

**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.

Larry W. Segars, PharmD, BCPS  
University of Health Sciences  
College of Osteopathic Medicine  
Kansas City, Missouri  
E-mail: lsegars@fac1.uhs.edu

## ■ 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.

Emily Lagace, MD  
St. Paul, Minnesota  
E-mail: lagace@iex.net