
Should Children With Otitis Media Be Treated With Antibiotics?

EBEM Commentator
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SYSTEMATIC REVIEW SOURCE

This is a systematic review abstract, a regular feature of the *Annals'* Evidence-Based Emergency Medicine (EBEM) series. Each features an abstract of a systematic review from the Cochrane Database of Systematic Reviews and a commentary by an emergency physician knowledgeable in the subject area.

The source for this systematic review abstract is: Glasziou PP, Del Mar CB, Sanders SL, Hayem M. Antibiotics for acute otitis media in children (Cochrane Review). In: *The Cochrane Library*. Issue 2. Chichester, United Kingdom: John Wiley & Sons, Ltd; 2004.

The *Annals'* EBEM editors prepared the abstract of this Cochrane systematic review as well as the Evidence-Based Medicine Teaching Points.

OBJECTIVE

To determine whether children with acute otitis media benefit from antibiotics.

DATA SOURCES

The authors searched both electronically and manually in Index Medicus (1958 to 1965), the Cochrane Controlled Trials Register (1966 to 2003), MEDLINE (1966 to 2003), Current Contents (1966 to 2000), and EMBASE (1990 to 2003) with the help of an expert librarian. References of all retrieved articles were reviewed. The search is considered updated to 2003.

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STUDY SELECTION

Randomized controlled clinical trials involving children with otitis media and comparing antibiotics versus placebo control were included.

DATA EXTRACTION

Methodological quality was appraised using rigorous criteria, which included assessment of randomization, degree of follow-up, and blinding. Disagreements were resolved by discussion; however, no measures of intra-observer agreement between assessors were provided. Data extracted were patient-oriented outcomes, namely severity and duration of pain, hearing problems, adverse effects, and recurrent attacks. For trials where intention-to-treat analysis was not used, where possible, this analysis was reconstructed for the review. For some results with low rates of occurrence, results were provided descriptively.

Because clinicians often have difficulties applying odds ratio (OR) results directly to their patients, for this analysis of the Cochrane review, number needed to treat and/or number needed to harm are reported. The calculation of number needed to treat and number needed to harm was completed using the summary data in the graphs and an online number-needed-to-treat calculator (<http://www.nntonline.net>), and includes 95% confidence intervals (CIs). For these computations, the control event rate was calculated by weighting the contributions of each individual study according to the weighting factors reported in the graphs. This method produces results that only approximate the actual exact treatment effect; however, the benefit to clinicians is a much better understanding of the summary measures. When the result was not statistically significant, the OR is reported. Whenever the OR result was significant, the number needed to treat/number needed to harm is reported.

MAIN RESULTS

Ten studies met inclusion criteria, and methodological quality was high, with all but 2 of the studies having the highest rating for allocation concealment. Of the 10 studies, 2 studies did not include patient-relevant outcomes and 2 had incomplete follow-up, but dropout rates in these studies were less than 10%.

Overall, 62% of patients in the placebo groups had no pain after 24 hours; between 2 and 7 days, this increased to

78%. Although antibiotics had no significant effect on pain at 24 hours (OR 1.03, 95% CI 0.76 to 1.39), at 2 to 7 days patients given antibiotics had less pain than patients given placebo (number needed to treat: 10, 95% CI 8 to 16). A L'Abbe plot of experimental event rate versus control event rate shows that the absolute benefit of antibiotics increases with the severity of disease, so the number needed to treat for sicker patients may be significantly less than 10.

Follow-up audiometry failed to identify a difference in hearing loss between treatment and placebo groups; however, this result was reported in only 2 studies and was reported incompletely. Antibiotics did not prevent relapse (OR 1.00, 95% CI 0.78 to 1.26), perforation (OR 0.51, 95% CI 0.20 to 1.26), or development of otitis media in the contralateral ear (OR 0.45, 95% CI 0.16 to 1.23). Adverse effects (vomiting, diarrhea, or rash) were more common in the antibiotic groups (number needed to harm: 8, 95% CI 5 to 23). In the included trials, one case of mastoiditis occurred in more than 2,000 children (rate=0.05%, 95% CI 0.0% to 0.15%), and this occurrence was in a patient treated with antibiotics. However, in a trial published in 1954 from Sweden, excluded because of significant methodological flaws, the baseline incidence of mastoiditis (17%, 95% CI 13% to 22%) was markedly higher, and penicillin and/or sulfonamides effectively prevented this complication (number needed to treat: 6, 95% CI 5

to 7; computed using an online calculator, <http://www.healthcare.ubc.ca/calc/clinsig.html>).

CONCLUSIONS

Antibiotics provide a small benefit for acute otitis media in children. Because most cases will resolve spontaneously, this benefit must be weighed against the possible adverse reactions, which occur at about the same rate as the benefit. However, sicker patients may have a greater benefit from antibiotics than other patients. Antibiotic treatment may play an important role in reducing the risk of mastoiditis in populations where it occurs frequently, but this disease occurred extremely rarely in the populations described in the included studies.

