


Homeopathic Ear Drops as an Adjunct in Reducing Antibiotic Usage in Children With Acute Otitis Media

Global Pediatric Health
January-December 2014: 1-7
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DOI: 10.1177/2333794X14559395
gph.sagepub.com


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Abstract

Objective. To determine if use of a homeopathic ear drop preparation reduces antibiotic use in children diagnosed with acute otitis media (AOM). **Methods.** Children 6 months to 11 years old, diagnosed with AOM and managed with a delayed antibiotic approach, were randomized to standard therapy alone or standard therapy plus a homeopathic ear drop preparation. The primary outcome was whether or not the antibiotic prescription given at the index visit was filled during a 12- to 15-day follow-up period. **Results.** Among 210 enrolled children, follow-up antibiotic data were collected on 206. During the 12- to 15-day follow-up period, fewer parents of children randomized to the homeopathic ear drops group filled the antibiotic prescription compared with those of children receiving standard therapy alone (26.9% and 41.2%, respectively, $P = .032$). **Conclusion.** Homeopathic ear drops may be effective in reducing the use of antibiotics in children with AOM managed with a delayed antibiotic approach.

Keywords

homeopathy, acute otitis media, delayed antibiotic approach, unnecessary antibiotics

In 2004, the American Academy of Pediatrics published a guideline on the diagnosis and management of otitis media in children, which was updated in 2013.^{1,2} A major goal of the guideline is to promote the judicious use of antibiotics by using a standardized approach to diagnosis and treatment. Specific clinical criteria are provided for the option of a delayed antibiotic approach in which the parent is given a prescription for antibiotics to fill only if the child's condition deteriorates or does not improve over the following 2 to 3 days.^{1,2} In addition, the guideline includes advice on reducing otalgia, both for the comfort of the child and to avoid the use of unnecessary antibiotics. Naturopathic and homeopathic remedies are included as possible treatments for reducing otalgia, with the caveat that there are limited data on their usefulness in children with otitis media.^{1,2}

Previously, we conducted a study on the effectiveness of a commercially available homeopathic ear drop ("Hyland's Earache Drops," manufactured by Standard Homeopathic Company, Los Angeles, CA) as an adjunctive therapy in children with acute otitis media (AOM).³ Using a validated questionnaire, the Ear Treatment Guide-5 (ETG-5),⁴ we found that there was a modest reduction in symptoms of AOM in children randomized to the homeopathic ear drops in addition to standard treatment compared with those receiving standard

therapy alone. The reduction in symptoms in those receiving the ear drops was during the first 24 to 36 hours after the diagnosis of AOM.³ For children managed with the delayed antibiotic approach, this time period likely would correspond to the time during which parents were deciding whether or not to fill the antibiotic prescription they were given.

In our prior study on homeopathic ear drops, patients managed using both an immediate and a delayed antibiotic approach were enrolled.³ Of the 120 enrolled children, a delayed antibiotic approach was used in 30. Follow-up data were collected on 28 of these children, including 14 randomized to homeopathic ear drops. Of the 14 children receiving standard therapy alone, antibiotic prescriptions were filled for 5 (36%), similar to the fill rate found in previous studies on delayed antibiotics for AOM.^{5,6} Surprisingly, the antibiotic fill rate for participants randomized to homeopathic ear drops was only 14% (2/14). Because of the small number of participants

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in whom this approach was used, the difference in fill rates (36% vs 14%) was not statistically significant ($P = .12$). However, based on this result, we postulated that among children with AOM who were managed with a delayed antibiotic approach, the addition of homeopathic ear drops to standard therapy would reduce the proportion of prescriptions that were filled.

Methods

A randomized trial was conducted. Eligible study participants were children 6 months to 11 years old diagnosed with AOM by a pediatric practitioner who elected to manage the patient with a delayed antibiotic approach. Children who were suspected of having another bacterial illness such as pneumonia or who appeared “toxic” to the clinician and those with myringotomy tubes or a perforated tympanic membrane were not eligible. In addition, children who had received systemic antibiotic treatment within the previous 7 days or homeopathic treatment within the past 30 days were not enrolled.

