Are antibiotics effective for otitis media with effusion?

EVIDENCE-BASED ANSWER

Antibiotics provide little or no long-term benefit for children with otitis media with effusion (OME), defined as fluid in the middle ear without signs or symptoms of infection.

Most meta-analyses show a modest, short-term reduction in effusion rates. However, the most rigorous meta-analysis shows no benefit (strength of recommendation [SOR]: **D**, based on conflicting meta-analyses). No significant effect was noted on longer-term (>1 month) outcomes after treatment (SOR: **A**, based on a meta-analysis of 8 trials). In addition, there is no reliable evidence regarding patient-oriented outcomes (hearing loss, speech delay).

EVIDENCE SUMMARY

Longitudinal studies show spontaneous resolution in more than half of children within 3 months of the development of the effusion. After 3 months, the rate of spontaneous resolution remains constant, so that only a small percentage of children have OME a year or longer. There is a theoretical basis for the use of antibiotics for OME, since between 27%–50% of middle-ear aspirates of patients with OME contain bacteria.[1]

In the last 10 years, 4 meta-analyses reported mild short-term improvement in OME with antibiotic treatment (effusion clearance rates of 23%,[2] 16%,[3] 14%,[1] and 4%,[4] respectively—see **Table**). The last study was the only meta-analysis that restricted inclusion to only randomized, blinded, placebo-controlled trials. The small difference reported (4%) was not significant. None of the studies that assessed outcomes beyond a month showed a significant difference in the persistence of OME.

The meta-analyses vary significantly in methodology, inclusion/exclusion criteria, and interpretation, making a definitive conclusion on treatment results difficult. The included trials varied in antibiotics chosen, use of placebo, duration of therapy, time to measurement of OME resolution, and method of diagnosis (tympanography, otoscopy, audiometry).

The reviews commented on potential harms of antibiotic therapy, including medication cost and the development of antibiotic resistance. Nausea, vomiting, and diarrhea were reported in 2%–30% of children on antibiotic therapy.[1] The reviews did not address the treatment of OME in the nonpediatric population or such long-term patient-oriented outcomes as hearing loss or speech delay.

RECOMMENDATIONS FROM OTHERS

The American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP),

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What is a Clinical Inquiry?

Clinical Inquiries answer real questions that family physicians submit to the Family Practice Inquiries Network (FPIN), a national, not-for-profit consortium of family practice departments, residency programs, academic health sciences libraries, primary care practice-based research networks, and individuals with particular expertise.

Questions chosen for Clinical Inquiries are those considered most important, according to results of web-based voting by family physicians across the U.S.

Answers are developed by a specific method:

- First, extensive literature searches are conducted by medical librarians.
- Clinicians then review the evidence and write the answers, which are then peer reviewed.
- Finally, a practicing family physician writes a commentary.

TABLE

Meta-analyses of otitis media with effusion

Meta-analysis	# of trials	Number of subjects	Description	Rate difference (95% CI)
Cantekin et al[4]	8	775 children	Includes only non-placebo-controlled RCTs. Variable timing of outcome measure	32 (25.8–38.8)
Rosenfeld et al[2]	10	1325 children	Includes some nonblinded and non-placebo-controlled RCTs. Variable timing	22.8 (10.5–35.1)
Williams et al[3]	12	1697 children	Includes some nonblinded and non-placebo-controlled RCTs. Short-term outcomes focused on bilateral resolution of OME within 1 month of starting therapy	16 (3–29)
Williams et al[3]	8	2052 ears	Includes some nonblinded and non-placebo-controlled RCTs. Short-term outcomes focused on unilateral resolution of OME within 1 month of starting therapy	25 (10–40)
Williams et al[3]	8	1313 ears	Includes some nonblinded and non-placebo-controlled RCTs. Long-term outcomes measured more than 1 month after treatment was completed	6 (-3–14)
Stool et al[1]	10	1041 children	All blinded RCTs. Not all placebo-controlled. Variable timing	14.0 (3.6–24.2)
Cantekin et al[4]	8	1292 children	Includes only blinded, placebo-controlled RCTs. Variable timing	4.3 (-0.1–8.6)

RCT, randomized clinical trial; CI, confidence interval; OME, otitis media with effusion

and the American Academy of Otolaryngology–Head and Neck Surgery participated in the meta-analysis by Stool et al,[1] under contract with the Agency for Health Care Policy and Research. The resulting clinical practice guideline has been adopted by the AAP, AAFP, and the Centers for Disease Control and Prevention. The guideline stresses that observation *or* antibiotics are treatment options for children with OME present less than 4 to 6 months. Antibiotic therapy is never considered a required treatment for OME of any duration. All published guidelines are applicable to the pediatric population only.

