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Hearing Loss in High-Risk Newborns: The Effectiveness of One-stage Hearing Screening in the Neonatal Intensive Care Unit of the Jose R. Reyes Memorial Medical Center

ABSTRACT

Objective: To determine the effectiveness of a one-stage hearing screening protocol in detecting hearing loss in high risk newborns at the Neonatal Intensive Care Unit of the Jose R. Reyes Memorial Medical Center.

Methods:

Design: Cross-Sectional Study

Setting: Tertiary Government Training Hospital

Population: High-risk newborns admitted at the Neonatal Intensive Care Unit of the Jose R. Reyes Memorial Medical Center from March to December 2023 underwent a one-stage universal newborn hearing screening protocol. Excluded from the study were patients who were admitted for less than 48 hours, without consent from their parents or guardians and babies who were not cleared medically to undergo testing, and those who presented with aural atresia and/or any physical anomaly of the head and the external ear.

Results: A total of 169 babies were initially seen with 16 babies lost to follow up resulting in a final total of 153 babies (or 306 ears) tested. The refer and false positive rates were 9.8% and 8.92%, respectively, on average comparable to or even better than the two-step protocol in most studies. Sensitivity was determined to be 100% while specificity was 91.08%. The incidence of hearing loss in the study population was 19.8/1000, consistent with various study outcomes for high risk newborns. There was no reported incidence of auditory neuropathy in this study. The primary risk factors that were present in babies with hearing loss were: low birth weight, prematurity, neonatal intensive care unit admission of more than 5 days and exposure to ototoxic medications.

Conclusion: The one-staged Automated Auditory Brainstem Response (AABR) is an effective and efficient newborn hearing screening protocol for high-risk newborns in the Neonatal Intensive Care Unit (NICU) setting and eventually, may be considered as an alternative hearing screening technique whenever available in this cohort. More studies about improving newborn hearing screening, cost-analysis, diagnostics and interventions of hearing loss should be pursued in implementation of the Universal Hearing Screening Law in the Philippines.

Keywords: *newborn screening; evoked potentials; auditory; brain stem; otoacoustic emission; spontaneous; neonatal intensive care*

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In 1995, the World Health Organization (WHO) encouraged its member nations to develop a national policy for universal newborn hearing screening (NBHS),[1] and since then, universal newborn hearing screening has evolved and become standard practice in most countries, the Philippines included.[2] Several studies have been reported regarding the performance[3-7] and cost[5] of newborn hearing screening protocols, however, the inherent problems of the program like drop-outs and costs have restricted its proper implementation.[8] In the Philippines, even if the NBHS program is constantly being refined and reports of improving drop-out rates, the overall performance of the program in the country still leaves much to be desired.[9]

The current screening setup in the country adopts the two-step screening protocol for well-born and high-risk infants.[10] A failed initial screening will automatically entail a rescreen within a month regardless of the hearing instrument used. e.g. Otoacoustic Emissions (OAE) or Automated Auditory Brainstem Response (AABR), as suggested in the position statement of the Joint Committee on Infant Screening (JCIH).[11] While the two-step technique has become the default protocol for most hearing screening programs, it could have caused certain inconveniences for some hearing screening providers because in the Philippines, the additional costs of the rescreening like personnel salary, equipment calibration, and replenishment of consumables are no longer subsidized by the government.[12] The advantage of a two-step over a one-stage protocol is clear in studies that reported a lesser refer rate and a lower false positive rate.[6] However, one study recommended that one stage AABR was more cost-effective compared to other screening protocols,[5] and another study showed a reduction in the refer rate when AABR was added to the protocol and the screening was performed 48 hours or more post-birth.[3]

In this study, high risk newborns admitted at the Neonatal Intensive Care Unit (NICU) of a tertiary medical center were screened for hearing loss using the one-stage AABR protocol. High-risk newborns, who are usually admitted beyond 48 hours, are at an increased risk of developing permanent hearing loss [6,13,14] and auditory neuropathy.[6,13,15-17] This paper aims to determine the effectiveness of a one-stage hearing screening protocol in detecting hearing loss in high risk newborns at the NICU.