Study participants were recruited from either the University of Washington Medical Center Roosevelt Pediatric Care Center or practices that are members of the Puget Sound Pediatric Research Network. All study participants were enrolled by on-site research assistants. As with other studies on the use of the delayed antibiotic approach, the diagnosis of AOM was based solely on the determination by the examining clinician. At all sites, when making the diagnosis of AOM, clinicians were advised to manage the patient as they thought was appropriate. If the diagnosing clinician determined that a delayed antibiotic approach was the appropriate management, he/she informed the parent about the study and asked if the parent would be interested in potentially participating. If so, the research assistant discussed the project with the parent, reviewed the eligibility criteria, and obtained written informed consent.

Data on demographic characteristics that might influence the parent’s decision to fill an antibiotic prescription were collected including the child’s age, presence of other siblings in the household, presence of smokers in the household, and use of daycare (>20 hours/week) for children <6 years old and/or attendance in school (for children ≥ 5 years old). At enrollment parents were asked to complete the ETG-5, which was developed to quantify the severity of symptoms of AOM in children.⁴ The severity of the following 5 AOM symptoms were rated: ear ache or tugging, fever, feeding, irritability, and sleep. For each symptom, the parent selected 1 of the 3 ratings of severity that was most appropriate for her/his child. These ratings were transformed to a numeric scale (0, 4, or 7), and the scores for all 5 symptoms were summed to provide an overall ETG-5 score that ranges from 0 to 35.

The examining clinician for each child confirmed that a delayed antibiotic approach had been recommended to manage the patient. The provider also indicated whether the parents had been given an antibiotic prescription to fill only if the child did not improve over the following 2 to 3 days or got worse, or had advised the parent to call the office for an antibiotic prescription using the same criteria.

After demographic and ETG-5 data were collected, the study participant was assigned a unique study ID number, which was assigned consecutively at each study site and had previously been randomly designated as being in either standard therapy plus the homeopathic ear drops treatment group or standard therapy alone treatment group. Randomization was performed using a computerized database; randomization was stratified by study site and in blocks of 4.

Parents whose children were randomized to the homeopathic ear drop group were given a small plastic bottle with a tip suitable for administering the study medication, “Hyland’s Earache Drops,” and were advised to administer 3 to 4 drops in the affected ear(s) up to 3 times/day as needed to relieve symptoms of AOM. The bottles were labeled specifically for the study without any commercial information. Standard therapy for both groups included all treatments recommended by the examining clinician including use of analgesics and directions on when to fill the antibiotic prescription.

Parents were informed that the purpose of the study was to assess the effectiveness of the homeopathic ear drops, but they were not told that the main outcome of the study was whether or not the delayed antibiotic prescription was filled. Parents were given a study logbook that they were asked to complete twice daily for 3 days. Items at each assessment included use of analgesics (including acetaminophen ibuprofen or antipyrene/benzocaine ear drops) and other symptoms experienced by their child, including vomiting, rash, diarrhea, “hyper” behavior, headache, and lethargy. Parents were asked to write in any additional symptoms that their child displayed. The parents were asked to return completed logbook by mail.

Parents were contacted by telephone 5 to 7 days, and 12 to 15 days after the initial visit. At each telephone contact the parent was asked whether the initial antibiotic prescription (given or promised) had been filled, if there had been additional contacts with health care providers, and if so, whether a new antibiotic had been prescribed at that encounter. In addition, parents verbally completed the ETG-5 questionnaire, at each follow-up phone call, and were questioned about any side effects in the study participant.

The primary study outcome was whether or not the antibiotic prescription for AOM was filled in the 15

days following the index visit, based on information obtained at the follow-up phone calls. Study participants were considered to have filled the prescription if the parent so indicated at either the 5- to 7-day or 12- to 15-day follow-up. Participants were classified as not having the antibiotic prescription filled if the parent so indicated at the 5- to 7-day and 12- to 15-day follow-up. If the parent could not be reached for the initial follow-up, but indicated that the prescription had not been filled at the 12- to 15-day follow-up, the prescription was classified as not filled. However, if the parent indicated at the 5- to 7-day follow-up that the prescription was not filled, but not reached for the 12- to 15-day follow-up, no determination regarding filling the prescription was made.

