Using Otoacoustic Emissions to Screen Young Children for Hearing Loss in Primary Care Settings

OBJECTIVES: Otoacoustic emissions (OAE) technology, used widely in newborn hearing screening programs and validated by professional organizations as a reliable and objective tool, is beginning to be recognized as superior to subjective methods when screening young children in a variety of settings. This study examines the efficacy of integrating OAE hearing screening into services routinely provided in health care settings.

METHODS: Three federally funded clinics serving low-income and uninsured people in a metropolitan area participated in the 10-month study. Subjects included 846 children (842 in the target population ≤5 years of age and 4 older siblings) who were screened during routine visits to their primary care providers using a distortion product OAE instrument. A multistep screening and diagnostic protocol, incorporating middle ear evaluation and treatment, was followed when children did not pass the initial screening. Audiological evaluation was sought for children not passing a subsequent OAE screening.

RESULTS: Of the 846 children screened, 814 (96%) ultimately passed the screening or audiological assessment and 29 (3%) exited the study. Three children (1 was ≤5 years of age and 2 were >5) were identified with permanent hearing loss.

CONCLUSIONS: The rate of identification of permanent hearing loss in this study is similar to findings from a study of OAE screening in early childhood educational settings. OAE screening holds the potential for being an effective method for helping to identify young children with permanent hearing loss in primary care settings.

WHAT’S KNOWN ON THIS SUBJECT: The incidence of permanent hearing loss doubles between birth and school age. Otoacoustic emissions screening has been used successfully in early childhood educational settings to identify children with losses not found through newborn screening.

WHAT THIS STUDY ADDS: Using otoacoustic emissions to screen the hearing of young children during routine health care visits is feasible and can lead to the identification of permanent hearing loss overlooked by providers relying solely on subjective methods.
Over the past 2 decades, screening newborns for hearing loss has become the standard of care in the United States, with >95% of infants now being screened at birth. As a result, approximately 1 to 3 infants per 1000 are being identified with permanent hearing loss. However, of the total 2% of infants not passing the newborn screen, nearly 40% may be lost to follow-up before the needed assessment to determine hearing status can be conducted or documented. This means that some infants at high risk for hearing loss are likely to remain unidentified and potentially untreated for months or years. In addition, illness, injury, and genetic factors cause hearing loss during early childhood, with estimates ranging from 1 to 3 per 1000 above those identified at birth. The age at which hearing loss is identified is critical in terms of the efficacy of intervention; children who are identified and receive intervention early are more likely to demonstrate language development within the normal range by the time they enter school than those who are not identified and served early.

The American Academy of Pediatrics preventive guidelines recommend that infants receive an objective screening at birth and that subjective methods for monitoring be applied until children reach 4 years of age and are able to respond reliably to pure-tone audiometry. Based on those guidelines, most primary care providers (PCPs) have assumed that subjective assessment of a toddler or young child is the only feasible option for monitoring hearing. This assumption is open to question, however, as closer examination of commonly used subjective measures, such as parental questionnaires, reveals low sensitivity and specificity whereas objective, otoacoustic emissions (OAE) screening has been found to be more effective in identifying hearing loss than subjective distraction tests administered by nurses. OAE technology, used widely in newborn screening programs and validated by professional organizations as a reliable and objective screening method, is beginning to be recognized as a way to screen young children in a variety of settings. In a study of 110 children ranging in age from 6 months to 15 years, OAE screening was found to be highly sensitive (100%) and reasonably specific (91%). In a study of 4519 children 0 to 3 years of age, the positive predictive value was estimated to be 67% and the estimated negative yield was calculated to be 99%. In 2 large-scale OAE screening studies, sensitivity was found to be 85% and 100%, with both studies reporting specificity of 95%. Most recently, research exploring the use of OAE screening in federally qualified health centers supports its viability as a screening tool for infants and toddlers while asserting the importance of objective hearing screening surveillance to promote age-appropriate language acquisition. This study further examines the efficacy of integrating OAE hearing screening into services provided routinely to young children in health care clinic settings.

**METHODS**

**Subjects and Settings**

A total of 3 clinics (2 school-based and 1 community clinic) in a metropolitan area took part in the 10-month study. These federally qualified clinics provide financial assistance, health care access, and service delivery to low-income and uninsured people. The target population to receive OAE hearing screening included children 0 to 5 years of age being served during regularly scheduled well-child visits or visits to address specific health concerns. The availability of hearing screening resulted in a small number of additional requests by parents and health care providers that older siblings, 5 to 10 years of age, be screened as well. A total of 846 children (842 <5 years of age and 4 older siblings) participated in the study.

