

Developing a screening program for identifying infants and toddlers at risk for otitis media with effusion using distortion product otoacoustic emission technology

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Evoked otoacoustic emissions (EOAEs) are low-level sounds produced by the outer hair cells of a healthy cochlea and are evoked by an acoustic stimulus. The transmission properties of the conductive mechanism influence the characteristics of EOAEs; thus, EOAEs are typically recorded in ears with both normal sensory (cochlear) and external ear and middle ear function. Middle ear pathology such as otitis media with effusion (OME) or external ear canal obstruction affects both the forward and backward transmission of acoustic stimuli. Therefore, OME can reduce the amplitude or eliminate the EOAE entirely. Predicting the exact effect of OME is complex as even mild negative middle ear pressure can affect the amplitude, spectrum, and reproducibility of EOAEs.¹

Screening hearing is considered difficult in infants and toddlers using behavioral methods. However, EOAE, an “objective” physiologic procedure, has been shown to be useful for screening hearing in neonates. Nozza and his colleagues² demonstrated that transient EOAE technology can be successfully incorporated into traditional identification programs (pure-tone and tympanometry screening), and the addition of EOAE technology to school screening may have significant advantages over existing screening protocols. To date, few data are available on the use of EOAE technology in young preschool children for identifying auditory disorders.

The prevalence of OME is known to be highest in infants and toddlers between the ages of 2 to 24 months, and young children from low-income families may be a group at particular risk.³ Socioeconomic factors and OME may have a synergistic effect on communication development, negatively impacting the acquisition of speech and language in early life.⁴

The current project was initiated by the New York Children’s Health Project (NYCHP) to begin the development of an early identification program for infants and young children (2–36 months of age) at risk for communication disorders. The NYCHP, a division of Community Pediatrics at the Montefiore Medical Center, Bronx, New York, provides medical services to children of all ages who are homeless and reside, for varying amounts of time, in shelters within New York City. Children receive routine medical care from pediatricians and pediatric nurse practi-

tioners (PNPs) in two types of settings: permanent clinics in the shelters and mobile medical vans. At the time this exploratory project was initiated, no formal hearing screening program existed for infants and young children serviced through the NYCHP. However, children of preschool age and older sometimes received audiometric and tympanometric screening whenever a primary care provider deemed it necessary. Thus, the 2- to 36-month-old children of the NYCHP were considered an underserved population relative to the early detection of hearing loss. The NYCHP desired to explore the clinical feasibility of adding EOAE screening technology to the routine medical follow-up of the young children in this age range.

Materials and methods

Ninety-two infants and toddlers (2–36 months of age) received distortion product EOAE (DPOAE) and tympanometry screening as part of their routine medical services from the NYCHP. The DPOAEs and tympanograms were collected from each child during a routine medical visit. A handheld, battery-powered screening DPOAE instrument (AuDx™, Biologic, Inc, Mundelein, IL) was used for the screening. Middle ear status was assessed using a screening tympanometer (AutoTym, Welch Allyn, Inc). For the purpose of this report, the criteria for judging an ear as OME positive (OME+) was determined by examining the quantitative parameter of peak admittance (Y_{TM}). Criteria for considering an ear OME+ was $Y_{TM} < 0.2$ mmho for infants (< 13 months) and $Y_{TM} < 0.3$ mmho for young children (13–36 months).⁵

A pediatric audiologist (ST) trained the physicians and the PNPs who administered the screening tests in the use of the DPOAE device. The tympanometric screening procedure was already used in the clinical setting. The screenings were considered part of each child’s routine medical care. The tympanometric/DPOAE screenings were conducted in two different settings, the stationary clinic or the mobile van.

First, the child’s routine medical examination (including an otoscopic examination of the ear canal and tympanic membrane) was conducted. Next, a soft probe tip was placed in the child’s ear canal for measuring

DPOAEs. Two sinusoidal signals were generated by the instrument, mixed acoustically and presented simultaneously. The ratio of the two primary frequencies (f_2/f_1) was 1.22, and the intensity of the lower primary frequency (f_1) was presented at 65 dB SPL and the higher (f_2) at 55 dB SPL. The manufacturer’s preset values and pass-refer criteria^{6,7} were used. A “pass” at a particular frequency required a minimum DPOAE–noise floor difference of 6 dB. In addition, a DPOAE amplitude minimum of –6, –5, –8, and –7 dB at the frequencies of 5,000, 4,000, 3,000 and 2,000 Hz, respectively, was also required to achieve a pass outcome at each frequency. An overall pass outcome for the session was set as a pass recorded at three of the four aforementioned frequencies in both ears.

