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Original Research Article

Diagnostic ability of otoacoustic emission and automated auditory brainstem response in hearing screening of high-risk newborn

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ABSTRACT

Background: Early identification of hearing impairment in infants and appropriate intervention can prevent severe psychosocial, educational, and linguistic repercussions. Infants who are not identified before 6 months of age have delays in speech and language development.
Methods: This was a prospective cohort study OAE and AABR were administered to high-risk neonates discharged from NICU and the diagnostic ability to pick up hearing loss was assessed by trained audiologist. Statistical analysis was interpreted by McNemar paired Chi-square test (χ^2) test. Factors which correlated with deafness were interpreted by Pearson chi-square (χ^2) test.
Results: Among 144 babies screened, 26 failed OAE while 6 failed AABR. Referral rate was 18.1% with OAE and 4.2% with AABR. All 6 babies failed with 40db and 90 db screening. Mean duration of NICU stay had a positive correlation with AABR positivity. Babies with higher duration of NICU stay had greater probability of hearing loss. Age and gender had no significant correlation with hearing loss. Sensitivity of OAE as 16.7 % and the specificity was 81.9 %. Positive likelihood ratio with OAE was.923. Negative likelihood ratio with OAE was 1.02. One neonate out of 6 with jaundice had profound hearing loss.
Conclusions: It was concluded that in high-risk neonates the diagnostic value of DPOAE for identification of hearing loss, when used alone, was limited since OAE has higher referral rate and lower specificity compared to AABR. Babies with higher duration of NICU stay had greater probability of hearing loss.

Keywords: Neonatal hyperbilirubinemia, Oto acoustic emission, Automated auditory brainstem response

INTRODUCTION

Early detection of hearing impairment is crucial for normal social and emotional development.[1] Prevalence of deafness estimated by various studies in newborn was 1.6 per 1000.[2] Prevalence of hearing impairment identified by neonatal hearing screening programs in India was also 1.6/1000 of at-risk infants.[3] When hearing loss is defined as loss of >25 dB, the prevalence of permanent congenital hearing loss (PCHL) reaches 3 babies per 1000. Universal neonatal hearing screening (UNHS) is followed in developed countries for the early detection of hearing loss. It involves the use of objective testing methodologies like Oto acoustic emission (OAE) testing or automated auditory brainstem response (AABR) testing) to screen the hearing of the whole population of newborn in a particular target region.[4] Early identification and intervention can prevent severe psychosocial, educational, and linguistic repercussions. Infants who are not identified before 6 months of age have delays in speech and language development. Intervention at or before 6 months of age allows a child with impaired hearing to develop normal speech and language, alongside his or her hearing peers.[5]

Targeted neonatal hearing screening is selective hearing screening in which only a specific population within a region are screened (NICU) neonates or patients coming under JCIH criteria.[6]

Present scenario

OAE is used as a screening tool in most countries while AABR is coming into vogue in developed countries as primary screening tool. In India TEOAE and DPOAE are the primary tools in first and second stage. In India both the levels are conducted only in tertiary care hospitals since audiological facilities in primary care level are still primitive. Policy regarding Hearing screening in India is still in evolution. Prevalence of Hearing loss in NICU setting is nearly 1% indicating urgent need for proper hearing screening programs.[3]

Etiological factors for hearing loss

Non-genetic causes (33.30 %): jaundice, embryopathies, toxemia of pregnancy, infection, ototoxic drugs, Rh incompatibility. Perinatal causes (10.8%): Birth asphyxia, LBW (<2.5 kg) or prematurity, post-term. post-natal causes (12.5%) eruptive fevers, meningitis, hyperbilirubinemia, traumatic, cerebral palsy, genetic causes, congenital syndromes (5.4%) and idiopathic (50.6%) are the other causes.[5]

Otoacoustic emission

An otoacoustic-emission (OAE) is an inaudible sound that is produced from the inner ear. It arises in the external auditory canal when the tympanic membrane receives vibrations transmitted in a retrograde manner, through the middle ear from the inner ear. When the inner ear gets affected, OAEs are not produced; hence it assumes clinical importance.

