

## FPIN's Clinical Inquiries

Clinical Inquiries provide answers to questions submitted by practicing family physicians to the Family Practice Inquiries Network (FPIN). Members of the network select questions based on their relevance to family medicine. Answers are drawn from an approved set of evidence-based resources and undergo peer review. The strength of recommendations and the level of evidence for individual studies are rated using criteria developed by the Evidence-Based Medicine Working Group ([http://www.cebm.net/levels\\_of\\_evidence.asp](http://www.cebm.net/levels_of_evidence.asp)).

This series of Clinical Inquiries is coordinated for American Family Physician by John Epling, M.D., State University of New York Upstate Medical University, Syracuse, N.Y. The complete database of evidence-based questions and answers is copyrighted by FPIN. If you are interested in submitting questions to be answered or writing answers for this series, go to <http://www.fpin.org> or contact [CI2Editor@fpin.org](mailto:CI2Editor@fpin.org).

## Clinical Question

Which treatments for persistent otitis media with effusion are beneficial?

## Evidence-Based Answer

Treatments such as antibiotics, steroids, antihistamines/decongestants, and mucolytics afford no long-term benefit in the treatment of patients with otitis media with effusion (OME). [Strength of recommendation: A] Surgical treatments such as ventilation tubes and adenoidectomy improve hearing. [Strength of recommendation: A] However, surgery has conflicting effects on improving language development and behavior. [Strength of recommendation: B] There is inconclusive evidence that autoinflation of the eustachian tube with a nasal balloon improves resolution of OME. [Strength of recommendation: B]

## Evidence Summary

OME is defined as middle ear effusion without acute inflammation. Many treatments have been recommended, although data supporting them are limited.

The results of three meta-analyses<sup>1-3</sup> showed that antibiotics increased the resolution of OME in the short-term (less than one month). However, the results of a conflicting meta-analysis<sup>4</sup> of only higher quality, placebo-controlled studies showed that antibiotic therapy resulted in no significant difference compared with placebo. One meta-analysis<sup>3</sup> looked at outcomes beyond one month and showed no significant difference in resolution of OME.

The results of a well-designed systematic review<sup>5</sup> of the use of steroids in patients with OME found that oral and nasal steroids do not have any significant benefit in the long-term (more than two weeks) when used alone or with antibiotics. A subsequent randomized controlled trial<sup>6</sup> (RCT) of oral steroids given with antibiotics reached similar conclusions.

The results of meta-analyses on antihistamines/decongestants<sup>1</sup> and mucolytics<sup>7</sup> showed no benefit in clearance of OME. Another meta-analysis<sup>8</sup> looked at opening the eustachian tubes by autoinflation with a nasal balloon. The methods of this meta-analysis were unclear, and the studies were generally of low quality. However, within a homogenous subgroup of three RCTs, the odds ratio for improvement of OME with autoinflation was 3.5 (95 percent confidence interval, 2.0 to 6.1). The number needed to treat was three. Unblinded outcome assessments led the authors of the meta-analysis to not recommend autoinflation for clinical practice.

Surgical options include ventilation tubes, adenoidectomy, and tonsillectomy. The results of a systematic review<sup>9</sup> of children with OME showed slight improvement (less than 12 dB) in hearing with the use of ventilation tubes or adenoidectomy alone. Combining the procedures offered little additional benefit. There were no data supporting tonsillectomy in the treatment of OME. A subsequent RCT<sup>10</sup> of children with OME confirmed this conclusion, showing a 5 to 6 dB improvement in hearing with ventilation tubes at six and 12 months postprocedure. The results of two additional RCTs<sup>11,12</sup> using the same group of children showed that early insertion of ventilation tubes improves language development and decreases behavior problems at nine months postprocedure compared with watchful waiting. However, 85 percent of the children in the watchful-waiting group received ventilation tubes by 18 months, and there no longer were significant differences in outcomes.

It is important to note that the inclusion criteria for these RCTs were baseline disruptions to speech, language, learning, and behavior. The results of other RCTs without these inclusion criteria showed no difference in language development or quality of life with early insertion of ventilation tubes versus watchful waiting for periods of six to 12 months. Furthermore, the majority of children in the watchful-waiting groups in these latter studies avoided surgery by the end of the follow-up periods.<sup>13-17</sup>

#### Recommendations from Others

A recent evidence-based practice guideline<sup>18</sup> from the American Academy of Family Physicians, the American Academy of Pediatrics, and the American Academy of Otolaryngology-Head and Neck Surgery recommends against the use of antibiotics, steroids, antihistamine/decongestants, mucolytics, and autoinflation in the routine treatment of OME. Surgery for persistent OME should be reserved for use in children with significant hearing loss, persistent symptoms, risk factors for developmental difficulties, or structural damage to the tympanic membrane or middle ear. Antibiotics, with or without steroids, can be considered if the parents or caregivers are strongly opposed to surgery.

