Ultrasonic Detection of Middle Ear Effusion

A Preliminary Study

Christopher M. Discolo, MD; Michael C. Byrd, MD; Teresa Bates, BA; Dov Hazony, PhD; Jan Lewandowski, PhD; Peter J. Koltai, MD

Objective: To assess the ability to detect and characterize middle ear effusion in children using A-mode ultrasonography.

Design: Prospective nonblinded comparison study.

Setting: Tertiary children’s hospital.

Patients: Forty children (74 ears) scheduled to undergo bilateral myringotomy with pressure equalization tube placement.

Interventions: Before myringotomy, ultrasound examination of the tympanic membrane and middle ear space was performed on each ear. Afterward, myringotomy was performed and the type of effusion (serous, mucoid, or purulent) was recorded. Pressure equalization tubes were then placed.

Main Outcome Measure: Comparison of ultrasound findings with the visual assessment of the type of middle ear effusion present.

Results: Of the 74 ears tested, 45 (61%) had effusion on direct inspection. The effusion was purulent in 8 ears (18%), serous in 9 ears (20%), and mucoid in 28 ears (62%). Ultrasound identified the presence or absence of effusion in 71 cases (96%) (P=.04). Ultrasound distinguished between serous and mucoid effusion with 100% accuracy (P=.04). The probe did not distinguish between mucoid and purulent effusion.

Conclusions: Ultrasonography is an accurate method of diagnosing middle ear effusion in children. Moreover, it can distinguish thin from mucoid fluid. Further refinements in probe design may further improve the sensitivity of fluid detection and allow differentiation of sterile vs infectious effusion.

Arch Otolaryngol Head Neck Surg. 2004;130:1407-1410

Otitis Media (OM), which is an inflammatory process involving the middle ear and mastoid spaces, represents the most common indication for outpatient antibiotic use in children and is second only to upper respiratory infections as the most common reason for a child to visit the pediatrician.1,2 In the United States, the cost of medical and surgical treatment of OM is estimated at $5 billion annually.3 Otitis media results in the development of a fluid effusion in the middle ear, which can persist for variable periods of time, resulting in an increased vulnerability to recurrent infections as well as in variable degrees of conductive hearing loss. Treatment options for middle ear effusion (MEE) vary depending on the frequency of recurrent infections and the severity of hearing loss. The most accurate methods for diagnosing MEE are myringotomy with fluid aspiration and needle tympanocentesis, invasive procedures that, in young children, are often performed with the patient under anesthesia. Most children with MEE initially present to their primary care physicians, so having an accurate noninvasive office-based method to complement the physical examination and to aid in diagnosis is desirable. None of the currently available options is as sensitive and specific as either myringotomy or tympanocentesis. Furthermore, consistent and accurate information regarding the nature of the MEE (purulent vs mucoid vs serous) may be gained only with surgical drainage.

Ultrasound, which uses high-frequency sound waves to image tissues, has been useful in various medical disciplines as a safe and accurate imaging modality that does not result in exposure to ionizing radiation. The amount of acoustic energy reflected back toward the probe (echo) is determined by the presence of tissue interfaces with different acoustic impedances along with the incident angle with which the beam strikes the tissue. As the acoustic properties of 2 tissues within an interface become more disparate, more energy will be reflected back toward the probe. Simply speaking, the viscosity of a tissue is the primary determi-
nant of its acoustic properties. This property makes ultrasound potentially valuable for imaging the middle ear, where a number of possible tissue and fluid interfaces may exist.

Ultrasound data can be displayed in multiple forms. A-mode (amplitude modulation) is the simplest of these and was used in this study. In A-mode, the amount of reflected energy is displayed as a vertical spike along a horizontal axis of time. Because the speed of sound is a constant, the interpeak distance between 2 echoes enables calculation of the distance between the 2 interfaces.

Ultrasound has been used in the past to detect MEE. Although it is thought to be a promising method of diagnosis, needed improvements in probe design were cited as limitations to its use.4,5 Furthermore, no attempts were made to characterize the type of MEE present. In this study, we sought to determine the feasibility of A-mode ultrasound to accurately detect and characterize MEE effusion in children.