Results

For the purpose of examining the screening results, children were divided into three age categories: < 13 (n = 36), 13 to 24 (n = 27), and 25 to 36 (n = 29) months. Of the 92 children tested using DPOAE, 59.7% (n = 54) received an overall pass result. Figure 1 presents the percentage of children who passed DPOAE screening (overall pass), failed in one ear only (fail 1), or failed in both ears (fail 2) as a function of age category. Increasingly greater percentages of children received an overall pass outcome with age. If fail 1 and fail 2 are considered together, there was no significant difference in the percentages of children in the < 13-month group who passed or failed screening. However, a significantly ($p < .01$) greater percentage of children passed DPOAE screening

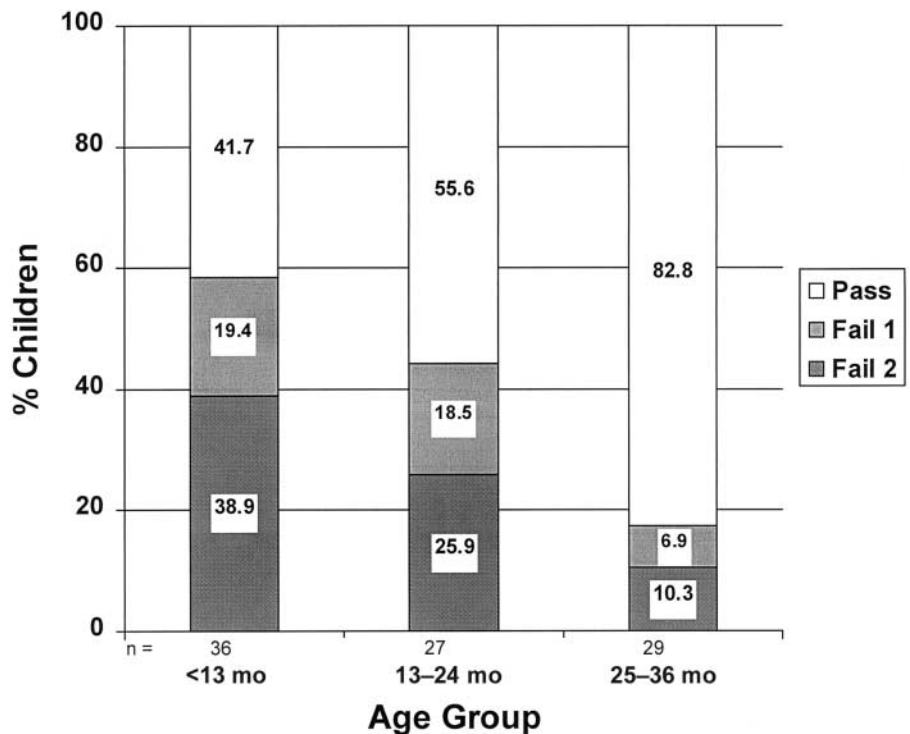
than failed in the 13- to 24-month and 25- to 36-month age groups.

The OME status was evaluated using tympanometry in 47 (51%: 93 ears; 1 ear could not be tested) of the 92 children who received the DPOAE screening. When considering all ages, the OME status (OME negative [OME–]; OME+; see the tympanometric criteria above) was related ($\chi^2 = 12.480$, $df = 1$, $p < .02$) to screening outcome. Considering each age category separately, there was no relationship ($p > .05$) between middle ear status and screening outcome in the two younger (< 13 and 13–24 months) age groups. However, when children 24 months of age and younger were grouped together, middle ear status did affect screening outcome ($\chi^2 = 4.85$, $df = 1$, $p = .03$). The OME status was related ($\chi^2 = 5.44$, $df = 1$, $p = .02$) to pass-fail outcome in the oldest (25–36 months) group of children.

The overall test sensitivity of DPOAE screening for detecting OME in an ear (using the aforementioned tympanometric criteria) in this age range (2–36 months) and environment was 55%. Test specificity was 81%. The positive predictive value of DPOAE screening for detecting OME in the 2- to 36-month age range was 78%. Two groups were then considered: ≤ 24 month olds (younger) and 25 to 36 month olds (older). The sensitivity and specificity of DPOAE for detecting OME were sensitivity 71%_{younger} and 19%_{older} and specificity 61%_{younger} and 96%_{older}. The positive predictive value was 76%_{younger} and 86%_{older}.

Figure 2 depicts the percentages of ears (total n = 92; missing values are a result of a no test outcome)

Figure 1 Pass (bilateral), unilateral fail (fail 1), or bilateral fail (fail 2) rates for distortion product otoacoustic emission screening in three age groups (<13, 13–24, and 25–36 months).