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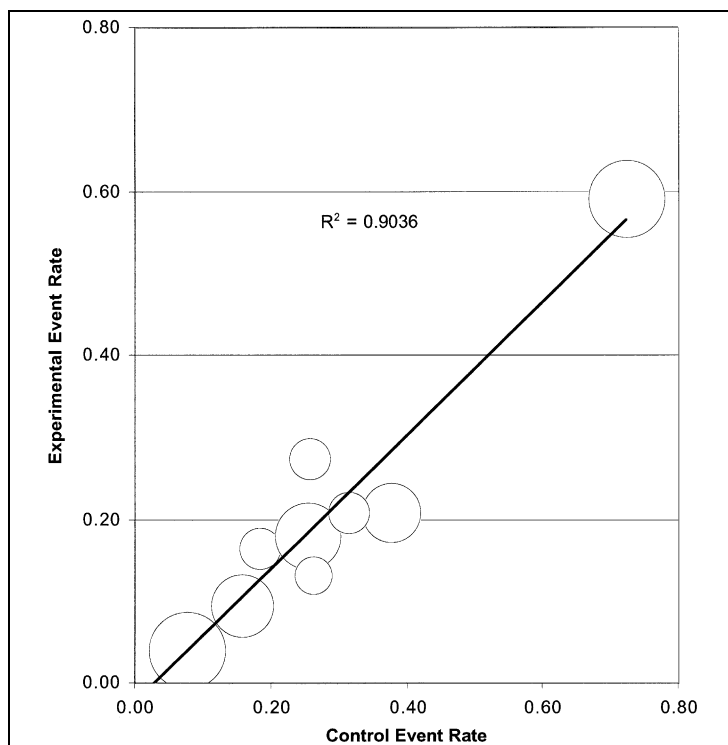
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COMMENTARY: CLINICAL IMPLICATION

Otitis media is a common diagnosis in emergency departments (EDs), clinics, and physicians' offices.¹

Figure.

L'Abbe plot for pain at 2 to 7 days. Glasziou PP, Del Mar CB, Sanders SL, et al. Antibiotics for acute otitis media in children (Cochrane Review). In: The Cochrane Library. Issue 2. Chichester, United Kingdom: John Wiley & Sons, Ltd; 2004. Copyright Cochrane Library, modified with permission.



Although tympanocentesis reveals bacterial pathogens in most cases of otitis media,^{1,2} it is largely a self-limited disease, and the vast majority of patients improve on their own, even without antibiotics.² Although the usual practice in North America is to prescribe antibiotics for otitis media, this is not the case in other parts of the world, particularly Europe. In other countries, parents are advised to give their children analgesics and return for re-evaluation and possible antibiotic prescription in 2 to 3 days if pain or fever persists² or are given the option of delayed antibiotic prescription after several days.^{3,4} There are now administrative data³ and clinical trial evidence⁴ that this approach reduces the use of antibiotics and is safe.

Possible advantages to delaying antibiotic therapy include reducing costs to patients and insurers, fewer side effects, and less emergence of antibiotic-resistant organisms in the patient and population as a whole.⁵ Despite these valid reasons to not prescribe antibiotics, they are still prescribed to most patients with otitis media in North America. Perhaps physicians feel more comfortable believing that they are doing "something" for the child who is crying, has a fever, and has physical examination findings suggestive of otitis media. Moreover, physicians often perceive that parents expect antibiotics will be prescribed for otitis media.⁶ Physicians may prescribe antibiotics in the belief that this will help lessen the risk of complications and possibly litigation. Finally, in the face of diagnostic uncertainty, many physicians err on the side of giving antibiotics.

The findings in this Cochrane Review give physicians support for an alternate approach to otitis media. In cases where the parents are agreeable, it may be reasonable for the emergency physician to provide an antibiotic prescription, then advise the parents not to fill it unless pain and/or fever persist for 2 days. This practice has resulted in a decreased use of antibiotics in children with acute otitis media, without significant adverse effects for the children.⁴ Physicians in clinics and private offices could do the same or agree to set aside an antibiotic prescription that could be picked up in 2 days with the same criteria.

The American Academy of Pediatrics and American Academy of Family Physicians recently published a clinical practice guideline recommending this approach in selected children older than 6 months.⁷ Some community physicians are already adopting this policy, and some parents of children with otitis media in the ED now accept this practice. Further research is required to determine the impact this approach will have on patient care in the future.

TAKE HOME MESSAGE

For most patients, antibiotics do not shorten the course of otitis media and can be safely withheld. Advantages of prescribing them are balanced almost equally with adverse effects. Antibiotics should be prescribed to children with prolonged duration of symptoms, failure of antipyretic treatment for 48 hours, and signs of toxicity. Attempts to reduce the use of antibiotics in milder forms of otitis media should be encouraged and evaluated.

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EVIDENCE - BASED MEDICINE TEACHING POINTS

L'Abbe plot. The L'Abbe plot is used for displaying results and investigating the potential sources of heterogeneity in a meta-analysis. Compared with other systematic review graphic presentations, the L'Abbe plot is useful to identify not only the studies having different results from other studies, but also the study arms that are responsible for such differences. The L'Abbe plot displays the outcomes in both the treatment and control groups of all included studies in the systematic review (Figure). The L'Abbe plot is different from Forrest and funnel plots, which are common graphical displays used in Cochrane reviews. The Forrest plot is a typical graphical display of the summary estimate and the 95% CI for each study with a summary/pooled estimate and 95% CI at the bottom of the graph. A funnel plot displays the relationship between effect size and sample size and helps determine the likelihood of selection bias in the meta-analysis.

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