Conflicting evidence indicates short-term or no benefit for antibiotics, and complications such as nausea, vomiting, diarrhea, and rash have been reported in 2%–32% of children. Long-term antibiotics lead to poor adherence, more office visits, and antibiotic resistance.[5]

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CLINICAL COMMENTARY

Conflicting meta-analyses and a guideline that hedges leaves the clinician who practices evidence-based medicine in the uncomfortable position of saying "maybe" when asked

Otitis media with effusion

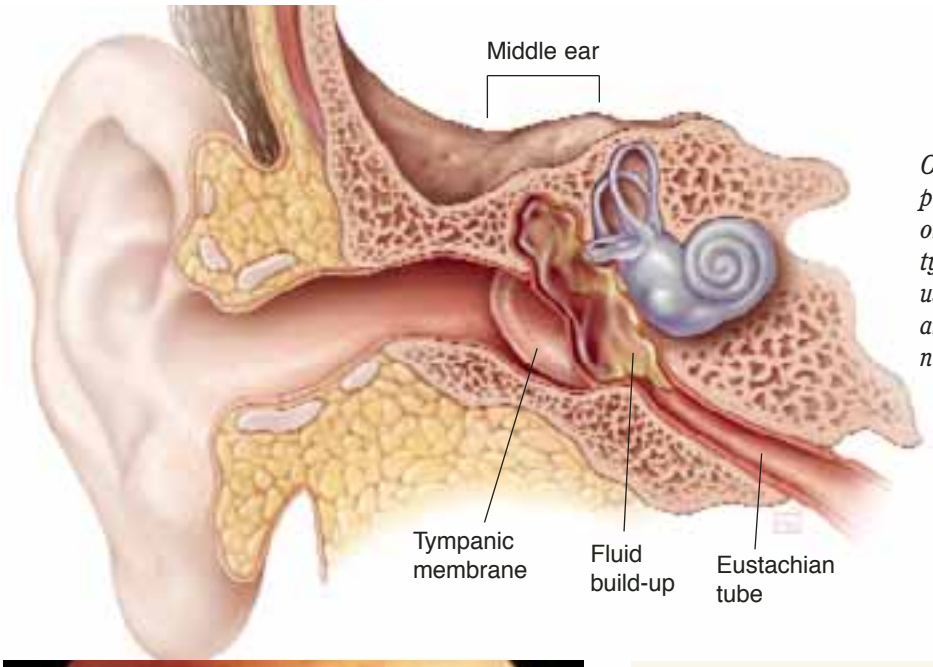
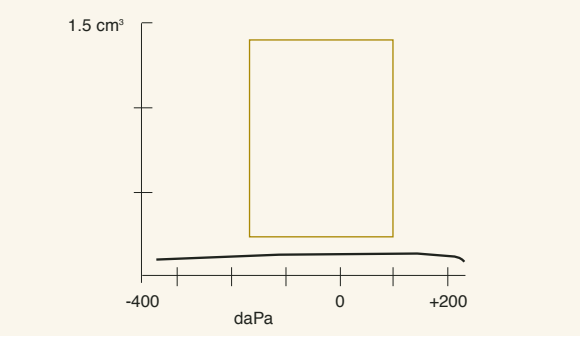


ILLUSTRATION BY STEVE OH

Otitis media with effusion produces characteristic findings on otoscopic examination and tympanometry. The condition usually resolves spontaneously, and antibiotic treatment does not hasten resolution.

IMAGE © CLINICA CLAROS

Fluid build-up in the middle ear causes the tympanic membrane to become somewhat opaque and appear orange or gray on otoscopic examination.



Fluid causes the tympanic membrane to become rigid, resulting in a nearly flat pressure curve on the tympanogram.

whether antibiotics are helpful. In the majority of cases of OME, I would seek to avoid the possible complications of antibiotics, given that there is no clear benefit. I await more data on speech and hearing outcomes in OME, as these studies will provide the most helpful evidence to primary care physicians.

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