

AUDIOLOGY

Comparison of Neonatal Hearing Screening Devices

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Incidence studies estimate that 1 - 3 per 1000 full term normal neonates and 2 - 4 % of high-risk newborns per 100 have severe bilateral hearing loss. In response, universal hearing screening has been proposed; however, choosing the most appropriate technology continues to be an obstacle. The purpose of the current preliminary study was to compare test results from thirty-two full-term newborns using three types of screening devices, Natus Algo 2 AABR, Otodynamics EchoCheck TEE, and Biologic AuDx DPE. Results indicate that the Natus had

the highest pass percentage rate for the right and left ears at 97% and 91% respectively, while the other two devices had pass percentage rates between 31% and 56%. Test duration time for the Natus was 22.5 minutes compared with 5.8-6.4 minutes for the other devices. Despite the longer duration time, our findings favor using the Natus, given its accurate representation of incidence data. *Key words:* Otoacoustic emissions, Distortion-product emissions, Transient emissions, Auditory brainstem response, Universal hearing screening

Approximately 3 million American children have hearing loss and 1.3 million of these are under the age of three (1). Congenital hearing loss is one of the most common abnormalities present at birth. Incidence studies performed in the United States estimate that 1-3 newborns per 1000 well babies have a severe bilateral hearing loss (2,3,4). Incidence rates for graduates of newborn intensive care units are even higher, with estimates of 2 - 4% of them (2,5).

Prevalence and incidence hearing loss data for Puerto Rico is practically non-existent. Recently, a group from the Neonatology Section of the Department of Pediatrics at the University of Puerto Rico completed a preliminary two year incidence study of hearing loss in high-risk newborns from their Neonatal Intensive Care Unit (6). Results from this study indicate an incidence of moderate to profound hearing loss of 1.5% and 1.8% for each year, respectively.

Universal hearing screening involves the testing of all newborns for hearing impairment prior to release from the hospital. The goal of universal hearing screening is to identify those newborns with a hearing loss as early as possible and implement early amplification. Unfortunately, universal hearing screening is not a standard practice among the majority of hospitals in the United States and none of the hospitals in Puerto Rico.

In the United States the average age of identification is between 2 ½ - 3 years of age and in the case of more moderate and/or unilateral hearing losses, much later (2,3,5,7). Furthermore, the average time interval from time of diagnosis to intervention is 1 year, making the average age of intervention 3½ years of age (8). There are no data available for age of identification or intervention in Puerto Rico, but considering the lack of any universal hearing screening program on the Island and the limited number of screening devices, it is reasonable to assume that average age of identification is probably greater.

There are currently two types of electrophysiologic tests used for screening hearing in newborns: the auditory brainstem response (ABR) and otoacoustic emissions (OAEs). The ABR is an electrical brainstem response to acoustical stimulation that is comprised of a series of waves, similar to an electroencephalogram (EEG). Latency, amplitude, and morphology are the clinical values used to make determination of auditory dysfunction. The OAE test presents a short or continuous acoustic stimuli in order to elicit a response from the outer hair cells (sensory cells) of the cochlea. This response or "otoacoustic

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emission” is then transmitted back through the ear apparatus to the newborn ear canal where it is recorded by a microphone. The presence of OAEs is indicative of normal hearing, while their absence may suggest abnormal function in the peripheral auditory system.

Until recently, the ABR and OAE equipment used for screening hearing in newborns was large, stationary, expensive, and relatively complicated to use (especially the ABR). However, with recent advances in computer technology, these devices are now smaller, portable, less expensive, and automated. The types of devices currently being used in the majority of existing universal hearing screening programs are the Automated Auditory Brainstem Response (AABR), Transient Evoked Otoacoustic Emissions (TEEs), and Distortion-Product Otoacoustic Emissions (DPEs).

