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# *Complementary and Alternative Medicine for Pediatric Otitis Media*

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## **Introduction**

Acute otitis media, one of the most common diseases of childhood, has a peak incidence between 6 and 15 months of age. Almost half of all pediatric antibiotic prescriptions are written for otitis media, which also prompts more physician visits than any other childhood illness. An excess of \$100 is spent per episode, and the cost of treating middle ear infections in the US is approximately \$2 to \$3.5 billion per year (Stool et al 1989) <sup>1</sup>.

The American Academy of Pediatrics (AAP) and the American Academy of Otolaryngology and Head and Neck Surgery define acute otitis media (AOM) a history of acute onset of signs and symptoms, the presence of middle ear effusion, and signs and symptoms of middle ear inflammation. It should be differentiated from both recurrent acute otitis media (ROM), defined as acute otitis media occurring at least 3 times within 6 months, and persistent (or chronic) otitis media with effusion (COM), defined as the presence of middle ear fluid in the absence of symptoms for greater than 8 weeks.

Eighty percent of acute otitis media episodes resolve spontaneously within three days. Therefore, Western Europe, concerned over antibiotic resistance and treatment side effects, advocated in the 1980's for watchful waiting as initial management for acute otitis media.

In 2004 the American Academy of Family Physicians (AAFP) and AAP published recommendations highlighting initial watchful waiting in children with otitis media. In 2004, as part of their guidelines, the American Academy of Pediatrics and the American Academy of Family Physicians recommended initial observation of AOM in selected patients:

- 6 months to 2 years: non severe illness at presentation **and** uncertain diagnosis
- 2+ years: non severe illness at presentation **or** uncertain diagnosis
- If symptoms do not resolve in 24 to 48 hours, they should then be treated with antibiotics.

Unwilling to let a child's illness run its course and seeing a persistence of symptoms, many families seek alternative modes of treatment. Unfortunately these interventions are difficult to evaluate secondary to the rapid resolution and natural history of AOM; a trial to prove any treatment effect must demonstrate even more prompt resolution of symptoms. In this chapter we will discuss current concepts of complementary and alternative medicine as they apply to otitis media. The literature shows that while many of these modalities are promising, few have been assessed with randomized controlled trials and, thus, there is need for further research.

## Prevention

One of the first tenets of many complementary and alternative modalities is prevention. The identification of risk factors for otitis media has spurred research ranging from lifestyle modification to immunization to dietary changes. Many well-documented studies demonstrate increased rates of otitis media with bottle-feeding compared with breast feeding (Sabirov 2009) <sup>2</sup>. Additionally, smoking around children, large daycare settings and pacifier use can also play a role in causing AOM ( Uhari et al 1996<sup>3</sup> - **Table 1**).

**Table 1.** Risk factors for recurrent acute otitis media (AOM): Uhari M et al. 1996

Risk factor	Risk for	RR	<i>p</i> value
Family history of AOM	AOM	2.6	<0.001
Daycare outside home	AOM	2.5	0.003
Not breastfeeding at all	Recurrent AOM	2.1	<0.001
At least one sibling	Recurrent AOM	1.9	0.001
Child care outside home	Recurrent AOM	1.8	0.004
Parental smoking	AOM	1.7	<0.001
Family daycare	AOM	1.6	0.002
Pacifier use	AOM	1.2	0.008
Breast feeding <3 months	AOM	1.2	0.003

Recently nutrition and food allergies have been implicated in the pathogenesis of otitis media. In a study by Lasisi in 2009 (Lasisi et al 2009<sup>4</sup>), patients with COM were found to have retinol/vitamin A levels that were lower than age-matched controls. The levels were also significantly lower in patients with recurrent AOM compared with those who experienced a single episode of AOM. In a meta-analysis in 2009, Elemraid et al. (Elemraid et al 2009<sup>5</sup>) found some evidence that deficiencies of zinc and/or vitamin A may lead to increased rates of otitis media. However, Abba et al. in 2010 (Abba et al 2010<sup>6</sup>) reviewed 12 randomized controlled trials in which placebo was compared to zinc (given at least once a week for at least one month) and found conflicting reports regarding the efficacy of supplementation.

