Contemporary management of childhood ear infections

The pathophysiology and bacteriology of the draining ear are well-understood, but differentiating between types of ear infections is challenging given the shared clinical presentations. Once the correct diagnosis has been established, contemporary management of draining ears or otorrhea relies increasingly on antimicrobial ototopical preparations along with the use of systemic antibiotics when appropriate. Antimicrobial ototopical preparations, either with or without corticosteroids, such as hydrocortisone or dexamethasone, are available. The clinician’s choice of treatment must be guided by clinical presentation, the spectrum of pathogen activity, and the potential for ototoxicity.

Various types of infection
Acute otitis media (AOM)—the most common infection for which antibiotics are prescribed—is an acute infection of the middle-ear space. AOM is differentiated from otitis media with effusion (OME), which may accompany viral upper respiratory tract illness or be a prelude or sequel to AOM. According to the clinical practice guideline for the diagnosis and management of AOM, jointly issued by the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP) in the spring of 2004, AOM must meet 3 criteria: rapid onset of illness, presence of middle-ear effusion (MEE), and signs and symptoms of middle-ear inflammation. To confirm the diagnosis, the clinician must see the tympanic membrane (TM) and identify MEE (fluid) and inflammatory changes.

In OME, fluid fills the middle-ear space. Hearing loss is present to a variable degree but pain and fever are absent. Myringotomy and insertion of tympanostomy tubes into the eardrum is the usual treatment for OME, and it is the surgical procedure most frequently performed in the United States. Otorrhea occurs in 3.4% to 74% of patients with tympanostomy tubes in situ.

AOM with otorrhea through tympanostomy tubes (AOMT) is characterized by an abundant, often purulent, discharge. It frequently follows an upper respiratory tract infection. Unlike patients with AOM who have an intact TM, the patient with AOMT will not generally experience pain and systemic symptoms such as fever.

Otorrhea is also a frequent manifestation of chronic suppurative otitis media (CSOM), which is characterized by chronic inflammation of the middle ear and mastoid and persistent TM perforation. A potentially dangerous clinical condition, CSOM is difficult to treat because the most common infecting organisms are not sensitive to the oral antibiotics commonly used in children.

Acute otitis externa (AOE), or swimmer’s ear, is an acute inflammation of the external ear canal; it does not involve the middle ear. Pain upon manipulation of the pinna is the diagnostic hallmark of AOE; redness and swelling of the ear canal and a thin, milky white discharge may also be present.

Distinctions between these different ear infections are not always readily apparent. For example, patients who have AOMT with profuse otorrhea may develop a secondary infection of the external canal that results in edema in the canal, making this condition clinically indistinguishable from AOE.

 Likely pathogens
The same pathogens do not cause all ear infections, though there is some overlap across diagnoses. When a child is suffering from AOM with an intact eardrum, however, the 3 likely pathogens are Streptococcus pneumoniae, nontypeable Haemophilus influenzae, and Moraxella catarrhalis. S pneumoniae has been recovered from the middle-ear fluid of approximately...
FIGURE 1

Distribution of AOMT pathogens by age

Preventing ear infections

Childhood ear infections are pervasive, costly, and to some extent, preventable. Clinicians cannot change some of the factors associated with ear infections including genetic predisposition, premature birth, male gender, Native American/Inuit ethnicity, family history of recurrent otitis media, presence of siblings in the household, and low socioeconomic status.  

Parents and caregivers can be advised of preventive measures they can take during their children’s infancy and early childhood years. For example, altering child care center attendance patterns can significantly reduce upper respiratory tract infections, which are often precursors to ear infections. Further, breastfeeding for at least the first 6 months of the baby’s life also seems to be helpful because it provides the mother’s antibodies, which are transmitted in breast milk.  

Avoiding supine bottle feeding (bottle propping), reducing or eliminating pacifier use, and eliminating exposure to passive tobacco smoke are believed to reduce the incidence of ear infections during infancy. The usefulness of these interventions is unclear, however.  

The only preventive measure available against chronic suppurative otitis media is to make sure that episodes of acute otitis media are treated promptly, advises Peter S. Roland, MD, professor and chairman, department of Otolaryngology-Head and Neck Surgery at the University of Texas Southwestern Medical Center in Dallas. “Individuals with otottrhea should see a health care provider within a few days of onset,” adds Dr Roland.  

