Quinolone Ear Drops Beat Generics

Quinolone drops may represent a better choice for treating swimmer’s ear in children than are the generics that we’re accustomed to using.

Both Floxin (ofloxacin otic solution 0.3%) and Ciprodex (ciprofloxacin 0.3% and dexamethasone 0.1% sterile otic suspension) have recently been approved for the treatment of acute otitis externa in children as young as age 6 months. Otolaryngologists are using these drugs extensively in children, but so far, the pediatric community has not embraced them.

This lag is due in part to the way these products have been marketed. But I believe that inappropriate concern about fluoroquinolone-associated arthropathy has also impeded use of what appear to be products with greater efficacy and convenience, and possibly even lower cost, in the case of Floxin.

Overall, the data suggest that efficacy of Floxin and Ciprodex drops in treating acute otitis externa in children is greater than 90%, compared with about 80% for the generics such as Cortisporin (neomycin, polymyxin B sulfates, and hydrocortisone otic solution), and about 70% for astringents such as acetic acid, isopropyl alcohol, or hydrogen peroxide.

In an open-label, phase III trial involving 439 children with acute otitis externa in Latin America, a 7-day course of Floxin given once daily—5 drops for children aged 6 months to 12 years, 10 drops for those 13 years and older—produced eradication rates of 96% overall (Clin. Ther. 2004;26:1046-54).

Similar efficacy for Ciprodex was seen in a recent randomized, blinded multicenter trial in 396 otitis externa patients older than 1 year. Clinical cure rates at day 18 were 90.9% after 7 days of Ciprodex (3-4 drops twice daily), compared with 83.9% after 7 days of Ciprosin (3-4 drops three times daily), while microbiologic eradication rates were 94.7% and 86%, respectively (Curr. Med. Res. Opin. 2004;20:1175-83).

Antimicrobial resistance to the older topicalics might be one reason for the quinolones’ superior efficacy. Data from two multicenter trials conducted by Flox-in manufacturer Daiichi Pharmaceuticals Inc. suggested that the two most common organisms associated with otitis externa—Pseudomonas aeruginosa and Staphylococcus aureus—appear to develop resistance to Cortisporin but not to Floxin (South. Med. J. 2004;97:465-71).

The quinolones are also more convenient to administer. Floxin is available in 5-ml. and 10-ml. plastic dropper bottles and as “singles” containing individual once-daily doses (one packet for ages 6 months to 12 years and two for children aged 13 years and older, given for 7 days). The dropper bottles also allow for once-daily dosing (5 drops for ages 6 months to 13 years and 10 drops for ages 13 and older). Ciprodex dosing for patients 6 months and older is four drops twice daily for 7 days. In contrast, 3 drops of Cortisporin must be administered three or four times daily to children with acute otitis externa.

There is some disagreement about whether a corticosteroid—contained in Ciprodex and Cortisporin but not Floxin—adds significant benefit. While the anti-inflammatory effect does produce greater symptomatic relief, it also may dampen the immune response. Because the data suggest Floxin is just as effective as Ciprodex, and more effective than Cortisporin, the steroid may not be much of an advantage.

Floxin can be slightly cheaper than the generic Cortisporin on a per-treatment basis: Computed with the average wholesale price for a 5-ml. bottle, the cost of 5 drops of Floxin daily for 7 days is $17.60, compared with $18.34 for a 10-day treatment of Cortisporin, 4 drops daily. The cost of Ciprodex is somewhat higher than the generic Cortisporin but not Floxin (South. Med. J. 2004;97:465-71).

The third is trauma. Children—or their parents—may stick cotton swabs or bobbing pins in the child’s ear, perhaps in an attempt to remove wax, and end up abandoning the canal. This kind of trauma can introduce bacterial contamination. Such practices should be discouraged.

I served as a one-time consultant to Floxin manufacturer Daiichi. I have no affiliation with Bayer Pharmaceuticals Corp. or its subsidiary Alcon Laboratories Inc., the makers of Ciprodex.

Dr. Pichichero, a specialist in pediatric infectious diseases, practices in Rochester, N.Y. He is also professor of pediatrics, medicine, microbiology, and immunology at the University of Rochester.

ID Consult
Antibiotics Not Always Needed In Childhood Conjunctivitis

Most children with conjunctivitis will get better by themselves and don’t need an ophthalmic antibiotic, Peter W. Rose, M.B., and his colleagues reported.

“Parents should be encouraged to treat children themselves without medical consultation, unless their child develops unusual symptoms or the symptoms persist for more than a week,” said Dr. Rose of Oxford (England) University. The researchers suggest that parents cleanse their children’s eyes with eye drops instead of rushing to the pediatrician at the first sign of conjunctivitis (Lancer 2005;366:37-43).

The investigators randomized 326 children (mean age 3.3 years) with a diagnosis of conjunctivitis to chloramphenicol eye drops (0.5%) or placebo (distilled water containing 1.5% boric acid and 0.3% borax). Parents used drops every 2 hours for the first 24 hours when the child was awake and four times a day until 48 hours after symptoms resolved.

After 7 days, 86% in the antibiotic group were clinically cured, compared with 78% of the placebo group. When 307 of the children were followed up at 6 weeks, fewer than 5% had experienced a relapse or new infection.

Only one reaction—a case of swollen eyelids and face—was attributed to antibiotic treatment. Baseline cultures showed 80% had bacterial infections. In this group, the clinical cure rate did not differ significantly between chloramphenicol and placebo (85% vs. 80%), but more of the chloramphenicol group than the placebo group experienced bacterial eradication (40% vs. 23%).

Although eradication is not necessary for a clinical cure, the researchers said failure to eradicate bacteria could impact transmission. “Despite our results, antibiotic treatment might still reduce the absolute number, and, hence, transmissibility of pathogens, and further research might be necessary if antibiotics cease to be prescribed for this disorder.”

The data appear to support prescription policy changes for uncomplicated conjunctivitis, but it still could be a tough sell for parents and schools, they admitted.

Here is a case of hemorrhagic conjunctivitis with subconjunctival hemorrhages and lid swelling.

Infectious Diseases 13

DATA WATCH

Estimated Chickenpox Vaccination Coverage, 2003

©MOSBY, INC. 2004. GERSHON: KRUGMANS INFECTIOUS DISEASES OF CHILDREN, 11E

*2003 national coverage rate, ≥2.5%. Source: National Partnership for Immunization.