Evidence Report

Chapter 1. Introduction

Purpose

The purpose of this evidence-based report is to review the evidence on the diagnosis, natural history, and late effects of otitis media with effusion (OME) on long-term speech, language, and hearing. The evidence compiled in this report is intended to aid clinicians, health care provider organizations, and others to develop clinical practice guidelines or medical review criteria for OME. The report will also identify areas for future research. Despite the relatively recent publication of the 1994 Otitis Media with Effusion in Children guideline (Stool, Berg, Berman, et al., 1994), the technical experts believed that OME remained a topic worthy of evidence-based inquiry due to the continued controversy over the care of children with OME and the potential availability of new information.

Scope of Work

The technical experts initially proposed 20 questions that addressed 10 broad areas related to the diagnosis and treatment of otitis media with effusion: (1) allergens, (2) natural history, (3) speech and language, (4) diagnostic methods, (5) surgical interventions, (6) hearing, (7) antibiotics, (8) steroids, (9) antihistamines and decongestants, and (10) alternative or complementary therapies. These twenty questions were ranked based on the following criteria: (1) degree of potential impact on OME outcomes and on future guideline development and (2) the feasibility of answering the question within the one year time frame and the availability of new information in the literature. The scope of this report covers the four highest ranked questions: (1) the natural history of otitis media with effusion (OME), (2) the long-term impact of early-life otitis media on speech and language, (3) the long-term impact of early-life otitis media on hearing, and (4) the accuracy of methods of diagnosis of otitis media with effusion.

Definition

The definition of otitis media has been a complicated issue. Ben H. Senturia, quoted in Bluestone (1999), stated that “In the past, there has been a confusion of terms, in part because of a failure to distinguish conceptually between the disease process, otitis media, and one of the manifestations of that disease process, namely otitis media with effusion. Otitis media is dynamic and at any one time should be considered a single point in a continuum of the disease process.”

Recent comments on the definition of OME point to some of the complex issues involved:

1. The OME guideline (Stool, Berg, Berman et al., 1994) defined OME as "fluid in the middle ear without signs or symptoms of ear infection." The guideline listed the following synonyms for OME: serous otitis media, secretory otitis media, allergic otitis media, catarrhal otitis media, nonsuppurative otitis media, mucoid otitis media, secondary otitis media, hydrotubotympanum, exudative catarrh, tubotympanitis, tympanic hydrops, glue ear, fluid ear, middle ear effusion, and tubotympanic catarrh.

2. Bluestone (1999) defined otitis media with effusion (OME) as "an inflammation of the middle ear with liquid collected in the middle-ear space. The signs and symptoms of acute infection are absent and there is no perforation of the tympanic membrane." He stated that middle-ear effusions can be acute (< 3 weeks), subacute (3 weeks to 3 months), or chronic (> 3 months). He also stated that researchers should precisely define OME.

3. Patterson and Paparella (1999) agreed that the different forms of otitis media (OM) are "interrelated and occur in a continuum." They recognized OME as one of the three major forms of OM, the other two being chronic OM (active or inactive) and silent OM. They classified OME as serous OM, purulent OM, and chronic OM. They divided serous OM into acute serous OM, chronic serous OM, and mucoid OM.

4. Jung and Hanson (1999) agreed that OM consists of various stages. Though they viewed purulent otitis media, serous otitis media, and mucoid otitis media as different stages, they considered OME to encompass all three, except the early stages of acute otitis media (AOM).

5. Paradise (1995) also agreed that "AOM and OME constitute elements in an otitis media disease spectrum, that there often is a transition zone between them and that the two conditions sometimes may be indistinguishable from each other diagnostically."

For this evidence report, the Technical Expert Panel decided to use the definition used in the OME Guideline (Stool, Berg, Berman et al., 1994): "fluid in the middle ear without signs or symptoms of ear infection."