Preventive measures for post tympanostomy tube otottrhea have never been clearly defined. Some otolaryngologists believe that swimming should be avoided, or at least that ear plugs should be used when swimming even though, according to Dr Roland, research has not shown these measures to be effective.  

Individuals who experience recurrent episodes of external otitis from swimming should use an astringent acidifying drop after water exposure to prevent the development of external otitis. A solution of half alcohol and half vinegar appears to be an effective home remedy if the eardrum is intact. There are a number of commercially available preparations designed for this purpose, and they can be purchased at most drug stores. It is unlikely that using ear drops or solutions after swimming provides any benefit to individuals who do not have a history of otitis externa.

25% to 50% of children with AOM, *H. influenzae* from 15% to 30%, and *M. catarrhalis* from about 3% to 20.1

*S. pneumoniae, H. influenzae, and M. catarrhalis* are the pathogens often implicated in AOM, but *Staphylococcus aureus* and *Pseudomonas aeruginosa* are also frequently isolated (see Figure 1, page 2). The peak incidence of tube otitis media caused by staphylococci occurs during the colder months, while *P. aeruginosa* is most active in the summer, typically when people are swimming. *P. aeruginosa, S. aureus, and Proteus mirabilis* are the bacteria most frequently responsible for CSOM.3 *P. aeruginosa* and *S. aureus* comprise most pathogens causing OE.

Organisms found in the ear fluid of patients with tympanostomy tubes can also vary depending on the patient’s age and any prior exposure to antibiotics. *H. influenzae, S. pneumoniae, Staphylococcus epidermidis,* and *P. aeruginosa* accounted for the majority of bacteria in a study of children younger than 3 years.2 In the same study, *S. aureus* was prominent in children older than 3 years.

**Treatment considerations**

Whatever the causative organism, the acute conditions AOM and AOE can be painful. So, after diagnosis, pain management is a top priority. Acetaminophen or ibuprofen is recommended for mild to moderate pain. While some clinicians like to use pain-relieving drops like benzocaine, Peter S. Roland, MD, a consultant for this article, discourages their use because efficacy is limited and repeated use can result in the development of topical sensitization.

After achieving pain relief for the patient, the clinician treating AOM must determine whether antibiotics are necessary immediately or if a wait-and-see approach is preferable. While some clinicians believe ear infections should be treated right away with oral antibiotics, there are good reasons to delay antibiotic treatment in some children. Evidence that they can get well without taking oral antibiotics continues to mount as do general concerns about bacterial resistance and cost.1

The likelihood of recovery without antibacterial therapy depends on the severity of signs and symptoms at presentation. According to the new AAP-AAPF guideline, there are children who are not likely to develop a serious illness when their ear infections are not treated immediately with antibiotics.1 For these reasons, the guideline encourages clinicians to consider the “observation option,” which includes deferring systemic antibacterial treatment of selected children for 48 to 72 hours and limiting management to symptomatic pain relief. Successful implementation of this strategy requires a method for early follow-up evaluation and the assurance that an oral antibiotic prescription can be conveniently obtained later, if it is needed. If oral antibiotics are necessary, high dosages of amoxicillin (80-90 mg/kg/d) divided into 2 daily doses can be used.1

**Ototopical antibiotics**

For AOMT, CSOM, and AOE, clinicians will see more immediate results by using an ototopical antibiotic, advises Dr. Roland. He recommends a fluoroquinolone that includes a potent corticosteroid. Ototopical agents offer a variety of advantages, the most significant being their ability to concentrate medication in the ear. Ototopical therapy also provides rapid delivery, a

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**TABLE 1**

<table>
<thead>
<tr>
<th>Clinical variable</th>
<th>Ciprofloxacin/dexamethasone (%)</th>
<th>Ofloxacin (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days to cessation of otitis media</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Clinical cure rate</td>
<td>90</td>
<td>79</td>
</tr>
<tr>
<td>Microbiologic success rate</td>
<td>91</td>
<td>82</td>
</tr>
<tr>
<td>Treat failure rate</td>
<td>5</td>
<td>15</td>
</tr>
</tbody>
</table>