Of the 846 children, 619 (73%) were served in the 2 school-based clinics and 227 (27%) were served in the community clinic; 693 (82%) were from families whose incomes were at or below the federal poverty level, and 714 (84%) were being seen for well-child check-ups, 71 (8%) for ear-related concerns (primarily otitis media [OM]), 46 (5%) for non–ear-related complaints/illnesses, and 15 (2%) did not have a reason for the visit documented. Table 1 provides additional descriptive demographic information.

**OAE Hearing Screening Methodology**

During OAE screening, a small probe is placed in the ear canal, which delivers sound stimuli into the auditory system. In a healthy ear, the sound stimuli are transmitted through the middle ear to the inner ear where the outer hair cells of the cochlea produce an active response or emission. These emissions are picked up by a microphone in the probe, analyzed by the screening unit, and an automated

<table>
<thead>
<tr>
<th>TABLE 1 Demographic Characteristics of 846 Children Receiving OAE Screening</th>
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<tbody>
<tr>
<td>Gender, n (%)</td>
</tr>
<tr>
<td>Female 507 (60)</td>
</tr>
<tr>
<td>Male 339 (40)</td>
</tr>
<tr>
<td>Age, mo, n (%)</td>
</tr>
<tr>
<td>0–12 143 (17)</td>
</tr>
<tr>
<td>13–24 117 (14)</td>
</tr>
<tr>
<td>25–36 113 (13)</td>
</tr>
<tr>
<td>37–48 97 (11)</td>
</tr>
<tr>
<td>49–60 372 (44)</td>
</tr>
<tr>
<td>61–112 4 (&lt;1)</td>
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<tr>
<td>Ethnicity (as self-identified), n (%)</td>
</tr>
<tr>
<td>Hispanic 351 (41)</td>
</tr>
<tr>
<td>White 99 (12)</td>
</tr>
<tr>
<td>Pacific Islander 66 (8)</td>
</tr>
<tr>
<td>Other 33 (4)</td>
</tr>
<tr>
<td>Ethnicity not stated, n (%) 297 (35)</td>
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"pass" or "refer" result is displayed on the unit’s screen. The ear is likely to refer from the screening if there is (1) impaired cochlear function associated with permanent hearing loss, (2) a middle ear disorder such as OM or effusion that interferes with hearing, or (3) a blockage in the ear canal such as impacted cerumen.

This study used handheld Biologic AudiOAE distortion product (DP) OAE instruments (Natus Medical Incorporated, San Carlos, CA) at all 3 screening sites. The instrument’s external probe is attached to the screening unit by a cord ~4 feet long that allows the probe to stay seated in the ear canal when children are upright and moving. The cost of equipment was $3700 per unit. Disposable pediatric foam probe covers (~$1 per child; Natus Medical Incorporated, San Carlos, CA) were also used to maximize probe seal in the canal to reduce interference from external noise. DP OAEs are elicited with the presentation of a set of 2 pure-tone frequencies (F2 and F1) at a moderate decibel sound pressure level (SPL). The instrument screening protocols were set to deliver stimuli and measurement levels sensitive to mild hearing loss as low as 25 dB hearing level. The collection parameters included F2 frequencies of 5000, 4000, 3000, and 2000 Hz each with an intensity level of 65 dB SPL for F1 and 55 dB SPL for F2. A typical F2/F1 ratio of 1.22 was used. It is typical to determine whether a reliable and repeatable OAE is present by obtaining an OAE that is large enough that its amplitude exceeds the noise of the room. Therefore, frequency-specific pass/refer criteria included a minimum DP amplitude of −6 at 5000, −5 at 4000, −8 at 3000, and −7 at 2000, with a DP noise floor of 6. The number of frequencies for an overall screening pass was 3. Before data collection, a pediatric audiologist provided training to 4 medical assistants (MAs), 1 at each of the 2 school-based clinics and 2 at the community clinic, on OAE screening procedures and a follow-up protocol. Standardized training materials (video, printed manuals and materials) from the Early Childhood Hearing Outreach Initiative were used during a 4-hour training session, along with live demonstrations and hands-on practice. The audiologist was also available to provide ongoing technical support and consultation as needed. The trained MAs conducted the hearing screenings on children in clinic examination rooms as part of the regular patient intake process that included the collection of vitals before seeing the PCP. The average amount of time required for OAE screening, based on the first 350 children screened, was 4 minutes per child. Parents of children served in these settings routinely sign a consent form as a part of the intake process that provides for appropriate evaluation and treatment as designated by PCPs. Institutional review board approval for this study was also obtained. Screening and follow-up outcome data were collected on each subject.

