Sensitivity of the Automated Auditory Brainstem Response in Neonatal Hearing Screening

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**BACKGROUND:** In a 2-stage neonatal hearing screening protocol, if an infant fails the first-stage screening with an otoacoustic emissions test, an automated auditory brainstem response (ABR) test is performed. The purpose of this study was to estimate the rate of hearing loss detected by first-stage otoacoustic emissions test but missed by second-stage automated ABR testing.

**METHODS:** The data of 17,078 infants who were born at Lis Maternity Hospital between January 2013 and June 2014 were reviewed. Infants who failed screening with a transient evoked otoacoustic emissions (TEOAE) test and infants admitted to the NICU for more than 5 days underwent screening with an automated ABR test at 45 decibel hearing level (dB HL). All infants who failed screening with TEOAE were referred to a follow-up evaluation at the hearing clinic.

**RESULTS:** Twenty-four percent of the infants who failed the TEOAE and passed the automated ABR hearing screening tests were eventually diagnosed with hearing loss by diagnostic ABR testing (22/90). They comprised 52% of all of the infants in the birth cohort who were diagnosed with permanent or persistent hearing loss >25 dB HL in 1 or both ears (22/42). Hearing loss >45 dB HL, which is considered to be in the range of moderate to profound severity, was diagnosed in 36% of the infants in this group (8/22), comprising 42% of the infants with hearing loss of this degree (8/19).

**CONCLUSIONS:** The sensitivity of the diverse response detection methods of automated ABR devices needs to be further empirically evaluated.

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**WHAT'S KNOWN ON THIS SUBJECT:** Adding second-stage automated auditory brainstem response (ABR) testing for infants who failed the initial OAE test in a two-stage neonatal hearing screening has been shown to reduce false referrals to the hearing clinic.

**WHAT THIS STUDY ADDS:** Infants with hearing loss may be missed by a 2-stage hearing screening because they pass the automated ABR test. In our study, a significant number of infants with hearing loss >45 decibel hearing level passed screening with automated ABR.
Universal neonatal hearing screening was implemented in Israel on January 1, 2010. The 2-stage protocol approved by the Israeli Ministry of Health\(^1\) indicates that otoacoustic emissions (OAE) testing be performed in all infants before discharge from the birth hospital. Infants who fail the OAE test twice and infants with risk indicators for neural hearing loss undergo automated auditory brainstem response (ABR) testing as well. Infants who fail the OAE test but subsequently pass the automated ABR test are considered to have passed the hearing screening.

Adding the automated ABR test for infants who failed the initial OAE test as the second stage of a 2-stage protocol was shown by a number of investigators to reduce the false-positive rate and to minimize unnecessary referrals to the hearing clinic.\(^2\)\(^-\)\(^6\) However, little is known about the effect of adding the automated ABR stage on the procedure’s false-negative rates (ie, infants with hearing loss who are missed). Johnson et al.\(^7\) estimated that ∼23% of infants with hearing loss are not identified by a 2-stage protocol because they pass the automated ABR stage. Their study was based on a follow-up behavioral hearing evaluation at the age of 9 months. The study conclusions were limited by partial enrollment (44%), the exclusion of infants with inconclusive audiology status (8%), and the possible inclusion of infants with late-onset hearing loss.

The purpose of this study was to further investigate the percentage of infants with subsequently confirmed hearing loss who failed the OAE but passed the automated ABR hearing screening tests. The study included an early follow-up evaluation at the hearing clinic with objective measurements (eg, repeated OAE and/or diagnostic ABR testing) for all infants who failed screening with OAE testing, including those who passed the automated ABR testing.

**METHODS**

**Study Design**

This cohort study was performed on prospectively collected clinical data at Lis Maternity Hospital and at the hearing clinic of the Tel Aviv Sourasky Medical Center between January 1, 2013, and June 30, 2014 (18 months). The study was approved by the Institutional Review Board for Human Experimentation, which waived obtaining written consent from the parents of the infants included in the study.

**Study Population**

During the study period, 17 097 infants were born at Lis Maternity Hospital. After the exclusion of 19 infants who died shortly after birth, the study cohort included 17 078 infants. One infant with an occluded ear canal caused by a congenital malformation could not undergo hearing screening.