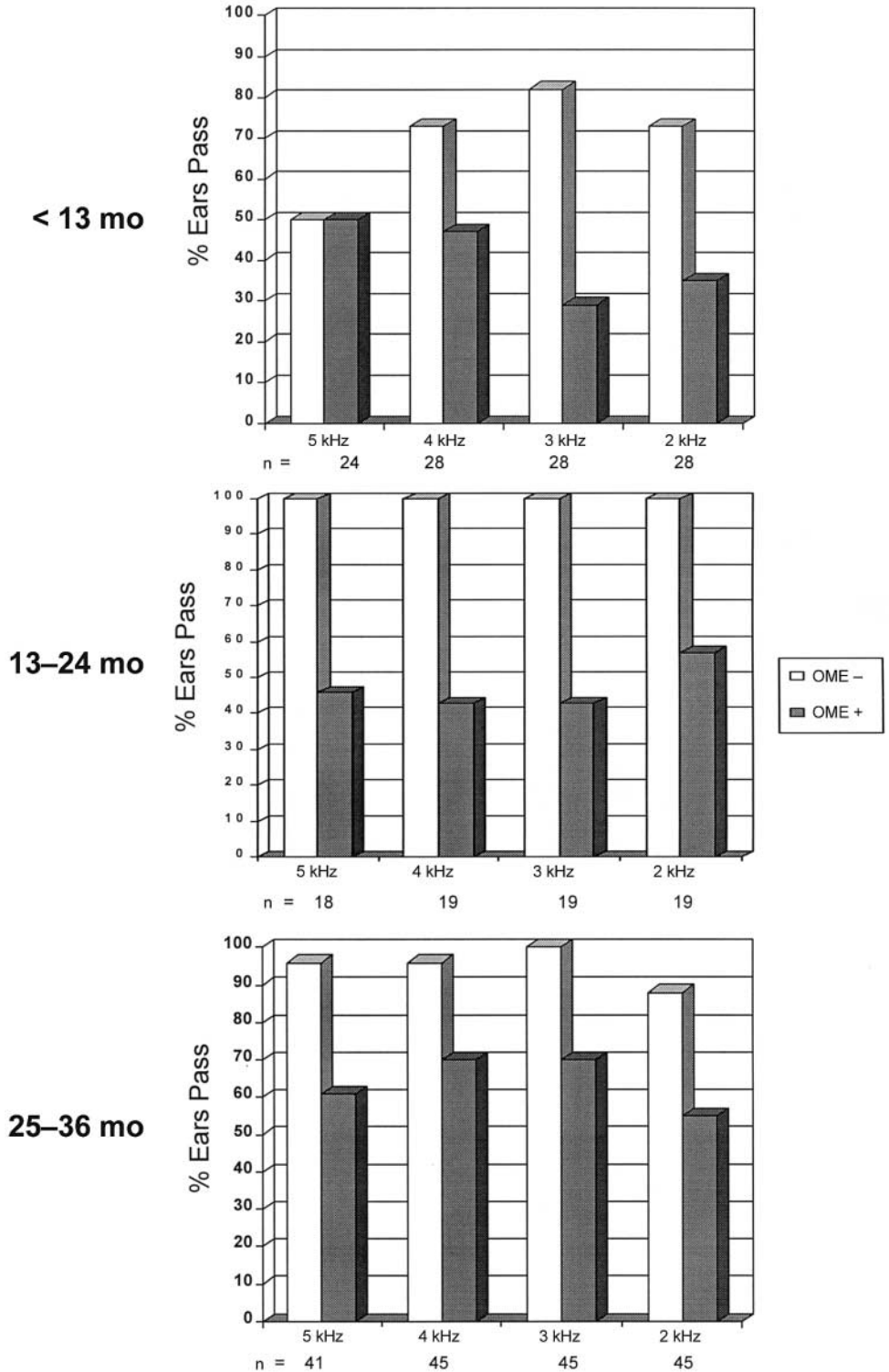


passing DPOAE screening at each frequency (5, 4, 3, and 2 kHz) according to age group (< 13 months, n = 29; 13–24 months, n = 20; 25–36 months, n = 44) and middle ear status (OME– or OME+). Note that nearly all ears (generally ≥ 95%) considered OME– in the 13- to 24- and 25- to 36-month groups met the pass criterion

at each of the four frequencies. In the youngest group (<13 months), far fewer OME– ears passed screening at the four frequencies than in the two older groups.