Mechanism

OAE is recorded via ear canal probe that is inserted into the ear canal. Click stimuli at 80 dB level can evoke a robust Transient Evoked OAE response only if hearing threshold is more than 20 dB. 2 types of OAEs include spontaneous oto-acoustic emissions (SOAEs), that does not require stimuli, and transient evoked oto-acoustic emissions (TEOAEs), that requires a stimulus to evoke emissions.

Automated auditory brainstem response

AABR measurements are generally obtained by placing disposable surface electrodes high on the forehead, on the mastoid, and on the nape of the neck. The click stimulus (usually set at 35 dB hearing level-HL) is delivered to the infant's ear via small disposable earphones designed to attenuate background noise. Most AABR systems compare an infant's waveform with that of a template developed from normative ABR infant data. A pass or fail response is determined from this comparison. Most commercially available systems can be used as an effective screening tool in infants younger than 6 months**:**

NICU screening protocol (NNF guidelines)

AABR is the hearing screening method of choice for all NICU infants; OAE in settings where AABR is unavailable. Initial screen: each ear is tested twice to collect valid recording. Second screen: Should be done on the subsequent day. Two attempts can be made. Maximum: avoid doing hearing screening more than twice. Any neonate needing more than 5 days of NICU care must be screened with ABR, so as not to miss sensorineural loss. ABR failures require confirmatory BERA testing.

The relevant studies done in the area of hearing screening in both India and other countries are listed below. A descriptive study was done in the year 2014 in ENT department, CMC Vellore by Balraj et al in which 9448 babies were screened and followed up for 11 months.[7] 164 had suspected hearing loss and on subsequent follow up, 39 had deafness. Newborn babies suspected to have hearing loss then underwent confirmatory testing using ASSR (auditory steady state response audiometry). In addition, serological testing for TORCH infections (6 were tested positive), and connexin gene (1 proved positive) mutation was done. Neonatal hearing screening using BERA was identified to be a feasible service. The estimated prevalence of confirmed hearing loss (1.4) was comparable to that in literature (1.6). Comparative evaluation of BERA and TEOAE as screening modality for hearing impairment in neonates was done by Mathur et al in Lady Hardinge medical college in the year 2007.[8] 200 randomly selected neonates were subjected to TEOAE and BERA (400 ears). Pass rate was 92%. In <48 hour age group, it was 55% suggesting high prevalence of obstructed ear canal. Feasibility of a 2-stage hearing program was first assessed by Vaid et al in Pune, India.[9] From August 2005 to August 2007 a total of 2621 babies were tested using otoacoustic emissions (OAE), followed by second stage (BERA) for those who were referred on the second OAE testing. 249 were referred on the second OAE testing and of these, only 52 came back and were further evaluated using BERA. 15 of these 52 babies were found to have a significant hearing loss.

Study justification

Importance of screening for major diseases in newborn is on the rising trend. Burden of hearing impairment is expected to rise due to increase in number of preterm babies and babies who have received intensive care. Optimisation of hearing screening protocols is essential. While OAE remains the ideal tool in low resource settings, AABR screening is needed to rule out auditory nerve dysfunction. OAE has a higher referral rate due to higher false positive results. This leads to parental anxiety and need for multiple visits to tertiary care centre.

AABR screening is limited by its expense, need for trained audiologist for testing and validation. Noise free environment with insulation from electrical disturbances and proper power connections are necessary for obtaining a valid result. Though a number of studies have been done in other countries regarding hearing screening protocols, data regarding Indian population with regards to high-risk screening is lacking. This study has been envisioned to bridge that gap and to add data to our existing pool of resources, to make an informed decision regarding choice of hearing screening tool, protocol and the man power.