METHODS

With Institutional Review Board approval (IRB No. 2022-222), this cross-sectional study attempted to screen all high-risk newborns admitted at the NICU of the Jose R. Reyes Memorial Medical Center to confirm the presence or absence of hearing loss using a one-stage AABR protocol within a ten-month period from March 1, 2023 to December 30, 2023. Patients who were admitted for less than 48 hours as well as those without consent from their parents or guardians were excluded from the study. Likewise, babies who were not cleared medically to undergo testing, and those with aural atresia and/or any physical anomaly of the head and the external ear that could preclude placement of the transducers were also excluded.

Sample size was computed using the formula for sample size calculation for sensitivity and specificity studies calculator developed by Dr. Lin Naing at School of Dental Sciences, Universiti Sains Malaysia in 2004.[18] Using the expected sensitivity of one-stage neonatal screening to be 80%, prevalence of permanent hearing loss among high-risk newborns of 6.3%, confidence level of 95% and margin of error of 20%, the computed sample size was 267.

The hearing screening protocol was a one-stage AABR test performed on infants who were eligible to undergo hearing screening and confirmatory tests based on the inclusion and exclusion criteria. There was no rescreening, instead, all subjects underwent diagnostic click ABR regardless of whether the patients passed or failed the AABR screening to allow measurement of the sensitivity of the one-stage protocol. Distortion Product Otoacoustic Emissions (DPOAE) served as an adjunct diagnostic tool and was performed only when an AABR test yielded a refer response. A pass DPOAE and absent ABR were considered indicative of Auditory Neuropathy Spectrum Disorder. The complete hearing screening procedure is presented in *Figure 1*.

The Interacoustics Sera™ Automated Auditory Brainstem Response (AABR) (Intereacoustics, Middelfart, Denmark) was used to screen for the auditory nerve and brainstem response pathway. The default screening protocol of the Sera™ using the CE-chirp® stimulus was used in this study. The algorithmic sensitivity of the Sera™ was reported to be at 99.9%.[19] The AABR test result is a binary outcome of either pass or refer.

The Welch Allyn® 39500 Series Otoacoustic Emission Hearing Screener (Welch Allyn, Inc., Skaneateles Falls, NY, USA) was alternately used as a second screener to assess DPOAE in its default fixed protocol. The collection parameters tested frequencies at 2000, 3000, 40000 and 5000 Hz. intensity of L1/L2 is at 65 and 55 dB SPL respectively and an F1/F2 of 1.22. A positive OAE response from three out of the four frequencies and a signal to noise ratio of not less than 6dB were considered a pass result.

Click ABR was the gold standard in this study utilizing the Eclipse platform (Interacoustics, Middlelfart, Denmark) to confirm the presence or absence of hearing loss and to ascertain hearing threshold estimation. Each ear was tested separately. The test parameters were performed using a click stimulus at 45.1 stimuli per second with the recording window set at 20 msec and stimulus sweep fixed at 2500. High pass