METHODS

The institutional review board at the Cleveland Clinic Foundation, Cleveland, Ohio, granted approval for this study. From February 2002 to June 2002, all children aged 6 months to 17 years with a diagnosis of OM and MEE who were scheduled to undergo bilateral myringotomy with pressure equalization tube placement were invited to enroll. Children were undergoing concurrent procedures, such as adenoidectomy or tonsillectomy and adenoiectomy, were included in the study. Full written informed consent was obtained for all subjects, and no patients were recruited solely for the purposes of this research study. Ears with tympanic membrane (TM) perforation or an indwelling pressure equalization tube at the time of surgery were exluded. After the children were anesthetized (either by mask or endotracheal intubation), their ears were examined with the operating microscope. Any debris within the external ear canal (EAC) was removed, and the TM was visualized. To provide a transducing medium for the ultrasound, 0.5 to 1.0 mL of sterile water at room temperature was placed into the EAC with a dropper. The broad-band ultrasound probe was inserted into the EAC under direct visualization and placed just lateral and perpendicular to the TM.

The experimental setup consisted of an ultrasonic pulser/receiver (PCIPR 300; US Ultratek, Inc, Martinez, Calif) and a digital data acquisition system (GageScope; Tektronix, Inc, Beaverton, Ore). Both instruments are assembled on personal computer boards, which were installed inside the desktop personal computer. During testing, ultrasonic scans were observed in real time on the monitor and saved on the hard drive in digital format. The water was then removed from the EAC, and myringotomy was carried out in the usual fashion. After myringotomy, the presence or absence of MEE was noted, and the type of effusion, when present, was categorized according to our experimental protocol as serous, mucoid, or purulent by the operating surgeon. After tube placement, the procedure was repeated for the contralateral ear. Less than 5 minutes of total anesthesia time was added for the completion of this examination.

A total of 40 children (74 ears) were enrolled in the study. There were 23 boys (57%) and 17 girls (43%), with an age range of 8 months to 11.7 years. Of the 74 ears in our study, 29 (39%) had no effusion after myringotomy. Of the 45 ears (61%) in which effusion was found, 8 (18%) were purulent, 9 (20%) were serous, and 28 (63%) were mucoid. Two ears with mucoid effusions were noted to contain only small amounts of fluid. In general, the type of effusion in one ear was the same as that in the other ear. Among the 34 patients who had both ears tested, there were 9 instances in which the status of the middle ears was different on myringotomy. Of the 6 children who had only 1 ear tested, 4 had an indwelling tube in the contralateral ear; in the remaining 2 cases, there were technical problems with the data acquisition software. The anesthetic time was not extended to repair the acquisition problem.

Previous in vitro work using an ear phantom model demonstrated expected ultrasonic echoes based on the presence or absence of effusion (Figure 2). Ears without effusion will not effectively transmit the ultrasound wave into the middle ear and will demonstrate only 1 pulse as the echo from the TM is recorded. Ears with effusion are able to transmit the ultrasound wave to the promontory of the middle ear and will therefore demonstrate 2 pulses. Furthermore, the amplitude of the echoes helps differentiate between various fluid viscosities (serous, mucoid, or purulent). Figure 3 demonstrates how, in vitro, the amplitude of the echo diminishes as the viscosity of the medium increases. Each patient examined underwent several scans for each ear in an attempt to position the probe optimally within the EAC using real-time imaging. The scans used

METHODS

The institutional review board at the Cleveland Clinic Foundation, Cleveland, Ohio, granted approval for this study. From February 2002 to June 2002, all children aged 6 months to 17 years with a diagnosis of OM and MEE who were scheduled to undergo bilateral myringotomy with pressure equalization tube placement were invited to enroll. Children were undergoing concurrent procedures, such as adenoidectomy or tonsillectomy and adenoiectomy, were included in the study. Full written informed consent was obtained for all subjects, and no patients were recruited solely for the purposes of this research study. Ears with tympanic membrane (TM) perforation or an indwelling pressure equalization tube at the time of surgery were excluded. After the children were anesthetized (either by mask or endotracheal intubation), their ears were examined with the operating microscope. Any debris within the external ear canal (EAC) was removed, and the TM was visualized. To provide a transducing medium for the ultrasound, 0.5 to 1.0 mL of sterile water at room temperature was placed into the EAC with a dropper. The broad-band ultrasound probe was inserted into the EAC under direct visualization and placed just lateral and perpendicular to the TM.