Aim and objectives

Aim of the current study was to compare the diagnostic ability of oto-acoustic emission and automated auditory brainstem response (AABR) in hearing screening of high-risk infants. Objectives of current study were to determine the ideal hearing screening tool in high risk newborn, to study the referral rate of OAE and AABR in populations with the following risk factors prematurity, low birth weight, neonatal jaundice and birth asphyxia and to reduce false positive rate of OAE by 2-stage hearing program.

METHODS

Study design, location and duration

Current study was a prospective cohort study conducted at newborn department, institute of obstetrics and gynecology, institute of child health, Madras medical college from March 2015 to September 2015.

Inclusion and exclusion criteria

High risk newborns with risk factors for hearing impairment according to JCIH 2007 Criteria (joint committee of international hearing JCIH criteria) JCIH criteria were; concern from family members regarding hearing loss, positive family-history of hearing impairment, neonates requiring NICU care >5 days, including administration of ototoxic medications, assisted ventilation, hyperbilirubinemia requiring exchange transfusion, postnatal infections (meningitis, sepsis). In utero infections, including TORCH-CMV, herpes virus, rubella, syphilis, and toxoplasmosis anomalies of the pinna or ear canal, cleft palate or lip ear tags, ear pits, or temporal bone anomalies and other craniofacial anomalies. Syndromic causes of hearing loss.[6] Babies without risk factors for hearing loss were excluded from the study.

Sample size

All consecutive high-risk newborns who satisfied the inclusion criteria during the study period were enrolled.

Study manoeuver

Written consent was obtained from parents in a pre-structured proforma, prior to the procedure. AABR: RMS BERA mark 2 machines were used. OAE: neurosoft machine (TEOAE) was used. All high-risk babies discharged during study period were included in the study. Parents or grand-parents of the babies were informed about the study and consent was obtained**.** Details of the baby including name, gestational age, gender, birth weight, address and contact number were noted. Significant antenatal history and course of NICU stay including treatment details of birth asphyxia, Neonatal jaundice and ototoxic drugs used was obtained. Family history of hearing loss was asked for and noted. A detailed examination was done looking for craniofacial anomalies especially ear anomalies like microtia, pre-auricular tags or pits. Details were noted in the proforma; the screening results were filled in by the audiologist. OAE result was obtained separately from routine screening program and was added to data. OAE was done with complete automated screener which displayed the results as either “pass” or “refer”. Parents of babies who failed were explained about the prognosis and the need for further testing. AABR was done with RMS^{TM} screener. Waveforms were observed and validated by audiologist in real time. Waves were stored in hard disc for future reference. OAE was done in 144 babies in IOG by routine screening by the audiologist. All babies were then referred to ENT department ICH where AABR was performed by trained audiologist hired for this study. OAE failures were asked to return for repeat testing to rule out blockage of ear canal. Babies who failed in AABR were asked to return after 2 months for confirmatory BERA testing. 2 Contact numbers were obtained from both OAE and AABR referrals. OAE failures were asked to return for repeat OAE testing after 1 month. AABR failures were informed about the prognosis and the need for repeat testing at 3 months and the importance of early intervention. Further testing was advised at Audiology department at MMC after 2 months. Details of the cases were given to Paediatric ENT department at ICH.

Statistical analysis

The diagnostic ability of hearing loss among the children was diagnosed by AABR Vs OAE. The ability of the test was identified and inferred by McNemar paired Chi-square test (χ^2) test. The diagnostic ability was interpreted with likelihood ratios. The factors which are correlated with deafness were interpreted by Pearson Chi-square (χ^2) test. The significance of the measurable characteristics like age and NICU admissions were compared between the diagnosed subjects by students’ “t” test. The p values less than 0.05 were considered as statistically significant ($p<0.05$).