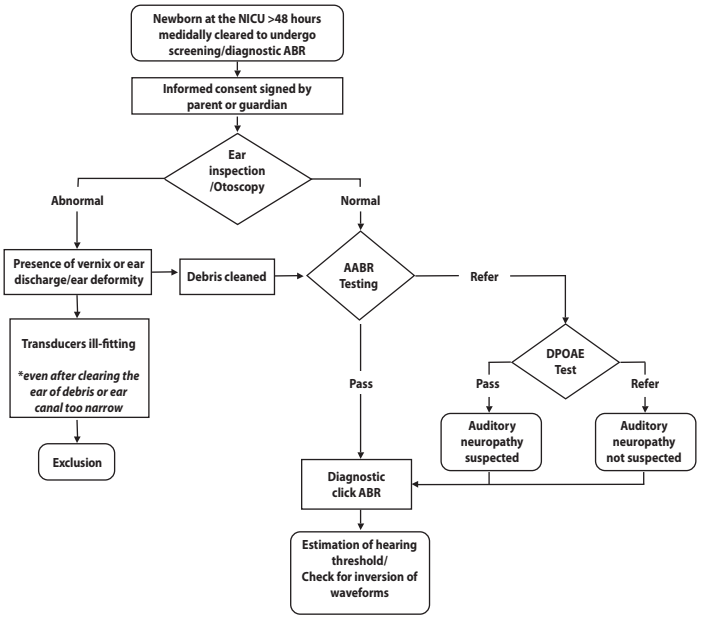

Figure 1. Hearing Screening Procedure

and low pass filters were set at 30 Hz and 1500Hz, respectively. The estimation of the hearing threshold was determined by the presence of clearly identifiable and repeatable Wave V. The initial intensity level of 80 dB was presented to each ear by alternating the stimulus polarity i.e., alternating rarefaction and condensation to check for the cochlear microphonics (CM). Because the CM is generated by the cochlea, their characteristic waveforms become inverted or out of phase with each other with alternating rarefaction and condensation. The ABR waveform of patients with auditory neuropathy mimic the waveform of the CM which is abnormal. Conversely, in normal individuals, ABR waveforms do not invert regardless of the stimulus polarity.

All equipment was calibrated according to the manufacturer's standards. The DPOAE, AABR and Diagnostic ABR tests were independently performed individually by one of two certified newborn hearing screeners with more than 15 years of experience between them. Otoscopy was performed by an otorhinolaryngology resident in training. Findings were recorded on the data collection form as normal or abnormal. Removal of vernix and ear discharge were done when necessary. Estimates of the hearing threshold were established by the smallest but clearly identifiable and repeatable Wave V. Any ABR thresholds of 40dBnHL and below were considered normal, anything above 40dB (e.g., 45dB) were considered abnormal or with hearing loss. If hearing loss was established, patients were automatically enrolled for hearing intervention.

Statistical Analysis

Data were encoded using Microsoft® Excel for Mac Version 16.77.1 (Microsoft Corp., Redmond WA, USA) and analyzed using STATA Statistical Data Analysis 14 software (StataCorp LLC, College Station, TX, USA). Categorical data were summarized using counts and frequencies, while continuous data were summarized as mean and standard deviation or median and interquartile range as appropriate. Demographic data comparisons between groups of patients with and without hearing loss were statistically determined using Fisher exact test except for age at the time of hearing screening where independent T-test was used. For sub-analysis of comparison between babies with false positive results and babies with true positive results, Fisher exact test was also used. Statistical significance was defined as $p < .05$.

The incidence of hearing loss was computed as the number of neonates diagnosed with at least one ear having a hearing threshold of more than 40dB based on diagnostic click ABR divided by all neonates tested during the given period multiplied by 1000. Sensitivity of the one-stage automated ABR test was computed as the number of true positives ears divided by the sum of the true positive and false negative ears. Specificity was also computed as the number of true negative ears divided by the sum of the true negative and false negative ears. Positive predictive value and negative predictive value were also computed for accuracy tests.

Logistic regression was performed to investigate the effect of the different risk factors for neonatal hearing loss identified in the literature. An univariate analysis was performed to explore the unadjusted association between each of the risk factors and hearing loss. Next, multivariate logistic regression was performed to assess the independent association of the relevant risk factors with hearing loss. Odds ratios and 95% confidence intervals were estimated and a p value of $< .05$ was considered significant.

RESULTS

A one-stage universal newborn hearing screening protocol using AABR was performed in 169 high-risk newborns admitted at the NICU from March to December 2023. After the one-time AABR screening, all participants underwent confirmatory diagnostic click ABR regardless whether the result was a pass or a refer. Sixteen (16) of these babies were not able to complete the examination because of large artifacts found in the EEG during the confirmatory testing. Their parents or guardians were advised to return at a later date to complete the test but these babies were eventually lost to follow-up, and therefore, were

removed from the study, for a dropout rate of 9.5%. After exclusion, 153 babies or a total of 306 ears were included in this study.