**TABLE 2**

<table>
<thead>
<tr>
<th>Clinical response to ototopical ciprofloxacin/dexamethasone in pediatric patients with otitis media</th>
<th>Day 3 N (%)</th>
<th>Day 11 N (%)</th>
<th>Day 18 N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cured</td>
<td>64 (30.9)</td>
<td>174 (84.1)</td>
<td>174 (84.1)</td>
</tr>
<tr>
<td>Improved</td>
<td>130 (62.8)</td>
<td>25 (12.1)</td>
<td>20 (9.7)</td>
</tr>
<tr>
<td>Unchanged</td>
<td>9 (4.4)</td>
<td>4 (1.9)</td>
<td>6 (2.9)</td>
</tr>
<tr>
<td>Worsened</td>
<td>4 (1.9)</td>
<td>4 (1.9)</td>
<td>7 (3.4)</td>
</tr>
</tbody>
</table>

broad spectrum of activity, the capacity to combine different medications into one solution, and low cost. It has a good level of patient adherence. Consequently, the rate of clinical cure is also higher. Occasionally, oral or parenteral antibiotics are given in tandem with ototopical antibiotics. Patients with AOMT, CSOM, and AOE should first be treated with ototopical antibiotics because topical administration can allow the delivery of antibiotic directly to the infected area, according to Dr Roland. With systemic antibiotics, there is more risk with a reduced likelihood of benefit.

| The gram-negative pathogens that are commonly involved in draining ears and in AOE are not sensitive to the penicillins. The antibiotics most effective against gram-negative pathogens are aminoglycosides and fluoroquinolones. The aminoglycosides, which include gentamicin, tobramycin, and neomycin, have been in use for decades. These agents are potentially ototoxic and have a limited antibacterial spectrum. In contrast, fluoroquinolones, which were introduced in 1998, are not ototoxic and have a wider antibacterial spectrum. Aminoglycoside topicals are often combined with one of the peptide class of antibiotics (polymyxin B or polymyxin E, for example) and/or with a corticosteroid (hydrocortisone or dexamethasone, for example). Until recently, these agents were the primary choice for treating otorhea. The preparations, however, are not FDA approved for use in the middle ear. In fact, their labels warn against their use if the TM is not intact. Ototoxicity is a known risk of aminoglycosides, although it is uncommon. Aminoglycosides can be both cochleotoxic and vestibulotoxic. The pathology of aminoglycoside cochlear ototoxicity generally involves injury to the outer hair cells in the basal turn of the cochlea. Streptomycin, the first clinically used aminoglycoside, was recognized very early to be a vestibulotoxic agent. Aminoglycosides are almost always ototoxic in animal studies, although they may not affect humans in the same way.

While the potential for ototoxicity has been well-established, the incidence of clinical ototoxicity from aminoglycoside use ranges from 2% to 5%, according to one estimate. Another study found that even using the broadest possible criteria to define ototoxicity, the incidence of cochleotoxicity was approximately only 1 in 10,000.

Some patients, however, are highly susceptible to aminoglycoside toxicity as a result of an inherited mitochondrial gene abnormality. Specifically, patients in Asian and Middle Eastern populations can experience significant hearing loss after exposure to relatively small amounts of systemic aminoglycosides. Genetic susceptibility to topically applied aminoglycosides, however, has not been studied.

Aminoglycosides, most especially neomycin, can induce topical allergic reactions. Such reactions classically manifest as a maculopapular eruption over a portion of the skin that comes in contact with the medication. However, there are more subtle forms of

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**Reaching the infection**

Although topical antibiotic drops are highly effective in the treatment of ear diseases, they do occasionally fail if the medication does not reach the infected tissues. Often this occurs because debris and infectious secretions fill the external auditory canal and block the area. Ineffective administration of the drops also interferes with optimal results.

Consequently, an important adjunct to the use of topical antibiotic drops is cleansing of the external auditory canal, often referred to as "aural toilet." Several methods can be used to perform aural toilet. At the simplest—and probably the least effective—level, is "dry mopping." This measure involves taking a cotton swab or loose piece of cotton and "mopping" secretions and debris from the external auditory canal. It can be performed in virtually any setting by any health care provider or caregiver.