Vaccines also play an important role in prevention of otitis media. In 2001, the CDC recommended that the PCV7 (initial Prevnar vaccine) be administered to all infants and young children. Research since 2004 (when shortages of the vaccine were resolved) has shown an overall decrease in rates of otitis media caused by pneumococcus (Kilpi et al 2002<sup>7</sup>). The Finnish Otitis Media Study Group further demonstrated a decreased rate of tympanostomy tube placement for recurrent disease<sup>7</sup>. Cost analyses have suggested that immunization of all healthy infants could prevent over one million episodes of AOM. A second-generation 13-valent pneumococcal conjugate vaccine (PCV13) was recommended for universal immunization of children through age 5 in 2010. Its introduction is intended to address the residual burden of pneumococcal diseases that persists after the introduction of PCV7.

The incidence of acute otitis media may also be reduced by prevention of preceding upper respiratory infections or other viral illnesses such as influenza. In a study by Block et al. in 2011 (Block 2011 <sup>8</sup>), influenza vaccination was thought to be protective for otitis media. Block et al compared live attenuated influenza vaccine (approved for children greater than 2 years old) with placebo and found overall efficacy against influenza-associated AOM was 85.0% <sup>8</sup>.

### **Symptomatic Relief**

Symptomatic relief of AOM is of paramount importance to patients and families, especially with watchful waiting recommendations. Many find relief with warm compresses and steam. Alternately, gargling salt water may help reduce the inflammation of swollen mucosa and thereby drain the Eustachian tubes. Judicious use of over-the-counter decongestant nasal sprays may benefit some patients. Others find Herbal eardrops helpful, but their efficacy is difficult to determine secondary to variable composition. They usually contain some combination of: *Calendula flores* (marigold), garlic (*Allium sativum*), mullein (*Verbascum thapsus*), St. John's wort (*Hypericum perforatum*), lavender, and vitamin E. In 2001, Sarrell et al. (Sarrell et al 2001 <sup>9</sup>) compared Otikon Otic Solution, a naturopathic herbal extract containing *Allium sativum*, *Verbascum thapsus*, *Calendula flores*, and *Hypericum perforatum*, with anesthetic ear drops (containing ametoacaine and phenazone) and found comparable rates of analgesia in patients with AOM. Similarly, Taylor and Jacobs (Taylor 2011 <sup>10</sup>) found significantly faster resolution of symptoms with administration of a homeopathic eardrop compared to “standard therapy”. A Cochrane systematic review in 2004 (Glasziou 2004 <sup>11</sup>) concluded that naturopathic eardrops were “modestly therapeutic” for ear pain associated with otitis media with no safety concerns. But a subsequent Cochrane review in 2006 (Foxlee 2006 <sup>12</sup>) found there was insufficient evidence to determine the effectiveness of naturopathic eardrops.

### **CAM in general**

Evaluating the efficacy of Complementary and Alternative Medicine for otitis media is fraught with difficulty, including language barriers, lack of randomization, unclear time to effect, and even disagreement on the definition of CAM itself. Most think of CAM as “anything not in the realm of conventional medicine”. Others prefer to think of CAM as treatment based in historical or cultural traditions rather than science. Regardless, it is based on the premises of individualizing treatments, self-treatment and prevention. Despite this ambiguity, CAM is quite common: 50% of US adults have tried some form of CAM at some point, and 37% of US hospitals offer at least one CAM therapy. Perhaps most relevant, Marchisio et al. (Marchisio 2011 <sup>13</sup>) found 46% of children aged 1 to 7 years with 3 or more episodes of AOM in 6 months had used some component of CAM. Interestingly, they found many fewer were PCV-7 or influenza vaccinated (34% and 15%, respectively).

Complementary and Alternative medicines are generally not regulated by the FDA. That there are no patents for CAM modalities results in little economic incentive for research; however, the National Center for Complementary and Alternative Medicine has spent \$2.5 billion on CAM research since 1992. Nonetheless,

most of the studies have significant methodological flaws making definitive conclusions difficult. Furthermore, studies of the cost-effectiveness of such treatments need to be performed.

### **Homeopathy**

Homeopathy is based on the principle that “like cures like”; in other words, any substance that produces symptoms in a healthy patient can relieve those same symptoms in an ill patient. Use of homeopathic remedies in general is common and can include belladonna, chamomilla, and hepar sulphuricum (see **Appendix 1** for a list of the most common homeopathic remedies and their uses). Treatments are individualized. Those that are used for otitis media are generally regarded as “safe”, but there have been reports of an initial worsening of symptoms in approximately 10% to 20% of patients (Dantes 2000<sup>14</sup>). Also, in one study, there was a report of 3 cases of severe adverse events in the practice of a homeopathic provider over 7 years (one perforation of a tympanic membrane, one cholesteatoma, and one case of mastoiditis), though it is unclear if these are necessarily directly attributable to the homeopathic interventions (Frei 2001<sup>15</sup>).