The demographic profile (gestational age, sex, birthweight) of majority of the babies tested were male in sex, had reached their full term and had a birth weight appropriate for gestational age. For the timing of testing, it was mostly done between the 10th to 16th day of life, while babies with hearing loss were identified during their 29th to 32nd day of life. These characteristics, however, did not present with statistical significance in the development of hearing loss as shown in *Table 1*.

Table 1. Demographic profile of high-risk newborns

	Total N=153 N (%)	With Hearing Loss N=3	Without Hearing Loss N=150	P-Value
Birth weight classification				
SGA: < 2500 g	73 (47.71)	2 (66.67)	71 (47.33)	.606
AGA: 2500-4500 g	80 (52.29)	1 (33.33)	79 (52.67)	
LGA: > 4500 g	0	0	0	
Sex				
Male	81 (52.94)	0	81 (54.00)	.102
Female	72 (47.06)	3 (100.00)	69 (46.00)	
Gestational age				
Preterm	53 (34.64)	1 (33.33)	52 (34.67)	1.000
Term	100 (65.36)	2 (66.67)	98 (65.33)	

Table 2. Subgroup analysis of false positive results in relation to timing of hearing screening and birth weight

Timing of hearing Screening	No. of babies tested N (%)	No. of babies with false positive result (unilateral and bilateral) N (%)	No. of babies with true positive result N (%)	P-Value
>48 hours to ≤7 days	113 (73.86)	12 (75.00)	1 (33.33)	.1145
>7 days to ≤14 days	11 (7.19)	2 (12.50)	0 (0.00)	(Fisher
> 14 days·	29(18.95)	2 (12.50)	2 (66.67)	exact test)
Birth weight classification				
SGA: < 2500 g	73 (47.71)	8 (50.00)	2 (66.67)	1.000
AGA: 2500-4500 g	80 (52.29)	8 (50.00)	1 (33.33)	(Fisher
LGA: > 4500 g	0	0 (0.00)	0 (0.00)	exact test)

Table 3. Degree of hearing loss

Hearing range (dB nHL)	No. of ears tested N = 306 (%)
40 and below	303 (99.05)
41 - 55	2 (0.65)
56 - 70	0 (0.00)
70 - 90	1 (0.32)

Of the 306 ears that were screened, 276 passed while 30 ears failed the hearing screening for a refer rate of 9.8%. The performance of the one stage-hearing screening revealed sensitivity of 100%, specificity at 91.08%, positive predictive value of 10% and negative predictive value of 100%. Twenty seven (27) ears were classified as false positives after a confirmatory test showed normal hearing thresholds. Twenty two (22) of these ears were from 11 babies with bilateral false positives while five babies had unilateral false positives. Subgroup analysis of false positive results in relation to birthweight and timing of hearing screening is shown in *Table 2*.

Three babies were diagnosed to have hearing loss based on the parameters set in this study. All involved females and were unilateral in nature. One baby had unilateral profound hearing loss but no babies were found to have Auditory Neuropathy Spectrum Disorder (ANSD). Incidence of hearing loss was computed at a rate of 1.98% The degree of hearing loss is shown in *Table 3*.

One hundred fifteen (115) or 75% of high-risk newborns presented with two or more risk factors while 25% had only one as the reason for their admission at the NICU. The primary risk factors that were present in babies with hearing loss were: low birth weight, prematurity, neonatal intensive care unit admission of more than five days and exposure to ototoxic medications. Regression analysis was done to test the correlation of the aforementioned risk factors with hearing loss. Low birth weight and prematurity showed non-significant odds ratio of 3.19 (95% CI: 0.18 to 56.30, p = .429) and 0.35 (95% CI: 0.02 to 5.63, p = .456) respectively. Other risk factors revealed odds ratios of 1 thus representing no association with hearing loss.

