



Acute otitis media: To follow-up or treat?

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ABSTRACT

Acute otitis media (AOM) is the most common diagnosis for which antibiotics are prescribed in children. However, due to their widespread use, we are witnesses to increased development of bacterial resistance to antibiotics. The purpose of this study was to evaluate the necessity of antibiotic treatment in patients with AOM. Our study included 314 children, aged between 2 months and 6 years. Children were divided into two groups: the first group included children with less severe forms of AOM, who received symptomatic therapy and “wait-and-see” approach (237 children); the second group presented with purulent ear infection and received antibiotic treatment from the beginning (77 children). After symptomatic therapy, resolution of the disease, without use of any antibiotics, was established in 61% of patients, compared to the overall sample of children with AOM. None of the children developed complications that would require surgical treatment. In the second group of children, receiving antibiotics, almost the same therapeutic effects (80%) were achieved with the use of amoxicillin, amoxicillin-clavulanate and cefixime, while the worst results were obtained after using azithromycin.

The wait-and-see approach is recommended in forms of AOM without serious signs and symptoms, because it significantly reduces the use of antibiotics and their potential adverse effects.

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1. Introduction

More than 70% of children under 2 years of age experience at least one episode of acute otitis media (AOM), which is the most common diagnosis for which antibiotics are prescribed in children [1–3]. Although numerous guidelines are available, antibiotic treatment of AOM is still controversial. Apart from their potential benefits, their common adverse effects (rash, abdominal pain, diarrhea, vomiting and, fungal infections), should always be considered, as well as increased treatment costs and multi-bacterial resistance [4,5]. Therefore, it is necessary to revise the list of conditions that require antibiotic therapy. Therapeutic approach to AOM, in which antibiotic treatment was optional, has been evaluated in several trials. In these studies, the complication rates were similar in the antibiotic treatment group and symptomatic treatment group [6–9]. Avoiding initial antibiotic therapy and wait-and-see approach (for up to 72 h) followed by eventual initiation of antibiotics for AOM is confirmed by a cohort study from Netherlands which included 4.860 children aged between 2 and 12 years. The study has confirmed that a three-day follow-up of children with AOM is safe, but at the same time *a priori* rejection of antibiotic therapy of AOM may be dangerous: one child from this study did not receive antibiotics after a 72-h period of observation,

in spite of worsening of otoscopic finding, and developed mastoiditis [10]. Besides the above mentioned, it is hard to crack the physicians' prejudice and accept that a large number of children with AOM can be treated with analgesics alone.

The aim of this study was to analyze the efficacy of wait-and-see approach in children with AOM until complete resolution or until delayed initiation of antibiotic therapy, as well as to analyze the efficacy of the applied antibiotics.

2. Patients and methods

The study protocol was approved by the Local Ethics Committee. This prospective study was performed during the period from January 2008 to May 2009, and analyzed children diagnosed with AOM based on recommendations of the Subcommittee on Management of Acute Otitis Media, American Academy of Pediatrics and Good Clinical Practice Guidelines of the Ministry of Health of the Republic of Serbia [11,12]. The study included all children diagnosed with AOM during the above-mentioned period, excluding children with concomitant pneumonia, bronchitis or acute tonsillitis. All children were followed-up under identical conditions, regardless whether antibiotic therapy or wait-and-see approach was used. Follow-up examinations were initially performed after 72 h (more often or on daily basis, if necessary), and afterwards, depending on recovery, weekly or monthly. If AOM was accompanied with pain, analgesics were administered (Ibuprofen and Paracetamol). Antihistamines, secretolytics and

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local decongestants were not prescribed. All parents were informed in detail about reasons for performing one of the two treatment modalities. Wait-and-see approach was used in children who had at least one of the following findings: redness of malleolar folds or of the whole tympanic membrane without strain, and body temperature up to 38.5 °C. In children with positive findings of purulent ear infection, evident secretion within the middle ear cavity and/or strain of tympanic membrane, elevated body temperature (above 38.5 °C), antibiotic treatment was administered. If the body temperature was above 38.5 °C at the control examination, otoscopic findings aggravated or children complained of prolonged ear pain, an antibiotic was introduced, while continued wait-and-see approach was used in cases when local findings were unchanged or improved. In the group of children receiving antibiotics from the beginning, the follow-up was also performed after 72 h. In cases with impaired otoscopic findings or prolonged pain, the antibiotic was replaced, while in children with improved condition antibiotic therapy was continued for a total of 10 days. The above-described treatment was conducted regardless of the age of children (even in children up to 6 month of age). Amoxicillin was used in doses of 80–90 mg/kg, amoxicillin-clavulanate in doses of 80–90 mg/kg of amoxicillin and 6.4 mg/kg of clavulanate. We used 10 mg/kg of Azithromycin on the day 1, followed by 5 mg/kg up to day 10, while Cefixime was prescribed in doses of 8 mg/kg for 10 days. The treatment efficacy criteria were as follows: appearance of the tympanic membranes, presence of pain, evaluation of general symptoms, and data on child's behavior and suspected hearing loss obtained from parents. Tympanometric follow-up was regular in all children with frequent AOM or in children with purulent AOM, as well as in all children with suspected or unclear exudative otitis media (EOM).

