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Original Research Article

Critical appraisal of appropriate method for early detection of hearing impairment in newborns in a tertiary care centre

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ABSTRACT

Background: Hearing plays a vital role in developmental of a child. Hearing loss not only affects the speech and language development of a child but also affects the social, emotional and intellectual development. Hearing is important in the first 2 years of life as this is the critical period for language acquisition. Thereby early detection and intervention for hearing loss is recommended. However, there are no standard protocols for newborn hearing screening. Hence, this study is undertaken to evaluate the appropriate protocol for early detection of hearing impairment in newborns and to ascertain the sensitivity and specificity of Distortion Product Oto-acoustic Emission (DPOAE) and Auditory Brainstem Response (ABR).
Methods: A prospective study was conducted in the Department of Paediatrics and Department of Audiology and Speech Pathology in SRM Medical College Hospital and Research Centre. A total of 122 neonates were screened for hearing loss using both DPOAE and ABR before discharge from the hospital. A rescreening with ABR after 1 month was done for those infants who had hearing loss at the initial screening.
Results: The study revealed that 16.4% of infants had hearing loss. The referral rate of DPOAE was 54.1% and ABR was 16.4%. ABR had higher passing rates when compared to DPOAE. In a combined screening with both DPOAE and ABR, 17 (13.9%) babies had failed DPOAE with abnormal hearing in ABR (True positives), 49 (40.2%) babies failed DPOAE but had normal hearing in ABR (False positives), 3 (2.5%) babies passed DPOAE but had hearing loss in ABR (False negatives) and 53 (43.4%) babies passed DPOAE and had normal hearing in ABR (True negatives). The association between the results of DPOAE and ABR was statistically significant (0.002). Auditory neuropathy was detected in 3 out of 122 neonates. All these 3 babies belonged to high-risk population. The prevalence of auditory neuropathy is 2.5% which is much lower when compared to other studies. The sensitivity and specificity of DPOAE is 85% and 51.9% respectively. The sensitivity and specificity of ABR was 100%.
Conclusions: Present study concludes that the use of combination protocol using both DPOAE and ABR identifies babies with auditory neuropathy spectrum disorder and also ensures high sensitivity and acceptable specificity. Thus, helps in early identification and intervention of congenital hearing loss.

Keywords: Auditory neuropathy, ABR, DPOAE, Hearing loss, Newborn, Newborn hearing screening

INTRODUCTION

It has been recognized that unidentified hearing loss at birth can affect speech and language development as well as social, emotional and intellectual development of the children. This can be reduced by early detection and intervention. Therefore, screening of newborn babies for hearing loss is recommended.[1-3]

According to the 2012, World Health Organization estimate, 360 million people are affected with hearing loss worldwide.[4] In India, the incidence of hearing impairment in neonates varies from 5-6 per 1000 screened neonates.[5] Joint Committee on Infant Hearing (JCIH) estimates the prevalence of congenital hearing loss in healthy newborns as 1-3 per 1000 births and for high-risk newborns referred from NICU the prevalence increases by 2-4%.[1,2]

Screening the high-risk babies alone will miss about 50% of neonates with hearing impairment.[6,7] According to the Joint Committee on Infant Hearing (JCIH), year 2007 position statement, all infants should be screened for hearing impairment before 1 month of age.

Those who do not pass the initial screening should undergo a comprehensive audiological evaluation within 3 months of age and those infants with confirmed hearing loss should receive appropriate interventions within 6 months of age.[1,2] The Government of India has initiated various programs namely National Programme for Prevention and Control of Deafness and Rashtriya Bal SwasthyaKaryakram for newborn hearing screening. These programmes are aimed at early detection and intervention. Thereby, reducing the burden of hearing loss.[8,9]

Transient Evoked Otoacoustic Emission (TEOAE), Distortion Product Otoacoustic Emission (DPOAE), Auditory Brainstem Response (ABR) Automated Auditory Brainstem Response (AABR) and Behavioural Observational Audiometry (BOA) are the commonly used screening technologies in newborn hearing screening programme. Using these methods various screening protocols are being followed across the world.