In a small, non-blinded, randomized controlled trial by Harrison et al. in 1999 (Harrison 1999<sup>16</sup>), 33 children (aged 18 months to 8 years) with otitis media with effusion, abnormal tympanograms, and hearing loss (greater than 20 decibels) were randomized to either “homeopathic therapy” or watchful waiting. More patients in the homeopathic group had normal tympanograms compared to the watchful waiting group (75% vs. 31%,  $p = 0.015$ ). There was also a trend toward improvement in hearing, lower antibiotic use, and lower referral rates to specialists in the homeopathic group, but this was not significant.

In a double blinded randomized controlled trial by Jacobs et al. in 2001 (Jacobs 2001<sup>17</sup>), 75 children diagnosed with AOM (as defined by middle ear effusion plus ear pain or fever, for less than 36 hours) were randomized to either “homeopathic therapy” or placebo 3 times daily for 5 days. The homeopathic group had a decrease in symptoms at 24 and 64 hours after treatment ( $p < 0.05$ ). Frei and Thurneyen in 2001 (Frei 2001<sup>15</sup>) looked at symptomatic improvement in a group of 230 children with AOM who received an initial dose of homeopathic medicine and found 39% had pain control after 6 hours. After a subsequent dose at 12 hours, an additional 33% had pain control. They also found homeopathic remedies to be 14% less expensive than traditional remedies. More recently in 2005, Wustrow et al. (Wustrow 2005<sup>18</sup>) looked at symptomatic improvement in 390 children (aged 1 to 10 years) with AOM self-selected to receive either “conventional treatment” (decongestant nose drops, mucolytics, analgesics, and antibiotics) or homeopathic remedies (Otoovowen). Patients taking “conventional therapy” overall took more analgesics (66.8% vs. 53.2%;  $p = 0.007$ ) than patients taking homeopathic remedies but time to recovery was similar in the two groups.

Sinha et al (Sinha 2012<sup>19</sup>) compared homeopathic treatment to “conventional treatment” including antipyretics, analgesics and anti-inflammatory medications and found the homeopathy treatment group was less likely to require antibiotics by day three for treatment failure than the conventional treatment group. There was a trend toward faster symptom improvement in the homeopathy group as well.

Overall, homeopathy may result in a more rapid reduction of symptoms, shorter duration of pain, and a reduction in antibiotic use. However, to accurately assess the efficacy and safety of these treatments, more and larger blinded randomized controlled studies are required.

### **Other Natural Health Products**

Natural health products such as echinacea, cod liver oil, and xylitol are generally regarded as safe, though efficacy is unclear and some patients experience significant gastrointestinal symptoms. While there are many natural health products available (see **Appendix 2** for a more complete list), one of the most common herbs taken in the United States is echinacea, which is generally taken for or to prevent the common cold. Unfortunately, most echinacea products in the United States are derived from *Echinacea Augustifolia*, an herb which has never been shown to improve symptoms related to upper respiratory infections. Only *Echinacea pallidum* root and *Echinacea purpurea* leaf have demonstrated efficacy in this regard. Looking at a mixture containing echinacea (as well as propolis and vitamin C), Cohen et al (Cohen 2004<sup>20</sup>) found the mixture reduced the number of AOM episodes per child by 68% ( $p < 0.001$ ) compared to placebo among 430 children. Unfortunately, side effects involving gastrointestinal-type symptoms were reported in 9 children, including 7 from the mixture group and 2 from the placebo group ( $p = 0.54$ ).

Lindsay et al.<sup>21</sup> found children with ROM had lower blood concentrations of EPA (an omega 3 fatty acid), vitamin A, and selenium, all of which possess immunomodulatory properties. With 7 months of supplementation, children had 12% fewer days of antibiotics prescribed than prior to study enrollment ( $p < 0.05$ ), though it is unclear if there was a direct effect on otitis media itself (Lindsay 2002<sup>21</sup>).