The secondary outcome was whether or not the participant received any antibiotics during the 12 to 15 days following the index visit, including either filling the original prescription or receiving another antibiotic prescription from a clinician during an additional encounter. Other outcomes included ETG-5 scores at the 5- to 7-day and 12- to 15-day follow-up, use of other analgesics, and reports of other symptoms (ie, adverse events).

An intention-to-treat analysis was used. Data on participants randomized to the homeopathic ear drop group were included regardless of whether or not any doses of the ear drops were administered. Prescription fill rates for antibiotics among those receiving homeopathic ear drops were compared with those receiving standard therapy alone using logistic regression; a similar procedure was used to compare the use of any antibiotics during the 12- to 15-day follow-up period. To assess possible confounding despite the randomized nature of the study, we assessed whether there were other measured variables that were statistically associated with filling the antibiotic prescription in bivariate analyses using logistic regression. A logistic regression model was used to assess the independent effect of the homeopathic ear drops in reducing antibiotic usage after controlling for variables statistically associated with filling the prescription in bivariate analyses.

ETG-5 scores in children randomized to the homeopathic ear drop or standard therapy alone groups were compared using Mann–Whitney tests. Logbook data were used to compare reports of adverse events and the use of analgesics between children in the 2 treatment groups. An adverse report was considered to have occurred if it was ever reported in the log books. Similarly, we classified a participant as receiving acetaminophen, ibuprofen, or antipyrene/benzocaine ear drops if it was reported at least once in the log books. Chi-squared tests were used to assess the statistical significance of differences.

We initially conducted a sample size analysis based on the difference in antibiotic fill rates that we observed in our previous study (14% in the homeopathic ear drop group vs 36% in those randomized to standard therapy). Based on these fill rates, a sample size of 150 was planned to provide a power of 0.8 to detect a difference between groups. After data had been collected on 148 study participants, the antibiotic fill rates in the homeopathic ear drop and standard therapy treatment groups were 26.7% and 39.7%, respectively ($P = .09$). Because this nonsignificant trend was suggestive of a difference, we elected to recruit participants over an additional 18 months in order to enroll up to 100 additional participants.

The study was approved by the University of Washington Institutional Review Board. Signed informed consent was obtained from parents of study participants; assent was obtained from study children who were ≥ 7 years old. The study was registered on clinicaltrials.gov (NCT01003210). Study data were collected between November 2009 and May 2013.

Results

A total of 210 participants were enrolled in the study, including 105 randomized to homeopathic ear drops in addition to standard therapy. Follow-up antibiotic data were collected on 206 children (98% of those enrolled); 104 of these were in the homeopathic ear drop treatment group and 102 were randomized to standard therapy alone. The demographic and clinical characteristics of these 206 study participants are summarized in Table 1. As can be seen in the table, there were no significant differences between the 2 treatment groups for most demographic variables. Participants in the ear drop treatment group were significantly less likely to be exposed to tobacco smoke than those receiving standard therapy alone, and there were significantly more girls randomized to the standard therapy group than to the homeopathic ear drop group. There were no significant differences between the groups in baseline ETG-5 scores or for the proportion of parents who were asked to call the practice if they wanted an antibiotic prescription for their child versus getting a prescription at the study visit.

Data on antibiotic usage during the 15-day period following the index visit where a diagnosis of AOM was made are shown in Table 2. As is shown in the table, significantly fewer parents of children randomized to the homeopathic ear drops group filled the antibiotic prescription compared with those of children receiving standard therapy alone (26.9% and 41.2%, respectively, $P = .032$). The odds ratio (OR) for filling the original antibiotic prescription among parents of children

Table 1. Characteristics of Study Participants on Whom Outcome Data Were Collected.

Characteristic	Homeopathic Ear Drops (n = 104)	Standard Therapy Alone (n = 102)	P Value
Female gender (%)	47 (45.2)	68 (66.7)	.002
Mean age, years (standard deviation)	3.9 (2.7)	4.1 (2.5)	.57
<2 years old (%)	32 (30.8)	23 (22.6)	.18
Passive exposure to tobacco smoke (%)	8 (7.7)	17 (16.7)	.047
Siblings in household (%)	60 (57.8)	72 (70.6)	.054
Mother is college graduate (%)	74 (71.2)	72 (72.7) ^a	.80
Attends school/day care >20 hours/week (%)	61 (58.7)	58 (56.0) ^b	.70
Mean baseline ETG-5 (standard deviation)	15.2 (6.4)	15.5 (7.2) ^c	.71 ^d
Call back for antibiotic prescription ^e (%)	12 (11.5)	16 (15.7)	.39

Abbreviation: ETG-5, Ear Treatment Guide–5.