The purpose of this study was to compare test results among three types of screening devices: AABR, TEE and DPE. Specifically, internal and external variables that contribute to pass percentage and test duration variability were evaluated in attempt to determine which device is most appropriate for hearing screening purposes.

Methods

Subjects. Thirty-two full-term newborns from the well-baby nursery of the University Hospital at the University of Puerto Rico participated in the present study. Three audiologists performed all testing within 48 hours of birth. The tests were purposely undertaken in the well-baby nursery itself; therefore no attempt was made to control noise levels. Institutional Review Board approval was granted and parental consent was obtained prior to testing.

Equipment. Three screening devices were evaluated, the Natus Algo 2, an AABR, the Otodynamics EchoCheck, a TEE, and the Bio-logic AuDx, a DPE. The devices were chosen based on the latest in technological innovation and reputed ease of use.

The Natus Algo 2 AABR is a laptop-based device with a corresponding base housing the soundboard and analyzing hardware. The total weight of the device is 21 lbs. and a small cart was needed to do the recording and transport the unit. The unit has a computer monitor display of the testing procedure in a step-by-step fashion including electrode impedance information. It reports a pass or fail response for each ear. The Natus Algo 2 was used with the appropriate Natus disposable earphones and electrodes.

The Otodynamics EchoCheck TEE is a handheld device weighing less than 2 lbs. It has a series of lights that provide information regarding fit of the probe, stimulus level, noise level and pass or fail results. The device is

completely automated, including the “on” button, only two buttons need to be pressed for proper test initiation and completion. The device can run from an outlet or with a rechargeable battery.

The Bio-logic AuDx DPE is a handheld device weighing less than 2 lbs. It has a small LED display that provides information regarding probe fit, stimulus calibration, stimuli and noise levels and pass or fail results. Similar to the EchoCheck, it is completely automated, only requiring the use of two buttons and it can be run from an outlet or a rechargeable battery. Figure 1 shows all three devices used in the present investigation.



Figure 1. Three types of hearing screening devices, the Natus Algo 2, an AABR, the Otodynamics EchoCheck, a TEE, and the Bio-logic AuDx, a DPE.

Procedure. All testing was performed in the well-baby nursery. All three devices were used to screen each newborn. The order of the devices used to screen the newborns was randomly assigned to each subject. The AABR involved scrubbing the newborns on top of the forehead, on the nape, and the upper portion of the shoulder in order to place corresponding disposable surface electrodes. Electrode impedance (resistance) was then measured. This measurement correlated with how well the skin had been scrubbed or cleaned prior to electrode placement. The AABR did not allow for the procedure to continue if the electrode impedance was too high (>12 ohms). Following impedance testing, the appropriate disposable earphones were placed over each of the newborns’ ears and testing was initiated.

The TEE and DPE protocol was identical. The probe housing the single earphone for the TEEs and the two

earphones for the DPEs along with the low noise microphone was inserted in the newborns' ear canal. The screening device then reported whether the probe fit was appropriate and if so, testing began.

Results

Conditions in the well-baby nursery were not constant. There were variations in the number of newborns and personnel in the nursery during testing sessions, which may have contributed to ambient noise fluctuations. Also, the mood or disposition of the newborn influenced the ease of testing, and certain newborns were simply "noisier", particularly with regards to their breathing. Nevertheless, these variations are typical of most newborn nurseries and cannot be fully controlled.

Each screening device was used to evaluate the hearing of all of the 32 newborns. The pass rate or pass percentage varied depending on the device used for the screening. Figure 2 shows the pass percentages for all devices according to ears tested. The Natus Algo 2 ABR has the highest pass percentage among the devices tested. Only

