Complementary, Holistic, and Integrative Medicine: Therapies for Acute Otitis Media

Cecilia Bukutu, PhD,* Janjeevan Deol,* Sunita Vohra, MD, FRCPC, MSc*

Introduction

Acute otitis media (AOM) is diagnosed frequently in early childhood; its peak incidence is between 6 and 15 months of age. (1) Streptococcus pneumoniae, Haemophilus influenzae, and Moraxella catarrhalis are the leading bacterial causes. Eighty percent of AOM cases resolve without treatment within 3 days. (2)(3) This high rate of spontaneous resolution along with variations in diagnostic criteria complicate studies of otitis media. Most cases of AOM are treated with antibiotics and pain relievers, but antibiotics may contribute to antimicrobial resistance or produce adverse effects (AEs) such as diarrhea. (4) These concerns, in part, have led some parents to turn to the use of complementary and alternative medicine (CAM) to treat childhood AOM. This review of published scientific literature examines some commonly used CAM therapies in the prevention and treatment of childhood AOM.

Natural Health Products

Naturopathic Herbal Ear Drops (NHEDs)

A Cochrane systematic review conducted in 2004 (4) assessed the effectiveness of NHEDs in the management of ear pain associated with AOM in two randomized, controlled trials (RCTs) (Table 1). The first study compared an NHED comprised of Calendula flores (marigold), garlic (Allium sativum), mullein (Verbascum thapsus), and St. John’s wort (Hypericum perfoliatum) in olive oil with anesthetic eardrops. (5) The second study compared NHED (garlic, mullein, marigold, St John’s wort, lavender, and vitamin E in olive oil) to anesthetic eardrops with and without antibiotics. (6) Findings from these trials point to NHEDs being modestly therapeutic for pain associated with AOM compared with anesthetic eardrops. However, the trials have some methodologic problems: lack of allocation concealment, power calculation, and intention-to-treat analysis. Two children dropped out of the first study because of the odor of NHED; no other AEs were documented. (5) The evidence regarding safety and efficacy of NHEDs seems promising.

Other Natural Health Products

An Israeli double-blind RCT in which 430 children ages 1 to 5 years ingested either 5 mg/mL or 7.5 mg/mL of a mixture containing echinacea, propolis, and vitamin C or placebo twice daily for 12 weeks found the mixture to be effective in preventing AOM. (7) Compared with placebo, the mixture reduced the number of AOM episodes per child by 68% (P<0.001). AEs reported in nine children, including seven from the mixture group and two from the placebo group (P=0.54), were mild gastrointestinal and palatability symptoms.

Xylitol

Used as a sweetener in chewing gums and other dietetic products, xylitol is a natural sugar found in strawberries, raspberries, rowanberries, and plums. In addition to inhibiting the growth of S. mutans, which is responsible for dental cavities, it also prevents S. pneumoniae from growing or attaching to nasopharyngeal cells. (8)

Four double-blind RCTs (9)(10)(11)(12) have examined the effectiveness of xylitol in...
preventing AOM in children attending child care centers in Finland (Table 2). In two RCTs, xylitol reduced the risk of developing AOM by 41% and 40%. (9)(10) In these studies, healthy children ingested 8.4 to 10 g of xylitol divided into five doses daily for 2 or 3 months. Two children who took xylitol dropped out due to diarrhea in the earlier trial; in the later trial, 16 children who took xylitol dropped out due to abdominal discomfort compared with five who took placebo.

A third RCT using the same dosing schedule, but in which xylitol (as a mixture, chewing gum, or lozenge) was administered to children who had acute respiratory infection, found xylitol to be ineffective in preventing AOM. Seven children who took xylitol dropped out

