

# Is Amoxicillin Effective in Treatment of Acute Otitis Media in Routine Outpatient Practice?

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## ABSTRACT

**Aim and objective:** To evaluate the effectiveness of low-dose amoxicillin in otitis media.

**Materials and methods:** All children presenting to our outpatient clinic with signs and symptoms suggestive of otitis media and need of antibiotics according to AAP criteria were enrolled.

**Intervention:** A 10-day course of oral amoxicillin at 40 mg/kg/day in three divided doses.

**Main outcome:** Symptomatic relief after 48 hours and normal tympanic membrane at the end of therapy.

**Results:** There were 201 cases. One hundred and sixty-one out of these completed a 10-day course of amoxicillin. One hundred and forty-six (90.68%, 95% CI 86.17–95.18%) responded to amoxicillin. On follow-up of these 67.44% had normal tympanic membrane whereas 33.56% had persistent middle ear fluid.

**Conclusion:** Amoxicillin remains the first-line therapy in the treatment of acute otitis media (AOM) in children.

**Keywords:** Acute otitis, Amoxicillin, Antibiotics, Effectivity.

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## INTRODUCTION

Acute otitis media (AOM) is a very common pediatric problem and a common reason for an antibiotic prescription. The bacteria causing AOM are acquiring resistance to commonly used antibiotics. Various guidelines recommend “wait and watch approach” or amoxicillin in different dose for the treatment of AOM.<sup>1</sup>

Age-wise recommendations and antibiotic usage are mentioned in tabular form (Table 1).<sup>2</sup>

In fact, drug of choice for AOM in some epidemiological situations [high level of drug resistance streptococcus pneumonia (DRSP)] is either high-dose amoxicillin (80 mg/kg/day) or amoxicillin with clavulanate combination.<sup>3</sup> Drug resistance streptococcus pneumonia is increasingly found even from India.<sup>4,5</sup>

Although the data about the effectiveness of low-dose amoxicillin in the treatment of AOM are available from various developed countries, there are no studies as to the effectiveness of amoxicillin in AOM from India.

In this clinic-based study, we aimed to find out the effectiveness of low-dose (40–50 mg/kg/day) amoxicillin in AOM.

## MATERIALS AND METHODS

### Type of Study

Prospective observation case-control study.

### Statistical Analysis

In the descriptive analysis, quantitative data were described with means, standard deviation, and qualitative data were described with number and percentage. Standard statistical methods were used for analysis.

Sample size calculation for minimal sample size: with expected efficacy of 90% ( $p$ ) to be predicted with 95% confidence ( $u$ ) and 5% level of precision (margin of error) ( $b$ ) and unlimited population, the sample size was calculated by the following formula.

$$n = z^2 \times \frac{p(1-p)}{b^2}$$

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Where  $z$  value for 95% confidence was 1.96 we got a sample size of 138.

Assuming ~20% loss to follow-up the total sample size was 156 patients.

The study was done at Jupiter hospital outpatient for a period of 1 year from June 2016 to June 2017.

Ethical committee approval was taken. Informed consent was taken from the caretakers. Assent was obtained from patients above 8 years old.

Patients, >6 months of age, coming to the outpatient department for various complaints were enrolled if they had evidence of AOM.

Red bulging tympanic membrane or presence of middle ear fluid with evidence of inflammation in form of fever and pain was taken as evidence of AOM. The decision to treat with antibiotics were made according to AAP guidelines on the treatment of AOM.<sup>6</sup>

Patients were prescribed 40 mg/kg/day of amoxicillin for 10 days. Those who were already on some other antibiotic or who had taken amoxicillin in the previous 30 days were excluded.

They were asked to follow up if there was no response in symptoms any time after 48 hours or after 10 days to check for complete resolution.

Persistent or worsening of the symptoms after 48 hours was taken as amoxicillin failure.

The otoscopy was done at the end of the treatment to note the presence of middle ear fluid.

The data were entered in a Microsoft Excel sheet.