Aural irrigations are a much more effective way to provide aural toilet. A small bulb syringe is used to irrigate the external auditory canal with a commonly used solution, such as a solution of 3% medicinal hydrogen peroxide. If the peroxide stings, then it can be diluted by mixing it 50/50 with sterile saline. Five to 20 mL of this solution can be used to irrigate the external auditory canal. "This is quite safe and, if the solution is brought to body temperature, is reasonably comfortable," advises Dr Peter Roland. The irrigation fluid is allowed to drain out of the external auditory canal for 10 to 15 minutes, then the drops are instilled into the ear. This procedure can be performed at home by the patient or a caregiver.

The most effective method of cleaning the external auditory canal is the use of a microscope with microinstrumentation, because these devices permit complete visualization of the external auditory canal and meticulous cleansing. Often material can actually be extracted from the middle ear itself. The technique requires expensive equipment that is not widely available, special training, and a cooperative and compliant patient.

Antibiotic drops should be administered with the patient lying on his back with the head turned to one side. Three to 5 drops of medication should be placed into the ear canal of the uppermost ear. The index finger should then be utilized to "pump" the tissue just in front of the tragus (the small piece of cartilage at the front of the ear canal) 5 to 6 times. The patient should then be asked to stay in the same position for 5 to 10 minutes. If necessary, the procedure can then be repeated on the opposite side. Cotton balls or ear plugs should not be placed into the external auditory canal to "hold the drops in." Occluding the ear canal for more than a few minutes simply increases moisture in the ear and results in retention of infected material.
neomycin sensitivity. Consequently, it can be very difficult to distinguish between persistent infection and topical sensitization. Often, the only way to make the distinction is to stop the aminoglycoside without instituting any other medication.

In these less obvious cases, the clinician might not recognize hypersensitivity because the patient's major signs and symptoms may include only continued redness, pain, inflammation, and itching. The clinician might misinterpret these findings as a failure to heal rather than a hypersensitivity reaction.4

Since topical sensitization is less frequent with fluoroquinolones, the likelihood of this complication can be minimized by using a fluoroquinolone rather than an aminoglycoside. Although much of the ototoxic risk of the aminoglycosides is obviated when treating patients when the TM is intact, clinicians must remain aware that a patient with significant edema of the ear canal might have an unsuspected membrane perforation. Therefore, even in a patient with known AOE, complications associated with topical antimicrobials other than fluoroquinolones are potentially severe.4

**Recommendations for potentially ototoxic topicals**

In March 2004, the American Academy of Otolaryngology-Head and Neck Surgery Foundation issued its consensus position on the appropriate use of potentially ototoxic antibiotic topical drugs in the treatment of ear disease.6 The recommendations are grounded in an evidence-based review of the clinical literature. After considering many issues relating to the potential ototoxicity of certain ototopical antibiotics, the panel unanimously agreed to the following recommendations:

- When possible, topical antibiotic preparations free of potential ototoxicity should be used in preference to potentially ototoxic preparations if the middle ear or mastoid are open.
- If used, potentially ototoxic an-

**Case study: A 2-year-old with tympanostomy tubes**

A 2-year-old girl presented with 2 days of drainage from her right external auditory canal. Tympanostomy tubes had been inserted 2 months earlier because of frequently recurring acute otitis media (AOM) associated with a bilateral 30 decibels (dB) conductive hearing loss.

On examination, the right ear canal was full of sticky, mucopurulent drainage. The ear was cultured, and the child was started on amoxicillin-clavulanic acid at 90 mg/kg/d. With no improvement after 10 days, the child was referred to her pediatric otolaryngologist.

The otolaryngologist removed all of the exudate from the right external auditory canal and from the orifice of the tympanostomy tube. The lab reported the causative organism was methicillin-resistant *Staphylococcus aureus*.

The girl was placed on ciprofloxacin/dexamethasone ototopical drops, 3 drops bid. The drainage resolved 3 days later. Upon examination, the tympanostomy tube in the right ear was in good position, patent, and uninfected.

**Comment**

This case illustrates the considerable advantage of the high concentration (0.3% = 3000 mcg/mL) of antibiotic in topical drops. This child was cured even though she had a resistant strain of *S aureus*.

