

Antibiotics for Acute Otitis Media in Infancy: Based on Fear or on Facts?

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Abstract

Acute otitis media is treated in the majority of cases with antibiotics. The evidence that antibiotics are of little value for this common childhood illness is increasing. Even for infants with acute otitis media, the efficacy of these drugs seems to be limited. And since antibiotics are certainly not harmless, their use should be questioned. This paper points out that watchful waiting is a safe policy for acute otitis media for most infants.

Key words: Acute otitis media – Antibiotics – Infancy

Introduction

In most countries it is recommended that episodes of acute otitis media (AOM) should be treated with antibiotics^{1,2}, although there is an increasing call for restricting their use³⁻⁵. The restriction is meant mainly for children over 2 years, since the effectiveness of antibiotics for these children appears to be limited^{6,7}. For children under 2 years, in general antibiotics are still strongly recommended, mainly because of the increased risk of poor outcomes in these young children, although until recently there was no proper evidence of the effectiveness of antibiotics at this age⁸. A recent trial that included children aged 6 months to 2 years has shown the limited effectiveness of antibiotics for AOM⁹. The question then arises as to whether one trial is enough to take away the fear of not treating AOM in infancy initially with antibiotics. In the Netherlands this is already the policy and the outcome of episodes of AOM does not seem to be any worse compared with other countries¹⁰. This paper points out what happens in practice in the Netherlands concerning the management of AOM, and further considers the reasons why antibiotics could be given and what the evidence is.

The Dutch Situation

In the Netherlands AOM is normally treated in general practice¹¹. The first guidelines (1990) of the

Dutch College of General Practitioners for the management of this common childhood malady divided children into three groups by age: under 6 months, between 6 months and 2 years, and over 2 years¹².

For those older than 2 years, symptomatic treatment and watchful waiting for 3 days was recommended, with antibiotics if symptoms persisted for more than 3 days. Van Buchem et al. estimated that in a general practice population more than 90% of such older children with AOM recovered within 3 days simply with symptomatic treatment (nose drops and analgesics)¹³. A severe course (persistent illness with severe pain or high temperature, or both, after 3–4 days) was estimated to occur in fewer than 3% of cases, and these children responded well to antibiotics. These findings justify this policy for children aged over 2 years.

For children aged under 6 months, antibiotics were recommended at the first visit (together with close monitoring) and consideration was even given to immediate referral. These recommendations were based on consensus opinion and the high risk of complications¹².

For children aged between 6 months and 2 years the early guidelines recommended watchful waiting for 24 hours and antibiotics if there was no improvement in that time. The reason for the more intensive monitoring of this group was the higher risk of

Table 1. Summary of the revised guideline of the Dutch College of General Practitioners on acute otitis media

| Age | Diagnosis | Management | Indication for antibiotics | Agent of first choice |
|----------------|-------------------|-------------|---|-----------------------|
| (a) < 6 months | History, otoscopy | Antibiotics | | Amoxicillin |
| (b) > 6 months | History, otoscopy | Symptomatic | Risk groups*, abnormal course: earache or fever lasting more than 3 days, or more than 14 days' otorrhoea | Amoxicillin |

*Riskgroups:

Patients with recurrent otitis media
Patients with ENT malformations
Patients with immunodeficiencies

complications, such as bacteraemia and dehydration, compared with older children¹². The revised guidelines (1999) no longer distinguish this age group separately from the older children¹⁴ (Table 1).

In a nationwide study of 161 general practices, it was shown that an antimicrobial was prescribed in only one quarter of the patients with AOM. The youngest patients did not receive antibiotics any more often¹⁵. In an international comparative study of AOM, the Netherlands showed the lowest prescription rate for antibiotics with 30% vs. 85–98% for Israel, UK, Australia and the USA¹⁰. The outcome of episodes of AOM does not seem to be any worse compared with other countries.

In a qualitative study in the Netherlands, reasons, other than those stated in the guidelines of the Dutch College of General Practitioners on AOM, for prescribing antibiotics for this common childhood disease were explored. Seventy antibiotic prescriptions for AOM, prescribed by 22 Dutch general practitioners, were evaluated to see whether they followed the guidelines on AOM of the Dutch College of General Practitioners. In total 77% of these prescriptions did not follow the guidelines on AOM. Forty-two of them were discussed in stimulated recall interviews with the GPs regarding their prescribing behaviour of antibiotics for AOM. Medical reasons (e.g. severity of illness at the first contact) for prescribing antibiotics were mentioned most often for non-guideline-based antibiotic prescriptions; however, in a substantial number of cases, doctors gave non-medical reasons as well¹⁶. It was remarkable that, despite the existing guidelines, which are well accepted by Dutch GPs¹⁷, 77% of the antibiotic prescriptions did not conform! The process of prescribing is an interaction between the doctor and the patient, and many reasons for prescribing, objective as well as subjective, can be found. Because of the complexity of this process, guidelines will never be able to control this behaviour completely. In 1993 Kassirer asked, 'If guidelines do become rules, can they be sufficiently detailed to cover the myriad clinical variations

among patients?'¹⁸ Guidelines, instead, should be of help in choosing the best treatment, but each individual case needs to be judged as such. The value of guidelines in the process of rational antibiotic prescribing in general practice should not be overestimated.

The differences among countries can be explained by transcultural differences in health care and payment systems, and in different opinions concerning health and disease¹⁹.

Antibiotic Treatment of an Episode of Acute Otitis Media in Infancy

In order to answer the question of whether children under 2 years of age with AOM need to be treated with antibiotics, we should first consider the reasons for giving antibiotics and how efficacious they are. We should also take into account their potential adverse effects.