In our country, Newborn Hearing Screening (NHS) commonly uses the following protocol, where 1st and 2nd stage screening is done with Otoacoustic emission followed by Auditory brainstem response for those who fail both the stages of otoacoustic emission.[5]

Various studies have shown that, in auditory neuropathy there is asynchrony in the transmission of neural signal. OAE may be normal, whereas ABR is abnormal. Thus, in protocols where ABR or AABR is used only to confirm abnormal OAE, may fail to detect auditory neuropathy.[10] There are very fewer studies regarding this study in the general population including both the NICU babies as well nursery babies. Hence, the purpose of this is to analyse the appropriate method for newborn hearing screening programs.

METHODS

A prospective study was conducted in the Department of Paediatrics and Department of Audiology Pathology in the SRM Medical College Hospital and Research Centre. The neonates were included in the study consecutively.

Neonates delivered in the hospital, during the study period were included in the study and were screened before discharge. Both high-risk babies and well babies were included. Neonates who got discharge from the hospital before the screening and those whose parents were not willing for hearing assessment were excluded from the study.

Criteria for high-risk babies

High-risk neonates were defined as per the Joint Committee on Infant Hearing in 2007.[2] The risk factors are listed below:

- Family history of permanent childhood hearing loss.
- Admission to Neonatal Intensive Care Unit of more than 5 days or any of the following regardless of length of stay: ECMO, assisted ventilation, exposure to ototoxic drugs (gentamycin, amikacin, vancomycin and tobramycin) or loop diuretics (furosemide), and hyperbilirubinemia that requires exchange transfusion.
- In utero infections, such as CMV, herpes, rubella, syphilis, and toxoplasmosis.
- Craniofacial anomalies, including those that involve the pinna, ear canal, ear tags, ear pits, and temporal bone anomalies.
- Physical findings, such white forelock, associated with syndromes causing hearing loss.
- Syndromes associated with hearing loss or progressive or late-onset hearing loss, such as neurofibromatosis, osteopetrosis, and Usher syndrome, Waardenburg's syndrome, Alport's syndrome, Pendred's syndrome, and Jervell and Lange Nielson syndrome.
- Neurodegenerative disorders such as Hunter syndrome, or sensory motor neuropathies, such as Friedreich ataxia and Charcot-Marie-Tooth syndrome.
- Culture-positive postnatal infections associated with sensorineural hearing loss, including confirmed bacterial and viral (especially herpes viruses and varicella) meningitis.

Sample size

Sample size was calculated considering the expected incidence of congenital hearing impairment of 5.65 per 1000 screened, (As per the study by Nagapoornima, P et al 2007) with 95% confidence interval and 6% absolute precision, the required sample size was calculated to be 122 subjects.[5]

The sample size was calculated using the following formula,$n = 4pq/ d$.[2] Where, n = sample size, p = prevalence, q = 100% - p, d = precision.

The study was approved by the Institutional Ethics Committee. For all eligible neonates, informed written consent was sought from parents or guardian after fully

explaining the purpose and nature of the study and voluntary nature of their participation. Only the neonates whose parents or guardian was willing to provide written consent was included in the study.

Study procedure

A detailed history was taken, and physical examination was done. The findings were recorded in the Case Report Form. Each neonate underwent hearing assessment using both DPOAE and ABR. The testing was done in a sound treated room with permissible noise levels. Prior to the test the babies were well fed, and the tests were carried out with the baby on mother's lap. No sedations were used for keeping the baby quiet. Initially, babies were screened by DPOAE using Neuro-Audio.NET.lnk software. Stimulus levels were calibrated in each ear according to the manufactures specifications. The stimulus for F1 and F2 frequencies were presented at a ratio of 1:2 at 65/55 dB. The responses were recorded at frequencies of 1000 Hz, 1429 Hz, 2000 Hz, 2857 Hz, 4000 Hz, 5714 Hz and 8000 Hz. The pass criteria was difference of 6 dB Signal to Noise Ratio (SNR) in three consecutive frequencies.

Second level of screening was done using Neuro-Audio.NET.lnk Auditory Brainstem Response instrument. Auditory brainstem response was recorded using 3 electrodes placed over the forehead (reference), ipsilateral mastoid (active) and contralateral mastoid (ground). ABR was recorded using stimulus presented at intensity levels of 70 dBnHL, 50 dBnHL and 30 dBnHL. Click evoked ABR were used. The morphology and the replicability of the wave V were tested. The pass criteria were based on the presence of the wave V and its replicability. For those infants who had hearing loss in the initial screening, a repeat screening with ABR was done after 1 month to confirm hearing loss.