3. Results

The study included 314 children diagnosed with AOM. Children were 2 months to 6 years of age. Informed consent was obtained from parents of all children included in the study regardless of the choice of treatment. Out of the total number of children, 237 (76%) were observed for 72 h and underwent symptomatic treatment, while 77 (24%) received antibiotic therapy from the beginning.

Out of 237 children in the wait-and-see group, spontaneous resolution was established in 191 (81%) children, while 46 (19%) children required initiation of antibiotic therapy. Therefore, compared to the whole sample of 314 children, spontaneous resolution without use of antibiotics was observed in 191 patients (61%), while antibiotics were used in 123 children (39%) (Fig. 1).

Out of 123 children treated with antibiotics, complete resolution was obtained in 77 (63%), while 46 (37%) children experienced a relapse of AOM with three or more ear inflammation episodes, or recurrent – exudative otitis media (EOM). Nine children had from 3 to 11 AOM episodes within the mentioned period, with fast recovery and without signs of EOM, with normal tympanometric findings, while 25 children had EOM in shorter and longer periods, but with eventual recovery and subsequent normal tympanometric findings. Twelve children or approximately 4% of all examined children included in the study, presented with recurrent EOM and underwent surgery (myringotomy and ventilation tube insertion with adenoidectomy).

Treatment effects of 238 AOM in 123 children receiving antibiotics (some children had recurrent ear inflammations) were analyzed based on the antibiotics that were used (Fig. 2).

In 125 cases of AOM, amoxicillin was the antibiotic used from the beginning. A satisfying therapeutic effect was achieved in 111 (89%) of cases, while in 14 (11%) children there was no

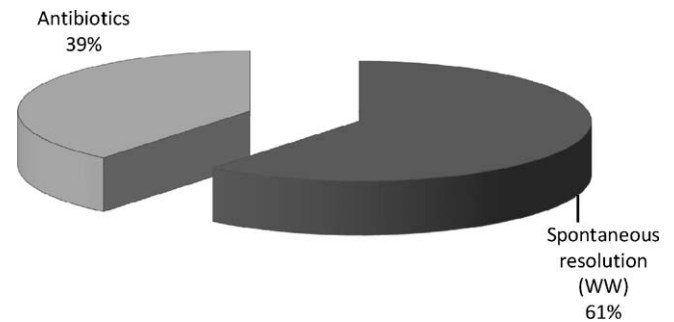


Fig. 1. Resolution of AOM after delayed administration of antibiotics and wait-and-see approach.

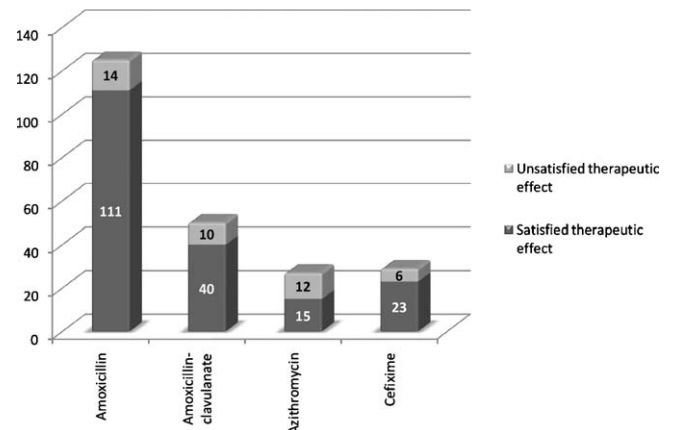


Fig. 2. Efficacy assessment of the antibiotic treatment of AOM.

improvement 72 h after initiation of therapy and therefore it was replaced with another antibiotic.

Amoxicillin-clavulanate was the treatment of choice for 50 out of 238 treated AOM cases (21%). Out of 80% of cases, a satisfactory effect was achieved in 68% of cases receiving antibiotics, from the beginning, and in 12% of cases receiving a second line antibiotic. In 10 cases (20%), it was replaced by another antibiotic, due to poor therapeutic effects. Diarrhea occurred in five children, and it was not the cause for replacing the antibiotic.

Out of 238 cases of AOM, 27 received azithromycin and satisfactory effects were obtained in 15 cases or 56% (in 37% of cases it was the initial antibiotic, and in 19% it was the second line antibiotic). In 12 cases (44%) it was replaced by another antibiotic due to poor therapeutic effects. In one child, it was replaced due to rash.

Cefixime was prescribed in 29 (12%) of cases. Satisfactory effects were achieved in 79% of cases (in 10% of cases it was the initial antibiotic, and in 69% of cases it was the second line antibiotic), while in six cases of AOM (21%) it was replaced by another antibiotic due to inefficiency.

4. Discussion

The use of antibiotics in the treatment of AOM is recommended by Guidelines for Good Clinical Practice, although wait-and-see approach is proposed as an alternative. Disparity in attitudes concerning initiation of antibiotic treatment, time of initiation and duration of therapy is resulting from differences between the traditional opinion that antibiotics are necessary in the treatment of any AOM, in order to prevent complications on the one hand, and more liberal opinion, that most of simple AOM resolve spontaneously using symptomatic therapy and without any risk of serious

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