**Neonatal Hearing Screening**

Transient evoked otoacoustic emissions (TEOAE) tests (Otoport Screener; Otodynamics, Hatfield, Hertfordshire, UK) were used for the first-stage screening of all infants before discharge. Term infants underwent the first TEOAE test on the second day of life. Preterm infants were tested at 35 to 36 weeks of corrected gestational age. The pass criterion for the TEOAE test was set to 6 dB signal-to-noise ratio in 3 of the 4 frequency bands tested (1.5, 2.0, 3.0, 4.0 kHz) in both ears. In infants who failed the TEOAE test, a second TEOAE test was performed 1 or more days after the first trial. Infants who failed the TEOAE test twice and infants with risk indicators for neural hearing loss\(^8\) were tested with automated ABR (GSI AUDIOScreener +; Grason-Stadler, Minneapolis, MN) before hospital discharge. Risk indicators for neural hearing loss included all infants admitted to the NICU for >5 days. The response detection method used in our automated ABR device is termed Fsp and is designed to estimate the ratio of a signal (ABR) to background noise for a given averaged ABR.\(^9\)\(^-\)\(^10\) The pass criterion was set to Fsp of 3.2 in both ears. The stimulus intensity level was set to 45 decibel hearing level (dB HL) (in-ear calibrated). This intensity level was used in well infants as well as in NICU infants to ensure that the neural response could be recorded, unaffected by any possible conductive hearing loss caused by postnatal debris in the external ear canal or by middle ear fluids.

In infants who failed the TEOAE screening test twice, urine samples were taken before hospital discharge for the detection of congenital cytomegalovirus (CMV).

**Hearing Clinic Follow-up**

Infants who failed the automated ABR screening and those with risk indicators for hearing loss were referred to the hearing clinic for a hearing evaluation with diagnostic ABR (Smart EP; Intelligent Hearing Systems, Miami, FL, or Eclipse EP25; Interacoustics, Assens, Denmark) testing.

Infants who passed the automated ABR, after a failure on the TEOAE test, were referred to the hearing clinic for a repeated TEOAE test at 10 to 30 days of age (Otoport Advance; Otodynamics). If normal TEOAE results could still not be obtained at this age, those infants were also referred for a hearing evaluation with a diagnostic ABR test.

Diagnostic ABR testing was conducted during natural sleep before 3 months of corrected age. It consisted of estimating the hearing threshold to an air-conducted click stimulus. Infants with hearing loss were further tested with a bone-conducted click stimulus to determine the type of hearing loss (ie,
conductive or sensorineural). A frequency-specific ABR evaluation during sedative-induced sleep was conducted in some of these infants in another session.

Our hearing screening procedure is described in Fig 1 A and B.

Data Collection

The data were obtained from the Lis Maternity Hospital hearing screening and the hearing clinic databases. The screening results from the automated ABR tests were compared with the diagnostic ABR thresholds to the click stimuli11 to estimate the percentage of infants with hearing loss who were missed by the automated ABR test.

RESULTS

Of the 17 078 infants included in the study cohort, 16 965 (99.34%) were screened for hearing loss before hospital discharge. Among them, 918 (5.4%) infants were admitted to the NICU for >5 days, and an additional 60 (0.35%) infants were known to have other risk indicators for hearing loss.8

At the time of hospital discharge, 16 753 (98.1%) of the infants had a “pass” result on the TEOAE screening, and 212 (1.24%) infants had a “fail” result. Unilateral failure was recorded in 134 (0.78%) of the infants and bilateral failure in 78 (0.46%) of them. Twenty-two (0.13%) infants who failed the TEOAE screening failed the automated ABR screening as well, but 90 (0.53%) infants passed it successfully. The screening procedure was not completed in 100 (0.59%) of the infants. This group included 79 (0.46%) infants who failed the first TEOAE test but were discharged before a second trial was performed and 21 (0.12%) infants who failed the second TEOAE test but in whom the automated ABR was not performed. Most often these tests were performed on the day of discharge; therefore, the most frequent reasons for incomplete screening were discharge on a weekend or inadequate conditions for automated ABR testing in infants who could not be calmed.

The initial follow-up at the hearing clinic was considered to be accomplished if an infant passed the repeated TEOAE or underwent a diagnostic ABR. Overall, 71% of the infants who failed the TEOAE screening before discharge completed the initial follow-up at the hearing clinic (151/212). The initial follow-up was completed in 68% of the infants who failed both the TEOAE and the automated ABR tests (15/22), in 73% of those who failed the TEOAE but passed the automated ABR tests (66/90), and in 70% of those who had incomplete screening results (70/100).

At the diagnostic ABR, hearing loss was determined to be present if an infant had a hearing threshold >25 dB.