The experimental setup consisted of an ultrasonic pulser/receiver (PCIPR 300; US Ultratek, Inc, Martinez, Calif) and a digital data acquisition system (GageScope; Tektronix, Inc, Beaverton, Ore). Both instruments are assembled on personal computer boards, which were installed inside the desktop personal computer. During testing, ultrasonic scans were observed in real time on the monitor and saved on the hard drive in digital format. The water was then removed from the EAC, and myringotomy was carried out in the usual fashion. After myringotomy, the presence or absence of MEE was noted, and the type of effusion, when present, was categorized according to our experimental protocol as serous, mucoid, or purulent by the operating surgeon. After tube placement, the procedure was repeated for the contralateral ear. Less than 5 minutes of total anesthesia time was added for the completion of this examination.

A total of 40 children (74 ears) were enrolled in the study. There were 23 boys (57%) and 17 girls (43%), with an age range of 8 months to 11.7 years. Of the 74 ears in our study, 29 (39%) had no effusion after myringotomy. Of the 45 ears (61%) in which effusion was found, 8 (18%) were purulent, 9 (20%) were serous, and 28 (63%) were mucoid. Two ears with mucoid effusions were noted to contain only small amounts of fluid. In general, the type of effusion in one ear was the same as that in the other ear. Among the 34 patients who had both ears tested, there were 9 instances in which the status of the middle ears was different on myringotomy. Of the 6 children who had only 1 ear tested, 4 had an indwelling tube in the contralateral ear; in the remaining 2 cases, there were technical problems with the data acquisition software. The anesthetic time was not extended to repair the acquisition problem.

Previous in vitro work using an ear phantom model demonstrated expected ultrasonic echoes based on the presence or absence of effusion (Figure 2). Ears without effusion will not effectively transmit the ultrasound wave into the middle ear and will demonstrate only 1 pulse as the echo from the TM is recorded. Ears with effusion are able to transmit the ultrasound wave to the promontory of the middle ear and will therefore demonstrate 2 pulses. Furthermore, the amplitude of the echoes helps differentiate between various fluid viscosities (serous, mucoid, or purulent). Figure 3 demonstrates how, in vitro, the amplitude of the echo diminishes as the viscosity of the medium increases. Each patient examined underwent several scans for each ear in an attempt to position the probe optimally within the EAC using real-time imaging. The scans used
for statistical evaluation were selected from this series using the following criteria: (1) scans with no echoes were rejected because of a misaligned transducer, as even empty ears will display a single pulse from the TM; and (2) scans with the highest amplitudes from the remaining group were selected for analysis. Using these criteria, 5 ears were excluded from statistical analysis owing to an absence of pulses, indicating poor probe placement within the EAC. The first pulse amplitude and the number of pulses were used to predict the presence or absence of effusion as well as its characteristics.

A model for the presence of fluid as a function of the first pulse amplitude and the number of pulses was created using binary logistic regression. Using this model, the probe correctly predicted the fluid state of the middle ear in 71 cases (96%) (P = .04) (Figure 6). A second goal of this study was to determine whether ultrasound could distinguish between types of effusion. Once again, a binary logistic regression model was fitted using the first and second pulse amplitudes to distinguish fluid states. The probe was able to distinguish between mucoid and nonmucoid (serous and purulent combined) states with 100% accuracy (P = .04) (Figure 6). Using similar models, the probe did not distinguish between serous and purulent states (P = .97). Although the accuracy of the ultrasound device in distinguishing mucoid from nonmucoid states was statistically significant (P = .04), there were relatively few observations in this data set. More data will be necessary to adequately characterize the true potential of this device. There were no adverse events reported during the conduction of this study.