^aData missing on 3 children in the no drops group.

^bData missing on 2 children in the no drops group.

^cData missing on 1 child in the no drops group and 3 children in the ear drops group.

^dP value calculated using Mann–Whitney test.

^eAs opposed to being given a prescription at the index visit.

Table 2. Use of Antibiotics in Children With AOM Randomized to Homeopathic Ear Drops in Addition to Standard Therapy or Standard Therapy Alone Within 15 Days of Diagnosis.

Outcome	Homeopathic Ear Drops (n = 104)	Standard Therapy Alone (n = 102)	OR (95% CI)	P Value
Filled original antibiotic prescription	28 (26.9%) ^a	42/102 (41.2%) ^a	0.53 (0.29, 0.95)	.032
Filled original prescription or received another antibiotic prescription	31 (29.8%) ^a	45 (44.1%) ^a	0.54 (0.30, 0.95)	.034
Filled antibiotic prescription by day 7 after diagnosis	23 (25.8%) ^b	37 (38.5%) ^b	0.55 (0.29, 1.03)	.062

Abbreviations: AOM, acute otitis media; OR, odds ratio; CI, confidence interval.

^aIncludes parents who called back for the antibiotic prescription or were given a prescription at the visit.

^bData collected on 89 participants randomized to homeopathic ear drops and 96 randomized to standard therapy alone.

randomized to the homeopathic ear drops, compared with parents of children receiving standard therapy alone, was 0.53 (95% confidence interval [CI] = 0.29, 0.95). During this same period, 2 children in the ear drop treatment group and 3 randomized to standard therapy alone had another visit with a health care provider at

Table 3. Association of Demographic and Clinical Characteristics With Filling Antibiotic Prescription for AOM in Study Children.

Characteristic	OR	95% CI
ETG-5 at baseline	1.06	1.01, 1.11
Having to call back for prescription ^a	0.28	0.094, 0.85
Child's age	1.04	0.93, 1.16
Female gender	1.86	1.02, 3.38
Smoker in household	1.96	0.84, 4.55
Daycare or school attendance	1.55	0.85, 2.81
Siblings in household	0.77	0.42, 1.39
Mother with college degree	1.07	0.56, 2.05

Abbreviations: AOM, acute otitis media; OR, odds ratio; CI, confidence interval; ETG-5, Ear Treatment Guide–5.

^aAs opposed to receiving a prescription at the visit, but being advised to not fill prescription unless child does not improve or gets worse.

which antibiotics were prescribed. When these numbers are added to the fill rate data, the use of any antibiotics within 15 days of the index visit was still significantly less among those receiving the homeopathic ear drops than among children in the standard therapy alone group.

To assess possible confounding, we assessed whether there were other measured variables that were statistically associated with filling the antibiotic prescription. These results are summarized in Table 3. A higher ETG-5 score at enrollment, indicative of more severe AOM symptoms, was associated with an increased fill rate ($P = .009$). In addition, parents who were instructed to call back for an antibiotic prescription were less likely to fill the prescription than those given a prescription at the index visit, but advised to not fill it unless the child's condition warranted ($P = .025$). Finally, the rate of filling antibiotic prescriptions was significantly lower for boy than girl patients ($P = .041$). None of the other variables assessed were statistically associated with antibiotic fill rate. In a regression model that included the confounders of baseline ETG-5 and having to call back for the antibiotic prescription, the adjusted OR for randomization to the homeopathic ear drop group was 0.54 (95% CI = 0.29, 1.00; $P = .050$). When gender was included in the model, the adjusted OR for assignment to the homeopathic ear drop treatment group was 0.60 (95% CI = 0.32, 1.13; $P = .11$).

