Xylitol syrup and xylitol chewing gum were both effective in preventing acute otitis media


**Question**
Among healthy children in day-care, do xylitol syrup, xylitol chewing gum, or xylitol lozenges prevent acute otitis media (AOM)?

**Design**
Randomised controlled trial with 3-month follow-up.

**Setting**
A department of paediatrics in a university medical centre in Oulu, Finland.

**Patients**
857 children (54% boys) were recruited from 34 day-care centres. Children who were receiving antimicrobial prophylactics or had a congenital craniofacial malformation or structural middle-ear abnormality were excluded. 764 children (89%) completed the study.

**Intervention**
Children who were too young to chew gum (mean age 2.2 y) were allocated to xylitol syrup (10 g of xylitol/d) (n = 159) or a control syrup (0.5 g of xylitol/d) (n = 165) at a dosage of 5 mL given 5 times/d. Children who were old enough to chew gum (mean age 4.6 y) were allocated to xylitol chewing gum (8.4 g of xylitol/d) (n = 179), control chewing gum (0.5 g of xylitol/d) (n = 178), or xylitol lozenges (10 g of xylitol/d) (n = 176). 2 pieces of gum or 3 lozenges were given 5 times/d and chewed for ≥ 5 minutes.

**Main outcome measure**
Incidence of AOM defined as tympanometric evidence of middle-ear effusion, otoscopic evidence of tympanic membrane inflammation, and the presence of symptoms of acute respiratory infection.

**Main results**
Fewer children who received xylitol syrup had ≥ 1 episode of AOM than did children who received control syrup (P = 0.028) (Table). Xylitol chewing gum also led to fewer children with ≥ 1 episode of AOM than did control gum (P = 0.025) (Table). Children who received xylitol lozenges had a lower incidence of AOM than those chewing control gum, but the difference did not reach statistical significance (P = 0.30) (Table). Antimicrobial use was lower in the xylitol syrup group than in the control syrup group (P = 0.012) and lower in the xylitol chewing gum group than in the control gum group (P = 0.046).

**Conclusions**
Xylitol syrup and xylitol chewing gum were effective in reducing the incidence of acute otitis media in children attending day-care centres. Xylitol lozenges were less effective.

**Xylitol syrup vs control syrup and xylitol gum or lozenges vs control gum for incidence of ≥ 1 episode of acute otitis media at 3 months**

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Event rates</th>
<th>RRR (95% CI)</th>
<th>NNT (CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xylitol syrup vs control syrup</td>
<td>29% vs 41%</td>
<td>30% (4.6 to 53)</td>
<td>8 (4 to 53)</td>
</tr>
<tr>
<td>Xylitol gum vs control gum</td>
<td>16% vs 28%</td>
<td>40% (10 to 71)</td>
<td>9 (5 to 36)</td>
</tr>
<tr>
<td>Xylitol lozenges vs control gum</td>
<td>22% vs 28%</td>
<td>20% (–13 to 51)</td>
<td>Not significant</td>
</tr>
</tbody>
</table>

*Abbreviations defined in Glossary; NNT and CI calculated from data in article.*

**Commentary**
Uhari and colleagues provide solid evidence that xylitol reduces the incidence of AOM in children by about one third, a clinically important effect. However, several problems preclude immediate recommendation for its use.

First, the safety of gum and lozenges for young children is suspect. In this study, gum and lozenges were given to children as young as 18 months. Hard candies and gum are known choking hazards and advising young children to use them regularly would almost certainly lead to an increase in aspiration (1, 2). The absence of aspiration in a study of this size is nevertheless consistent with an actual aspiration rate as high as 6 per 1000 children in 3 months.

Second, among children taking xylitol in any form, the dropout rate was nearly twice that for those receiving placebo (13% vs 7%, relative risk 1.8, 95% CI 1.2 to 2.8). This excess may have been caused by chance, but it was confined to the syrup and lozenge groups, suggesting side effects specific to those forms. The side effects of xylitol syrup, the only acceptable dosage form for young children, clearly warrant further study.

Finally, the syrup was administered 5 times daily over several minutes. Long-term compliance with this regimen would be difficult.

A study showing safety and efficacy of xylitol syrup given as a twice-daily bolus would greatly increase the feasibility of using xylitol for prevention of AOM in children.

**References**