

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

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SUMMARY

Background. Appropriate use of antibiotics is one of the major issues in medicine today. In most countries, acute otitis media in children is treated with antibiotics; however, the efficacy of antibiotic use in every acute otitis media is a controversial issue. It may be worthwhile looking for special risk groups that benefit more from antibiotic treatment for acute otitis media. Children under two years of age with acute otitis media are at risk of poor outcome.

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

Method. Systematic literature review and a quantitative analysis with an assessment of the methodological quality of published trials, comparing antibiotic treatment with non-antibiotic treatment in acute otitis media in children aged under two years.

Results. Six trials were included. Trials from before 1981 had a poor methodological quality. Four were suitable for the quantitative analysis. Only two of them were truly placebo-controlled. Of these two, one included only recurrent acute otitis media and the other included only non-severe episodes. With these restricted data, no statistically significant difference was found between antibiotic-treated children and controls under two years of age with acute otitis media, judged on the basis of clinical improvement within seven days (common odds ratio = 1.31; 95% CI = 0.83–2.08).

Conclusion. 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. Few randomized placebo-controlled trials using reliable methodology are needed in this young age group.

Keywords: antibiotics; infants; acute otitis media; prescription rates.

Introduction

ALTHOUGH most children with acute otitis media (AOM) may need only symptomatic treatment, up to 86% of all episodes of the infection are treated with antibiotics.^{1,2} Two

recent meta-analyses on the effect of antibiotic treatment for AOM showed only a modest effect.^{3,4} Rosenfeld *et al* included 33 studies of children aged four weeks to 18 years, and the outcome of AOM was improved in only one in seven children treated with antibiotics.³ Del Mar *et al* included six studies of children aged seven months to 15 years and they found that 17 children needed to be treated to prevent pain in one child at 2–7 days after presentation.⁴ Currently, no studies have identified subcategories of patients with AOM in whom antibiotic treatment is more effective. Howie introduced the 'otitis prone' condition for children suffering six or more episodes of otitis media before the age of six.⁵ Of his 'otitis prone' patients, 91% had their first AOM episode during the first year of life. Appelman found, in his study of children with recurrent AOM, that those under two years of age were more likely to follow an abnormal course of illness, defined as pain and/or fever after three days.⁶ Other authors report a higher recurrence rate and a higher rate of persistent middle ear effusion (MEE) in this age group.^{7–10} This is probably the reason why antibiotic therapy is prescribed more often in children under two years with AOM than in older children.² Whether this strategy is justified by an established increased efficacy is not known.

We systematically reviewed the available literature to determine the efficacy of antibiotic treatment for AOM in children under two years of age.

Method

We carried out a computer search using MEDLINE on articles published between 1966 and January 1997, and using EMBASE from 1974 until January 1997, using the following keywords: otitis media, child, clinical trial, and placebo. In addition, the reference sections of these articles, and of several major review articles, were checked for missing trials meeting the inclusion criteria. Furthermore, an extensive hand search for clinical trials of therapy for AOM in patients of all ages, performed by our group in 1991, was used.¹¹ An article was included when the following criteria were met:

- Random allocation to the different treatment groups.
- Comparison of antibiotic treatment with non-antibiotic treatment in AOM (not comparison of different antibiotics or different durations of treatment).
- Inclusion of children aged under two years, with separate presentation of the results for these young children.

The quality of the studies was assessed using the scoring system proposed by Chalmers *et al*.¹² The items included in this method are divided in four main categories (Box 1):

1. study protocol,
2. blinding procedures,
3. testing procedures, and
4. statistical analysis.

The items 'blinding of physicians and patients as to ongoing results' and 'multiple looks considered' were not considered in our analysis because no interim analyses were performed in the relatively short-term AOM trials. Because 'retrospective analysis' may be viewed as both a positive and a negative aspect of a

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Evidence Based Otitis Media

Mr. Rohit Manglik

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