The Diagnosis and Management of Otitis Media with Effusion

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Children with otitis media account for one-third of all pediatric sick visits in this country, with more than 31 million physician visits for acute otitis media (AOM) reported each year. Two-thirds of these children will subsequently develop otitis media with effusion (OME). It is not, therefore, surprising that the diagnosis, management, and treatment of this condition is of great interest to parents, physicians, and third-party payers. There has been, to date, a great deal of variation in the practice patterns of general pediatricians, family practitioners, and otolaryngologists with regards to OME. In an effort to address variations in quality of treatment for OME, the Agency for Health Care Policy and Research (AHCPR) issued a guideline for the management of OME in 1994. This article will review the 1994 guideline as well as the diagnosis and medical and surgical management of OME.

DEFINITION AND NATURAL HISTORY

Otitis media with effusion is defined as fluid in the middle ear without associated signs or symptoms (fever, otalgia, irritability) of infection and should not be confused with AOM. OME usually follows an episode of AOM, with the mean duration of middle ear effusion (MEE) of 23 days. The pathogenesis of OME is multifactorial, involving the host (immature...
TABLE 1
Risk Factors for Chronic Otitis Media with Effusion

<table>
<thead>
<tr>
<th>Host</th>
<th>Environment</th>
<th>Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>Bottle-feeding</td>
<td>Bilateral middle ear effusion</td>
</tr>
<tr>
<td>Age &lt;2 Years</td>
<td>Passive smoke</td>
<td></td>
</tr>
<tr>
<td></td>
<td>exposure Group day-care</td>
<td></td>
</tr>
<tr>
<td>Anatomical</td>
<td>Group day-care</td>
<td></td>
</tr>
<tr>
<td>defect:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cleft palate;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Down syndrome</td>
<td></td>
<td></td>
</tr>
<tr>
<td>History of acute otitis media</td>
<td>Season:</td>
<td>Winter&gt;Summer</td>
</tr>
</tbody>
</table>

TABLE 2
Important History In the Evaluation of Otitis Media with Effusion

<table>
<thead>
<tr>
<th>History of acute otitis media</th>
<th>Duration of middle ear effusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive smoke; Group day-care;</td>
<td>Season</td>
</tr>
<tr>
<td>Impact on hearing and language</td>
<td>Impact on overall quality of life</td>
</tr>
</tbody>
</table>

anatomy and immune system), the environment (group day care, passive smoke exposure), and infectious agents (viruses and bacteria). The role of bacteria in OME is not completely understood. By conventional culture methods, approximately 30% of MEE will yield pathogenic bacteria, most commonly non-typeable Haemophilus influenzae, Streptococcus pneumoniae, and Moraxella catarrhalis. More recently, however, PCR studies have indicated that 77% of MEE are positive for one or more pathogenic bacteria. The isolation of bacteria in MEE gives credence to the use of antibiotics in the treatment of OME.

The majority of cases of OME will resolve spontaneously, with resolution expected in 80% to 90% of children by 3 months. Chronic OME is defined as a MEE present continuously for over 3 months. Risk factors for chronic OME are given in Table 1. Chronic OME has reported rates of spontaneous resolution of only 20% to 30%, even after years of observation. Most cases of OME are associated with a conductive hearing loss averaging about 25 dB. It is hearing loss as well as the possibility of language delay, behavior problems, and poor academic performance that has led to investigations of multiple medical and surgical treatments for OME.

DIAGNOSIS

Most cases of OME occur after an episode of AOM, with 67% of children developing a MEE. The effusion is usually noted during a follow-up visit. However, because it has been shown that parental judgment of symptom resolution correlates well with resolution of AOM, many children may not receive scheduled follow-up. Because it may be difficult for a young child with OME to communicate symptoms such as aural fullness, decreased hearing acuity, and tinnitus, they may appear to be asymptomatic to the parents, and OME is noted incidentally during a well child exam.

OME is diagnosed by direct visualization of the tympanic membrane (TM). Otoscopy may reveal a dull, non-erythematous TM and the presence of an effusion, which may be documented by air bubbles or an air fluid level behind the membrane. Because these findings are not always present, pneumatic otoscopy should be performed to assess the mobility of the TM. The most consistent physical finding in OME is impaired mobility of the TM by pneumatic otoscopy.

The presence of fluid may be confirmed by tympanometry, which should reveal a flat, type B curve, indicating the TM admittance is uniformly low, or a type C curve, indicating negative peak pressure values, which may be associated with some degree of middle ear effusion.