FIGURE 1

A. Our hearing screening flowchart: summary. AABR, automated auditory brainstem response. A AABR also was performed in NICU infants who passed the TEOAE screening test. Infants with risk indicators were referred to diagnostic ABR testing regardless of their hearing screening results. B. Our hearing screening flowchart: detailed. A AABR also was performed in NICU infants who passed the TEOAE screening test. Infants with risk indicators were referred to diagnostic ABR testing regardless of their hearing screening results.
Our birth cohort. Although hearing ABR, was diagnosed in 19 infants in ears, as measured by the diagnostic Hearing loss. In this group (2/22, 9%). After the urine tests, congenital indicators for hearing loss (13/22, 55%) and mixed hearing loss in 1 of these infants (12/22, 55%). Sensorineural hearing loss was diagnosed in 12 of the infants (12/22, 55%). Hearing loss was most frequently observed in infants who failed both the TEOAE and the automated ABR screening tests (11/22, 50%); however, a substantial percentage of hearing loss cases were also found among infants who failed the TEOAE but passed the automated ABR screening (22/90, 24%). Hearing loss was least frequently observed among infants with an incomplete screening result at the time of discharge (6/100, 6%).

The 22 infants who were diagnosed with hearing loss after a “failed TEOAE/passed automated ABR” screening result comprised 52% of all infants diagnosed with hearing loss (22/42). If infants with this screening result would be considered to have normal hearing, these infants would be missed by the screening procedure. The hearing status of these 22 infants is specified in Table 1. Bilateral versus unilateral hearing loss was diagnosed in 12 of the infants in this group (12/22, 55%). Sensorineural hearing loss was diagnosed in 12 of the infants (12/22, 55%) and mixed hearing loss in 1 of them (1/22, 5%). This group included 13 infants without any known risk indicators for hearing loss (13/22, 59%). After the urine tests, congenital CMV was diagnosed in 2 of the infants in this group (2/22, 9%).

Hearing loss >45 dB HL in 1 or both ears, as measured by the diagnostic ABR, was diagnosed in 19 infants in our birth cohort. Although hearing loss in this range is considered to be of a moderate to profound severity, 8 of these infants passed the hearing screening with automated ABR to a click stimulus presented at 45 dB HL (8/19, 42%). They comprised 36% of the infants with a failed TEOAE/passed automated ABR screening result (8/22). Overall, our screening procedure detected 39 of the 42 infants diagnosed with hearing loss.

Three infants with hearing loss were not detected by the hearing screening procedure. This number includes the 1 infant with a congenital occluded ear canal who could not undergo the screening tests and 2 infants who were diagnosed with auditory neuropathy. These 2 infants passed both the TEOAE and the automated ABR screening tests before discharge and were referred to the hearing clinic because they were admitted to the NICU.

**DISCUSSION**

The goal of universal neonatal hearing screening is to detect infants with permanent hearing loss that is present at birth.8 Permanent childhood hearing loss may impair the development of speech and language and may lead to difficulties in educational progress and in social-emotional development. Early detection and intervention have been shown to be beneficial and to improve language development outcomes.12–14 According to the recommendations of the Joint Committee on Infant Hearing,8 screening for the detection of hearing loss in newborns should be completed by the end of the first month of life, and a diagnostic audiological evaluation for those who failed should be accomplished by the third month, so that appropriate intervention may begin before the age of 6 months.

Our results show that in a 2-stage screening protocol, a substantial portion of the infants who failed the TEOAE and passed the automated ABR hearing screening tests were eventually diagnosed with hearing loss (22/90, 24%). They comprised 52% of all of the infants in the birth cohort who were diagnosed with permanent or persistent hearing loss >25 dB HL in 1 or both ears. Hearing loss >45 dB HL, which is considered to be in the range of moderate to profound severity, was diagnosed in 36% of the infants in this group (8/22), comprising 42% of the infants with hearing loss of this degree (8/19). If a failed TEOAE/passed automated ABR screening result would be considered to reflect normal hearing, these infants would be missed by our screening procedure.

Previous studies have shown that it is possible for infants with hearing loss to pass the newborn hearing screening. Young et al15 reported that one-third of their pediatric cochlear implant recipients had passed the hearing screening at birth. In an earlier study, Johnson et al7 estimated that ~23% of infants with hearing loss are missed because they pass the automated ABR screening test; yet, the concerning issue of infants who are missed by the hearing screening has been widely overlooked. Infants with hearing loss who pass their hearing screening may not show any clinical manifestation before language impairment is evident. At this time, it may not be possible to differentiate between neonatal and late-onset hearing loss.16,17

Obtaining quality data on the sensitivity of a hearing screening program is complex and counterintuitive: the study has to focus on infants who passed the screening, the study sample needs to be large enough to include a sufficient number of confirmed hearing loss cases, and the screening results need to be compared with a diagnostic evaluation within a short time interval. The current study was
designed to overcome these obstacles. Our results support those of previous studies that addressed the potentially missed detection of infant hearing loss by neonatal hearing screening. However, our estimates of the rate of infants missed by the hearing screening because they pass the automated ABR test are more pessimistic than the rates that have been previously reported.