---

**Table 1. Clinical Trials of Naturopathic Ear Drops for Acute Otitis Media in Children**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Study Type</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Sarrell et al. | Double-blind RCT | 103 children ages 6 to 18 y who had otalgia associated with AOM (Israel) | Group A: Naturopathic drops (*Allium sativum, Verbascum thapsus, Calendula flores, Hypericum perforatum* in olive oil)  
Group B: Anesthetic ear drops (amethocaine, phenazone, glycerine)  
In both groups, drops instilled 3 times daily for 3 days  
At start, all children given a single dose of acetaminophen (15 mg/kg) | Severity and duration of pain  
Two visual (linear and color) analog scales used  
Ear pain assessed prior to treatment and at 15 and 30 min after treatment | NHED reduced pain as effectively as anesthetic ear drops  
Pain score improved throughout the course of the study period (*P*=0.007) | Children older than the age group in which peak AOM incidence occurs (6 to 15 mo); thus, likely greater chance of spontaneous recovery |
| Sarrell et al. | Double-blind RCT | Ambulatory clinic, 171 children (5 to 18 y) who had otalgia associated with AOM (Israel) | Children randomized into 1 of 4 treatments and received eardrops 3 times daily for 3 days  
Group A: NHED alone (*Allium sativum, Verbascum thapsus, Calendula flores, Hypericum perforiatum, lavender, and vitamin E in olive oil*)  
Group B: NHED with oral amoxicillin (antibiotic)  
Group C: Anesthetic eardrops alone  
Group D: Anesthetic eardrops with oral amoxicillin (antibiotic) | As in Sarrell, 2001 | After 3 days, rate of pain reduction:  
Group A=95.9%,  
Group B=90.9%,  
Group C=84.0%,  
Group D=77.8%  
Pain was mostly (80%) self-limited and explained by the passage of time | Children older than the age group in which peak AOM incidence occurs (6 to 15 mo); thus, likely greater chance of spontaneous recovery |

AOM=acute otitis media, NHED=naturopathic herbal ear drops. RCT=randomized, controlled trial.
versus two who took the control. Furthermore, 11 children dropped out due to disliking the intervention product (10 from the xylitol lozenge group and one from the xylitol chewing gum group).

Taking xylitol five times per day to prevent AOM may be impractical for children and parents. The fourth trial of 663 children ages 7 months to 7 years assessed whether administering xylitol (chewing gum or a oral mixture) less frequently (three times daily) would reduce the occurrence of AOM. (12) Xylitol (9.6 g/d divided into three doses) was found to have no preventive effect. Thirty-eight children (11%) dropped out in the control group and 58 (17%) in the xylitol group ($P = 0.028$). The common reason for dropping out was refusal to take the preparation.

Xylitol has few reported AEs. In large doses, it may cause abdominal pain and loose stools. (9) A study examining various doses in 13 children (ages 7 to 16 y) found flatulence increased at a 45-g/d dose, but no diarrhea occurred at doses less than 65 g/d. (13) A tolerability study of 120 children (ages 6 to 36 mo) found oral xylitol solution doses of 5 g taken three times a day and 7.5 g taken once daily to be well tolerated. (14) The effectiveness of this dosing schedule has yet to be evaluated through an RCT. The occurrence of AEs was not significantly different between groups and included ex-

### Table 2. Summary of Xylitol Intervention Trials

<table>
<thead>
<tr>
<th>Citation</th>
<th>Study Type</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uhari et al. (1996)</td>
<td>Double-blind RCT</td>
<td>306 healthy children (mean age, 4.9 y) at child care centers</td>
<td>Group A: Xylitol chewing gum (8.4 g/d) Group B: Sucrose chewing gum Dosages taken 5 times daily for 2 months</td>
<td>Reduction in AOM episodes</td>
<td>Xylitol reduced occurrence of AOM by 41% (95% CI: 4.6% to 55.4%)</td>
<td>2 children dropped out due to diarrhea (Group A)</td>
</tr>
<tr>
<td>Uhari et al. (1998)</td>
<td>Double-blind RCT</td>
<td>857 healthy children at child care centers</td>
<td>Group A: Xylitol chewing gum (between 8.4 g/d and 10 g/d) Group B: Xylitol syrup (between 8.4 g/d and 10 g/d) Group C: Xylitol lozenges (between 8.4 g/d and 10 g/d) Group D: Placebo Dosages taken 5 times daily for 3 months</td>
<td>Reduction in AOM episodes</td>
<td>Xylitol reduced occurrence of AOM by 40% (95% CI: 10% to 71.1%)</td>
<td>16 dropouts due to abdominal discomfort in Groups A to C versus 5 in Group D</td>
</tr>
<tr>
<td>Tapiainen et al. (2002)</td>
<td>Double-blind RCT</td>
<td>1,277 children (ages 10 mo to 7 y) who had acute respiratory infection</td>
<td>Group A: Xylitol mixture Group B: Control mixture Group C: Xylitol chewing gum Group D: Xylitol control chewing gum Group E: Xylitol lozenges Dosages taken 5 times daily until symptom resolution or up to 3 wk</td>
<td>Occurrence of AOM</td>
<td>AOM occurrence: Group A= 20.5% versus Group B= 20.4% (NS) Groups C (14.1%) and D (11%) versus Group E (15.5%) (NS) Xylitol ineffective</td>
<td>Dropouts: Disliked intervention product: group E=10, group C=1 Abdominal discomfort all xylitol groups=7, control=2</td>
</tr>
<tr>
<td>Hautalahti et al. (2007)</td>
<td>Double-blind RCT</td>
<td>663 healthy children (ages 7 mo to 7 y)</td>
<td>Group A: Xylitol chewing gum (9.6 g/d) Group B: Control (0.5 g/d) Dosages taken 3 times daily for 9 mo</td>
<td>Number of AOM episodes</td>
<td>156 AOM episodes in xylitol group versus 142 in control (NS) Xylitol ineffective</td>
<td>Dropouts: control= 38 (11%) versus 58 (17%) in the xylitol group ($P=0.028$)</td>
</tr>
</tbody>
</table>

