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Why Don't Those Ear Drops Work for My Patients?

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IN THIS MONTH'S *Pediatrics Electronic Pages*, Dohar et al¹ present "Topical Ciprofloxacin/Dexamethasone Is Superior to Oral Amoxicillin/Clavulanic Acid in Acute Otitis Media With Otorrhea Through Tympanostomy Tubes," the latest in a series of pharmaceutical industry-funded articles and consensus conferences on the subject of the draining ear.^{2,3} These authors contend that, on the basis of good cure rates with ear drops and concerns about resistance with systemic antibiotics, fluoroquinolone ototopical drops are the only reasonable choice for treating a child with a draining ear. This conclusion may not be valid for infants with acute tube otorrhea, who make up much of the population seen in daily pediatric practice.

We know a lot about acute infectious drainage through tympanostomy tubes. Mandel et al⁴ performed an exhaustive study of otorrhea among 246 children with tubes. They found 2 very distinct groups. Infants and young children usually developed otorrhea after an upper respiratory infection. Cultures of their discharges yielded the usual pathogens of acute otitis media (*Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, and *Streptococcus pyogenes*). By contrast, children over the age of 6 were more likely to have ear infections in the summer swimming season. Cultures from their ear canals more often grew biofilm-producing organisms (*Pseudomonas aeruginosa* or *Staphylococcus aureus*), which are much less sensitive to the common oral antibiotics. Similarly, cultures from children who have been treated previously with antibiotics or who have had otorrhea for more than a week often grow *P aeruginosa*, *S aureus*, or other resistant pathogens.

If one were trying to design a study to demonstrate the superiority of ototopical drops over oral antibiotics, the ideal population would be older children, children with ear drainage for more than a week, or children who

had been treated previously with antimicrobial agents. Cleaning their ears before instilling drops would likely improve topical antibiotic penetration.⁵ The majority of recent studies of tube otorrhea are biased in just these ways.^{3,6} To their credit, Dohar et al have excluded children whose ear cultures grew pure *P aeruginosa*. Still, their patient population is quite different from the ill infants with new-onset ear drainage seen by pediatricians. More than half of their subjects were >22 months of age, and some had been treated as recently as 4 days before with antibiotics. The organisms they recovered from culture do not reflect the usual pathogens of acute otitis media, with only 15 of 154 cultures growing *S pneumoniae*.^{2,7}

Ototopical antibiotic drops have been an important part of the treatment of draining ears for 3 decades. They are highly effective against the biofilm-forming microorganisms, especially when instilled into a thoroughly cleaned ear. Fluoroquinolone drops seem to be about as effective as aminoglycoside drops.⁸ They (Floxin otic, Ciprodex) are approved by the US Food and Drug Administration for use in the ear and are not ototoxic in animal models. What is less clear is whether they work when dribbled on top of a collection of pus from a rapidly discharging acute otitis. Studies suggest little middle-ear penetration from drops in the ear canal.⁹ In addition, topical antibiotics have no systemic effect and, thus, do not treat early concomitant pneumonia or sepsis.

Opinions expressed in these commentaries are those of the authors and not necessarily those of the American Academy of Pediatrics or its Committees.

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A protocol for controlling acute tube otorrhea was devised by clinicians at the Otitis Media Research Center in Pittsburgh, Pennsylvania. It is based on the best information about the microbiology of otorrhea in different clinical situations. The protocol is time tested, highly effective, and cost-conscious.¹⁰

1. For ill infants with acute tube otorrhea, treat with oral antibiotics that are effective against the common pathogens of acute otitis media.
 - If they fail to respond within 5 days, add an ototopical drop with activity against *P aeruginosa* and *S aureus* (clean the ear canal with an 8F suction catheter if possible and consider culturing the discharge).
 - If otorrhea persists, refer to a pediatric otolaryngologist for thorough cleaning under a microscope and culture of the tube orifice.
2. For children over the age of 3 years or for mild episodes of otorrhea, observe (remember that acute otitis media has a 70% spontaneous cure rate) or use an ototopical drop.

One of the advertisements for Floxin ear drops shows a handsome clinician stating, "I like using a drop I don't have to think twice about." We should think twice about our approach to infectious disease in children and choose best practices on the basis of strong evidence.

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