Reduction of symptoms could be a reason for giving antibiotics but until now little evidence has been available that they achieve this in this age group⁸. Our study showed only a modest effect of antibiotics on symptoms. Seven to eight children needed to be treated in order to improve the symptomatic outcome in one at day 4, and the duration of fever was reduced by only one day⁹. Antibiotics, therefore, cannot be recommended routinely for relief of symptoms.

A second reason for prescribing antibiotics is the eradication of micro-organisms. Howie and Ploussard²⁰ showed in the early 1970s that antibiotics were highly effective in eradicating bacteria. The correlation between bacteriological outcome (based on the demonstration of the eradication of a pathogen on repeat tympanocentesis) and clinical outcome based on the resolution of symptoms and signs in general, is poor^{21,22}. A recent study in children aged 3–24 months, with a positive middle-ear fluid culture, reported that those in whom the bacteria were

eradicated had a better clinical outcome, and the conclusion was that a subset of patients with AOM clearly benefits from antibiotic treatment²³. But all children received antibiotics at entry and effective eradication of the pathogens could not be predicted. Furthermore, it is still impossible to identify bacteria in middle ear fluid at the first visit since a culture result will take at least some days. And even if, in the near future, it becomes possible to identify bacteria at such an early stage, it is doubtful whether all children in primary care should be subjected to tympanocentesis. Finally, it should be mentioned that in this latter study most patients improved regardless of the bacteriological outcome.

Complications

Rosenfeld and Bluestone²⁴ said that preventing complications is the primary purpose of antimicrobial therapy for AOM. They attribute the decline of acute mastoiditis since the 1940s (from 20% to a current rate of < 0.1%) to the introduction of antibiotics. Rudberg²⁵ showed in 1954 a reduction of 17% in clinical mastoiditis in a group treated with penicillin compared with controls, but in the Netherlands, where most episodes of AOM were not treated with antibiotics, a similar drastic decline of the incidence of acute mastoiditis has been seen. There must be other causes. One could consider the overall improvement in physical health and environmental conditions, and the variation in the pathogenicity and epidemiology of the causative bacteria²⁶. Since the incidence of acute mastoiditis in the Netherlands is very low in spite of the restricted use of antibiotics for AOM, prevention of mastoiditis cannot be an argument for routine use of antibiotics for AOM.

Another very rare complication of AOM is meningitis. In our study we saw one case of meningitis in the placebo group⁹ but when meningitis was diagnosed on the third day, the child was already on oral antibiotics, and a recent review showed that oral antibiotics do not prevent meningitis²⁷. Close monitoring for deterioration, and proper treatment, is probably more effective²⁸.

Another reason for prescribing antibiotics is to prevent recurrent AOM or persistent middle-ear effusion. In placebo-controlled studies, antibiotics had no effect on these sequelae^{9,29–31}.

In summary, the effectiveness of antibiotics for AOM in children aged 6–24 months is limited as far as all the outcomes discussed are concerned. If we also take into account the adverse effects of antibiotics (diarrhoea, vomiting, allergic reactions) and the increasing problem of resistance of microbes world-wide, then watchful waiting at the first visit of these children should be recommended,

as in the revised guidelines of the Dutch College of General Practitioners¹⁴. Although complications, such as mastoiditis or meningitis, are rare, close monitoring for deterioration should be discussed with the parents.

Persisting Symptoms

What if symptoms persist? A recent paper reported that 50% of the children under two years of age had symptoms lasting for more than 8 days, and that this was not influenced by the use of antibiotics³². Therefore persistence of symptoms beyond 3 days is not a good criterion for starting antibiotic therapy in this age group, as is recommended by the Dutch College guidelines. Perhaps children with AOM who are 'toxic', severely ill, or who have high fever, benefit more from antibiotics, as Kaleida *et al.*³⁰ have shown in their study in older children with severe infection (severity was based on fever and otalgia score). In clinical practice we have found that severity of illness at the first contact was a frequent reason for prescribing antibiotics in children of all ages¹⁶. A good definition of severity, with clinical (and, perhaps, laboratory findings) at the first visit that predicts outcome, is needed to identify a subgroup that may benefit much more from antibiotics.

Conclusion

Children aged 6–24 months with AOM can initially be managed by watchful waiting. Parents can be told how long symptoms are likely to persist and that this duration is not influenced by antibiotics. More emphasis should be laid on proper relief of symptoms, mainly by analgesics.

The question arises as to whether antibiotics are completely obsolete for AOM. In daily practice we found that severity of the disease was a reason for prescribing antibiotics in children of all ages. There is no evidence that infants who are 'toxic', have high fever and are severely ill, benefit significantly more from antibiotics. A doctor faced with such a case should weigh the benefits of antibiotics against the adverse effects, and, when such a child has to be managed, may choose to play safe by prescribing an antibiotic. This cannot be regarded as malpractice. In spite of all the evidence from clinical trials, doctors treat individuals and not populations. It has previously been reported that non-medical reasons underlie doctors' prescribing of antibiotics^{16,33}. Doctors should be made aware of this phenomenon and discuss their thoughts with parents and then take the decision as to whether or not to prescribe an antibiotic.

Furthermore, children should be watched carefully for deterioration of their condition or development

of complications. When complications (mastoiditis, meningitis) arise, the child should be referred to a paediatrician or an ENT specialist. The decision on whether or not to prescribe an antibiotic should not be guided by fear, but by good clinical reasoning.

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