AOM=acute otitis media, CI=confidence interval, NHED=naturopathic herbal ear drops, NS=not significant, RCT=randomized, controlled trial.
cessive gas and diarrhea. Although the results for xylitol effectiveness are mixed, its use is safe except in huge doses. Moreover, xylitol (taken in a mixture or chewing gum) may provide dual protection for children by helping to prevent AOM as well as dental caries. (8)(9)

**Probiotics**

Probiotics are believed to reduce upper respiratory tract colonization with pathogenic bacteria by stimulating antibody production and enhancing the phagocytic activity of blood leukocytes. (15) Findings from three double-blind RCTs are presented.

Hatakka and colleagues (16) assessed the long-term effectiveness of oral probiotics for AOM prevention in 571 children (ages 1 to 6 y) from 18 Finnish child care centers. Children drank milk formula either with (n=282) or without (n=289) *Lactobacillus rhamnosus GG* (LGG) three times daily, 5 days a week for 7 months. On average, children from both groups drank 260 mL/d of milk. Over the study period, children who drank milk with LGG were absent from child care for fewer days (4.9 versus 5.8 days, P=0.03). They also had fewer antibiotic treatments and fewer episodes of AOM. This result was not statistically significant when adjusted for age.

In a later study, Hatakka and associates (17) assessed the effectiveness of a probiotic combination (LGG and *Bifidobacterium breve* C705, *Propionibacterium freudenreichii* JS) for reducing the occurrence and duration of AOM in 306 AOM-prone children (ages 10 mo to 6 y). Children consumed either one probiotic capsule (n=155) or placebo (n=154) daily for 24 weeks. Probiotic treatment did not reduce the occurrence or recurrence of AOM episodes, nor did it affect the carriage of *S pneumoniae* or *H influenzae*. However, the intervention did increase the prevalence of *M catarrhalis* (odds ratio=1.79, 95% confidence interval, 1.06 to 3.00, P=0.028). Each group had 20 dropouts due to sickness, noncompliance, personal reasons, and “not known.” One AE was reported in the probiotics group (no additional description given).

A 3-month Swedish study investigated the efficacy of using a probiotic nasal spray of streptococci (*S gasseri, S mitis*, and *S oralis* in equal portions) for preventing the recurrence of AOM in 108 children (ages 6 mo to 6 y). (15) Children who had an AOM recurrence within the previous month (n=82) received 20 mg/kg of amoxicillin/clavulanic acid twice daily for 10 days followed by 10 days of a nasal “probiotic” spray, then 60 days of no use, and another 10 days of the nasal spray. During this time, children who had no AOM recurrences within 1 month (n=22) received 25 mg/kg of phenoxymethylpenicillin and placebo nasal spray. More children (42%) given probiotic streptococcal nasal spray had no AOM recurrences and normal tympanic membranes than children given placebo (22%, P=0.02). Of 45 AEs reported, 22 were in the streptococcal group and 25 were in the placebo group. Details of the AEs were not provided.

Probiotics have a favorable safety profile in healthy individuals. In immunocompromised adults, there have been reports of pneumonia, bacteremia/septicemia, and meningitis. LGG has been associated with bacteremia in two immunocompromised pediatric patients. (18) Although favorable findings of the effectiveness of probiotics exist, additional investigations are needed before conclusive recommendations for their use to prevent AOM can be made.

**Cod Liver Oil**

Cod liver oil is an excellent source of omega-3 fatty acids and vitamins A and D. Lindsay and colleagues (19) found that children who have recurrent AOM have lower red blood cell concentrations of the omega-3 fatty acid eicosapentaenoic acid (EPA), vitamin A, and selenium than those who do not have recurring AOM. These micronutrients are believed to have important effects on immune function. The authors conducted a small open-label pilot study in which eight children (0.8 to 4.4 y) took 1 tsp of lemon-flavored cod liver oil (containing EPA and vitamin A) plus half a tablet of multivitamin supplement containing selenium for up to 7 months. During this period, children received antibiotics for OM for 12% fewer days than before taking part in the study (P<0.05). One child who could not tolerate the taste of cod liver oil discontinued participation. Concerns regarding the possible AEs of long-term consumption of cod liver oil are related to the dangers of polychlorinated biphenyls and dioxin residues found in fish oil that have been implicated in a range of health conditions. Although this small open-label study suggests that cod liver oil may be beneficial, definitive recommendations are premature.

