Dynamic Chiropractic

PEDIATRICS

A Review of the Federal Guidelines for OME

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In July 1994, the Agency for Health Care Policy and Research released Clinical Practice Guideline for otitis media with effusion (OME). The guideline panel was comprised of MDs, PhDs, and several RNs.

Otitis media is considered a general term for numerous conditions that can affect the middle ear, ranging from acute to chronic and with or without symptoms. The condition of otitis media with effusion (OME) is characterized by the presence of fluid in the middle ear without signs or symptoms of an infection. OME has also been referred to as noninfected middle ear effusion, secretory otitis media, and serous otitis media, among other terms. The condition of OME is considered one of the most common problems of infancy and early childhood, and is responsible for significant morbidity and expense. A majority of children will have one or more episodes during early childhood with a notable number having repeated episodes.

The National Center for Health Statistics reports that otitis media is the most common diagnosis for a physician's office visit by children under 15. Specifically, children under two have the highest rate of visits to a physician's office for OME. From 1975-1990, office visits for OME increased by 150 percent. Children under 15 accounted for 24.5 million more visits to the physician's office, or an increase of 81 percent office visits for the diagnosis and treatment of OM.

The guideline panel reviewed a 1991 cost analysis of private health insurance claims regarding the cost impact to the consumer for this pediatric disorder. The analysis revealed estimated direct and indirect medical management costs (office visits, medications, parents' time lost from work) at approximately $406 per patient episode, and direct or indirect surgical treatment costs (office visits, parents' time lost from work, and charges from myringotomy with insertion of tympanostomy tubes) at $2,174 per patient episode. With limited data, the guideline panel extrapolated from the cost analysis the estimated expense for the two-year-old population of children in the U.S. The average cost of treatment per 2-year-old for the reported 821,700 cases for 1991 across all treatment categories was estimated to be $1,330 per case or a total direct or indirect cost of $1.09 billion.

OME should not be confused with acute otitis media, which is fluid in the middle ear accompanied typically by signs or symptoms of ear infection. This can include bulging of the ear drum, usually accompanied by pain, or perforated ear drum, often with drainage. The panel discussion of the identification and management of OME was limited to a specific target patient, children 1-3 years old, with no craniofacial or neurological abnormalities or sensory deficits, and considered healthy except for this specific disorder. Common causes of middle ear fluid are past ear infections, blockage of the eustachian tubes and a cold or the flu. Common signs of suspected OME are discomfort and behavior changes, sometimes accompanied with the child not paying attention or turning the sound on the television louder to compensate for the fluid in the middle ear.

The Clinical Practice Guideline informs the medical professional not to diagnose and render treatment to the pediatric patient based on otoscope findings. Performing an assessment with the pneumatic

otoscope (to visualize mobility of the tympanic membrane) is recommended. Usage of the pneumatic otoscope improves the diagnosis of OME to 70-79 percent accuracy. The use of tympanometry may also be performed to confirm suspected OME. The tympanometry provides an indirect measure of tympanic membrane compliance and can estimate middle ear pressure. However, it is noted that as few as half of the ears with normal tympanograms may have OME and, therefore, this test alone should not be performed to diagnose and treat OTM. Finally, the guideline suggests that after the third month, if both ears have OME, that a hearing evaluation be performed.

Studies of the natural history and outcome of OME have shown that in three months, approximately half of the children will have spontaneous resolution. From the third to the sixth month, the rate of spontaneous resolution remains constant so that only a small percentage of children experience OME lasting a year or longer. With the likelihood that middle fluid will resolve by itself, the panel considered the following recommendations for the management of OME. An observation period was suggested for effusion that was present less than four to six months, and at any time in children without a 20 decibel hearing threshold level or worse. Since the majority of cases of OME will resolve spontaneously, the leading therapeutic intervention for OME was observation.

A meta-analysis of controlled studies showed only a 14 percent increase in the resolution of effusion when antibiotic therapy was introduced. Antibiotic therapy is not without its own adverse effects ranging from common to rare, and from nuisance to life threatening. Potentially serious adverse effects were noted, especially in allergic reactions. Common adverse effects of antibiotic drug therapy are gastrointestinal and skin reactions. Other severe reactions to antibiotic therapy, although less common, are anaphylactic reactions, severe hematologic, cardiovascular, central nervous system, endocrine, renal, hepatic, and respiratory adverse effects. The panel was also concerned and stated so, that the unnecessary use of antibiotics might lead to antimicrobial drug resistance and potentially more serious illness with later episodes of infection.

Because of the limited scientific evidence, steroid medication is not recommended for the treatment of OME. After a thorough review of literature, antihistamine/decongestant therapy was also not recommended. Further, due to lack of evidence, adenoidectomy is not recommended as an appropriate treatment for uncomplicated middle ear effusion in children under four (when adenoid pathology is not present). Potential harm for children of all ages with adenoidectomies include the risk of the general anesthesia and the possibility of excessive postoperative bleeding. Tonsillectomies, either alone or with adenoidectomies, have also been found not to be effective for the treatment of OME.