It is possible that our study included more infants with mild hearing loss than previous studies because the stimulus intensity level in our automated ABR testing was set to 45 dB HL, whereas the intensity level commonly used in most programs is 35 dB HL. This higher intensity level was used in our screening both for NICU infants who had to be screened for neural hearing loss and for infants who failed the TEOAE tests. For the former, an intensity level of 45 dB HL was used to ensure that the neural response could be recorded, unaffected by any possible conductive hearing loss caused by postnatal debris in the external ear canal or by middle ear fluids. For the latter, this intensity level was used to differentiate between moderate or severe hearing loss on the one hand and mild hearing loss on the other. We assumed that in the case of mild loss, the best way to distinguish between transient and persistent hearing loss would be a repeated TEOAE testing at 10 to 30 days. It should be noted that the normal threshold range to a click stimulus is 0 to 20 dB HL; thus, a response to a 35- or 45-dB HL click stimulus does not necessarily reflect normal hearing. In addition, because it is composed of a wide range of frequencies, a click stimulus is not suitable for the detection of frequency-confined hearing loss, such as high-tone or low-tone loss. These shortcomings of the automated ABR testing may be worsened if the intensity of the stimulus is not calibrated in the ear at the beginning of every test, leading to testing with higher stimulus intensities than intended.

An unexpected outcome of our screening procedure was the missed detection of infants with moderate or profound hearing loss by the automated ABR testing. In our study, 42% of the infants with hearing loss >45 dB HL passed the automated ABR test. Apparently, our automated ABR device detected an auditory brainstem response where it was absent. This could be a result of random (nonauditory) neural activity or electromagnetic background noise that is misinterpreted by the device as an auditory brainstem response. The number of infants with hearing loss who are missed because of this type of error may vary across different studies, depending on the statistical methods being used by the different screening devices and on the

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AABR, automated auditory brainstem response; dB nHL, decibel (normal) hearing level; F, female; M, male; NA, not available; —, not tested.

* Frequency-specific thresholds were not available for all infants. The estimated thresholds to narrow-band chirp stimuli are presented, with a correction of −10 dB at 1 KHz.

TABLE 1

Hearing Status of Infants with Hearing Loss Who Failed TEOAE but Passed AABR Screening Tests
number of repetitions made by the tester. Nevertheless, the estimates in our study as well as those of previous studies are alarmingly higher than expected.

There are a number of limitations to our study that need to be considered. One is the use of only 1 type of automated ABR device in our screening program. The sensitivity of other automated ABR devices and of the different response detection methods used in neonatal hearing screening also should be evaluated. Another is that participation in the initial follow-up evaluation in our hearing clinic was 71%. In Israel, parents are free to choose to complete the follow-up in any other hospital’s audiology clinic. Therefore, we cannot exclude any specific bias in our results related to those who completed the follow-up in another clinic or those who did not complete it at all.

CONCLUSIONS
Automated ABR testing missed 42% of the infants with subsequently confirmed hearing loss >45 dB HL who had been previously detected by the first-stage TEOAE testing. This rate of missed detection may seriously compromise achievement of the goals of neonatal hearing screening. In well infants, if a 2-stage protocol is being used, it is recommended to refer infants with a failed TEOAE/failed automated ABR screening result to an audiology clinic for a follow-up. Furthermore, a repeated TEOAE test at the age of 10 to 30 days, as conducted in our study, may serve as a good alternative for the second-stage screening. Our experience, as well as that of others,19–21 shows that screening with TEOAE alone can yield reduced false referrals if the initial test and the repeated tests are properly scheduled according to the timeline. It seems reasonable that retesting within the correct time interval is the best way to differentiate between transient and permanent hearing loss.

Nevertheless, screening with automated ABR testing is the only currently available technique for detecting neural hearing loss (eg, auditory neuropathy/dysynchrony), and it is strongly recommended for infants who are admitted to the NICU.8 Our results suggest that it is possible for an automated ABR screening device to falsely identify an auditory brainstem response when it is absent. This implies that even neural hearing loss may be missed by the automated ABR test. This notion underscores the need for further evaluation of the sensitivity of the diverse automated ABR devices currently in use. The probability of the false identification of random electrophysiological activity as an ABR response should be examined empirically to support the theoretically expected level of confidence.

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ABBREVIATIONS
ABR: auditory brainstem response
CMV: cytomegalovirus
dB HL: decibel hearing level
OAE: otoacoustic emissions
TEOAE: transient evoked otoacoustic emissions

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