Statistical analysis

The data were compiled in Microsoft Excel 2010 and the statistical analysis done by Statistical Package for Social Sciences (SPSS) version 17.0. The results of DPOAE and ABR were compared. The descriptive analysis of the screening outcomes and the risk factors were explored by cross tables. Chi- square test was used to analyse the data. P value of less than 0.05 was considered to be statistically significant.

RESULTS

A total of 122 participants were included in the study. Their age ranged from 2 days to 28 days in the study population.

Table 1: Results of DPOAE in high-risk and well babies in the study group (N=122).

DPOAE	High-risk babies		Well babies	
	Count	Percentage	Count	Percentage
Pass	14	11.5	42	34.4
Refer	36	29.5	30	24.6

Table 2: Results of ABR in high-risk and well babies in the study group (N=122).

ABR	High-risk babies		Well babies	
	Count	Percentage	Count	Percentage
Normal	31	25.4	71	58.2
Abnormal	19	15.6	1	0.8

The pass rate of DPOAE was 56 (45.9%) and the refer rate was 66 (54.1%). Of these, 26 (21.3%) had unilateral hearing impairment and 40 (32.7%) babies had bilateral hearing impairment on screening with DPOAE.

Table 3: Analysis of DPOAE and ABR with all factors for hearing loss.

Risk factors	DPOAE		P value	ABR		P value
	Pass	Refer		Normal	Abnormal	
Family history of permanent childhood hearing loss	3 (33.3%)	6 (66.7%)	0.432	5 (55.6%)	4 (44.4%)	0.018
NICU admission >5 days	10 (32.3%)	21 (67.7%)	0.133	20 (64.5%)	11 (35.5%)	0.004
Mechanical Ventilation	2 (25%)	6 (75%)	0.220	1 (12.5%)	7 (81.5%)	0.000
Exposure to ototoxic medications	9 (25.7%)	26 (74.3%)	0.005	23 (65.7)	12 (34.3%)	0.001
Hyperbilirubinemia requiring exchange transfusion	1 (50%)	1 (50%)	0.907	0	2 (100%)	0.001
Intrauterine infections-CMV, Herpes, Rubella, Syphilis, Toxoplasmosis	0	4 (100%)	0.099	1 (100%)	0	0.600
Craniofacial anomalies	0	2 (100%)	0.189	1 (50%)	1 (50%)	1.960
Bacterial or viral meningitis	0	3 (100%)	0.106	3 (100%)	0	0.437
Culture positive sepsis	7 (30.4%)	16 (69.6%)	0.098	14 (60.9%)	9 (39.1%)	0.098

The number of babies with normal ABR was 102 (83.6%) and the number of babies with abnormal ABR was 20 (16.4%). Of these 20 (8.2%) babies had unilateral hearing loss and another 20 (8.2%) babies had bilateral hearing loss.

The number of high-risk babies who passed DPOAE was 14 (11.5%) and failed DPOAE was 36 (29.5%). The number of well babies who passed DPOAE was 42 (34.4%) and failed DPOAE was 30 (24.6%). The P value was 0.001 which is statistically significant (Table 1).

The number of high-risk babies who had normal ABR was 31 (25.4%) and abnormal ABR was 19 (15.6%). The number of well babies who had normal ABR was 71 (58.2%) and abnormal ABR was 1 (0.8%). The P value was 0.000 which is statistically significant (Table 2).

The association between DPOAE and all possible risk factors for hearing loss revealed that only exposure to ototoxic medication was statistically significant with a P value of 0.005 (Table 3).

The association between ABR and all possible risk factors for hearing loss revealed that family history of permanent hearing loss, NICU admission for more than 5 days, mechanical ventilation, exposure to ototoxic medications, hyperbilirubinemia requiring exchange transfusion and history of birth asphyxia was statistically significant (Table 3).

Table 4: Comparision of DPOAE and ABR.