Children with OME lasting four to six months with bilateral hearing deficit (defined as 20 decibels hearing threshold level), the panel only gave a moderate recommendation for surgical intervention based on limited scientific evidence to support the procedure. The principal benefit of this surgical intervention is the restoration of hearing to pre-effusion thresholds. Associated complications to myringotomy and insertion of tympanostomy tubes can include external auditory canal wall laceration, persistent otorrhea, granuloma formation at the myringotomy site, and permanent tympanic membrane perforation. In the case of repeated tube insertions, structural changes in the tympanic membrane can exist, such as flaccidity, retraction, and/or tympanosclerosis.

Based on limited scientific evidence and strong panel consensus, parents are encouraged to control environmental risk factors. Reports were found to implicate an association of infant feeding practices, passive smoking, and child care facility placement with the occurrence of OME. Although available literature on infant feeding practices and otitis media is focused on acute otitis media and not OME,

these studies suggest that bottle fed infants are two or three times more likely to have episodes of acute otitis media during the first year of life. The available research linking infant feeding practices to OME is considered limited. Studies have shown a moderate association between passive smoking and OME. There is a lack of proof that cessation of passive smoking will help prevent OME, however, if the possibility of decreasing a child's risk for OME exists, then parents and child care providers should be informed of the possible benefits of the child being in a smoke-free environment.

Over the past 15 years there has been consistent descriptive research conducted showing a relationship between OME and child care in group facilities. The research demonstrates an association between many common childhood infections and child care facility attendance. A study by Fiellau-Nikolajsen revealed a three to four-fold increase in the prevalence of secretory otitis media in children attending child care facilities, regardless of the season of the year.

During the process of their open meeting, the panel discovered the testimony on other therapies, both enlightening and disappointing. They were very impressed by the variety of apparent safety of many of the proposed therapies, but were disappointed that a lack of scientific studies were submitted. The "other therapies" for the treatment of OME included chiropractic, holistic, naturopathic, traditional or indigenous, and homeopathic methods. The panel was unable to comment on the frequency with which these therapies are used in the U.S. and their cost impact. The panel stated they were unable to locate data, including computer search of literature, letters to schools of education in their relevant fields, and personal communications with practitioners of other treatment methods. Invitations to representatives from societies and institutes of higher education for practitioners of these methods were asked to participate in the open meeting and to submit written testimony on this topic. I would personally be interested to see their contact list. From my personal attempts to contact noted authorities within our profession in the field of pediatric chiropractic as well as ICA and numerous of the college campuses, I have found at this time that none of these individuals or institutes were contacted to respond to the U.S. Department of Health and Human Services.

Lacking data obtained in controlled studies, the panel did not make any recommendations regarding other therapies for treatment of OME in children. The panel did find that the "other therapies" are apparently without notable risk of morbidity and are inexpensive. The panel recommended that randomized controlled studies of these therapies for OME in children be undertaken. In a positive light, both the Clinical Practice Guideline and Quick Reference Guide for Clinicians both noted the inclusion of "other therapies," which is a first. The category guideline used the "no recommendation" when scientific evidence was lacking and there was no compelling reason to make an expert judgment. Considering that chiropractic was mentioned without any representation from our profession, speaks of the results derived from children receiving spinal adjustments.

The panel was very critical in regard to the lack of scientific evidence, however literature does exist in the osteopathic and manual medicine profession. In a study reported by Gutmann,[1] there is a propensity towards ear, nose, and throat infections in children with upper cervical subluxation. The causation of the lower resistant is correlated with the neurophysiologic connection between the area of the atlanto-occipital joint. And upon the detection and correction of this specific vertebral subluxation, the response of the improved immune function and therefore the elimination of these disorders were noted in the study.

It has been established that otitis media may also be preceded by upper respiratory infection, the common cold, a sore throat, sinusitis, or eustachian tube blockage. A literature review can reveal the

benefits of spinal adjustment which may prevent the development of OME. Since there is a correlation to upper respiratory infection and the other disorders leading to otitis media, there have been more studies and research in this particular area. Gutmann reports amelioration of tonsillitis in children who received upper cervical adjustments. Lewit[2] found that 92 percent of children with chronic tonsillitis had upper cervical subluxation. Gutmann further cites the observations of Mohr, who states that when the disturbances of the functional atlanto-occipital joint was corrected, no tonsillectomies were necessary. Purse[3] investigated 4,500 cases of respiratory infection. Seven hundred and eighty of these specific cases had other complications ranging from simple conjunctivitis and acute otitis media to acute bronchitis and bronchial pneumonia. This osteopath discovered upon analysis upper cervical spinal motion restrictions specifically associated with acute otitis media. Further, once establishing through manipulative therapy spinal motion, rarely were complications developed in these children. This study indicated that manipulative therapy was considered a superior treatment to antimicrobial therapy and that pharmocologic therapy is not indicated unless complications develop.