The high concentration of antibiotic can eradicate any relevant organism if the medication can be delivered effectively to the middle-ear space. Exudate can be removed at home by irrigating the canal with a half-strength solution of commercial medicinal hydrogen peroxide (3%). Drops containing corticosteroids help prevent granulation tissue from impairing delivery of the medication to the middle ear.

**Quick facts about ear infections**

- The treatment of otorrhea has been described for more than 3500 years, but a scientific basis for therapy was lacking until late in the 20th century. Among the remedies that were used over the centuries were frankincense, goose grease, and cumin.1

- Children with a history of ear infections are 57% more likely than other children to be diagnosed with asthma and 70% more likely to have had wheezing in the previous year. Moreover, the risk of asthma and wheezing increased as the number of ear infections rose.2

- About 6% of children younger than 18 years have had 3 or more ear infections in the past year.3

- When it comes to ear infections, there is a marked difference between young children and older children. Among children younger than 3 years, 13% (1 in 8) has had at least 3 ear infections in the past 12 months. Once children reach age 3, this number drops to less than 5%.3

- Most pediatric ear infections are treated in clinicians' offices, but ailing and infected ears account for some 55,000 emergency department visits.3

- About two thirds of all patient visits for ear infections occur during the fall and winter months of October through March.3


Case study: A 19-year-old camp counselor with chronic suppurative otitis media

A 19-year-old man with a 2-year history of perforated tympanic membrane (TM) after a water skiing accident now presents with pain in his left ear, which has been draining for 5 weeks. The patient, a camp counselor, had been swimming daily in the camp’s lake. The physical examination demonstrated mucopurulent drainage filling the external auditory canal. He was started on cephalexin, po 500 mg bid. There was no improvement after 2 weeks. The follow up examination revealed persistent thick otorrhea now tinged with blood. The lab culture revealed Pseudomonas aeruginosa as the causative organism. The patient was then placed on oral ciprofloxacin, po 500 mg bid for 10 days. The drug is known to be effective against P aeruginosa.

Ten days later, the ciprofloxacin had been exhausted without improvement. He went to the county hospital emergency department where the on-call otolaryngologist examined him. Using an operating microscope, the otolaryngologist observed mucopurulent drainage leaking around the margins of a large granulation tissue polyp that filled the perforation and arose from the middle ear space. The exudate was meticulously removed from the external auditory canal, TM, and around the polyp. The patient was started an antibiotic drop containing ciprofloxacin and dexamethasone, 3 drops bid for 10 days.

A follow-up visit revealed complete resolution. The polyp was absent and the patient had a clean, dry, central TM perforation of 4 to 5 mm. He agreed to operative repair of the TM perforation at the county hospital where it was more affordable. It is worth noting that since the perforation was already 2 years old, it is unlikely it would have healed by itself. The patient, who had a chronic perforation, developed otorrhea because he contaminated his middle ear space while swimming. Had the perforation developed within the past 5 to 6 weeks, then the chances of spontaneous healing would be quite high. The patient should have discontinued swimming until the infection resolved and used earplugs for swimming and activities thereafter.

Comment

P aeruginosa is a common cause of acute otorrhea in individuals with non-intact TM. Topical therapy is often effective when systemic therapy fails—even when the same antibiotic is used—because a higher concentration of antibiotics can be delivered. Chronic suppurative otitis media is almost twice as likely to resolve with topical therapy than it is with systemic therapy even when the organism is sensitive to the systemic antibiotic utilized.1


Contributed by Peter S. Roland, MD

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ototoxic preparations presents no risk of ototoxic injury.