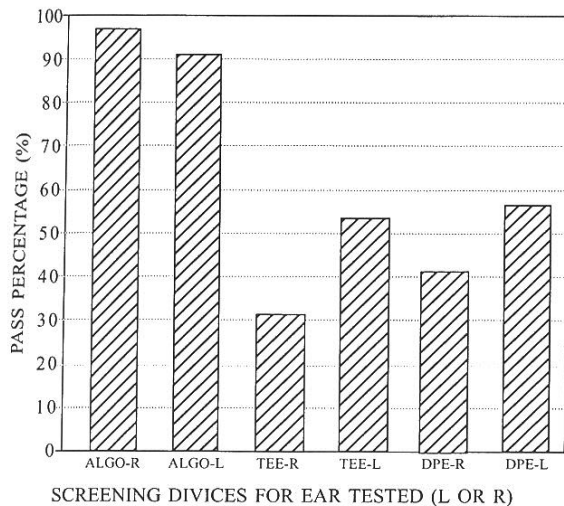


Figure 2. The pass percentages for all screening devices according to ear tested.

one newborn failed the screening of ABR for both ears and two failed for the left ear, making the passing percentage 97% and 91%, respectively. The passing percentages for the TEE for the right and left ear were 31% and 53%, respectively and the DPE passing percentages for the right and left ears were 41% and 56%, respectively.

The testing time varied depending on the screening device used. There was also a great deal of variation in

testing time between subjects. Figure 3 shows the average testing time for all three devices and the corresponding standard deviation for the testing time data. The ABR had the longest average testing time at 22.5 minutes. The TEE and DPE devices had comparable testing times of 5.8 and 6.4 minutes, respectively.

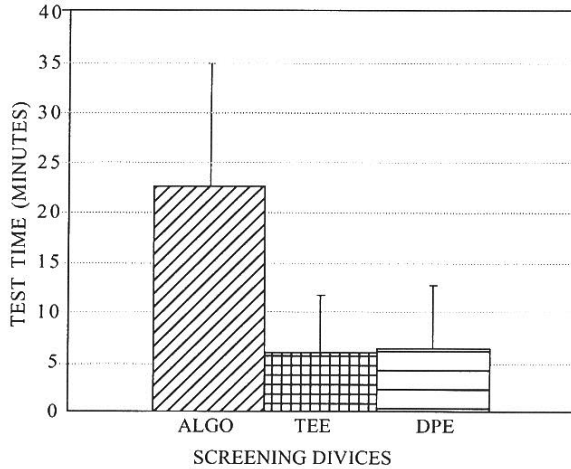


Figure 3. The test time for all screening devices. The error bar corresponds to the standard deviation.

Discussion

Currently in the majority of hospitals in the US and Puerto Rico, it is common practice to screen newborns for hearing loss based on the *High Risk Register* (4,9,10). The High Risk Register is a list of ten high risk indicators for hearing loss including asphyxia, meningitis, congenital or perinatal infections, anatomic defects or stigmata, hyperbilirubinemia, family history of hearing loss, low birth weight, ototoxic medications, and neonatal illnesses requiring mechanical ventilation (4,7). The problem with the High Risk Register is that it is not an effective tool, missing 50% of all newborns with a hearing loss. A retrospective study of infants in Colorado screening programs revealed that 63 of 126 (50%) newborns with a hearing loss did not have any of the risk indicators (9). Furthermore, it has been recently suggested that the "critical" or "optimal" period in which auditory stimulation is most integral in the normal development of speech and language is much shorter than previously believed. Children identified with a hearing loss and no secondary disability that received intervention prior to 6 months of age, demonstrated language development within normal limits from birth through 5 years of age (9). These findings support those recommendations made by the Joint

Committee on Infant Hearing (7) and the American Academy of Pediatrics (2) that universal hearing screening is now a priority.

The AABR uses the same procedure as the ABR, however, the tester no longer evaluates the ABR recordings. Determinations regarding the presence of an auditory brainstem response, its wave latencies and wave amplitudes are now done automatically by the device. Specific criteria regarding these parameters are based on normative values and are present in a template, which the device uses to determine a "pass" or "fail" result. This design is advantageous in that it reduces the actual testing time and reduces the training time of personnel with limited or no experience in ABR testing. The average time of testing per newborn is 15 - 45 minutes. All newborns that do not pass a screening are referred for further diagnostic testing, which commonly involves a regular ABR. The referral rate ranges between 1 - 10%, with an average of 4% (11).