Xylitol, a natural sugar found in many fruits and used as a sweetener in chewing gum, is also thought to have preventative properties in otitis media. Uhari et al. 2000<sup>22</sup> found xylitol inhibited the growth of *S. pneumoniae* and inhibited the attachment of both *S. pneumoniae* and *H. influenzae* to nasopharyngeal cells (Uhari 2000<sup>22</sup>). Kurola et al. in 2009<sup>23</sup> offered a possible explanation for this: exposure to xylitol lowered cpsB (pneumococcal capsular locus) gene expression which changes the ultrastructure of the pneumococcal capsule (Kurola 2009<sup>23</sup>). Perhaps more clinically relevant, Uhari et al. in 1996<sup>24</sup> found in a randomized controlled trial that xylitol (8.4 g/d in divided doses 5 times daily) reduced the occurrence of AOM by 41% (95% CI: 4.6% to 55.4%). In addition, fewer of the children receiving xylitol required antibiotics during the study period (18.5% vs. 28.9%,  $p = 0.032$ ) (Uhari 1996<sup>24</sup>). In 1998 the same group demonstrated a 40% reduction of otitis media in patients receiving xylitol gum, 30% reduction in those receiving syrup, and 20% reduction in those receiving xylitol lozenge, compared with controls (Uhari 1998<sup>25</sup>). In 2000, they further corroborated these findings in a study looking at chewing gum vs. syrup vs. controls and found the efficacy at 2 to 3 months was 40% with chewing gum and 30% with syrup. Interestingly, xylitol was ineffective in children with indwelling tympanostomy tubes (Uhari 2000<sup>22</sup>). While most studies show some efficacy of xylitol in preventing AOM, Tapiainen et al. (Tapiainen et al 2002<sup>26</sup>) compared xylitol mixture, control mixture, control

chewing gum, xylitol chewing gum, and xylitol lozenges given during an active upper respiratory infection and found no preventive effect for xylitol in any form. Most studies report a 5-times-a-day dosing schedule, which likely limits full compliance. To address this, Hautalahti et al. (Hautalahti 2007) <sup>27</sup> looked at 3 times daily xylitol for 3 months (9.6 g/d divided into 3 doses) and found no preventive effect over control solutions/gum in preventing otitis media. Furthermore, xylitol has common side effects including abdominal pain and diarrhea, which often lead to high dropout rates.

### **Probiotics**

Probiotics are microorganisms (most commonly lactobacilli and/or bifidobacteria) that are added to food products in order to confer health benefits by restoring microbial balance. Probiotics are thought to reduce upper respiratory tract colonization with pathogenic bacteria by enhancing the phagocytic activity of blood leukocytes and stimulating antibody production (Roos 2001 <sup>28</sup>). Although considered safe in immunocompetent individuals, they do have the potential to interact with other medications. In immunocompromised patients, there are reports of adverse health effects such as pneumonia, meningitis, and sepsis.

There is conflicting evidence on the effectiveness of probiotics in preventing AOM. In a randomized controlled study by Hatakka et al. in 2001 <sup>29</sup> (Hatakka 2001), 571 children were randomized to receive milk with or without *Lactobacillus rhamnosus* 3 times daily, 5 days a week, for 7 months. There was a significant decrease in the number of days absent from daycare in the probiotic group but only a slight trend toward fewer episodes of AOM. In a later study by Hatakka et al. in 2007 <sup>30</sup> (Hatakka et al 2007), children were randomized to receive a probiotic capsule or placebo daily for 24 weeks. While there was a large dropout rate, they found probiotics did not reduce the occurrence or recurrence of otitis media. They also obtained nasopharyngeal samples at 3 points in time and showed no reduction in the presence of *S. pneumoniae* or *H. influenzae* but an increased prevalence of *M. catarrhalis*.

Conversely, Roos et al. in 2001 (Roos 2001 <sup>28</sup>) reported on the use of a probiotic nasal spray in children and found preventive effects on AOM and COM (42% without recurrence in the probiotic group vs. 22% in the placebo group,  $p = 0.02$ ). More recently in 2009, Stecksén-Blicks et al <sup>31</sup>. (Stecksén-Blicks et al 2009) showed milk supplemented with probiotics and fluoride consumed once daily, 5 days a week, for 21 months, had preventive effects on otitis media (0.4 days of otitis media vs. 1.3 days of otitis media,  $p < 0.05$ ). Rautava et al. in 2009 <sup>32</sup> (Rautava 2009) looked at probiotics in infants by supplementing the formula of infants younger than 2 months compared to placebo supplementation daily until the age of 12 months. There was a significant reduction in the number of episodes of otitis media in the first 7 months of life (22% vs. 50%, risk ratio [RR], 0.44 [95 % CI 0.21, 0.90];  $p = 0.014$ ) and a decrease in the amount of antibiotics prescribed (31% vs. 60%, RR, 0.52 [95 % CI 0.29, 0.92];  $p = 0.015$ ). These conflicting reports highlight the need for further research in this area.