RESULTS

Demographic data

Total 144 neonates discharged from the NICU who were considered High risk and needing hearing evaluation were enrolled in the study. There were 137 term and 7 preterm babies in the study. Out of the 144 babies enrolled there were 89 male babies and 55 female babies. The total hearing loss predicted by OAE was 26 (18.1%) and AABR 40 and 90 db predicted as 6 (4.2%) each**.** But AABR 90, predicted hearing loss in 6 and the same was considered as gold standard. Among 26 tested positive with OAE, 13 had hearing loss in both ears. 13 had unilateral hearing loss with 9 in right ear and 4 in left ear. The percentage of positive prediction by OAE (18.1%) was significantly greater than the AABR 90 (4.2%) positive prediction (p<0.001).

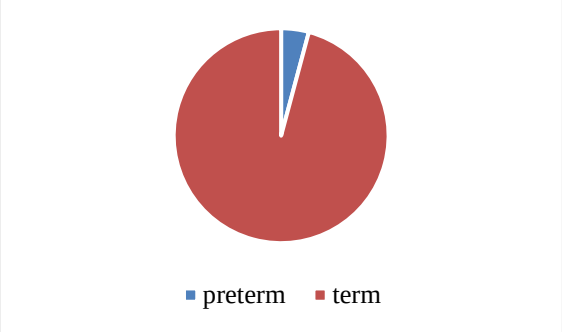

Figure 1: Gestational age.

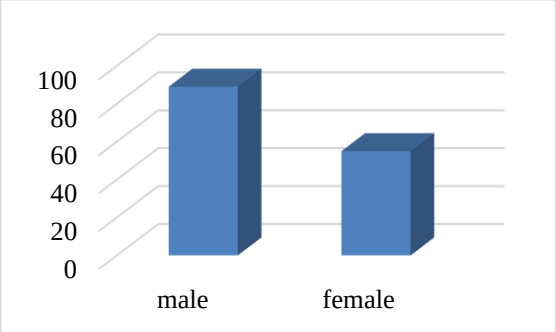

Figure 2: Birth weight.

Diagnostic ability of prediction

The predicting capacity of the tests was analysed by screening tests with reference to the AABR 90 as Gold standard and OAE diagnostic test. The results of the test were interpreted by positive and negative likely hood ratio.

The sensitivity of the test (OAE) was 16.7% and specificity of the test was 81.9%. LR+ =0.923 and LR- = 1.02. or 102%. The interpretation of LR+ was "A +ve result on OAE is 0.923 times more likely to occur in a subject with hearing loss as compared to a subject who does not have hearing loss". The interpretation of LR- was "A -ve result on OAE is 1.02 times more likely to occur in a subject who really has hearing loss as compared to a subject who does not have hearing loss". At the context of low prevalence rate of hearing loss the above interpretations are acceptable and AABR 90 has more diagnostic ability than the OAE. The above table analyses the age and stay of the hearing positive and negative subjects at NICU in respect of AABR 90 and OAE. The mean ages of Negative and positive with AABR 90 was not statistically significant (p>0.05). But the mean duration of NICU stay AABR positive (15.3±6.6 days) was statistically significantly greater than the negative mean duration of 11.1±4.2 days, p>0.05. In respect of OAE neither age nor NICU stay was statistically significant (p>0.05).

Table 1: Classification of hearing loss in the three diagnostic tests.

Hearing loss	OAE		AABR 90 dB.		AABR40 dB.	
	N	%	N	%	N	%
Nil	118	81.9	138	95.8	138	95.8
Left ear	4	2.8	0	0.0	1	0.7
Right ear	9	6.2	0	0.0	0	0.0
Both	13	9.1	6	4.2	5	3.5
Total loss	26	18.1	6	4.2	6	4.2
Total	144	100	108	100.0	144	100

Factors associated with the hearing loss diagnosed by AABR 90 dB and OAE

The factors like gender, neonatal jaundice, birth asphyxia, ototoxic drugs, sepsis, Birth weight and gestational age of the infant were studied to identify the association between AABR and OAE.