The OME+ ears that met the pass criterion at one or more frequencies were most frequently found in the 25-

Figure 2 The pass rates (see text for criterion) for distortion product otoacoustic emission screening as a function of individual frequency (5, 4, 3, and 2 kHz) for ears considered OME free (OME–) and OME positive (OME+) (based on tympanometry outcome: see text) in three age groups (<13, 13–24, and 25–36 months).



to 36-month age group; at all frequencies, more than 50% of the ears considered OME+ passed the screening. In the < 13-month and 13- to 24-month age categories, in all but one case (2 kHz, 13- to 24-month group), fewer than 50% of ears considered OME+ passed the screening criterion at each frequency.

Overall pass-refer screening results from the two test locations (van and clinic) were examined. Considering all age categories, the pass rate was not significantly different in the van versus the clinic test locations ($p > .05$).

Discussion

The outcome of this project provides preliminary evidence of the feasibility of incorporating a DPOAE screening for infants and preschoolers (≤ 36 months) during routine medical visits.

Across the age range considered, the expected relationship was found between middle ear state and screening outcome such that children considered OME+ were more likely to fail the DPOAE screening and children considered OME- were more likely to pass the test. Calculations of sensitivity and specificity suggest that for the overall group, DPOAE screening is useful for identifying ears as having normal middle ear function but is not particularly sensitive to OME. For the 2- to 36-month age range, there was about an equal probability that ears with OME would pass the DPOAE screening as would fail it.

A different view of the outcome was achieved when the groups were broadly divided into a 24-month and younger category ($n = 49$ ears) and a 25- to 36-month age category ($n = 44$ ears). This examination of the results was undertaken because screening test efficiency is affected by the prevalence of the disease within the target population, and it was expected that the youngest children in this sample would have more OME than the older. The results for the younger group suggest much lower specificity (61%) than in the older (96%). This suggests that DPOAE screening is very good at correctly identifying an ear as OME free in the eldest (24-36 months) children considered here but over-refers a large number of younger children with normal middle ear function. Conversely, the DPOAE screening appears much more sensitive for detecting ears with OME (based on the tympanometric criteria described previously) in infants and the younger children (71%) than in the older group (19%). In the older group, many children considered OME+ (at least according to our criteria) were missed by the screening.

The results may also have been impacted by the choice of screening frequencies. A pass result at each DPOAE screening frequency was nearly always present in ears considered OME- in the two oldest age groups (children 13 months and older). Infants < 13 months of age, however, had the lowest percentage of OME- ears that passed DPOAE screening at each frequency, at least in the clinical environments in which the present out-

comes were collected. However, 80% of OME- ears in this youngest age group passed DPOAE screening criterion at 2 kHz. Conversely, more children in the oldest group considered OME+ by tympanometry had a pass outcome at the four frequencies used for DPOAE screening than in the two youngest age categories. For this group, 2 kHz had the lowest percentage of OME+ ears that passed screening.

A much larger screening sample is required to examine whether one or more DPOAE frequencies are optimal for screening in populations of young children at risk for OME. An examination of the relationship between the pass-fail outcome at individual DPOAE frequencies and quantifiable parameters of the tympanogram is also warranted as these associations may change with age. New methods for identifying OME (such as middle ear reflectance measurement) may also improve screening test sensitivity.⁸ Finally, it is also important to consider the acoustic environment of the screening location that may impact the choice of target frequencies for DPOAE screening. In very young children (less than 1 year of age), screening in hostile acoustic environments (such as those encountered by the NYCHP) may necessitate the use of different pass-fail criteria than used for older children. Evoked otoacoustic emission screening may be more negatively impacted by acoustic test environment conditions in infants than older children. The above considerations suggest that a screening instrument used for the early detection of young children at risk for conductive and sensory disorders should be flexible for use with various populations and screening environments.

A two-technology (EOAE and a measure of middle ear function) screening protocol may be most useful in detecting auditory disorders in young children. When a child fails EOAE screening and has an atypical tympanogram, the risk for middle ear involvement is high. Of course, if a child fails EOAE screening and has a normal tympanogram, then the child would be considered at risk for sensory hearing loss. To our knowledge, none of the children in this sample had cochlear hearing loss, although this was not confirmed by audiometry, so the efficiency of this two-technology approach could not be examined. A problem, of course, would be the case of mixed hearing loss. The screening result of such a child would suggest that EOAE screening failure was owing to middle ear pathology. Unfortunately, the middle ear disease would mask the presence of the underlying sensory hearing loss. This possibility supports the need to refer all children for audiometric and medical evaluation who have persistent abnormal tympanograms and absent EOAE, particularly when communication development is of concern. Owing to limited follow-up resources, the over-referral of young children with normal middle ear function or transient OME for otolaryngologic and audiologic evaluation is to be avoided. Regardless of the proliferation of newborn hearing screening programs, it is important that a feasible and efficient screening plan be

designed for the identification of children in the 2- to 36-month age range, a period critical for communication development.

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