POEMs

Patient-Oriented Evidence that Matters

Each month, the POEMs editorial team reviews more than 80 journals of interest to primary care physicians, identifying the articles you have to know about to stay up to date. We call these articles POEMs (Patient-Oriented Evidence that Matters) because they deal with common primary care problems, report outcomes that matter to patients, and have the potential to change the way we practice. The 8 most important articles are critically appraised each month by a team of more than 50 reviewers who make a recommendation for clinical practice. The collected reviews of the POEMs are available at the Journal's *World Wide Web site at http://jfp.msu.edu. Additional POEMs and other related evidence-based material are published in a monthly newsletter called* Evidence-Based Practice, *available through subscription (1-800-451-3794; fax 1-203-406-4603) or via the Web site at http://jfp.msu.edu/ebp.htm*

Saw Palmetto Extracts for Benign Prostatic Hyperplasia

Wilt TJ, Ishani A, Stark G, MacDonald R, Lau J, Mulrow C. Saw palmetto extracts for treatment of benign prostatic hyperplasia: a systematic review. JAMA 1998; 280:1604-9.

Clinical question **Are saw palmetto extracts effective for the treatment of benign prostatic hypertrophy (BPH)?**

Background Symptoms associated with BPH are common in elderly men and can include urgency, frequency, hesitancy, weak stream, and incomplete voiding. Phytotherapy (using plant extracts to treat a condition or disease) has been described for centuries, with many extracts available in the United States as over-the-counter dietary supplements. The authors review available data regarding the effect of various preparations of the saw palmetto berry (*Serenoa repens*), with and without other phytotherapies, for treating symptoms of BPH.

Population studied The review included English and non-English studies enrolling men (n=2939) with a mean age of 65 years (range 40 to 88 years) with signs and symptoms, on average, of moderate BPH.

Study design and validity The review included randomized controlled trials conducted for an average duration of 9 weeks (range 4 to 48 weeks) in men with symptoms of BPH. To find these studies the authors used MEDLINE, the Cochrane Library and its associated databases, EMBASE, and Phytodok, a database of plant-derived products from Germany. References of the studies located were reviewed to identify additional studies. Pharmaceutical companies and relevant experts were also contacted to identify additional published or unpublished studies.

The quality of the identified studies ranged from good to poor. Many of the trials used nonvalidated methods of determining urologic symptoms. Different doses and preparations of saw palmetto extract were used, and some studies used other phytochemicals as part of the active treatment. Finasteride was the only active control used in comparative trials that met the authors' criteria for the studies they selected.

Sixteen of the 18 studies reviewed were said to be double-blinded (89%). However, half of the studies did not adequately conceal treatment allocation. As a result, investigators enrolling patients may have known which treatment the patient was to receive, and some patients may not have been enrolled as a result. While not a strong drawback, it may affect the applicability of those studies.

Outcomes measured The primary outcome was the efficacy of saw palmetto extracts (*S repens*) in altering urologic symptom scores. Other outcomes included mean and peak urine flow, residual urine volume, prostate size, and nocturia.

Results Both study participants and physicians reported greater improvement in BPH symptoms with saw palmetto extracts than with placebo ($P < .001$). Specifically, episodes of nocturia (0.76 fewer times per night; 95% confidence interval [CI], -1.21 to -0.32) and overall symptom scores (1.41-point difference out of 19 points; 95% CI, -2.52 to -0.30) were significantly better in patients treated with saw palmetto. The extract also had a greater effect than placebo on peak and mean urine flow rates, as well as on residual urine volumes.

Saw palmetto also performed well when measured against finasteride. Urinary symptom scores and peak urine flow rate improvements were similar in the 2 treatments. Adverse effects were mild with saw palmetto and were similar among the finasteride and the placebo groups. None of the therapies decreased prostate size.

Withdrawal rates were greater with placebo. Erectile dysfunction was encountered equally in placebo and saw palmetto–treated patients and less than with finasteride ($P < .001$).