**Fluoroquinolone therapy**

Fluoroquinolone-containing ear drops cover the organisms that are commonly encountered in AOMT, AOE, and CSOM, so they can be used for infections in the middle and external ear.4 Clinical experience has shown the efficacy of these antimicrobial agents for chronic ear infections.5 Topical fluoroquinolone therapy, with or without a corticosteroid additive, is the treatment of choice for otorrhea in patients with TM perforation or a ventilating tube in situ.4 Clinical trials of the fluoroquinolones in adults and children have shown no evidence of ototoxicity.5

Local administration of high concentrations of fluoroquinolone drops effectively and rapidly decrease bacteria density, and the development of bacterial resistance is rare. The 2 available fluoroquinolone preparations—ciprofloxacin/dexamethasone and ofloxacin otic—can deliver a concentration of 3000 mcg/mL. This far exceeds the tissue concentration delivered to the middle ear via systemic medications and the minimum inhibitory concentrations for any known ear pathogens.5

The concentration is critical because infectious processes of the middle ear are usually difficult to cure, probably because of the low absorption of antibiotics at this site and the frequent etiologic role of Pseudomonas organisms, which are resistant to several classes of antibiotics. One study showed that the use of topical ciprofloxacin in pediatric patients was curative in nearly 70% of patients with otorrhea associated with P aeruginosa who were previously unresponsive to other antimicrobial agents.2 No adverse reactions were reported in the study population.

**The additive effect of corticosteroids**

Corticosteroids downregulate the inflammatory process, decrease tissue edema and tissue hyperemia, and
When referral is the next step

Most childhood ear infections can be resolved in the primary care clinician’s office. Regardless of the type of ear infection, clinicians should consider a consultation with an otolaryngologist when:

- The child’s ear infection does not respond to first-line therapy. For acute otitis media (AOM), many clinicians prefer the observation option which encourages clinicians and caregivers to monitor the child for 48 hours to see if the AOM will resolve without antibiotic treatment. If the child continues to have pain and/or remains febrile after 48 hours, antibiotics are given. If there is no improvement after 48 hours of antibiotics, then the child is not responding to first-line therapy.
- There is persistent pain beyond 48 hours or a temperature elevation of over 101°F (38.3°C) continues 48 hours after the initiation of treatment.
- There is evidence of complications such as redness and tenderness around the ear, unexpected lethargy, a stiff neck, changes in vision, facial nerve weakness, marked disequilibrium, or vertigo.
- The volume of drainage increases after the initiation of therapy or fails to resolve within 7 days after the onset of therapy. Note: The color of the drainage is not important.
- Fluid in the middle-ear persists for more than 3 months.

Limit the transudation of fluid from inflamed tissues. Decreasing neovascularization prevents granulation tissue formation.10 “Corticosteroid drops have been shown both to improve cure rates for post-tympanostomy tube otitis media and to hasten the rapidity with which granulation tissue is eliminated from an infected ear,” according to Dr Roland.

Granulation tissue can be a significant barrier to the delivery of antibiotic drops to infected tissues by blocking the passage of drops down the ear canal and through the TM into the middle-ear space. It is not known with certainty why corticosteroids increase the rapidity with which post-tympanostomy tube otitis media resolves, but it may be a consequence of reducing edema of the mucous membranes in the middle-ear space.

Because of the inflammation induced by microorganisms, topical corticosteroids are often given with topical antibiotics to reduce the sequelae.3 The corticosteroid component offers benefit if there is inflammation associated with infection or disease.

Compared to single fluoroquinolone agents, the combination of a fluoroquinolone and a corticosteroid has been shown to be superior for clinical cure (90% versus 79%) and microbiologic success (91% versus 82%) in treating children with AOMT (see Table 1, page 3).3

Ciprofloxacin/dexamethasone produces fewer treatment failures than ofloxacin (4.4% versus 14.1%) and results in a shorter median time to cessation of otitis media (see Table 2, page 5).11 The 2-day difference in favor of ciprofloxacin/dexamethasone over ofloxacin is clinically meaningful because it represents a 33% improvement in clinical response and results in using considerably less drug (96 drops compared with 100 drops) for a shorter period (7 days compared with 10 days).11 Pretherapy pathogens in the study included S pneumoniae (16.8%), S aureus (13%), P aeruginosa (12.7%), H influenzae (12.4%), S epidermidis (10.2%), and M catarrhalis (4.1%). Patients in the ciprofloxacin/dexamethasone group received 4 drops bid for 7d, and those in the ofloxacin group received 5 drops bid for 10 d.

In general, adverse events were mild to moderate, usually resolved with or without treatment, and did not interrupt patient participation.

References
A clinician’s guide to frequently asked questions

Q. Do topical drops work in patients older than 3 years? What age-specific treatment protocols should be considered?

A. The efficacy of topical drops is not related to age. Rather, efficacy arises from the higher concentration of medication that a topical preparation can deliver. A topical drop containing 0.3% fluoroquinolone contains 3000 mcg/mL of medication.