DISCUSSION

This present study aimed to determine the effectiveness of the one-stage AABR protocol in high-risk newborns in lieu of the standard two-step protocol. The main idea was to validate an alternative screening method which is as effective, but more efficient than the two-step version. One study suggested the one-stage AABR was more cost-effective compared with other screening protocols and that it was worth considering a change from a two-step to an AABR alone protocol.[6]

Our results showed 100% sensitivity, meaning all newborns with hearing thresholds greater than 40dB (e.g., 45dB) were correctly identified as true positives. In our study, testing the sensitivity was paramount considering that most UNHS studies[3-7] mainly focused on the refer and false positive rates for benchmarking a hearing screening

program. The 2019 JCIH position statement reiterated the need for more studies testing for sensitivity of a screening protocol and/or equipment until such time that a standard system for auditory evoked potentials has been established and accepted worldwide.[11] Additionally, false negatives should be kept to a minimum since not all hearing losses may be detected, e.g., Otoacoustic Emissions can detect hearing loss between 30 to 35dB at mid to high frequencies and AABR may pass hearing loss up to 40 to 45dB,[20] and therefore will miss babies with mild and/or low frequency hearing loss[11]. Moreover, Auditory Neuropathy cannot be detected by OAE alone.[21]

A refer rate of 4% or less is an ideal index of an efficient screening program.[22] A program with high refer and false positive rates poses a burden on the screening facility, not to mention the anxiety it brings to the parents and/or guardians of a child.[23] The Philippine Health Insurance Corporation (PhilHealth) covers newborn hearing screening for a meager 3.50 USD per child,[12] but only 75% of this amount technically goes to the facility since 25% goes to the national hearing screening registry.[10] In this study, the refer and false positive rates were pegged at 9.8% and 8.92%, respectively, albeit much higher than the quality indicator, still on average comparable to and even better than the two-step protocol in most studies.[3-5] During the testing, we noticed that babies with smaller heads and those screened early were more likely to have false positive results, however, a subgroup analysis of false positive results in relation to the timing of hearing screening and birth weight showed no statistical significance, but false positivity was leaning towards those high-risk newborns who were screened before one week, similar to the study of Van Dyk *et al.*[3]

The incidence of hearing loss in our study population was 19.8/1000, consistent with various study outcomes for high-risk newborns.[6,13] Only one baby presented with profound hearing loss for an incidence rate of 6.5/1000. There were no reported incidences of auditory neuropathy in this study, probably because the sample size of 153 babies may not have been large enough to capture this rare auditory phenomenon because of its very varied occurrence.[6,13,15,16]

One limitation of our study is that we only determined the participants' hearing threshold at one particular period in time and the actual incidence may be higher if some infants will present later with delayed or progressive types of hearing loss.[13] The incidence could also have been worse if the authors decided to bring down the normal hearing threshold to less than 40dBnHL e.g. 35 dB similar to the study of Ong *et al.*[5] However, since there is still no current standard defining the use of auditory evoked potentials like ABR for estimation of behavioral hearing threshold, the authors decided to set the abnormal threshold level at >40dB considering that AABR screening may pass thresholds up to 45dB, and click ABRs may sometimes overestimate hearing threshold at normal or low intensity levels[24] which can potentially increase the false negative rate of the hearing screening protocol being tested. Additionally, while some reports have documented a negative effect on speech and language of even minimal mild hearing loss, there is still much controversy and ambiguity about whether to aid a child with this kind of hearing loss.[25] A direct comparison of the two-step protocol versus the one-staged AABR could also have been adopted in our report but the authors decided against it considering that the two-step protocol requires patients to follow-up, and therefore, is prone to dropouts. Another limitation has to do with not attaining our computed sample size of 267. Although we only came up with 153 babies, all qualified participants were completely enumerated within the study's timeline. We somehow mitigated the effect of not fulfilling the number of participants since the primary outcome of our study was determined by the number of ears tested and not by the number of babies. This was so because it would be very difficult for us to analyze the sensitivity of the one stage AABR if the ears were not analyzed separately (i.e. one ear pass, one ear refer).

In conclusion, considering the excellent sensitivity and respectable specificity and refer rates, our study proved the one-stage AABR to be effective to use as newborn hearing screening protocol for high-risk newborns in the NICU setting. This may be eventually be considered in the future as an alternative method hearing screening technique for the high-risk newborn population. More studies about improving newborn hearing screening, cost-analysis, diagnostics and interventions of hearing loss must continue for a seamless implementation of the Universal Hearing Screening Law in the Philippines.

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