
Antibiotic treatment of acute otitis media in children under two years of age: evidence based?

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Authors' objectives

To assess whether the current high prescription rates of antibiotics for acute otitis media (AOM) in children under two years of age (being a risk group for poor outcome) are based on an established increased efficacy.

Searching

MEDLINE (1966 to January 1997) and EMBASE (1974 to January 1997) were searched using the following keywords; otitis media, child, clinical trial, and placebo. The reference sections of these articles and of several major review articles were checked for further articles. An extensive handsearch for clinical trials of therapy for AOM in patients of all ages was performed by the authors' group in 1991 (see Other Publications of Related Interest).

Study selection

Study designs of evaluations included in the review

Articles with random allocation to the different treatment groups were included. Studies had to compare antibiotic treatment with non-antibiotic treatment in AOM (not comparison of different antibiotics or different durations of treatment).

Specific interventions included in the review

The following antibiotic treatments were included: ampicillin/penicillin-sulfa (+ myringotomy-A), penicillin, erythromycin, sulfonamide (+ myringotomy-A), amoxy/clav (+ myringotomy-B), amoxy/clav, amoxicillin. Controls were: placebo (+ myringotomy-A), placebo (+ myringotomy-B), placebo alone and symptomatic. Myringotomy-A was for bacterial culture only, and myringotomy-B was as part of treatment only (only half of the antibiotic group).

Participants included in the review

Children under two years of age with acute otitis media.

Outcomes assessed in the review

The outcome was symptomatic clinical improvement within seven days after the start of treatment. Otosopic appearance, middle ear effusion, or bacterial results were not considered as end points because they were presented infrequently in the available studies.

How were decisions on the relevance of primary studies made?

The authors do not state how the papers were selected for the review, or how many of the authors performed the selection.

Assessment of study quality

The quality of the studies was assessed using the scoring system proposed by Chalmers et al (see Other Publications of Related Interest). The items included in this method were divided into four main categories:

1. Study protocol (15 points).
2. Blinding procedures (30 points).
3. Testing procedures (15 points).
4. Statistical analysis (30 points).

The items "blinding of physicians and patients as to ongoing results" and "multiple looks considered" were not considered in the analysis because no interim analyses were performed in the relatively short-term AOM trials. The term "retrospective analysis" was not included because the authors thought it may be viewed as both a positive and negative aspect of a study. The term "blinding statistician" was not included in any study and thus not included in the assessment. As a consequence of excluding several items, the maximum possible score was 79 points. All studies were scored independently by the four authors. The papers were blinded by removing all identifying information prior to distribution to the four reviewers. A consensus meeting was held to discuss any disagreements on assessment after the initial scoring, with differences resolved by discussion.

Data extraction

The authors do not state how the data were extracted for the review, or how many of the authors performed the data extraction.

Methods of synthesis

How were the studies combined?

An estimate of the common odds ratio (with appropriate 95% confidence intervals) was computed using the Mantel-Haenszel approach (see Other Publications of Related Interest).

How were differences between studies investigated?

Tests for heterogeneity were not reported.

Sensitivity analyses were performed on studies with a methodological quality score of 60% or more, by excluding one study in which only non-severe episodes were included, and by excluding one study which reported strong positive results.

Results of the review

Six studies, comprising 832 patients under the age of two years were included.

The methodological quality of the six studies ranged from 27% to 73% of the maximum score. The studies published after 1981 scored better (range 60 to 73%) than those published earlier (range 27-43%).

Four individual studies reported, at short term, a statistically significant reduction in clinical failure, persistent effusion at two weeks, persistent bacterial growth (at 2-7 days), or otoscopic signs of AOM in favour of antibiotic treatment. Three studies mentioned long term results, and no differences were found between antibiotic therapy and placebo.

The authors were able to extract data for the quantitative analysis from four studies. Clinical improvement in the four studies included in the quantitative analysis was assessed after a period lasting from 24 hours to six days after the start of treatment. The common odds ratio of clinical improvement in patients treated with antibiotics, compared with the reference group was 1.31 (95% CI: 0.83, 2.08).

Restricting the quantitative analysis to studies with a methodological quality of 60% or more did not change the results (OR= 1.42; 95% CI: 0.85, 2.39). Exclusion of one study, in which only non-severe episodes were included, yielded an odds ratio of 1.10 (95% CI: 0.56, 2.15). Exclusion of one study with rather strong positive results, yielded an odds ratio of 1.20 (95% CI: 0.74, 1.94).

Authors' conclusions

The current high prescription rates of antibiotics among children under two years of age with acute otitis media are not sufficiently supported by evidence from published trials. New randomised placebo-controlled trials using reliable methodology are needed in this young age group.

CRD commentary

Inclusion criteria were reported and these were appropriate. The validity of included trials was adequately assessed. Sufficient details of the individual studies were presented.

The review question is not entirely appropriate, as the authors seem to be investigating whether antibiotics for AOM are effective, rather than whether or not there is an established increased efficacy.

A test for heterogeneity was not conducted before the studies were combined, however, a sensitivity analyses was performed. The authors note that the conclusion of their pooled analysis should be judged with caution because only four studies were involved and only two were truly placebo-controlled.

It may have been more appropriate to conclude that there was not enough evidence to judge whether or not the high prescription rates of antibiotics for children with AOM under two years of age is supported.

Implications of the review for practice and research

Practice: The authors do not state any implications for practice.

Research: The authors state that more randomised placebo-controlled trials using a reliable methodology are needed to assess the effects of antibiotic treatment for AOM in children aged under two years.

Bibliographic details

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Other publications of related interest

1. Chalmers TC, Smith H, Blackburn B, Silverman B, Schroeder B, Reitman D, et al. A method for assessing the quality of a randomized control trial. *Control Clin Trials* 1981;2:31-49. 2. Claessen JQ, Appelman CL, Touw-Otten FWMM, et al. A review of clinical trials regarding treatment of acute otitis media. *Clinical Otolaryngology* 1992;17:251-257. 3. Robins J, Greenland S, Breslow NE. A general estimator for the variance of the Mantel-Haenzel odds ratio. *American Journal of Epidemiology* 1986; 124:719-723.

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the reliability of the review and the conclusions drawn.