### Hearing Screening and Follow-up Protocol and Variables

Key components of the protocol implemented across all 3 sites included nonotoscopic visual inspection of the outer ear and an initial OAE hearing screening conducted by an MA. This was followed by otoscopic (pneumatic) examination of the middle ear (tympanometry conducted when available) performed by the PCP as part of the physical examination. No changes in diagnostic or treatment approach were introduced by this study; all PCPs followed their own standard diagnostic and treatment procedures. OAE rescreenings were conducted and referrals made to other specialists as needed to complete the screening/diagnostic process. Each subject was screened and the outcome documented by using the following protocol.

#### Nonotoscopic Visual Inspection

- If Pass on both ears (no observed abnormality, drainage, or blockage), proceed with OAE 1.
- If Refer on 1 or both ears (condition observed that would contraindicate further screening), consult with PCP before completing OAE 1.

#### OAE 1 Screen

- If Pass on both ears, OAE screening complete, no follow-up needed.
- If Refer on 1 or both ears, note middle ear examination outcomes. If no outer/middle ear problems identified, conduct OAE 2 Rescreen in 2 weeks. If effusion, acute OM, or blockage noted, treat medically and conduct OAE 2 rescreen in 2 weeks or as soon as feasible. Medical treatment of effusion or OM included (1) watch and wait, (2) medication, or (3) referral to an ear, nose, and throat specialist for subjects who had a history of repeated OM or were unresponsive to antibiotic treatment.
- If Could Not Test (CNT) 1 or both ears, because of lack of cooperation and/or excessive movement or noise on the part of the child, conduct OAE 2 Rescreen in 2 weeks.

#### OAE 2 Rescreen

- If Pass, screening complete.
- If Refer, and outer/middle ear noted as clear; refer for audiological evaluation.
- If outer/middle ear issues were unresolved, treat as described for OAE 1 above and when ear found to be clear, conduct OAE 3 Rescreen.
- If CNT, refer for audiological screening/evaluation.

#### OAE 3 Rescreen

- If Pass, screening complete.
- If Refer, and middle ear noted as clear; refer for audiological evaluation.
If CNT, refer for audiological screening/evaluation.

As described, the screening and follow-up protocol specified that children not passing the OAE screening be evaluated by a pediatric audiologist. These specialists followed their own standard diagnostic procedures and the outcomes were collected as part of the study. Children for whom no follow-up screening or diagnostic data could be obtained were documented as having exited from the study.

RESULTS

Based on the multistep screening protocol, of the 846 children screened, 814 (96%) ultimately passed the screening or audiological assessment, 29 (3%) exited the study (did not come back for rescreening or follow-up), and 3 (0.35%) were identified with permanent hearing loss. More detailed OAE screening outcomes are summarized in Fig 1. Subgroup analysis of OAE 1 Screen outcomes, categorized by the reason for the child’s health care visit, is shown in Table 2. These findings reflect differences in pass rates based on the reason for the health care visit.

Of the children who could not be tested, all were between 9 and 25 months of age (mean = 14.1 months).

Table 3 provides information about the 3 children identified with permanent hearing loss. Two had previously passed the newborn hearing screening and could therefore be documented as having true post neonatal or late-onset hearing loss. The child born outside the United States had no documentation of screening at birth and it remains unknown whether the loss was congenital or post neonatal. Records of these children indicated earlier documentation of concerns, but that no hearing evaluation follow-up had been completed.

DISCUSSION

This study addressed the efficacy of implementing OAE screening with children 0 to 5 years of age (and their older siblings based on parental or provider request) in community- and school-based clinics. Although newborn hearing screening has become the standard of care in the United States, most children do not have their hearing screened again until they enter school. The results of this study reinforce the importance of hearing screening during early childhood to identify children with post neonatal permanent hearing loss as well as providing further screening and diagnostic services to infants who were not screened at birth or who did not pass the newborn screening and were subsequently lost to follow-up.