## Osteopathy

Osteopathy is a system of therapy founded in the 19th century based on the concept the body can heal itself when it is in a normal structural relationship, in a normal environment, and has good nutrition. Osteopathy often includes chiropractics but is not limited to it. Craniosacral therapy, a practice in which the bones and tissues of the head and neck are manipulated, is also a component. According to some osteopathic practitioners, there are common patterns of cervical and cranial “osteopathic restrictions” that are found in children with otitis media, particularly with regard to the movement of the temporal bones. Treatment in children is often more gentle than adults.

A randomized controlled trial by Mills et al. in 2003<sup>33</sup> (Mills 2003) evaluated osteopathic procedures (OMT) including myofascial release, articulation, balanced membranous tension, balanced ligamentous tension, facilitated positional release, and/or counter strain on “areas of restriction” for treatment of otitis media. Children aged 6 months to 4 years with recurrent AOM were randomized to either standard care (such as antibiotics) with or without OMT over 6 months. Patients in the OMT group had fewer episodes of AOM per month ( $p = 0.04$ ) and less need for tympanostomy tubes ( $p = 0.03$ ). There was no difference in antibiotic use, parental satisfaction, or hearing results. Unfortunately, there was a large dropout rate (25%), making conclusions difficult. Meaningful conclusions were also difficult in a 2006 cohort study by Degenhardt and Kuchera<sup>34</sup> (Degenhardt 2006) where children with recurrent AOM were given weekly OMT and antibiotics for 3 weeks and then evaluated 1 year later. Five (62.5%) of 8 subjects had no documented episode of AOM at the 1-year follow up. Without a control group, it is difficult to interpret these results.

Osteopathic techniques can include the “Galbreath maneuver” or the “Muncie technique” for treatment of otitis media. In 1929, Dr Galbreath developed a technique in which the ipsilateral mandible is forced downward and medially in a repetitive gentle fashion generating a pumping action on the Eustachian tube, which can help drain the middle ear. It is also possible that this maneuver alternately compresses and releases the pterygoid plexus of veins and lymphatics, allowing middle ear drainage (Pratt-Harrington 2000)<sup>35</sup>. More recently, Ruddy et al.<sup>36</sup> (Ruddy 1962) and Heatherington<sup>37</sup> (Heatherington 1995) describe the “Muncie technique” in which the physician places a fingertip cephalad and lateral to Rosenmuller’s fossa and applies light repetitive pressure in this area, effectively pumping the Eustachian tube and allowing fluid to drain. This is often not tolerated well in children, and, therefore, Channell<sup>38</sup> offers the “modified Muncie technique” in which a finger is placed at the posterior tonsillar pillar and lateral, circular, repetitive motions are made in the soft tissue; motion is transmitted superiorly to the opening of the Eustachian tube. Effectiveness of these techniques is mainly anecdotal but may warrant future research.

## Chiropractics

“Chiropractics” comes from the Greek word meaning hand and is based on the principle that the body can heal itself when the skeletal system is in correct alignment. Practitioners feel chiropractic manipulation improves innervation and



function of the tensor veli palatini which helps treat or prevent otitis media.

Froehle<sup>39</sup> examined the effectiveness of chiropractics in 46 children with AOM aged 5 years and younger. Patients were given 3 treatments per week for 1 week and then 2 treatments per week for 1 week and then 1 treatment per week with termination at any point when parents, physicians, or chiropractic practitioner deemed the child improved. They found overall 93% of AOM improved, 75% of which improved within 10 days and 43% with only 1 or 2 treatments. In 2004, Zhang et al.<sup>40</sup> looked at otitis media resolution in 21 children (aged 9 months to 9 years) diagnosed with AOM (defined by tympanic membranes appearance and fever). These children were treated with “toftness” (low force) chiropractic adjustments over 14 days, and overall, 95% had return of normal-appearing tympanic membranes and a decrease in their fevers. Unfortunately, there was no control group and thus conclusions are difficult.

Fallon<sup>41</sup> examined 332 children (aged 27 days to 5 years) with a diagnosis of otitis media (acute or chronic) for effectiveness of chiropractic manipulation. Children who had AOM (n = 127) received an average of  $4 \pm 1.03$  adjustments and attained normal otoscopic exams and tympanograms after  $6.67 (\pm 1.9)$  and  $8.35 (\pm 2.88)$  days, respectively. These children also had an overall AOM recurrence rate of only 11% in 6 months. Patients with chronic OM required  $5.0 \pm 1.53$  adjustments, attained normal otoscopic exams in  $8.57 \pm 1.96$  days, and had normal tympanograms in  $10.18 \pm 3.39$  days. There is some concern over the safety of chiropractics in a pediatric population. Children may be at increased risk for injury following rapid rotational movements or forces secondary to anatomic immaturity.