MANAGEMENT

The AHCPR 1994 algorithm for managing OME is given in the Figure. The guideline was developed by a non-Federal, interdisciplinary expert panel of health-care professionals. The intent of the panel was to comprehensively analyze the medical literature concerning OME in young children and to issue a guideline for the management of OME based on scientific data. The guideline is directed toward a specific “target patient,” that being a child 1 to 3 years of age with no craniofacial, neurologic, or sensory deficits, who is healthy except for OME. The guideline assumes follow-up periods of 6, 9, and 12 weeks. The guideline provides an excellent, comprehensive review of the scientific literature related to OME. It has, however, been criticized for being narrow in scope, favoring medical as opposed to surgical management of OME, and minimizing the problem of drug-resistant bacteria. The guideline will be referred to throughout the sections on medical and surgical management of OME.

MEDICAL CONSIDERATIONS

At the initial visit, several important historical points should be elicited (Table 2). If the MEE has been present for less than 6 weeks, a period of observation is recommended. Sixty percent of MEE will resolve by 1 month and 80% by 2 months. Family
counseling regarding the elimination of environmental risk factors, especially passive smoke exposure, is also recommended. During the fall, consideration should be given to immunizing the child against influenza.

After 6 weeks, according to the AHCPR guidelines, a child with OME can be managed with continued observation or a trial of oral antibiotic therapy. Meta-analysis has shown a 14% increase in resolution of OME with antibiotics when compared to placebo. The guideline specifically discourages the use of decongestants and/or antihistamines or oral steroids. Surgery is not indicated at the 6-week visit.

Although there is currently sufficient evidence to indicate that antibiotics provide a therapeutic benefit in the treatment of OME, the AHCPR guideline does not make specific recommendations regarding the selection of an oral antibiotic agent or duration of therapy. The antibiotics that were evaluated by the expert panel included amoxicillin, erythromycin, erythromycin/sulfisoxazole, trimethoprim/sulfamethoxazole, sulfisoxazole, cefaclor, and amoxicillin/clavulanate. This list contains both β-lactamase stable and nonstable agents. In this era of increasing antibiotic resistance (β-lactamase production by H influenzae and M catarrhalis, and alteration in penicillin-binding proteins by S pneumoniae), the choice of an antibiotic agent should be individualized for each patient. Consideration should be given to the patient's prior experience with antibiotics, age, sex, and day-care attendance. If a patient is not penicillin allergic and has not failed amoxicillin in the past, then amoxicillin would be a reasonable medication with which to initiate treatment. Amoxicillin is usually well tolerated, safe, and inexpensive. In addition, it is efficacious against the most common bacteria involved in OME and is even effective against some penicillin-resistant S pneumoniae (PRSP) at dosages of 60 to 80 mg/kg/day. If the patient has been on amoxicillin in the previous 4
The majority of cases of otitis media with effusion will resolve spontaneously, with resolution expected in 80% to 90% of children by 3 months.

weeks, then a trial of a β-lactamase stable agent such as amoxicillin/clavulanate or one of the second- or third-generation cephalosporins can be attempted. The duration of antibiotic treatment is not well established, but for most agents would be approximately 10 days. Prolonged treatment has failed to show an advantage over 10 days of therapy.

At the 12-week follow-up, if the patient continues to have OME, then the guideline recommends testing the child’s hearing with subsequent management based on the outcome of the evaluation. If the child is found to have a bilateral deficit of 20 dB or greater at 3 months, then the recommendation is made for oral antibiotic therapy or bilateral myringotomy with tube placement. The management of the patient with unilateral hearing loss or insignificant hearing loss includes continued observation or oral antibiotic therapy. As stated previously, observation alone after 3 months is unlikely to result in significant improvement; therefore, a trial of a β-lactamase stable agent seems most appropriate. Factors that would favor early surgical intervention would include bilateral OME, age younger than 2 years, early onset AOM, recurrent AOM, group day-care attendance, passive smoke exposure, and fall or winter season.6

Additional medical therapies to consider prior to surgery include steroids and autoinflation of the middle ear. Neither of these have been recommended by the AHCPR, but both are inexpensive and, for parents wishing to exhaust all medical options prior to surgery, should be considered.