Diagnosis

Various methods have been proposed for the diagnosis of OME. The OME guideline panel drew several conclusions regarding diagnosis of OME (Stool, Berg, Berman et al., 1994). They recommended the use of pneumatic otoscopy as the primary diagnostic method with tympanometry as a confirmatory diagnostic method. These recommendations were based on limited scientific evidence and strong panel consensus and on limited scientific evidence and expert opinion, respectively. The OME guideline panel found no evidence linking the outcome of algorithms that combine the results of pneumatic otoscopy and tympanometry to the presence of middle-ear effusion. In addition, the panel believed that the evidence was insufficient to make any recommendation regarding the use of acoustic reflectometry in the diagnosis of OME. Finally, the panel decided not to make a recommendation on the use of tuning fork tests in the diagnosis of OME due to the lack of adequate studies. The OME guideline panel did not present any meta-analyses on diagnostic methods.

Pneumatic otoscopy is performed with a handheld unit that consists of a light source, a magnifying lens, and a speculum. The otoscope allows visual inspection of the tympanic membrane as well as the external ear canal. With the speculum securely in place, the degree of movement of the tympanic membrane in response to pneumatic pressure may be observed. Decreased tympanic membrane mobility in response to pneumatic pressure is believed to be related to the presence of middle-ear effusion as found in OME. (Carlson and Stool, 1999)

Tympanometry is performed by inserting into the ear a probe that emits a tone and measures the amount of sound energy reflected from the tympanic membrane as a function of ear canal air pressure. The instrument may or may not be handheld. The output of tympanometric measurement may be qualitative, that is, tympanogram patterns, or quantitative, for example static admittance, equivalent ear volume, tympanometric width, tympanometric peak pressure, or acoustic reflex. The flat or type B tympanogram is believed to be associated with the presence of middle-ear effusion. The type A tympanogram is believed to indicate normal middle-ear status. The relationship of the type C tympanogram to middle-ear status is less clear. (Carlson and Stool, 1999; Nozza, 1996)

The acoustic middle-ear muscle reflex, either ipsilateral or contralateral, may also be measured by acoustic emittance instruments and represents the contraction of the stapedius and tensor tympani in response to sound stimulation. Its absence may be related to the presence of middle-ear effusion depending on the clinical situation (Nozza, 1996).

Acoustic reflectometry is performed using a handheld instrument that measures the response of the tympanic membrane to a frequency-sweep sound spectrum. The spectral gradient angle, which is a function of the frequency and amplitude, may be related to middle-ear effusion presence. (Carlson and Stool, 1999; Nozza, 1996)

Evoked otoacoustic emissions are a measure of ear canal sounds that are generated in the cochlea. These sounds have the potential for clinical application (Nozza, 1996).

Audiometry measures hearing acuity, using behavioral or non-behavioral methods, at various sound frequencies. It is known that children may have decreased hearing in the presence of middle-ear effusion (Carlson and Stool, 1999). Although no "universal agreement" appears to exist regarding the definition of hearing loss, a hearing threshold no worse than 15 decibels (dB) is considered normal in children, and 20 dB may be considered normal in older children (Madell, 1999)

Epidemiology: Prevalence and Incidence

Accurate estimates of the prevalence or incidence of OME were not found, since published population-based estimates are not available on the specific diagnosis of OME. Data on office visits reported from the National Ambulatory Medical Care Survey (NAMCS) provide the best indication of prevalence and incidence of the disease, although nonsuppurative, suppurative, and unspecified otitis media were all grouped into the term otitis media, and OME was not separated from AOM in the analyses (Schappert, 1992; Schappert, 1996; Woodwell, 1997a; Woodwell, 1997b; Woodwell and Schappert, 1995). Gates (1996), commenting on the NAMCS data, stated, “for children it is probably safe to presume that AOME [AOM with effusion, i.e. AOM] is the principal disorder noted in these surveys.” The OME Guideline panel of the Agency for Health Care Policy and Research [presently the Agency for Healthcare Research and Quality (AHRQ)] estimated that 25 percent to 35 percent of the NAMCS visits for otitis media were for OME (Stool, Berg, Berman et al., 1994a).

