

CLINICAL INQUIRIES

Evidence-based answers from the
Family Physicians Inquiries Network

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**Otherwise
healthy
children with
uncomplicated
acute otitis
media don't
need antibiotics.**

Q / Should you use antibiotics to treat acute otitis media in children?

EVIDENCE-BASED ANSWER

A / **IN MOST CASES, NO.** Antibiotics are not necessary to treat uncomplicated acute otitis media (AOM) in an otherwise healthy child (strength of recommendation [SOR]: **A**, systematic review). Children younger than 2 years and children with bilateral infection, high fever, or vomiting may experience modest symptom relief from antibiotics (SOR: **B**, cohort studies).

No evidence supports any of the commonly used antibiotic regimens over another (SOR: **A**, meta-analysis). Amoxicillin (80-90 mg/kg per day in 2 divided doses) is the recommended first-line regimen (SOR: **C**, expert consensus). In otherwise healthy children, 5 days of therapy should be sufficient (SOR: **A**; systematic review).

CLINICAL COMMENTARY

In managing AOM, we should use a comprehensive strategy, prescribing an antibiotic only when clinically indicated. Spend the time necessary to counsel parents about the benefits and adverse effects of an antibiotic while considering a watchful waiting approach, which has been found to be both safe and well-accepted by most parents.¹

Discourage the use of antihistamines and decongestants because of their lack of efficacy and safety concerns, especially in children younger than 2 years.² Pain control with acetaminophen and ibuprofen and topical analgesic ear drops should always be part of the treatment plan. Finally, counsel parents carefully, when indicated, about the significant harms of passive smoke.

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Evidence summary

Otitis media is the most common outpatient diagnosis in children.³ Although these infections usually resolve without treatment, it is common practice in the United States to prescribe antibiotics.⁴

Antibiotic benefits are small in uncomplicated disease

A Cochrane review of 8 randomized controlled trials (RCTs)—6 double-blinded, 2287 children total—compared antibiotics with placebo for uncomplicated AOM in otherwise

healthy children.⁵ The review showed that children treated with antibiotics were no less likely to have pain at 24 hours after starting therapy than untreated children. However, 7% fewer children who received antibiotics had pain at 2 to 7 days than unmedicated children (number needed to treat [NNT]=15; 95% confidence interval [CI], 11-24).

Children treated with antibiotics had no significant decrease in recurrence of AOM (mean 0.70 vs 0.63; 95% CI, -0.22 to 0.34; odds ratio [OR]=0.99) or hearing loss (reported by a combination of tympanometry

and audiometry). They did have an increase in nausea, diarrhea, and rash, however. Only 1 case of mastoiditis was reported in the included studies.⁵

Of note, 2 of the studies showed a modest increase in failure rates of placebo treatment for children younger than 2 years and children with bilateral disease. Antibiotics may benefit these groups. Overall, both the potential benefits and harms of antibiotics for AOM are small.⁵

More on which children may benefit from antibiotics

A secondary analysis of cohorts from 6 RCTs (a total of 824 children untreated for AOM) identified age younger than 2 years (OR=2.07; 95% CI, 1.47-2.91; $P<.0001$) and bilateral disease (OR=1.70; 95% CI, 1.19-2.41; $P=.003$) as independent risk factors for pain and fever at 3 to 7 days of illness. However, the study did not address whether antibiotics would actually mitigate the risk factors.⁶

In another secondary analysis of cohorts from a single RCT (315 patients), children with high temperature or vomiting who were treated immediately with antibiotics were less likely to be in distress by day 3 of illness (32% immediate vs 53% delayed; $P=.045$; NNT=5) or have night disturbance (26% immediate vs 59% delayed; $P=.002$; NNT=3). The greatest benefit occurred among children younger than 2 years and children with bilateral infection (NNT=4). The outcomes were reported by parents, who were not blinded.⁷

One regimen is as effective as another

In meta-analyses of subsets of a systematic review that included 74 RCTs and 6 cohort studies, the 1- to 7-day clinical failure rate among children not given antibiotics for AOM was 19% (95% CI, 0.10-0.28). Patients treated with ampicillin or amoxicillin had a 2- to 7-day clinical failure rate of 7% (NNT=8; 95% CI, 0.04-0.20). Pooled analyses did not show any difference in efficacy between comparisons of penicillin, ampicillin, amoxicillin (2 or 3 times daily; standard or high dose), amoxicillin-clavulanate, cefaclor, cefixime, ceftriaxone, azithromycin, and trimethoprim-sulfamethoxazole.

An 8% higher incidence of diarrhea was noted for cefixime compared with amoxicillin (number needed to harm=12; 95% CI, 0.04-0.13). Azithromycin had a 19% lower adverse event rate than amoxicillin-clavulanate (NNT=5; 95% CI, 0.09-0.29).⁸

Five days of treatment are as good as 10

A 2000 Cochrane review found that 5 days of antibiotic therapy was as effective as a 10-day course of treatment in otherwise healthy children with uncomplicated AOM. A slight increase in signs, symptoms, relapse, or reinfection among children receiving 5 days of antibiotics was noted at 8 to 18 days after treatment (OR=1.52; 95% CI, 1.17-1.98), but the finding was no longer statistically significant at 30 days (OR=1.22; 95% CI, 0.98-1.54).⁹

Recommendations

The American Academy of Pediatrics recommends amoxicillin 80 to 90 mg/kg per day in 2 divided doses for:

- all children younger than 6 months with AOM
- children 6 to 24 months old with a certain diagnosis of AOM (rapid onset, signs of middle-ear effusion, and signs and symptoms of middle-ear inflammation) or severe illness (moderate to severe otalgia or fever $\geq 102.2^{\circ}\text{F}$ [39°C])
- children older than 24 months with severe illness.

All other children may be observed if the caregiver consents and is able to monitor the child and if systems are in place for follow-up communication, reevaluation, or access to medication.

Children with a non-type-I penicillin allergy can be given a second- or third-generation cephalosporin, such as cefdinir (14 mg/kg per day in 1 or 2 doses), cefpodoxime (10 mg/kg per day in 1 dose), or cefuroxime (30 mg/kg per day in 2 divided doses). If the child is at high risk of anaphylaxis, 2 acceptable options are azithromycin (10 mg/kg on day 1 followed by 5 mg/kg per day for 4 days as a single daily dose) or clarithromycin (15 mg/kg per day in 2 divided doses).

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Antibiotics may help alleviate symptoms in children with bilateral infection, high fever, or vomiting.

CLINICAL INQUIRIES

Amoxicillin should not be given to children at risk for highly amoxicillin-resistant organisms (eg, children who have had antibiotics in the previous 30 days, concomitant purulent conjunctivitis, chronic prophylac-

tic amoxicillin). The recommended alternative is high-dose amoxicillin-clavulanate (90 mg/kg per day of amoxicillin and 6.4 mg/kg per day of clavulanate in 2 divided doses).⁴ **JFP**

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