The TEEs and DPEs are both otoacoustic emission devices that record a response or emission in the auditory ear canal following the presentation of auditory stimuli. The major procedural difference between both of these devices is the stimuli used to elicit the emissions. TEEs use a transient or click stimulus, which is only present a very brief time. The emission is then recorded after the transient has been turned off. DPEs use two simultaneous pure tones that are on continuously, while the emission is recorded. Since TEE and DPE testing does not involve electrode placement, it is typically shorter, requiring only 5 - 0 minutes, compared with AABR testing. For the same reason, training of personnel with limited or no experience with OAE testing is also easier than AABR testing. Similar to the AABR, all newborns not passing the screening are referred for diagnostic testing. TEE referral rates range between 3 - 12%, with an average of 7%. The referral rates for DPEs range between 4 - 15%, with an average of 8% (11).

Studies regarding incidence of congenital hearing loss indicate that 1 - 3% newborns will be afflicted (2,3,4). Based on this incidence rate and the size of the subject sample size, the probability of detecting a newborn with a hearing loss in the present study was expected to be very low. Nevertheless, one newborn did fail all three screenings bilaterally and was referred to an audiologist for further diagnostic screening.

The results clearly show a discrepancy between the AABR findings and those reported by both the TEE and DPE screening devices. The majority of the newborns tested passed the AABR screening, 97% for the right ear and 91% for the left ear. The opposite was observed in the TEE and DPE screenings, where approximately 50% or

less of the newborns passed the screening. Based on existing incidence data, it is unlikely that these "fail" results are accurate, rather the implication is that some variable(s) are interfering or influencing the results. The fact that comparable low pass percentages were observed for both OAE devices seems to suggest a common variable(s), particularly in the recording procedure.

Assuming that this variable(s) does not affect the AABR to any significant degree, a probable explanation involving ambient and biological noise is proposed. OAE devices use a very sensitive low noise microphone to record low level emissions; this microphone will also record any other sounds present within its vicinity. If the intensity of the sounds or ambient noise is high, which it typically will be relative to the emissions, the emission will be masked. The end result will be a "fail" finding even if emissions were present. Another source of noise originates from the newborn, more specifically, from his/her breathing. While this source of noise can be intense in certain newborns, it still cannot justify such low passing percentages. If the proposed explanation is true, the OAE screeners used in this study are not appropriate for newborn hearing screenings in the well-baby nursery and most likely would also be inappropriate in a noisier setting, such as a neonatal intensive care unit.

It should be noted that these new generation handheld OAE screeners have just recently been released. While their larger laptop predecessors have been successfully used in several screening programs, these smaller versions have yet to be tested on a larger scale. One key difference between these devices and the laptop based OAE screeners is that the experimental parameters are fixed and cannot be changed. Recently, Quiñónez (12) reported that many of the current DPE screeners are using experimental parameters based on adult data and that these parameters may not be optimal when testing newborns. Therefore, this lack of flexibility may have contributed to the present study's findings.

Test time was another area where differences were observed between the AABR and OAE screeners. The test time was shorter on average for both TEEs and DPEs compared to the AABR. This characteristic is extremely desirable when the target population is large, as is the case at the University Hospital of the University of Puerto Rico, which attends to 100 - 150 births per month. An optimal screening device has to have high sensitivity and specificity, but in order to be applied universally; test administration should be relatively fast, particularly with healthy newborns that leave the nursery within 48 hours after birth.