Schappert (1992) reported on the 1975 to 1990 NAMCS data. Visits by patients younger than 15 years of age constituted 70.6 percent of all office visits with the principal diagnosis of otitis media in 1975, 78.9 percent of all office visits with the principal diagnosis of otitis media in 1980, 81.9 percent of all office visits with the principal diagnosis of otitis media in 1985, and 80.5 percent of all office visits with the principal diagnosis of otitis media in 1990. From 1975 to 1990, the percent of office visits with otitis media as the principal diagnosis increased among those less than 15 years of age; from 7.3 percent to 17.4 percent for children under 2 years old,

from 10.4 percent to 18.1 percent for the 2-5 year olds, from 6.9 percent to 10.5 percent for the 6-10 year olds, and from 2.6 percent to 5.2 percent for the 11-14 year olds. The number of visits with a principal diagnosis of otitis media per 100 persons per year for the same time period (1975 to 1990) increased from 31.5 to 102.1 for children less than 2 years of age, 20.8 to 47.8 for those 2-5 years of age, 10.2 to 18.2 for those 6-10 years of age, and 3.3 to 8.0 for those 11-14 years of age.

Rosenfeld (1994) noted that about a quarter of OME cases are discovered incidentally during well-child examinations. About 60 percent of children would have OME by 2 years old and 80 percent before school entry. The Agency for Healthcare Research and Quality 1994 OME guideline reported that in one study of children 2 to 6 years old in group child care, 53 percent had at least one episode of OME during the first year of the study, 61 percent had at least one episode during the second year of the study, and 30 percent had recurrent OME (Stool, Berg, Berman et al., 1994).

NAMCS also stratified data by specific physician type. From 1975 to 1990, the percent of office visits with a principal diagnosis of otitis media increased for pediatricians from 8.1 percent to 14.3 percent, for general practitioners and family physicians from 1.3 percent to 3.5 percent, and for otolaryngologists from 12.8 percent to 20.2 percent.

Data for 1975 to 1990 were also stratified by age. In 1990, the number of visits with a principal diagnosis of otitis media per 100 persons per year among children younger than 2 years was 62.9 for pediatricians, 24.0 for general practitioners and family physicians, and 9.1 for otolaryngologists. In 1990, the number of visits with a principal diagnosis of otitis media per 100 persons per year among children 2 to 5 years old was 29.0 for pediatricians, 11.4 for general practitioners and family physicians, and 6.6 for otolaryngologists (Schappert, 1992).

The reports on the NAMCS data for 1993 to 1996 did not stratify by age (Schappert, 1996; Woodwell, 1997a; Woodwell, 1997b; Woodwell and Schappert, 1995). However, if the 1993 to 1996 data were similar to that in 1975 to 1990, it would be reasonable to conclude that the majority of these patients were younger than 15 years of age.

NAMCS office visit data for 1993 to 1996 generally support earlier data. Suppurative and unspecified otitis media was the third most frequently listed principal diagnosis in 1993, the sixth most frequent in 1994, the fourth most frequent in 1995, and the seventh most frequent in 1996 for ambulatory care visits to physician offices, hospital outpatient departments, and emergency departments (Schappert, 1996; Woodwell, 1997a; Woodwell, 1997b; Woodwell and Schappert, 1995). In 1996, visits for a principal diagnosis of otitis media and eustachian tube disorders occurred 82.8 percent of the time in physician offices, 5.3 percent in hospital outpatient departments, and 11.9 percent in emergency departments (Woodwell, 1997a).