Based on ETG-5 results, symptoms of AOM decreased substantially during the 15-day period following the index visit regardless of treatment group assignment. At the 5- to 7-day follow-up, ETG-5 data were collected from 84 parents of children randomized to the homeopathic ear drops and 91 parents of children receiving standard therapy alone. The mean ETG-5 scores were 4.6 ± 5.9 and 3.3 ± 4.4 , respectively ($P = .14$ after

Table 4. “Other Symptoms” Reported by Parents of Study Children in Logbooks by Treatment Group.

Symptom ^a	Homeopathic Ear Drop Group (n = 72)	Standard Therapy Alone Group (n = 78)	P Value
Vomit	4 (5.6%)	5 (6.4%)	.83
Rash	3 (4.2%)	11 (14.1%)	.03
Diarrhea	5 (6.9%)	6 (7.7%)	.86
“Hyper” behavior	6 (8.3%)	10 (12.8%)	.37
Headache	9 (12.5%)	10 (12.8%)	.95
Lethargy	15 (20.8%)	23 (26.5%)	.22
Any additional symptom	16 (22.2%)	23 (29.5%)	.31

^aAs indicated one or more times in the logbooks.

adjusting for baseline ETG-5 scores); in 92 children (53%) the ETG-5 score was 0. By the 12- to 15-day follow-up, ETG-5 scores were 0 in 146/200 children whose parents completed the questionnaire (73%); there were no differences in ETG-5 scores between those in the homeopathic ear drops or standard therapy alone groups (mean scores 2.0 ± 4.5 and 2.0 ± 3.8 , respectively, $P = .87$, after adjusting for baseline ETG-5).

Study logbooks were returned by parents of 150 of the 206 participants on whom outcome data were collected (72.8%), including 72 participants randomized to homeopathic ear drops and 78 who received standard therapy alone. In this subgroup of study participants, those who received homeopathic ear drops were significantly less likely to receive any ibuprofen than those randomized to standard therapy alone (20.8% and 37.2%, $P = .027$). No participant randomized to the homeopathic ear drop group received a dose of antipyrene/benzocaine ear drops versus 10.3% of those in the standard therapy treatment group ($P = .007$). There was no difference in use of acetaminophen between groups (44.4% and 51.3%, respectively, $P = .40$). Among the subgroup of children whose parents returned logbooks, the antibiotic fill rates were 26.4% in the homeopathic ear drop group and 38.5% in the standard therapy alone group (OR = 0.57, 95% CI = 0.29, 1.15; $P = .12$). Controlling for ibuprofen or antipyrene/benzocaine ear drop usage did not substantially change the ORs or statistical significance of differences in antibiotic prescription fill rates between children in the 2 treatment groups.

The presence of specific symptoms and “other symptoms” were also noted by parents twice daily in the study logbooks. The rates of these symptoms are summarized in Table 4. In general, rates of other symptoms were similar in the treatment groups; the rate of rash was statistically significantly higher in those randomized to

standard therapy alone than in those in the homeopathic ear drop treatment group. Among the additional symptoms noted by parents of children randomized to the homeopathic ear drops group, 1 child was reported to have decreased hearing and ear “popping,” 1 child was reported to have a “plugged” ear and redness around the ear was noted in 1 study participant. These symptoms were not noted in any child randomized to standard therapy alone. At the 5- to 7-day and 12- to 15-day telephone follow-up, parents of children in both treatment groups were asked about any side effects in their children. No serious adverse events were reported in either group.

Discussion

The provision of a commercially available homeopathic ear drop preparation to parents of children diagnosed with acute AOM and managed using a delayed antibiotic approach was associated with a significant reduction in antibiotic use in children compared with children managed with standard therapy alone, including analgesics. The fill rate for the antibiotic prescription given, or promised, at the index AOM visit, was reduced by 35%, or 14.3 percentage points, among those given the ear drops. Overall, the results of our study validate the recommendation in the AAP guidelines for the use of homeopathic ear drops as a viable method to manage symptoms of AOM in that they reduce antibiotic usage and this reduced use of antibiotics did not appear to prolong or increase AOM symptoms in children receiving the drops.^{1,2}