Oral administration of antibiotics commonly used to treat acute otitis media (AOM) results in the following concentrations of antibiotic in middle-ear fluid: 8 to 10 mcg/mL (high-dosage amoxicillin); 1 to 2 mcg/mL (cefuroxime); 20 to 25 mcg/mL (cefuroxone). These concentrations are 100 to 1000 times lower than those found in topical drops.

In terms of the amount of antibiotic delivered to the middle ear, topical drops have a huge therapeutic advantage over systemic medications—whether the systemic medications are administered orally, IM, or IV.

Q. Do corticosteroids in topical drops affect physical growth in children?

A. Growth-specific studies have yet to be performed with these medications. The issue has not concerned clinicians, pediatric endocrinologists, or the FDA because the anticipated duration of therapy recommended by the manufacturer is short. Although some intranasal corticosteroids prescribed for asthma and allergies can suppress growth in children after exposure for several months or perhaps years, even moderate to high dosages of corticosteroids administered systemically to growing children for short periods of time do not appear to retard children’s growth velocity.

Q. Is it acceptable to use fluoroquinolones in children?

A. When systemic doses of fluoroquinolone are administered to laboratory animals, destructive changes have been detected in joints. This has lead to concern that similar changes might occur in growing children. However, fluoroquinolones have been administered systemically to children with cystic fibrosis for many years with no ill effects. No joint pathology has been found in the many thousands of children who have been evaluated after taking fluoroquinolones.

Consequently, there is little genuine concern about joint pathology, even when fluoroquinolones are administered to children in high dosages for long periods of time. In any case, the total dosage of fluoroquinolone administered in topical drops is very low. A typical dose (3-4 drops of a 0.3% solution) contains only about 1 mg of fluoroquinolone antibiotic. This is hundreds of times lower than a dose of fluoroquinolones administered systemically. Consequently, the blood levels are almost undetectable. Even if systemic doses of fluoroquinolones did cause significant joint changes, there is no evidence the minuscule dose circulating in the blood stream after topical therapy would be sufficient to harm joints.

Q. Does topical dexamethasone cause adrenal suppression?

A. It is possible that adrenal suppression might occur if topical drops are utilized for long periods of time. Pediatric endocrinologists, however, indicate that this is not a concern if duration of therapy is reasonably short—from 2 to 3 weeks.

Q. Are ear drops well-tolerated by most patients? Do they burn?

A. Topical drops are generally well-tolerated, although they can produce discomfort and cause a burning sensation in a small percentage of patients. The reason for this is unclear. Unless the pH level is very low, the proportion of recipients who complain of a burning sensation is small.

Q. What considerations can be taken to ensure drops are better tolerated?

A. Administering cold drops is probably a significant cause of discomfort in children, so drops should be warmed to body temperature whenever possible. Warming the bottle in the hand, carrying the bottle in a pocket close to the body or warming the bottle in a pan of lukewarm water, like a baby bottle, are all effective ways of warming the drops.

Q. What is the risk for aminoglycoside-related ototoxicity?

A. Published data indicates the risk of aminoglycoside-related cochlear toxicity and hearing loss is low. It is more difficult, however, to determine the incidence of toxicity to the vestibular system. Since vestibular toxicity occurs slowly and the contralateral vestibular system is likely to compensate, vestibular toxicity can occur with relatively few symptoms.

The only way to definitively establish the presence of vestibular toxicity is to perform a sophisticated evaluation such as electronystagmography. Such tests are virtually never performed on asymptomatic individuals who have received aminoglycoside otic drops. Consequently, the incidence of vestibular toxicity is unknown. However, recent work done at the University of Toronto suggests vestibular toxicity may occur more commonly than previously believed.

Since fluoroquinolones appear to have no ototoxicity at all, a recent consensus panel of the American Academy of Otolaryngology-Head and Neck Surgery has recommended that aminoglycoside-containing drops be reserved for second-line therapy. Because they lack ototoxic potential, the consensus panel unanimously agreed that fluoroquinolone drops were more appropriate for first-line therapy.