**Homeopathy**

Anecdotal evidence suggests that homeopathy may be beneficial for children who have AOM. Five studies (three RCTs and two observational) have evaluated the efficacy of homeopathy for treating AOM in children...
Findings suggest that homeopathy results in a rapid reduction in symptoms, a shorter duration of pain, and a reduction of both AOM recurrences and antibiotic use. One study also assessed the cost effectiveness of homeopathy compared with that of conventional treatment and found homeopathy to be 14% cheaper. A few AEs were observed in some of the studies, but these occurred in the control groups. One Swiss study noted three cases of severe AEs in 7 years of homeopathic care practice: one central perforation of a tympanic membrane, one cholesteatoma, and one case of mastoiditis. (23)

Due to their dilute nature, homeopathic remedies generally are regarded as carrying little risk of harm. Aggravation of symptoms, in which patients’ current symptoms worsened for a few hours after taking homeopathic medicine, have been reported in 10% to 20% of patients. Although findings for homeopathy are promising, more rigorously designed studies (large, blinded, randomized, and controlled) are needed to substantiate the results. It also would be useful to compare patients treated homeopathically with those treated with other treatments (eg, herbal ear drops, topical anesthetics, systemic antibiotics) in terms of their symptoms, AEs, costs, and parental satisfaction and interest in using such treatments in the future.

Chiropractic
Three cohort studies (ie, no control group) in the United States have examined the efficacy of chiropractic care to treat AOM in children and have reported positive findings. The first was a case series of 332 children (ages 27 d to 5 y) who had a previous diagnosis of OM (acute and chronic). Children who had AOM (n=127) and received an average of 4±1.03 adjustments attained normal otoscopic and tympanographic examination findings after 6.67 (±1.9) and 8.35 (±2.88) days, respectively. The overall AOM recurrence rate over a 6-month period was 11.02%. The second study, a retrospective cohort design, assessed the impact of care from one chiropractor on 46 children (ages <5 y) who had a total of 95 AOM episodes. Overall, 93% of AOM episodes improved, with 75% of the improvements occurring within 10 days. A 2004 cohort study of 21 children (9 mo to 9 y) who had severe red, bulging tympanic membranes in the middle ear and moderate fever (average 100°F [37.8°C]) found that after three to six “toftness” (low force) chiropractic adjustments over a 14-day period, tympanic membranes returned to normal in 95% of children. The temperature also was reported to decrease to an average of 98.6°F (37.0°C).

Given the combined high rate of spontaneous AOM resolution and methodologic limitations of the studies presented (convenience sample, nonstandardized outcome measures, nonblinded ratings of improvement, and lack of control groups), the effectiveness of chiropractic care for AOM is not well defined. Furthermore, the safety of pediatric spinal manipulation is not yet known. Although rare, serious AEs, including paraplegia and death, have been reported. (29) Due to anatomic immaturity, young children are particularly vulnerable to injury from rapid rotational movement or excessive force.

Osteopathy
Two studies (one cohort, one RCT) have assessed the efficacy of osteopathic manipulation techniques (OMTs) in treating AOM. One RCT evaluated its impact in children (6 mo to 4 y) on frequency of AOM episodes, subsequent ear surgery, hearing loss, behavior, antibiotic use, and parent opinion. (30) Children received either “gentle” OMT (n=32) or standard pediatric care (ie, antibiotics) (n=25). Treatment was administered at nine study visits: 3 weekly, 3 biweekly, and 3 monthly, with treatment duration between 15 and 25 minutes. Patients receiving OMT had fewer episodes of AOM, with a mean difference between groups of −0.14 (P = 0.04) per month. Only one ear surgery was required in patients receiving OMT compared with eight in those receiving standard care (P=0.03). No significant differences between the groups were noted in antibiotic use, hearing test results, parent-rated behavior, or parental satisfaction with treatment. The study had a high dropout rate (25%), with two primary reasons cited: loss of continuity of physician care and inconvenience of a 6-month study.

Positive findings also were reported in a 2006 pilot cohort study of eight children (ages 7 to 25 mo) who had recurrent AOM. The study consisted of a 1-year follow-up period of children who received weekly OMTs concurrently with routine medical care (ie, antibiotics) for 3 weeks. Although OMT was found to be beneficial in preventing the occurrence of AOM in five of eight children, the lack of a control group made it impossible to determine if OMT was responsible.