		ABR	
		Abnormal (n=20)	**Normal (n=102)**
DPOAE	Refer (n=66)	17 (13.9%) True positive	49 (40.2%) False positive
	Pass (n=56)	3 (2.5%) False negative	53 (43.4%) True negative

Out of the 66 babies who were deaf by DPOAE, 17 continued to be deaf in ABR. While 49 babies were found to have normal hearing in ABR. Thus, 49 babies were falsely diagnosed as deaf by DPOAE. Out of 56 babies, who were found to have normal hearing by OAE, 3 babies were found to have hearing loss by ABR and 53 babies continued to hear in ABR. Thus, DPOAE has not picked up 3 babies with hearing loss. Neonates who passed both DPOAE and ABR were defined as true negatives. A total of 53 (43.4%) babies fell in this category. 49 (40.2%) babies were false positives, i.e. they failed DPOAE but had normal hearing in ABR. True positives were those who failed both DPOAE and ABR. 17 (13.9%) babies had such results. False negatives were those babies who passed DPOAE but failed ABR. This included 3 (2.5%) babies. The P value was 0.002 which is statistically significant (Table 4). The sensitivity and specificity of DPOAE is 85% and 51.9% respectively. The sensitivity and specificity of ABR was 100%

DISCUSSION

Universal newborn hearing screening is a standard programme and is being followed in many institutions. With the emergence of newborn hearing screening programmes, the age of identification of confirmed hearing loss has reduced from 24-30 months to 2-3 months.[11] In infants who were intervened within 6 months of age showed significant improvement in language, social and emotional development when compared to those identified later than 6 months.[6] In most of the institutions, newborn hearing screening is done using either OAE or AABR/ABR alone or in combinations for detecting hearing loss, but there are no standard protocols. In present study, the passing rate with DPOAE alone is 45.9%. In other studies, the passing rate with DPOAE alone varies from 66.7% to 93.5%, depending on the study population and the centre.[3,12-16] The passing rate with DPOAE is much lower in present study when compared to other studies. This may be because in present study only a single stage screening with DPOAE was done the whereas other studies did a two-stage screening with DPOAE. In present study, the pass percentage with DPOAE in high-risk babies is lower (11.5%). The referral rates using DPOAE is 29.5% in high-risk and 24.6% in well babies. The presence of debris, amniotic fluid or middle ear pathology may contribute to higher referral rates. In the current study, the passing rate using ABR was 83.6%, which is much higher than DPOAE. This is similar to the passing rate of 82.9% in a study by Wahid et al.[3] Studies by Vohr et al., and Benito et al., have also demonstrated that AABR has higher passing rates when compared to OAE.[13,16]

The estimated frequency of hearing loss in present study using ABR as the gold standard was 16.4%. Of these, 15.6% babies belonged to the high-risk population and 0.8% babies were healthy normal babies. The prevalence of congenital hearing loss in other studies were reported as 1 to 6 per 1000 screened babies, including both high-risk and well babies.[7,17-20] The prevalence of congenital hearing loss in present study is much higher when compared to the other studies. In other studies, the study population was larger and also included a greater number of well babies than high-risk babies. In the current study, the study group included almost equal number of well babies and high-risk babies. Moreover, the maturational delay of the auditory pathway was not ruled out. This explains the possible cause for higher frequency of hearing loss in present study.

The combined screening with DPOAE and ABR showed a referral rate (Truly deaf) of 13.9%, a false positive rate (Falsely deaf) of 40.2% and a false negative rate (auditory neuropathy) of 2.5%. In a previous study by Rajiv et al., the referral rate was 1%, false positive was 12% and false negative was 1%.[21] Similarly in a study by

Z-Xu et al., in high-risk babies using both DPOAE and AABR, the referral rate, false positive and false negative rates were 5.03%, 2% and 0.06% respectively.[14] In present study, the referral rates of DPOAE alone is 54.1%, ABR alone is 16.4% and in combined screening using both DPOAE and ABR the referral rate is 13.9%.