The NAMCS also provided data on the duration of office visits for otitis media. The percent of visits for otitis media of duration 6-15 minutes increased between 1975 to 1990 from 64 percent to 78 percent and was associated with a decrease in visits less than six minutes from 24 percent to 13 percent (Schappert, 1992). In terms of surgical procedures, the rate of ambulatory surgery visits per 10,000 population for those younger than 15 years of age for otitis media and eustachian tube disorders was 86.9 in 1994 and 83.9 in 1995, based on 498,000 and 484,000 visits respectively (Hall and Lawrence, 1997; Kozak, Hall, Pokras et al., 1997). In 1995, the number of myringotomy with tympanostomy tube placements reported by NAMCS was 521,000 for a rate of 90.2 such procedures per 10,000 children less than 15 years of age (Hall and Lawrence, 1997).

In general, the NAMCS data demonstrated the significance of otitis media—and by implication OME—based on the prevalence and incidence of the disease and the frequency and duration of visits and surgical interventions.

Burden of Illness Due to Otitis Media with Effusion

The treatment, complications and sequelae, and adverse effects of otitis media, including OME, are a substantial financial burden to the nation. Three estimates of the cost of otitis media (OM) are found in the literature (Gates, 1996b; Stool and Field, 1989; Stool, Berg, Berman et al., 1994). A fourth study reported the cost per episode of "persistent middle ear infection" (Berman, Roark, and Luckey, 1994). We have assessed the strengths and weaknesses of these four studies and presented our own estimate of otitis media costs in a previous evidence-based analysis (Takata, Chan, Shekelle, et al., in press).

Gates (1996b) placed the annual national total cost of acute otitis media at $3.15 billion for the 0- to 4-year old age group in an unspecified date in the early or mid-1990's and placed the cost of treatment of chronic otitis media with effusion at $1.854 billion dollars per year (Gates, 1996). Stool and Field (1989) put the national cost of otitis media at $2.4-3.4 billion in the 0- to 6-year old age group in an unspecified year presumably in the middle or late 1980's. Both Gates (1996b) and Stool and Field (1989) assumed prevalences of otitis media that were at variance with the only available national data on the utilization of care visits for otitis media. Stool, Berg, Berman, et al. (1994) presented the only estimate of the national cost of otitis media using a data-based estimate of costs per case. Using claims data from more than 100 health insurers, they estimated the overall average cost of treating a 2-year old child with OME in 1991 to be $1,330 and the national total cost of OME in 1991 to be $1.09 billion. Berman, Roark, and Luckey (1994) estimated the cost of treating persistent middle ear effusion in a 13-month old boy at $720-$1,372 under Colorado Medicaid reimbursement levels in 1992 and $1,265-$2,588 under private practice reimbursement rates. Not all these studies included the indirect cost of family caregiving services required due to a child having otitis media.

An attempt to provide an updated estimate on the cost of otitis media included insights into the cost of OME and chronic middle ear infection (Takata, Chan, Shekelle, et al., in press). This estimate was derived for the year 1995, referred to children under 18 years of age, and was based on reports of national, rather than regional, utilization for otitis media such as the National Ambulatory Medical Care Survey and the National Health Interview Survey. Using these national data sets, it was estimated that 2.22 million episodes of OME or chronic middle ear infection occurred in 1995. It was assumed that eighty percent of these episodes were unrelated to acute otitis media. Data from three sources (Stool, Berg, Berman et al., 1994; Berman, Rourke, and Lucky, 1994; and the U.S. Bureau of the Census, 1992,1996) were used to estimate direct, indirect, and total costs of $1,321, $490.25, and $1,811 for treatment of an episode of OME or chronic middle ear infection. For 1995, the total national cost of treating OME or chronic middle ear infection would stand at $4.02 billion.

Whether based on the four prior estimates of otitis media or OME cost or the more recent estimate, the economic burden of OME on the nation is large. Any effort to improve cost-effective care of OME will result in significant savings in national medical expenditures as well as improved quality of care provided to children with OME.