Analysis of OAE pass rates provides initial information about the practicality of implementing hearing screening in clinic settings. The overall OAE 1 pass rate of 79% (see Table 2) is similar to the rate reported for children 0 to 3 screened in previous studies.3,16 As would be expected, the refer rate was by far the highest among children who were being seen for ear-related concerns because blockage in the ear canal or middle ear fluid typically causes the ear to refer on OAE screening. The clinic PCP indicated that the OAE screening contributed to middle ear diagnosis and treatment decisions and an enhanced understanding of the value of referral for audiological assessment. The percentage of children who could not be tested also confirms what common sense would suggest: children who are not feeling well and are being seen for ear-related or other concerns are
less cooperative and more difficult to screen. Participating providers reported that access to audiological support for training and follow-up evaluation was helpful, though they were able to conduct the OAE screening relatively independently. All participating clinics elected to continue OAE screening subsequent to the study.

Study results indicate that using a multistep OAE hearing screening protocol with children 0 to 5 years of age in clinic settings, which constituted the primary target population of the study, was effective in leading to the identification of children with permanent hearing loss at a rate of 1.2 per 1000. This rate is similar to findings from a study conducting OAE screening with children 0 to 3 years of age in educational settings. An unexpected outcome was that the availability of screening in the clinics resulted in requests that a small number of siblings be screened as well. Consequently, 2 children >5 years of age with previously undocumented hearing losses were also identified. All identified children were ultimately fit with amplification, and connected with audiological, speech, language, and academic intervention services.

Although the overall rate of identification in this study was 3.5 children per 1000, the inclusion of children >5 years of age in the data set, 2 of whom were identified with permanent hearing loss, does not provide a balanced sample of the large population of children in that age range being served in the clinics. At the same time, it is significant that these children had not been identified until a screening opportunity was readily available. It is also worth noting that the rate of identification previously reported for children 0 to 3 receiving OAE screening and follow-up in federally qualified health centers was approximately 2.5 per 1000. Much of the detailed data on permanent hearing loss in the early childhood population is drawn from studies providing services to underserved infants and toddlers in federally funded early childhood education and health care clinic settings. Future research replicating these studies with children representing different demographic characteristics, and receiving care from pediatricians in private practice, for example, will add significantly to the knowledge base.

All hearing screening results were provided to the state Department of Health Early Hearing Detection and Intervention (EHDI) program. Through this data-sharing process, the EHDI program was able to close the loop on 6 children previously regarded as lost to follow-up from newborn screening. The EHDI program was also informed specifically about the 3 children identified with permanent hearing loss, which resulted in a more accurate count of young children in the state with hearing loss and an enhanced capacity to connect the recently identified children and their families with supports and services.

Further examination of the characteristics of the 3 children identified with permanent hearing loss is informative. In all cases, the “red flag” presence of speech and language concerns had not led to previous identification of a hearing loss. Furthermore, the reason these children were being seen at the clinics was not for hearing-related issues. Two were being seen as a part of routine well-child checks and 1 for a non–ear-related illness. This suggests that a hearing loss significant enough to cause disruption in language acquisition is not readily identified as such by parents or PCPs using subjective screening methods. In fact, even when
a language delay arises as a symptom, the “invisible” causal hearing loss may remain unnoticed for months or years unless objective hearing screening and follow-up diagnostic evaluation is used. In 1 child, chronic OM may have further masked the fact that a sensorineural loss was present. Although it is fortunate that these children were identified through OAE screening and were thereby able to receive the needed diagnostic and intervention services to begin to ameliorate the hearing loss and the concomitant language disorder, one could argue that if periodic hearing screening were routinely provided to preschool children, hearing loss might be identified and intervention undertaken before a language delay occurred.

Although it was the intention of the researchers to be able to track billing and reimbursement for the OAE screening, systemic policy changes arising during the course of the study did not allow for collection of those data. Under the Affordable Care Act, OAE screening is considered preventive care, allowing reimbursement for the procedure. Future research should examine the extent to which the provisions of the Affordable Care Act facilitate screening young children for hearing loss. Likewise, the results of this study, combined with previous findings, should inform practice and preventive American Academy of Pediatrics guidelines targeted at early identification of hearing loss. OAE screening holds the potential for being more effective than subjective screening methods in helping to identify young children with permanent hearing loss in health care settings.

REFERENCES

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Pediatrics; originally published online June 3, 2013;
DOI: 10.1542/peds.2012-3868

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