Given the high rates of prescribing antibiotics for AOM in children, even a modest reduction in the rate of filling the prescription would result in a substantial decrease in use of these medications. In 2005-2006, it was estimated that the rate of antibiotic prescriptions for AOM in the United States was 484 per 1000 children.⁷ There are, to our knowledge, limited data on the frequency of use of a delayed antibiotic approach by clinicians when diagnosing AOM. However, even if a delayed antibiotic approach is used in as few as 15% of cases of AOM, a reduction in the fill rate for the prescription from 41.2% to 26.9% (as we found with the use of homeopathic ear drops) would lead to more than 400 000 fewer courses of antibiotics in US children each year.^{7,8}

The fill rate for antibiotic prescriptions of 41.2% among those children randomized to the standard therapy alone treatment group is similar, or higher, than rates reported in other studies of the delayed antibiotic approach for AOM. Little et al conducted a randomized controlled trial of antibiotic usage in children with AOM managed with immediate or delayed antibiotic prescriptions.⁹

Among 150 children randomized to the delayed approach, antibiotic prescriptions were filled in only 24%. However, parents had to return to the clinic site to obtain the prescription. In our study, among 16 children in the standard therapy group whose parents were asked to call back for the antibiotic prescription (as opposed to receiving the prescription at the index visit), 4 prescriptions (25%) were filled. Spiro et al randomized children with AOM, seen in a pediatric emergency department, to be managed with an immediate or delayed antibiotic approach.⁶ Parents of patients randomized to delayed antibiotics were given a prescription that was valid for 3 days after the index encounter. The prescription fill rate for these patients was 38%, which is similar to the 38.5% of participants in our study, randomized to standard therapy alone, whose parents reported filling the antibiotic prescription at the 5- to 7-day follow-up. Siegel and colleagues conducted a prospective observational study on use of the delayed antibiotic approach.⁵ Among the 175 patients on whom data were collected, the antibiotic prescription that was given at the index visit for AOM was filled in 54 (31%). This fill rate was substantially lower than the rate we observed in children receiving standard therapy alone. In the study by Siegel et al, there were strict criteria for study entry that excluded children with significant AOM symptoms.⁵ In our project, the examining clinician determined if a delayed antibiotic approach was indicated based on her/his judgment. This difference in design may have led to the higher fill rate seen in our study.

Because homeopathic medications include extremely dilute concentrations of the specific remedies used, the efficacy of these medications is controversial. There are very limited data on the effectiveness of most homeopathic remedies, including medications to reduce symptoms of AOM in children. However, in addition to our previous study,³ Jacobs et al conducted a randomized controlled trial comparing the effectiveness of an individually prescribed homeopathic remedy, administered orally, to placebo in reducing symptoms in 75 children with AOM.¹⁰ Parents completed symptom diaries 3 times each day for 3 days after the study visit using a numeric scale for each measured symptom. Overall symptoms were decreased in those randomized to the homeopathic remedy compared with placebo recipients, with statistically significant differences noted at 24 hours and 64 hours after the index visit. Finally, recently using techniques such as transmission electron microscopy, investigators have identified nanoparticles of the source material even in extremely dilute homeopathic preparations, which might provide an explanation for the possible mechanism of action for these medications.¹¹ It is interesting to note that nanoparticles of

sulfur, one of the components of the homeopathic ear-drops used in this study, have been shown to have antimicrobial activity.¹²

It is possible that the decreased rate of filling antibiotic prescriptions by parents of children randomized to the homeopathic ear drop group was due to decreased AOM symptoms in these children from a direct effect of the homeopathic drops. It is equally possible that the reduced antibiotic prescription fill rate for children in this group was because of a placebo effect, particularly since the treatment groups were not blinded. It was not the goal of the study to rigorously assess the efficacy of homeopathic ear drops on symptoms, which could be done in a future placebo-controlled trial. Rather, our aim was more pragmatic: to determine if an inexpensive and safe intervention (homeopathic ear drops) could reduce antibiotic usage without leading to increased AOM symptomatology or adverse side effects.

