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## SENIORS

# Antibiotic Rx of AOM in Children <2 Years: Redux

**Source:** Hoberman A, Paradise JL, Rockette HE, et al. Treatment of acute otitis media in children under 2 years of age. *N Engl J Med.* 2011;364(2):105-115; doi:10.1056/NEJMoa0912254

Investigators from the University of Pittsburgh studied the utility of antimicrobial treatment of acute otitis media (AOM) among Pittsburgh area children aged 6 to 23 months from 2006 to 2009. Participating children had received two doses of the pneumococcal conjugate vaccine and had a diagnosis of AOM based on: 1) onset of symptoms within the previous 48 hours as determined by a score of 3 or greater on the Acute Otitis Media Severity of Symptoms (AOM-SOS) Scale<sup>1,2</sup>; 2) the presence of middle ear effusion; and 3) bulging tympanic membrane, accompanied by otalgia or marked erythema. Exclusion criteria were presence of another acute or chronic illness, allergy to amoxicillin, prior receipt of antibiotics within 96 hours, presence of otalgia for more than 48 hours, or perforated tympanic membrane. Children were stratified based upon previous frequent bouts of AOM and exposure or lack of exposure to three or more children 10 hours per week or more.

After screening of 1,385 children, 291 were randomly assigned to receive either amoxicillin-clavulanate (90 mg of amoxicillin and 6.4 mg of clavulanate per kg) or a placebo with similar appearance and taste. Drug and placebo were administered twice a day for 10 days. Symptoms were assessed by a daily structured telephone parent interview until the first follow-up visit, and then in person at each visit. Otoloscopic exams were performed on day 4-5 of therapy, at the end of therapy on day 10-12, and at a follow-up visit on day 21-25. At each visit, children were designated as having met criteria for either clinical success or failure. Clinical failure at or before the 4-5 day visit was defined as lack of substantial symptom improvement, worsening otoscopic exam, or both. Failure at the 10-12 day visit was characterized as lack of complete resolution of all symptoms and otoscopic abnormalities except for persistence of middle ear effusion.

The primary outcome measures were the time to symptom resolution and the symptom burden over time. The children who received antibiotic had a 35% initial resolution of symptoms by day 2, 61% by day 4, and 80% by day 7 compared to 28%, 54%, and 74% for the corresponding periods in the placebo group ( $P=.14$ ). The rate of clinical failure, defined as the

persistence of otoscopic signs of acute infection, was lower in the treatment group compared to placebo, 4% versus 23% on day 4-5 ( $P<.001$ ), and 16% versus 51% ( $P<.001$ ) at the 10-12 day visit. One child in the placebo group developed mastoiditis, and adverse drug effects were increased in the treatment group.

The authors conclude that in children 6 to 23 months of age with AOM, treatment with amoxicillin-clavulanate for 10 days reduced the burden of symptoms and the persistence of otoscopic signs of acute infection.

### Commentary by

**Donald Schiff, MD, FAAP**, University of Colorado School of Medicine and The Children's Hospital, Denver, CO

*Dr Schiff has disclosed no financial relationship relevant to this commentary. This commentary does not contain a discussion of an unapproved/investigative use of a commercial product/device.*

Clinicians continue to face the challenge of accurately diagnosing and determining the optimal treatment for the child under 2 years of age who may have AOM. In addition to the study described above, a second paper in the same issue<sup>3</sup> by investigators from Turku, Finland remarkably duplicates and supports the data and conclusions reached by the Pittsburgh study. The controversy regarding the necessity of treating children with AOM with antimicrobial agents originated in Europe<sup>4,5</sup> and has gained major support in the United States over the past decade.

Many pediatricians, driven by concerns about the development of resistant bacteria and questions about the efficacy of antibiotics, have opted to prescribe fewer antibiotics and adopted a watch and wait approach, particularly if the child is not very ill or if the diagnosis of AOM is not certain. The AAP Subcommittee on Management of Acute Otitis Media in 2004 concurred that in children 6 months to 2 years of age with nonsevere illness, and for whom follow-up can be ensured and antibiotics can be given if symptoms become worse, observation constitutes an accepted level of care.<sup>6</sup> The new PCV 13 vaccine remains too new to enable us to evaluate its effectiveness against the strains of pneumococcus most responsible for bacterial otitis media. The studies from Pittsburgh and Turku provide sufficient data to support a clinical guideline which would recommend the use of an effective antibiotic for children who are 6 months to 2 years of age with a certain diagnosis of AOM. However, changes in the susceptibility of common causative organisms to current antibiotics will undoubtedly occur, potentially requiring adjustments in future treatment guidelines.

**See Editors' Note on Back Page.**

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**Key words:** acute otitis media, antibiotic

### PICO

**Question:** Does antimicrobial treatment affect the symptoms and signs of acute otitis media in children aged 6 to 23 months?

**Question type:** Intervention

**Study design:** Randomized, double-blind trial

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