Serious adverse events have been reported with chiropractics such as paraplegia and death (Lee 1995)<sup>42</sup>. Overall, the effectiveness of chiropractic medicine in treatment of otitis media is unclear because the few existent studies all possess significant methodological shortcomings.

### **Traditional Chinese and Japanese Medicine**

Traditional Chinese medical (TCM) practices encompass many healing modalities including acupuncture, moxibustion (heat therapy), Anma (or Tuina, an ancient massage technique), diet, and herbal medicines and are predicated on the idea of disease prevention through moderation and harmony/balance within the body. Traditional Japanese medicine is referred to as Kampo and likely has its roots in traditional Chinese medicine stemming from the 5th and 6th centuries, and, thus, it employs similar techniques to traditional Chinese medicine. Treatment is patient and practitioner specific, but for otitis media generally includes of a combination of herbs and acupuncture. Diagnosis often relies both on patient history and examination of the tongue and pulses. The provider determines the unique pattern of disharmony present in the patient at that point in time. Both acupuncture and Chinese herbal medicine are approved by the World Health Organization as therapies to treat AOM and COM. In children who do not tolerate acupuncture with needles, acupressure, adhesive magnets on acupuncture points, or laser acupuncture is employed instead.

Acupuncture is based on the notion that the body’s energy force, “chi,” travels known channels (“meridians”) that can become blocked; small needles are in-

serted to correct the flow of the energy. In a study by Sanchez-Araujo and Puchi in 2011<sup>43</sup> 31 dogs with ROM were randomized to either conventional medicine with either sham acupuncture or actual acupuncture in 4 sessions. Over the subsequent year, 14 (93%) dogs in the acupuncture group were free of otitis, compared with 7 (50%) in the sham group ( $p < 0.01$ ). There is little understanding why acupuncture may be effective in treating otitis media, but it is suggested that it has immunomodulatory properties that may play a role in the clearance of middle ear fluid.

Many herbs and combinations of herbs exist in traditional Chinese medicine and include skullcap (*Scutellaria baicalensis*), alisma (*Alisma plantago-aquatica*), plantain (*Plantago major*), bupleurum (*Bupleurum Chinese*), and licorice (*Glycyrrhiza uralensis*). The research on both Chinese and Japanese traditional medicine is limited; there are few studies in English, and many are limited by sample size, randomization, and outcome measures. However, there is more research of these techniques in animals; in the guinea pig “sairei-to” enhances mucociliary clearance<sup>44</sup> and prevents endotoxin-induced otitis<sup>45</sup> According to Zhang et al.<sup>46</sup> erylanting (EYL) liquid reduces the degree of inflammatory exudation and mucosal swelling in the guinea pig and may have a nonspecific enhancing effect on the immune system in mice. Sun et al. in 2005<sup>47</sup> examined the use of Qingqiao capsule (QQC) in treating otitis media. Patients were randomized to receive either QQC, 5 capsules, 3 times daily for 10 - 14 days or cefaclor capsules 20 mg/(kg.d) for 10 - 14 days. Those receiving QQC had improved hearing ( $p < 0.01$ ), but no difference was found with respect to ear pain. In a study by Jeong et al. in 2002<sup>48</sup> Allergina (a combination of many traditional herbs) was compared with antibiotics in 17 children with otitis media and was found to decrease the signs of otitis media compared with antibiotics. The authors also found different levels of cytokines in each group, suggesting a possible mechanism of action. Unfortunately, the study was limited by its small sample size and nonspecific outcome measure as well as unclear randomization. Other reports suggest the efficacy of other herbal compounds (such as that by Liu in 1990<sup>49</sup> concluding efficacy of borneol-walnut oil over neomycin in the treatment of otitis media and that of Liao et al. in 1998<sup>50</sup> stating efficacy of Tongqiao in COM) but are limited by sample size, randomization, and outcome measures. Furthermore, most research is not in English which adds difficulty to interpretation.

While Japanese traditional medicine (Kampo) bears many resemblances to Chinese traditional medicine, needles are not inserted as deeply in Kampo acupuncture as in TCM, which may make it easier for children to tolerate. The herbs are often a little different as well. Maruyama et al. in 2009<sup>51</sup> examined Juzentaiho-to (JTT, TJ-48), given at 0.10-0.14 g/kg/day twice a day for 3 months, in 24 otitis prone infants. Infants receiving JTT had fewer hospital visits, antibiotics, and fevers than before JTT administration; 95% had *no* otitis media while taking JTT. Interestingly, 66.7% (16 of 24) had purulent otitis media following discontinuation of JTT ( $p = 0.004$ ). Perhaps even more telling, rates of otitis media decreased again with JTT resumption ( $p = 0.005$ ). It has been suggested that Kampo’s effectiveness overall may be due in part to selective increase in ion transport across the ear epithelium<sup>52</sup>.