It is important to note that the evidence supporting the efficacy of other, widely used, medications in reducing symptoms of AOM in children is limited. In one of the few studies done on the effectiveness of ibuprofen and acetaminophen in reducing symptoms, Bertin et al reported that parents reported greater relief of pain in children with AOM treated with ibuprofen than with placebo ($P < .01$).¹³ There was no significant difference in pain relief in children randomized to acetaminophen compared with placebo and there were no differences in other symptom outcomes (sleep, appetite, and activity) between any of the treatment groups. Similarly, the authors of a Cochrane review of the effectiveness of antipyrine/benzocaine ear drops concluded that there is limited evidence that topical anesthetic drops provide some pain relief in children >3 years old with AOM, but that the effects of these drops may be related to a placebo effect or a soothing effect of the drug vehicle rather than from the medication itself.¹⁴

Regardless of mechanism, our data suggest that homeopathic ear drops are a useful adjunctive treatment to reduce antibiotic usage in children with AOM who are managed with a delayed antibiotic approach. In an effort to promote the judicious use of antibiotics in children, clinicians who determine that a delayed antibiotic approach is the optimal management for a child with AOM should consider recommending homeopathic ear drops to parents.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Dr Jennifer Jacobs has served as a paid consultant to Standard Homeopathic Company. Dr Taylor has no financial disclosures or conflicts of interests related to this study.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The study was funded by Standard Homeopathic Company, Los Angeles, CA. Standard Homeopathic Company manufacturers the ear drops used in this study. Standard Homeopathic Company is also providing the publication fee.

References

1. American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. Diagnosis and management of acute otitis media. *Pediatrics*. 2004;113:1451-1465.
2. Lieberthal AS, Carroll AE, Chonmaitree T, et al. The diagnosis and management of acute otitis media. *Pediatrics*. 2013;131:e964-e999.
3. Taylor JA, Jacobs J. Homeopathic ear drops as an adjunct to standard therapy in children with acute otitis media. *Homeopathy*. 2011;100:109-115.
4. Friedman NR, McCormick DP, Pittman C, et al. Development of a practical tool for assessing the severity of acute otitis media. *Pediatr Infect Dis J*. 2006;25:101-107.
5. Siegel RM, Kiely M, Bien JP, et al. Treatment of otitis media with observation and a safety-net antibiotic prescription. *Pediatrics*. 2003;112:527-531.
6. Spiro DM, Tay K, Arnold DH, Dziura JD, Baker MD, Shapiro ED. Wait-and-see prescription for the treatment of acute otitis media: a randomized controlled trial. *JAMA*. 2006;296:1235-1241.
7. Grijalva CG, Nuorti JP, Griffin MR. Antibiotic prescription rates for acute respiratory tract infections in US ambulatory settings. *JAMA*. 2009;302:758-766.
8. ChildStats.gov. Forum on child and family statistics. POP1 child population: number of children (in millions) ages 0-17 in the United States by age, 1950-2012 and projected 2013-2050. <http://www.childstats.gov/americas-children/tables/pop1.asp>. Accessed October 31, 2013.
9. Little P, Gould C, Williamson I, Moore M, Warner G, Dunleavy J. Pragmatic randomised controlled trial of two prescribing strategies for childhood acute otitis media. *BMJ*. 2001;322:336-342.
10. Jacobs J, Springer DA, Crothers D. Homeopathic treatment of acute otitis media in children: a preliminary randomized placebo-controlled trial. *Pediatr Infect Dis J*. 2001;20:177-183.
11. Chikramane PS, Suresh AK, Bellare JR, Kane SG. Extreme homeopathic dilutions retain starting materials: a nanoparticulate perspective. *Homeopathy*. 2010;99:231-242.
12. Choudhury SR, Roy S, Goswami A, Basu S. Polyethylene glycol-stabilized sulphur nanoparticles: an effective antimicrobial agent against multidrug-resistant bacteria. *J Antimicrob Chemother*. 2012;67:1134-1137.
13. Bertin L, Pons G, d'Athis P, et al. A randomized, double-blind, multicentre controlled trial of ibuprofen versus acetaminophen and placebo for symptoms of acute otitis media in children. *Fundam Clin Pharmacol*. 1996;10:387-392.
14. Foxlee R, Johansson A, Wejfalk J, Dawkins J, Dooley L, Del Mar C. Topical analgesia for acute otitis media. *Cochrane Database Syst Rev*. 2006;(3):CD005657.