Co-amoxiclav had short-term effectiveness for persistent otitis media with effusion in young children

van Balen FA, de Melker RA, Touw-Otten FW. **Double-blind randomised trial of co-amoxiclav versus placebo for persistent otitis media with effusion in general practice.** Lancet. 1996 Sep 14;348:713-6.

Objective
To determine the effectiveness of co-amoxiclav (amoxicillin and clavulanate potassium) suspension in children with persistent bilateral otitis media with effusion (OME).

Design
14-day randomised, double-blind, placebo-controlled trial.

Setting
57 general practices in the Netherlands.

Patients
Participating physicians used otoscopy and tympanometry to examine all patients 6 months to 6 years of age with ≥1 of the following: objective or subjective hearing loss, language or speech problems, mouth breathing, history of recurrent upper respiratory tract infections, history of recurrent otitis media among family members, or an episode of acute otitis media within the past 6 weeks. 433 patients in whom bilateral OME was detected received 3 months of watchful waiting, after which 223 patients were determined to have persistent bilateral OME. 162 patients had parental informed consent to be randomised. Exclusion criteria were antimicrobial therapy within 4 weeks preceding the trial; allergy to penicillin; compromised immunity; referral to an ear, nose, and throat surgeon; craniofacial abnormalities; the Down syndrome; or cystic fibrosis. 153 patients (94%) completed the 2-week follow-up.

Intervention
Patients were allocated to a suspension of co-amoxiclav, 20 mg/kg of amoxicillin and 5 mg/kg of clavulanate potassium given in 3 daily doses for 14 days (n = 82), or to placebo (n = 80). All patients received decongestant nosedrops.

Main outcome measures
Persistent OME in both ears and persistent OME in 1 or both ears, confirmed by tympanogram at 2 weeks.

Main results
149 patients had interpretable tympanograms. 42 patients (53%) who received co-amoxiclav had persistent bilateral OME at 2 weeks compared with 59 patients (84%) who received placebo (P = 0.001). {This absolute risk reduction (ARR) of 31% means that 4 patients would need to be treated (NNT) with co-amoxiclav for 2 weeks (compared with placebo) to prevent 1 additional patient from having persistent bilateral OME, 95% CI 2 to 6; the relative risk reduction (RRR) was 37%, CI 21% to 51%.}* Persistent OME in 1 or both ears was also decreased in patients who received co-amoxiclav compared with placebo (77% vs 93%, P = 0.03) {ARR 16%; NNT 7, CI 4 to 23; RRR 17%, CI 5% to 29%}*. Side effects, including gastrointestinal symptoms and rash, occurred more frequently with co-amoxiclav than with placebo (44% vs 22%, P = 0.03).

Conclusion
Co-amoxiclav provided effective antibiotic treatment in the short term in children with persistent bilateral otitis media with effusion.

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For article reprint: Dr. F.A. van Balen, Department of General Practice, University of Utrecht, 3584 CG Utrecht, The Netherlands. FAX 31-30-253-9028.

*Numbers calculated from data in article.

Commentary

The central concern in OME is the risk for delayed language development caused by hearing loss. However, the evidence in favour of this association is weak, and evidence that treatment makes a difference is weaker still. Indeed, Culpepper and Froom (1) ask whether the management of OME should not be thought of as treatment in search of a problem.

In their meta-analysis, Williams and colleagues (2) found that although antibiotic treatment of OME may be effective in the short term, no data show benefit beyond 1 month. They recommend that long-term restoration of hearing must be shown before antibiotics become the accepted therapy for OME.

Unfortunately, the study by van Balen and colleagues does not meet this criterion. Patients were followed only until the course of antibiotic treatment was completed. Although a short-term benefit was shown, we have no way of knowing the longer-term effects in a condition that is notorious for its high relapse rate. Only 43 patients (26%) in the study were younger than 3 years, the age group for which concerns about speech delay are the most pressing. 119 patients (73%) were reported to have had hearing loss, but it is unclear from the study how this was measured, what degree of loss was present, and whether treatment resulted in any reduction in loss—which is the outcome that would be of most interest.

This study shows that OME *can* be treated with antibiotics, but unfortunately, it will not help physicians decide whether it *should* be treated.

Anthony S. Dixon, MB, ChB
University of Hong Kong
Ap Lei Chau, Hong Kong

References

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