**RESULTS**

Out of 201 enrolled patients, 161 completed 10 days of treatment and follow-up or had shown non-response after 48–72 hours of amoxicillin (Flowchart 1). There was male preponderance ( $n = 91$ ).

**Table 1:** Age-wise antibiotic recommendations for treatment of acute otitis media

Age	Clinical characteristics of otitis media	Recommendation
>6 months old	Severe* either unilateral or bilateral	Treat with 10-day course of antibiotics
6–23 months	Non-severe otitis media if bilateral	Treat with antibiotics
6–23 months	Unilateral non-severe	Joint decision with parents about wait and watch approach Treat if clinical worsening or does not improve after 48–72 hours
24 months or more	Non-severe bilateral	Same wait and watch approach as above To treat if clinical worsening or non-improvement in 48–72 hours

\*Severe signs or symptoms including moderate or severe otalgia or otalgia >48 hours or temperature >39°C

The average age was 3.7415 years (SD 0.314, range 6 months–15 years). Sixty-six patients (40.99%) had bilateral ear involvement. One hundred and thirty patients (80.74%) had completed vaccination according to UPI.

Of these, 146 (90.68%, 95% CI 86.17–95.18) responded to amoxicillin. Fifteen patients did not respond to amoxicillin. The average time before the change in antibiotic was 5.6 days with the median at 3 days.

66.44% ( $n = 97$ ) had normal ears on otoscopy follow-up on tenth day, whereas 33.56% ( $n = 49$ ) had OME on follow-up.

**DISCUSSION**

In this study, we wanted to document the clinical effectiveness of amoxicillin in the treatment of otitis media.

There is perceived drug resistance to amoxicillin in AOM. A study reported 85% of pediatricians to prescribe co-amoxicillin clavulanate for the treatment of AOM and only 15% used amoxicillin.<sup>7</sup>

Also, a recent meta-analysis has reported 15% of isolates from otitis media were resistant to amoxicillin.<sup>8</sup>

In our study, the effectiveness of amoxicillin was >90%. The study was “non-regimental”, i.e., patients were asked to follow-up if there was no response in symptoms after 48 hours or after 10 days to check for complete resolution. The partial initial response may have delayed follow-up visits in some patients explaining a longer average duration of 5.6 days before antibiotics were deemed ineffective.

Findings of OME in 31.49% of patients is not an indication of treatment ineffectiveness. This observation is similar to the reported incidence of OME even when co-amoxicillin-clavulanate was used for the treatment.<sup>9</sup>

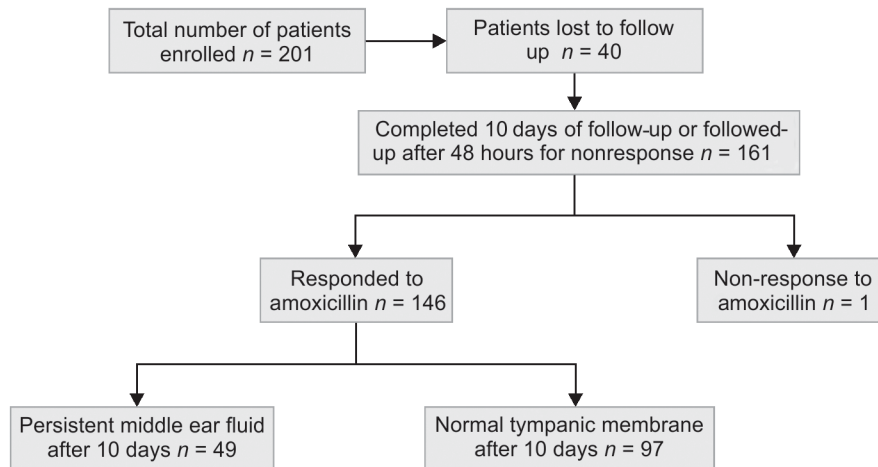
Limitations of our study include being a single-center study.

**CONCLUSION**

Amoxicillin in low dose was effective in >90% of children presenting with AOM in clinical practice.

Perceived resistance to amoxicillin is not commonly seen in day-to-day practice.

**Flowchart 1:** Flow diagram of the study



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