### Other Therapies

Aromatherapy has been used to treat otitis media. Lavender (*Lavandula officinalis*) essence may help to reduce inflammation and pain associated with ear infections. Other oils used include chamomile (*Matricaria recutita*), cajuput, evening primrose oil (*Oenothera biennis*), fatty acid, flax oil, and borage. Aromatherapy has not been well studied to date.

Ayurvedic medicine was developed in ancient India, is based on the principle of balance, and literally means knowledge for long life. In otitis media, Ayurvedic physicians massage the lymph nodes outside the ears to open the Eustachian tubes. Often a drink made with the herb amala is given; amala contains vitamin C and may possess antiviral and antibacterial properties. Again, more research is needed to fully evaluate these treatment modalities.

### Summary and Recommendations

According to the AAFP and AAP, management of AOM begins with watchful waiting. Herbal eardrops may help to relieve symptoms. Homeopathic treatments may help decrease pain and other symptoms, and may lead to a faster resolution of disease.

However, it is important to emphasize prevention with elimination of risk factors such as second hand smoke and bottle-feeding, as well as maintaining nutrition and vaccinations. In some cases, vitamin supplementation may be helpful (such as zinc, cod liver oil, and vitamins A, C, and D). Probiotics and xylitol may be beneficial in preventing otitis media and decreasing antibiotic use. Of all of the complementary and alternative medical therapies, only xylitol has been studied in well-designed, randomized, blinded trials; it has been shown to be effective but only in 5-times-daily gum-chewing, which limits its applicability.

Overall, safety profiles, drug interactions, and effects in immunocompromised and other patients are not known, especially with respect to chiropractic and osteopathic techniques in children. Promising results have been seen with traditional Chinese/Japanese therapies including acupuncture, but due to unclear risks, these deserve more rigorous study. Many methodologies have shown some positive trends in small groups, but few have shown benefit in double blind randomized controlled studies and, thus, remain speculative.

More severe cases of otitis media, such as those with complications or those that fail to improve with observation or complementary/alternative medicine (after 48 to 72 hours) should be treated with antibiotics and, in some cases, surgical intervention. It is best to consult a physician when making treatment decisions for full guidance on the risks and benefits of any treatment option.

## Appendix 1

*List of common homeopathic remedies used to treat otitis media and conditions they are used for. Most commonly used are indicated with \*\*.*

**\*\* *Aconitum/Aconite/Aconitum napellus*:** For throbbing ear pain that comes on suddenly after exposure to cold or wind and in children with high fever and whose ears are bright red or tender to the touch. Better in the initial stages of an ear infection.

**\*\* Belladonna:** For throbbing and sharp pain accompanied by fever, intense heat, and flushing in the outer ear and along the side of the face. Some suggest it is better for the right ear. It comes from an extract from a poisonous plant of the nightshade family and should be used with caution.

**Capsicum:** Treats heat and inflammation and significant pain.

**\*\* Chamomilla:** For children with otitis media who are very irritable, in great pain, and can't be consoled.

**Ferrum phosphoricum:** In early otitis media, this is a common remedy used; gradual onset of symptoms; patient has flushed face, doesn't like noise, wants to lie still.

**Hepar Sulphuricum:** Pain in ears especially with swallowing; yellowish-green discharge, wind or draft aggravates pain.

**Kali muraticum:** Popping and crackling sound heard in ear when swallowing and with nose blowing, hearing may be decreased, feeling of fullness and congestion in the ear. Also used to clear Eustachian tubes when fluid persists after AOM.

**Lycopodium:** For right-sided ear pain that is worse in the late afternoon and early evening; fullness of the ears, ringing or buzzing of the ears.

**Magnesia phosphorica:** Earache, especially after exposure to cold wind and drafts. May not be an infection at all, but rather nerve irritation, more right ear than left; pain relieved by heat, feels better with rubbing.

**Mercurius:** Good for chronic ear infections; for pain that is worse at night and may extend down into the throat; relief comes from nose blowing; earache may occur when damp or fog or weather changes occur, may salivate or sweat.

**\*\* Pulsatilla:** For infection following exposure to cold or damp weather; the ear is often red and may have a yellowish/greenish discharge from ear or nose; ear pain may worsen after sleep and with warmth, may be alleviated by cool compresses.