Results from small studies that have limited statistical power suggest that osteopathy might be a promising adjuvant therapy in the prevention of recurrent AOM, but larger clinical trials evaluating the safety and cost-benefit of osteopathy are essential before conclusions about its efficacy can be made.
<table>
<thead>
<tr>
<th>Citation</th>
<th>Design</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Friese et al. (1997)</td>
<td>Open prospective</td>
<td>131 children with AOM (age 6 mo to 11 y) (Germany)</td>
<td>Group A (n=103): Single homeopathic remedies (Aconitum anapellus, Apis mellifica, Belladonna, Capsicum, Chamomilla, Kalium bichromicum, Lachesis, Lycopodium, Mercurious solubilis, Okoubaka, Pulsatilla, Silicea)</td>
<td>Duration of pain and therapy, number of recurrences after 1 y</td>
<td>Median duration of therapy was significantly less in Group A (4 d versus 10 d)</td>
<td>No randomization (potential selection bias), unequal group sizes AEs observed in Group B (diarrhea, stomachaches)</td>
</tr>
<tr>
<td>Harrison et al. (1999)</td>
<td>Nonblinded RCT</td>
<td>33 Children (ages 18 mo to 8 y) with OM with effusion (OME), abnormal tympanogram finding, and hearing loss &gt;20 dB (United Kingdom)</td>
<td>Group A: Homeopathic treatments (range, 6 to 9) Group B: Standard care of wait and watch policy over 12 mo</td>
<td>Hearing loss, tympanography, antibiotic use, referral to specialists</td>
<td>More Group A patients (76%) had normal tympanogram findings compared with controls (31%) (P=0.015)</td>
<td>Small study, possibility of randomization being uncontrolled 2 patients from Group A withdrew (no reason provided)</td>
</tr>
<tr>
<td>Jacobs et al. (2001)</td>
<td>Double-blind RCT</td>
<td>75 children with AOM (ages 18 mo to 6 y) (United States)</td>
<td>Group A: Individualized homeopathic medicine (most common being Pulsatillanigran, Chamomilla, sulphur, Calcarea carbonica) Group B: Placebo taken orally 3 times daily for 5 d</td>
<td>Treatment failure after 5 d, 2 wk, and 6 wk Diary symptom scores</td>
<td>Decrease in symptoms at 24 h and 64 h in favor of homeopathy (P=0.05)</td>
<td>Definition of AOM Small sample size</td>
</tr>
<tr>
<td>Frei and Thruneysen (2001)</td>
<td>Open trial</td>
<td>230 Children with AOM (ages 0 to 16 y) (Switzerland)</td>
<td>Individualized homeopathic medicine</td>
<td>Pain reduction at 6 and 12 h after instillation</td>
<td>Improvement in 39% of patients after 6 h, another 33% after 12 h</td>
<td>No control group</td>
</tr>
</tbody>
</table>

(continued)
Numerous studies have evaluated the effectiveness or safety of natural health products, homeopathy, chiropractic, and osteopathic care to treat pediatric AOM, but methodologic shortcomings preclude definitive conclusions. This review suggests that xylitol, probiotics, herbal ear drops, and homeopathic interventions may be beneficial in reducing pain duration as well as decreasing the use of antibiotics and subsequent bacterial resistance. Cost-effectiveness and parent/child preferences need to be evaluated in large, well-designed research studies before general recommendations can be made regarding use of these CAM therapies for children who have AOM.

**NOTE:** References for this article are published in the online edition of this month’s *Pediatrics in Review*. 

<table>
<thead>
<tr>
<th>Citation</th>
<th>Design</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wustrow et al. (2004) (24)</td>
<td>Open, nonrandomized, controlled, parallel-group study</td>
<td>390 children with AOM (ages 1 to 10 y) (Germany)</td>
<td>Group A (n=192): Homeopathic formula (Echinacea purpurea, Sambucus nigra, Sanguinaria canadensis, Chamomilla recutita); parents decided whether child was intervention group or not Group B (n=193): Conventional treatment (ie, decongestant nose drops, mucolytics, analgesics, and antibiotics)</td>
<td>Time to recovery, pain resolution, antibiotic use</td>
<td>Fewer children given homeopathic treatment compared with control took antibiotics (14.4% versus 80.5%, (P=0.001)) and analgesics (53.2% versus 66.8%, (P=0.007))</td>
<td>Treatment allocation not randomized Group B: One adverse drug reaction (rash) reported</td>
</tr>
</tbody>
</table>

AE = adverse effects, AOM = acute otitis media, NS = not significant, RCT = randomized, controlled trial.