To prepare the AHCPR guideline, the expert panel reviewed the medical literature available through 1993. The panel found that the combination of steroids plus antibiotics improved clearance of MEE in 25.1% of patients. This did not, however, reach statistical significance, and the panel felt that the risk of steroids outweighed the potential benefits. Since the publication of the guideline, there has been another investigation of the use of steroids in combination with antibiotics for chronic OME.5 The author concludes that one out of four children treated with steroids may avoid or postpone surgery for 6 months. Steroids may have a role in selected children, especially those who might not be good surgical candidates. If steroids are to be used, they should be given in combination with a β-lactamase stable antibiotic. Oral prednisone or prednisolone at a dose of 1 mg/kg given for 5 to 7 days has been recommended by several authors.8 Steroids are contraindicated in children with a history of varicella exposure because of the possibility of life-threatening disseminated disease.9

Autoinflation of the middle ear is a technique that has been used with mixed results. However, two studies in children 3 to 10 years of age have shown statistically significant improvement in up to 60% of ears at short-term follow-up.10,11 A device known as the Otovent (Inotec International, Jacksonville, FL) is available at a cost of approximately $12 to $25. This treatment may be helpful for selected children when nonsurgical options have been exhausted.

SURGICAL CONSIDERATIONS

The decision for surgical treatment for OME should be individualized for each patient. Collaboration and communication between the primary care provider and the otolaryngologist is crucial. In addition, the treatment goals of the patient and the parents, as well as the impact of OME in the life of the family, must be carefully considered. Factors that favor surgical treatment of OME are given in Table 3.

More than 500,000 children in the United States undergo tympanostomy tube placement for chronic OME each year. Tympanostomy tube placement is the most common surgical procedure performed on children in the United States. Questions concerning the appropriateness of tube placement as well as the cost effectiveness of surgical treatment for OME led the AHCPR to issue very specific recommendations for the surgical treatment of OME.

The AHCPR guideline recommends that a child with OME that has persisted for 4 to 6 months and who has a bilateral hearing loss should have a bilateral myringotomy with tube placement. Placement of short-acting tympanostomy tubes results in immediate restoration of hearing and drainage of the MEE. Surgical intervention might be appropriate prior to 4 months in a child with the risk factors as described in Table 3.

Some investigators have recommended adenoidectomy either alone or in combination with tubes for the treatment of OME. The AHCPR did not support the use of adenoidectomy for children between the ages of
1 and 3 years. This decision was controversial, and arguments for the use of adeno-nectomy as the primary treatment of OME in older children and in children with recurrent OME after tympanostomy tube placement have been made.12 There is a significantly higher percentage of children requiring repeat surgical procedures after tubes alone (24%) than after tubes plus adeno-nectomy (12%).13 It has been postulated that by removing the adenoids, a reservoir of pathogenic bacteria is removed, thus lowering rates of recurrent AOM and subsequent OME. The principal risks of adeno-nectomy are postoperative bleeding, which occurs in approximately four per 1000 and anesthetic risk, which is estimated to be one per 10,000.14

Surgical procedures that are not recommended include myringotomy alone and tonsillectomy, neither of which appear to improve the outcome of OME.

COST EFFECTIVENESS OF TREATMENT

There are 1.9 million cases of OME in children younger than age 2 each year in the United States. Between $2 and $4 billion a year is spent on the medical and surgical management of these patients.15 The variation in physician practice has contributed to the high cost of treating OME. The AHCPR guideline noted that the average cost for medical management of OME is $402 per episode, while the surgical management averages $2174.1 Berman and colleagues used a computer model to determine the theoretical cost effectiveness of various treatment strategies for OME.15 The average per patient expenditures were calculated using the efficacy rates determined by meta-analysis of trials involving observation, antibiotics, steroids, and the combination antibiotics and steroids. The analysis indicated that the most cost-effective strategy was the use of steroids plus antibiotics at the 6-week visit and a second course of antibiotics at the 9-week visit, followed by tympanostomy tubes at 12 weeks in the nonresponders. The average expenditure per case to clear MEE was $600 based on insurance reimbursement of private practice charges. The difference between this strategy and sequential courses of antibiotics followed by surgery was almost $400.

Although the Berman study did not consider risks and side effects of treatment or parental preference, it did suggest that implementation of treatment guidelines could lower the national cost for managing OME. The availability of the AHCPR guidelines, which based recommendations for the treatment of OME on scientific data, is likely to decrease the costs associated with treating OME. Further research on the use of steroids and adeno-nectomy in young children for the treatment of OME is needed to determine the most efficacious and least costly alternatives for the treatment of OME.

REFERENCES