Recommendations for clinical practice **This carefully searched and well-performed review shows that, based on limited study, saw palmetto extracts (*S repens*) appear better than placebo and equal to finasteride in treating men with symptoms associated with BPH. The results of this review should be interpreted with some caution because of limitations of the available data. No data were provided on the purity, potency, or standardization of the various saw palmetto extract formulations, a critical issue to be addressed regarding phytotherapy. Given these limitations, saw palmetto extract appears to be an effective agent worthy of consideration for men suffering from symptoms associated with BPH.**

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Xylitol for Prevention of Acute Otitis Media

Uhari M, Kontiokari T, Niemela M. A novel use of xylitol sugar in preventing acute otitis media. Pediatrics 1998; 102:879-84

Clinical question **Can xylitol sugar prevent acute otitis media (AOM) in children?**

Background Xylitol is a sweetener commonly used in Europe as an alternative to sucrose. It has been shown to prevent dental caries, most likely by inhibiting bacterial growth. This study was designed to test whether it can also prevent AOM. A previous study suggested that xylitol chewing gum has this effect in older children, who are able to chew gum.

Population studied Children were enrolled from 34 day care centers in the city of Oulu, Finland. Children were excluded if they were receiving antimicrobial prophylaxis, or if they had congenital craniofacial or structural middle ear abnormalities.

Study design and validity This was a randomized controlled trial with 5 treatment groups. Children too young to chew gum received either xylitol syrup or control syrup. The rest of the children received either xylitol chewing gum, control chewing gum, or xylitol lozenges. The study was double-blind within the syrup and chewing gum groups and open between the chewing gum and lozenge groups. All agents were given 5 times a day for 3 months. Baseline characteristics of the intervention and control groups were similar. Over 90% of the infants were breast-fed for at least 6 months, and more than 80% had at least one previous episode of AOM. Nearly 40% of either or both parents smoked tobacco.

Outcomes measured The primary outcome was occurrence of AOM during the study period (3 months). Diagnosis required the presence of middle ear effusion verified by pneumatic otoscopy along with signs of tympanic membrane inflammation and symptoms of acute respiratory infection (earache, rhinitis, cough, conjunctivitis, or sore throat).

Results A total of 857 children from age 8 months to 6.9 years were randomized; the mean age in the syrup groups was 2.2 years, and mean age in the other groups was about 4.6 years. In the syrup group, children receiving xylitol (n=159) had 69 episodes of AOM, while the control children (n=165) had 114 (P = .006). This correlates with a number needed to treat [NNT] of 4 (4 children would need to receive the syrup 5 times daily for 3 months to prevent 1 ear infection). Children receiving xylitol gum (n=179) had 44 episodes of AOM, children receiving xylitol lozenges (n=176) had 52 episodes of AOM, and children in the control group (n=172) had 72 episodes of AOM. The decrease in AOM in the lozenge group was not significant compared with the placebo group(P = .3), but the decrease in AOM in the gum group was statistically significant (P = .025; NNT = 7). Although the authors state that xylitol was well tolerated, there are no data given on side effects. Almost 19% of the xylitol syrup group dropped out of the study compared with 10% of the syrup control group, a significant difference (P = .03).

Recommendations for clinical practice **Xylitol sugar, when given in a syrup or chewing gum, is effective in reducing episodes of AOM in children attending day care. Xylitol is not available in the United States in the forms used in this study. As with any medicine used to prevent illness, it is important that it be easy to take and have a low incidence of side effects, as well as be effective. Giving medication to resistant children 5 times a day is more than any but the most motivated parents can successfully accomplish. In addition, there is not enough information on side effects in infants and young children, who are most likely to develop AOM and in whom this treatment would be most needed. The investigators in this study have patented the use of xylitol in respiratory infections and it will be important for these results to be replicated in other centers with larger numbers of patients before xylitol should become a routine part of clinical practice.**

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