Recommendations from the present findings indicate that while the AABR screener is more expensive, its referral

rates are typically lower, which makes it a more cost-effective device in the long term. This device is less susceptible to ambient and certain types of biological noise, variables that are commonly present when testing the newborn population. The AABR screener is simple to use and ultimately training should be provided to those health professionals (nurses) that have more contact with the newborns. This training is important because at larger hospitals, an audiologist may not have the time to test all the newborns, particularly the healthy full-term newborns that leave the nursery within 48 hours. Therefore based on the preliminary findings, the AABR appears to be the preferred screening device. Future investigations in Puerto Rico may include a follow-up study with a larger sample size as a component of a full functioning screening program.

Resumen

Estudios de incidencia estiman que 1 – 3 de cada 1000 recién nacidos y desde 2 – 4 de cada 100 recién nacidos de “alto riesgo” tienen pérdida auditiva bilateral severa. Como resultado, el cernimiento auditivo universal ha sido propuesto; sin embargo, no hay consenso sobre el tipo de tecnología a usarse. El propósito del presente estudio preliminar fue comparar resultados en 32 neonatos a término usando tres tipos de equipo de cernimiento, el Natus Algo 2 AABR, el Otodynamics EchoCheck TEE, y el Biologic AuDx DPE. Los resultados indican que el Natus obtuvo el porcentaje más alto (97%) de neonatos que pasaron el examen y el 91% “pasando” el cernimiento para el oído derecho e izquierdo. Los otros dos equipos obtuvieron porcentajes más bajos (31-56%) de neonatos que pasaron la prueba. La duración del examen usando el equipo Natus fue más prolongada, tomando en promedio 22.5 minutos comparado con 5.8 - 6.4 minutos para los otros dos equipos. Sin embargo, aún con una duración

mas prolongada, nuestros resultados favorecen el Natus, considerando que los porcentajes de neonatos que pasaron el examen aproximan muy bien los estimados de incidencia.

References

1. American Academy of Otolaryngology - Head and Neck Surgery. Is my baby's hearing normal. Alexandria, VA: American Academy of Otolaryngology - Head and Neck Surgery, Inc. 1992.
2. American Academy of Pediatrics. Task Force on Newborn and Infant Hearing. Newborn and infant hearing loss: detection and intervention. *Pediatrics* 1999;103:527-30.
3. Mauk G, Behrens TR. Historical, political, and technological context associated with early identification of hearing loss. *Semin Hear* 1993;14:1-17.
4. Mehl AL, Thomson V. Newborn hearing screening: The great omission. *Pediatrics* 1998;101:1-6.
5. Oudesluys-Murphy AM, van Straaten HLM, Bholasingh R, & van Zanten GA. Neonatal hearing screening. *Euro JI of Pediatr* 1995;155:429-435.
6. Rivera J, Velez H, San Miguel R, Osorio F, Reyes G. Two years experience with universal hearing screening of newborn infants in the University Pediatric Hospital. Presented in the 20th Annual Research and Education Forum at the Medical Sciences Campus at the University of Puerto Rico, 1999.
7. Joint Committee on Infant Hearing. Position statement, 1994. *Pediatrics* 1995;95:152-6.
8. Strong CJ, Clark TC, Walden BE. The relationship of hearing loss severity to demographic, age, treatment and intervention effectiveness variables. *Ear Hear* 1994;15:126-137.
9. Yoshingata-Itano C, Sedey A, Coulter D, Mehl A. The language of early- and later-identified children with hearing loss. *Pediatrics* 1998;102:1161-1171.
10. Yoshingata-Itano C. Efficacy of early identification and early intervention. *Semin Hear* 1995;16:115-123.
11. White KR, Mauk, GW, Culpepper, NB, Weirather, Y. Newborn hearing screening in the United States: Is it becoming the standard of care? In: L. Spivak ed. *Universal newborn hearing screening*. New York: Thieme 1998:225-52.
12. Quiñónez, RE. Distortion-product otoacoustic emissions (DPEs) in neonates: frequency ratio (F2/F1) and stimulus level differences (L1-L2). *Acta Otolaryngol (Stockh)* 1999;119:431-436.