#### Clinical Commentary

Many patients and parents desire active treatment of OME, and treatment is still advocated by many physicians on the basis of habit, anecdote, or tradition. Therefore, it may be difficult for some physicians to not treat OME. Nevertheless, the evidence does not support most treatments. Instead of prescribing medicines, physicians must develop tracking and intervention systems to monitor children with OME over time and recognize complications such as significant hearing loss and developmental delays. Surgery should be considered for patients with these conditions. However, the optimal timing for surgery is unknown.

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## REFERENCES

1. United States Otitis Media Guideline Panel. Otitis media with effusion in young children. Rockville, Md.: U.S. Dept. of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, 1994.
2. Rosenfeld RM, Post JC. Meta-analysis of antibiotics for the treatment of otitis media with effusion. *Otolaryngol Head Neck Surg* 1992;106:378-86.
3. Williams RL, Chalmers TC, Stange KC, Chalmers FT, Bowlin SJ. Use of antibiotics in preventing recurrent acute otitis media and in treating otitis media with effusion. A meta-analytic attempt to resolve the brouhaha. *JAMA* 1993;270:1344-51.
4. Cantekin EI, McGuire TW. Antibiotics are not effective for otitis media with effusion: reanalysis of meta-analyses. *Oto-Rhino-Laryngologia Nova* 1998;8:214-22.
5. Butler CC, van der Voort JH. Oral or topical nasal steroids for hearing loss associated with otitis media with effusion in children. *Cochrane Database Syst Rev* 2002;4:CD001935.
6. Mandel EM, Casselbrant ML, Rockette HE, Fireman P, Kurs-Lasky M, Bluestone CD. Systemic steroid for chronic otitis media with effusion in children. *Pediatrics* 2002;110:1071-80.

7. Pignataro O, Pignataro LD, Gallus G, Calori G, Cordaro CI. Otitis media with effusion and S-carboxymethylcysteine and/or its lysine salt: a critical overview. *Int J Pediatr Otorhinolaryngol* 1996;35:231-41.
8. Reidpath DD, Glasziou PP, Del Mar C. Systematic review of autoinflation for treatment of glue ear in children. *BMJ* 1999;318:1177.
9. University of York Centre for Reviews and Dissemination. The treatment of persistent glue ear in children. *Eff Health Care* 1992;4:1-16.
10. Rovers MM, Straatman H, Ingels K, van der Wilt GJ, van den Broek P, Zielhuis GA. The effect of short-term ventilation tubes versus watchful waiting on hearing in young children with persistent otitis media with effusion: a randomized trial. *Ear Hear* 2001;22:191-9.
11. Maw R, Wilks J, Harvey I, Peters TJ, Golding J. Early surgery compared with watchful waiting for glue ear and effect on language development in preschool children: a randomised trial [published correction appears in *Lancet* 1999;354:1392]. *Lancet* 1999;353:960-3.
12. Wilks J, Maw R, Peters TJ, Harvey I, Golding J. Randomised controlled trial of early surgery versus watchful waiting for glue ear: the effect on behavioural problems in pre-school children. *Clin Otolaryngol* 2000;25:209-14.
13. Rovers MM, Straatman H, Ingels K, van der Wilt GJ, van den Broek P, Zielhuis GA. The effect of ventilation tubes on language development in infants with otitis media with effusion: a randomized trial. *Pediatrics* 2000;106:E42.
14. Paradise JL, Feldman HM, Campbell TF, Dollaghan CA, Colborn DK, Bernard BS, et al. Effect of early or delayed insertion of tympanostomy tubes for persistent otitis media on developmental outcomes at the age of three years. *N Engl J Med* 2001;344:1179-87.
15. Paradise JL, Feldman HM, Campbell TF, Dollaghan CA, Colborn DK, Bernard BS, et al. Early versus delayed insertion of tympanostomy tubes for persistent otitis media: developmental outcomes at the age of three years in relation to prandomization illness patterns and hearing levels. *Pediatr Infect Dis J* 2003;22:309-14.
16. Paradise JL, Dollaghan CA, Campbell TF, Feldman HM, Bernard BS, Colborn DK, et al. Otitis media and tympanostomy tube insertion during the first three years of life: developmental outcomes at the age of four years. *Pediatrics* 2003;112:265-77.
17. Rovers MM, Krabbe PF, Straatman H, Ingels K, van der Wilt GJ, Zielhuis GA. Randomised controlled trial of the effect of ventilation tubes (grommets) on quality of life at age 1-2 years. *Arch Dis Child* 2001;84:45-9.
18. American Academy of Family Physicians, American Academy of Otolaryngology-Head and Neck Surgery, American Academy of Pediatrics Subcommittee on Otitis Media With Effusion. Otitis media with effusion. *Pediatrics* 2004;113:1412-29.

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