**COMMENT**

Otitis media is a common clinical condition in children, but its diagnosis and treatment can be challenging. After an episode of OM, children can be expected to have persistent MEE for approximately 40 days, and younger children may have more difficulty clearing effusions. Middle ear effusion represents the most common cause of hearing loss in children, and adverse sequelae such as speech and language delay may result. Children with persistent MEE and conductive hearing loss will likely benefit from tympanostomy tube placement. Accurate diagnosis of MEE will help select those patients most likely to benefit from surgical intervention.
Otoscopy is widely practiced among both otolaryngologists and pediatricians and remains the mainstay of diagnosis. Unfortunately, false-positive results are not uncommon, especially in children with fever or who are agitated and crying at the time of examination. Although otolaryngologists may be comfortable performing both otoscopy and pneumatic otoscopy, 42% of general pediatricians do not routinely perform the latter. Also, a recent study suggests that current primary care residents may not be learning these important skills in regard to the diagnosis of OM, as there was only a fair correlation between the middle ear assessments made by the primary care residents and those made by the pediatric otolaryngologists. Another study suggested that the otoscopic skills of primary care physicians were not superior to those of medical students.

Antibiotics have been the mainstay of treatment for OM. Currently, there is growing concern over the development of antibiotic resistance among common middle ear pathogens such as Streptococcus pneumoniae, Haemophilus influenzae, and Moraxella catarrhalis. Reasons for this growing resistance include multiple and prolonged (prophylactic) antibiotic courses, premature termination of the regimen, and improper antibiotic administration. Physicians who have accurate information regarding the status of the middle ear will be able to make more informed treatment decisions, especially in regard to the prescription of antibiotics.

The goal of our work is to develop a handheld ultrasound device that can be used in the outpatient setting to give the most reliable information regarding the presence and characteristics of MEE in children. Currently, tympanometry is the diagnostic test most commonly used to determine the presence of MEE. Tympanometry is a graphic representation of the compliance of the TM as a function of air pressure within the EAC. It is a measure of admittance and, as such, is not a direct measurement of the middle ear system. Jerger proposed the most well-known system of classification for tympanograms, and his system was further modified by Paradise et al. When the type of tympanogram was correlated with the presence of MEE on myringotomy, an 83% correlation was achieved with those tympanograms thought to be most consistent with effusion. In the present study, ultrasound was able to correctly identify if the presence or absence of effusion in 96% of cases, and it appears that this technology can result in a more accurate method of assessing the middle ear space. Also, ultrasound was able to distinguish between serous and mucoid effusions in every case, a categorization that tympanometry cannot predict. Unlike tympanometry, which indirectly infers the presence of effusion, ultrasound gives a direct image of the middle ear space. Furthermore, tympanometry has certain limitations. For example, in children younger than 7 months, a more compliant EAC is present and a normal tympanogram is possible in the presence of MEE (“canalogram”).

The ultrasound probe used in this study was a handheld transducer placed on the tip of a 1.8-mm-diameter hypodermic tubing shaped as a Frazier suction. There were several challenges related to obtaining adequate ultrasonic echoes with this design of probe. In vitro work has demonstrated that optimal ultrasonic echoes are produced when the transducer is positioned perpendicular to the reflecting surface (TM). The overall size and geometry of a patient’s ear canal would occasionally make proper probe placement difficult. Furthermore, the manual insertion of the probe into the EAC made maintaining a stable and reproducible distance from the TM difficult. The probe was also very sensitive to slight hand movements. Also, the water that was placed into the EAC to act as a transducing medium slightly distorted the appearance of the TM and made accurate probe placement more difficult. Further refinements in probe design will address the limitations of our prototype.

Otitis media, which is a common inflammatory condition of the middle ear, may be associated with the presence of effusion. Current noninvasive diagnostic techniques are not as sensitive or specific as myringotomy or tympanometry. Difficulty in diagnosing MEE may result in some children being overtreated, while others may suffer adverse sequelae when MEE is not identified early. Ultrasonic imaging of the middle ear space has the potential to be a highly accurate method for determining the presence and characteristics of MEE in children. Refinements in probe design, currently under development, are needed to make this technique clinically applicable.

Submitted for Publication: December 15, 2003; final revision received July 14; accepted August 12, 2004.

Correspondence: Peter J. Kolts, MD, Division of Pediatric Otolaryngology, Stanford University, 801 Welch Rd, Stanford, CA 94305 (kolts@stanford.edu).

Funding/Support: This study was supported in part by grant 1R43 DC04741-01 from the Small Business Innovation Research Program, National Institutes of Health, Bethesda, Md, and by Biomec Inc, Cleveland, Ohio.

Previous Presentation: This study was presented in part at the Annual Meeting of the American Society of Pediatric Otolaryngology; May 5, 2003; Nashville, Tenn.

REFERENCES