The false negatives results (passed DPOAE, but failed ABR) suggests auditory neuropathy spectrum disorder. In present study, 3 (2.5%) babies were diagnosed to have ANSD. All these 3 babies belonged to the high-risk category. The estimated prevalence of ANSD in a study by Wahid et al., was 7.53% and in a study by Abbey et al was 24.1%.[3,22] The estimated prevalence of ANSD was much higher in other studies when compared to present study. In a study by Kirkim et al., the frequency of ANSD detected in universal hearing screening was 0.044%.[23]

Neonates with ANSD would have not been detected if only DPOAE or ABR is alone used for screening and therefore necessitates the need for a combination screening with both ABR and DPOAE. The risk factors associated with ANSD in present study are hyperbilirubinemia requiring exchange transfusion, prematurity, birth asphyxia, exposure to ototoxic medications (amikacin or vancomycin), culture positive sepsis and low birth weight babies. These causes were similar to those reported in other studies. In a study by Sanyelbhaa Talaat et al, hyperbilirubinemia was identified as the commonest cause of auditory neuropathy.[24] Foerst et al, reported prematurity as the commonest cause followed by hyperbilirubinemia.[25] Saluja et al., found that hyperbilirubinemia requiring exchange transfusion was associated with increased risk of ANSD.[26] Coenraad et al, showed a significant correlation between vancomycin and auditory neuropathy.[27] Martines et al., has reported that a combined screening with both OAE and AABR is the gold standard for screening of NICU babies at risk for auditory neuropathy.[28] The pass rate for the combined protocol with DPOAE and ABR (True negatives or normally hearing) is 43.4%. This was lower than the previous studies. The pass rate for true negatives was 69.9% in a study by Wahib et al., and 60.7% in a study by Olusanya and Bamigboye.[3,29]

The limitation of DPOAE is that it fails to diagnose infants with auditory neuropathy spectrum disorder and also has high false positive rates in the initial stages of screening. ABR has higher passing rates and lower false positive rates when compared to DPOAE.

All previous studies done in the West claim that a significant number of babies passing OAE, may fail ABR later and this proportion may even be up to 50%.[1,2] These are the children with auditory neuropathy. Such conclusions have led the JCIH to recommend ABR as the gold standard, as it picks up babies with auditory neuropathy.

However, in present study the percentage of babies passing OAE and failing ABR is merely 2.5%. Present study does not fall in line with the earlier consensus statement of JCIH. A more dedicated and large volume study is necessary.If that study also substantiates to present study, the boggy of ABR being the gold standard for identification of hearing loss in neonates will be demonstrated.

In the current study, the sensitivity and specificity of DPOAE was 85% and 51.9% respectively, which means that 15% of congenital hearing loss will be missed and 48.1% of the babies will have a false positive result if only DPOAE is used as a screening tool. The sensitivity and specificity of ABR was 100% at the initial screening (at birth) and repeat screening after 1 month.

The use of combined protocol in present study has not only picked up the 3 cases with auditory neuropathy but has also drastically reduced the referral rate and thereby reducing unnecessary parental anxiety. Even though a combined screening protocol with DPOAE and ABR incurs higher cost and takes longer time for screening, has the advantage of increasing the sensitivity and specificity of newborn hearing screening.

CONCLUSION

Congenital hearing loss is a major disability affecting speech and language development in children. Early detection and intervention have showed significant improvement in speech and language development. Screening of a newborn for congenital hearing loss and referrals for early intervention is a responsibility of the paediatrician as he/she is the primary care provider. Screening only high-risk babies will miss out healthy babies with hearing impairment. Thereby, necessitating the need for Universal new born hearing screening program.

Based on the results of present study, the prevalence of auditory neuropathy spectrum disorder is only 2.5% and all these cases belonged to the high-risk category. However, this does not fall in line with the previous studies. Present study concludes that the use of combination protocol using both DPOAE and ABR identifies babies with auditory neuropathy spectrum disorder and also ensures high sensitivity and acceptable specificity. Thus, helps in early identification and intervention of congenital hearing loss.

Recommendations

- All babies should be screened for hearing loss ideally before discharge from the hospital.
- Universal neonatal hearing screening is recommended rather than targeted high-risk screening.
- Until the time that Universal hearing screening programme is implemented, all newborns should be

screened for hearing loss as early as possible or at least before the age of 3 months to have better outcomes.

- All high-risk babies should be screened for congenital hearing loss with both DPOAE and ABR, as these babies are at an increased risk for auditory neuropathy.
- Well nursery babies can be screened with DPOAE followed by a rescreening with ABR for those who fail DPOAE.

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