**Silica:** For chronic or late stage infection when the child feels chilly, weak, and tired; sweating may also be present.

**Verbascum:** Especially left-sided otitis media, may have a cough or laryngitis as well.

## Appendix 2

### *List of common natural health products used to treat otitis media.*

**Chamomile** (*Matricaria chamomilla*): It is thought to have antiviral properties and has been used for infant colic, digestive upset, and diarrhea. The oil fraction is believed to have the anti-infective properties, while the flavonoids are thought to be anti-inflammatory. There is little evidence for its use in otitis media. It comes as a tincture (1-3 mL tid; infants: 1-3 drops/lb body weight tid) and a tea (1 cup of boiling water over 1 heaping tbsp of flowers). Occasionally patients are allergic to it.

**Cleavers:** Used to assist lymphatic clearance of debris during AOM or with serous otitis media. Tincture 0.5 to 2 mL 3 times daily. Tea is also used: 1 cup 2 or 3 times per day.

**Cod Liver Oil:** A source of omega-3 fatty acids and vitamins A and D. It has been shown that patients with ROM have low blood levels of some omega-3 fatty acids, vitamin A, and selenium. Safety of long-term consumption of cod liver oil is not known; studies have shown adverse health effects from polychlorinated biphenyls and dioxin residues found in fish oil.

**Echinacea** (*Echinacea purpurea*): Its activity is believed to be nonspecific activation of the immune system (including activating natural killer cells and macrophages and increasing circulating levels of alpha interferon), but there is some evidence that the caffeic esters are antibacterial and antiviral and the polyacetylenes may be bacteriostatic. It is most commonly used for treatment of upper respiratory infections, but it is not well studied for otitis media specifically. Dose of Echinacea: tinctures, either in alcohol or glycerites, are available. Children: 1-5 mL 3-5 times daily, infants: 1 or 2 drops/lb body weight tid. Tablets, capsules, and whole herb taken as tea or infusion are also used orally.

**Elder flower/berry** (*Sambucus nigra*), European alder (*Sambucus canadensis*), or American elder (*Caprifoliaceae*): Used to dry excessive nasal secretions, also has antiviral activity, best during AOM, especially if an upper respiratory tract infection is present. Tincture 0.5 to 3 mL 3 times daily. Tea is also used: 1 cup 2 or 3 times per day.

**Elecampane root** (*Inula helenium*): Bacteriostatic and antiviral activity and may strengthen resistance of mucosal lining. Can be used in AOM or chronic serous otitis media. Tincture 0.5 to 2 mL 3 times daily.

**Eucalyptus**: Administered usually as steam inhalation and is used mostly late in the course of AOM.

**Goldenseal** (*Hydrastis canadensis*): Used only during AOM when there is evidence of purulence. Tincture 0.5 to 2 mL 3 times daily.

**Marshmallow** (*Althea officinalis*): Used for soothing inflamed mucous membranes and helps loosen and moisten thick mucus. In otitis media, it is used particularly to help open the Eustachian tube. Tincture: 1 drop per 2 pounds of body weight (up to 2 mL) 3 to 6 times daily. Decoction: 1 tbsp root simmered in 1 cup of water for 10 minutes; 1 to 3 tbsp of the strained liquid is taken 2 to 6 times daily. If taking with prescription medications, take the medications at least 1 hour before or 2 hours after taking marshmallow root, because the herb may decrease the absorption of drugs.

**Mullein** (*Verbascum thapsus*): Decreases phlegm and strengthens the respiratory mucosa and acts topically as a local anti-inflammatory. It can be used as topical ear oil for otitis externa. For otitis media, it is chosen to unblock the Eustachian tube and to decrease inflammation. Tincture: 1 drop per 2 pounds of body weight every 4 hours. Tea: 1 to 2 tsp herb/cup of boiling water, steeped covered 10 to 15 minutes, and strained; 1 to 4 cups per day.

**Usnea** (*Usnea barbata*): Has antiviral and antibacterial properties, used during acute episodes of otitis media. Tincture 0.5 to 5 mL 3 times daily.

**Xylitol**: Used as an artificial sweetener in chewing gum and has been shown to inhibit the growth of *Streptococcus pneumoniae* by changing the ultrastructure of the bacterial capsule. Many studies show effectiveness of xylitol (gum > syrup) in preventing otitis media when given 5 times daily. It can cause abdominal pain and loose stools, which leads to large dropout rates from many studies and difficulty drawing meaningful conclusions. It also prevents dental caries.

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