Fidelibus[4] suggests that there is an increasing body of evidence that the nervous system is capable of modulating the immune response. Further, there has been evidence found on human T-lymphoctyes that receptors for the neuromodulators and neurohormones have been found. These receptors can be activated by a stimulatory or inhibitory process, depending on the neuroactive substance. Using neuromodulators and neurohormones secreted by lymphocytes, the immune system may be able to communicate with the nervous system. Further, the sympathetic innervation of the lymphoid tissue is not just restricted to blood vessels and smooth muscles but directly supplies lymphocytes and blood precurser calls. Fidelbus theorizes that spinal fixations may adversely affect the immune response through somatosympathetic reflexes. If spinal adjustments can correct the kinesiopathology of the vertebral subluxation complex, potentially this could eliminate the adverse effects of the somatosympathetic reflexes. Although documented research is limited to the positive effects of spinal adjustment for the vertebral subluxation and its effect of the physiologic response to OME, the clinical experience from doctors of chiropractic who have specialized in rendering pediatric care does exist. It does appear that the existence of the vertebral subluxation at the mid and upper cervical region[5] as well as occasionally the mid-thoracic region may be involved with the immune response of the child. It has been noted in some cases of chronic OME that the appearance of a vertebral subluxation at one of the sacral segments (specifically S2 and S3) may be involved. Although research has not established why a detected and corrected sacral subluxation can resolve OME, it is suspected that the parasympathetic system is involved.

Although chiropractic, with other therapies received a no recommendation because of a lack of scientific evidence, the common therapies used today to treat OME (i.e., antibiotics, steroids, and surgery) were strongly recommended for future scientific studies. The panel reviewed a large body of literature on antibiotic therapy for OME, but found major deficiencies in study designs which precluded considerations on most of this data in their guideline report. Published reports of antibiotic drug studies were also stated to have flaws. It was noted that there was a tendency for investigators and scientific journal editors to publish only reports of studies in which a positive effect of therapy is demonstrated.

Chiropractic research should be conducted in regard to the effects of detecting and correcting the vertebral subluxation complex with numerous pediatric disorders, including OME. Specifically, studies should be conducted to understand the kinesiopathology of the vertebral subluxation complex and how

it affects the neuropathophysiological, the myopathological, as well as the histopathological function of the pediatric patient. The first criteria to be undertaken is requiring each study to be well designed. These controlled studies should involve large populations and measure clinically important outcomes. Not only should we document and report on the positive clinical outcomes, but also document any adverse effects. The studies should also establish the sequence and duration of chiropractic care and the cost impact to the consumer.

Studies should not be limited just to common pediatric disorders but also should include the impact of what has been called prevention or wellness chiropractic care for the child. Designing controlled studies with large populations to measure statistical results should be conducted. Further, these long term studies could be conducted and outcomes reported and published. The chiropractic profession owes the general public studies that report the positive clinical effects that have been seen as a result of the detection and correction of the vertebral subluxation complex to the pediatric patient.

Upon reviewing the guidelines it is my opinion that chiropractic having been mentioned in the category of "other therapies" was positive. Although chiropractic as well as the other therapies were given no recommendation because of a lack of scientific evidence, the panel did discuss chiropractic as well as other therapies in an open meeting. It was during these testimonies that the panel considered it very interesting and enlightening that other therapies were able to deal with OME. Further, it was noted that they were impressed by the variety and apparent safety of many of these particular therapies including chiropractic.

Representing those chiropractors who have rendered care to the pediatric population, the majority of us are in a strong consensus that the detection and correction of the vertebral subluxation does have an impact to the immune response of the pediatric patient. If the immune response can enhance whole body function with the pediatric population, then chiropractic can be considered not only for the possible alternative choice for OME but also the prevention of it. This new guideline recommendation should be considered a positive direction for the rendering of care to children. Medical clinicians as well as parents are now being informed that the first recommendation for a majority of children is observation (the first three to six months), and secondly, warning of the over usage or lack of evidence to support traditional therapies. This may be a first to inform doctors to wait on such therapies as antibiotics, and to avoid therapies such as steroids, antihistamines, tonsillectomies, and adenoidectomies. Surgery is a last resort when warranted by diagnostic procedures.

Although the chiropractic profession is limited in controlled studies, this does not negate the clinical results seen in practices which render chiropractic care to the pediatric population. It appears despite the lack of published research, the results of chiropractic care speak for themselves. To be mentioned in the guidelines of the U.S. Department of Health and Human Services (without chiropractic representation or testimony) can be considered a positive development for the chiropractic profession. Although chiropractic has been limited to the funds necessary to conduct such recommended extensive studies, chiropractors for decades have clinically seen the responses to providing specific chiropractic care for the pediatric population and hopefully the time has arrived for access to federal grants that will allow chiropractic the opportunity to document clinical results.

Editor's note: Dr. Claudia Anrig Howe, a chiropractor in Fresno, California the past dozen years, is co-founder of Peter Pan Potential, a comprehensive chiropractic pediatric program. She is president of the Gonstead Clinical Studies Society, which conducts technique research. She is on the board of directors of the International Chiropractic Pediatric Assoc., and lectures for them at Life College as a

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