Administration–approved pharmacotherapy for nonpregnant adults.[3] The National Institute for Health and Care Excellence guidelines on smoking cessation include bupropion and varenicline as pharmacotherapeutic options for nonpregnant adults 18 years and older.[4]

Editor's Note: All instances of NNT, NNH, and related 95% CIs in this review were calculated by the authors based on raw data provided in the original Cochrane review.

The practice recommendations in this activity are available at https://www.cochrane.org/CD000031.

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