Association between hearing loss and gender

Among the males in AABR 90dB the test value was χ^2=.000and in OAE it was χ^2=0.004band in females it was df=1 and df=1respectively with a p value of 1.00 and 0.500 respectively. Therefore, there was no statistically significant association between hearing loss and gender. There was no statistically significant association between hearing loss and neonatal hyperbilirubinemia (Table 5)**.** There was no statistically significant association between hearing loss and birth asphyxia (Table 6). There was no statistically significant association between hearing loss and ototoxic drugs (Table 7). There was no statistically significant association between hearing loss and sepsis (Table 8). There was no statistically significant association between hearing loss and birth weight (Table 9). There was no statistically significant association between gestational age and hearing loss. Among 144 babies screened, 26 failed OAE while 6 failed AABR. Referral rate was 18.1% with OAE and 4.2% with AABR. All 6 babies failed with 40db and 90 dB. screening. They failed in behaviour response audiometry

done subsequently.

AABR hence is considered gold standard in hearing screening

Mean duration of NICU stay had a positive correlation with AABR positivity. Average duration of AABR positive cases (15.3 days) was significantly higher than AABR negative cases (11.3). Babies with higher duration of NICU stay had greater probability of hearing loss. Age and sex had no significant correlation with hearing loss.

One case with sepsis had hearing loss identified with OAE but it passed AABR in both ears. One case with history of ototoxic drug administration had the result REFER with OAE. But it passed AABR in both ears. Sensitivity of OAE as 16.7 % and the specificity was 81.9%. Positive likelihood ratio with OAE was 0.923. Negative likelihood ratio with OAE was 1.02. among 6 cases with profound hearing loss, one had neonatal jaundice. Two cases with hearing loss identified by OAE were preterm.

Table 2: Comparison of predicting positive percentage of OAE and AABR 90.

OAE	AABR 90			χ^2_{paird}	df	Significance
	Yes	No	Total			
Yes	1	25	26	12.033	1	P<0.001
No	5	113	118			
Total	6	138	144			

Table 3: Sensitivity and specificity of the tests.

OAE	AABR 90 (gold standard)		Total
	Positive	Negative	
Positive	1	25	26
Negative	5	113	118
Total	6	138	144

Table 4: Comparison of positive and negative results of AABR and OAE with infants age and NICU stay.

Test	Variable (days)	Negative		Positive		Difference b/w means	t	df	P value
		Mean	SD	Mean	SD				
AABR 90 dB.	Age	16.6	6.0	20.3	9.7	3.7	1.428	106	>0.05
	NICU	11.3	4.2	15.3	6.6	4.0	2.240	106	<0.05
OAE	Age	16.5	6.0	18.1	7.0	1.6	1.156	106	>0.05
	NICU	11.3	4.4	12.4	4.4	1.1	1.184	106	>0.05

Table 5: Association between hearing loss and neonatal hyperbilirubinemia (NNH).

NNH	AABR 90 dB				OAE			
	+ve	-ve	Total	Test value	+ve	-ve	Total	Test value
No	5	119	124	χ^2=0	23	101	124	χ^2=0
Yes	1	19	20	df=1	3	17	20	df=1
Total	6	138	144	p=1.00	26	118	144	p=1.00

Table 6: Association between hearing loss and birth asphyxia.

Birth asphyxia	AABR 90 dB				OAE			
	+ve	-ve	Total	Test value	+ve	-ve	Total	Test value
No	6	135	141	χ^2=0	26	115	141	χ^2=0
Yes	0	3	3	df=1	0	3	3	df=1
Total	6	138	144	p=1.00	26	118	144	p=1.00

Table 7: Association between hearing loss and ototoxic drug.

Ototoxic drug	AABR 90 dB				OAE			
	+ve	-ve	Total	Test value	+ve	-ve	Total	Test value
No	6	136	142	$\chi^2=0$	25	117	142	$\chi^2=0$
Yes	0	2	2	df=1	1	1	2	df=1
Total	6	138	144	p=1.00	26	118	144	p=1.00

Table 8: Association between hearing loss and sepsis.

Sepsis	AABR 90 dB				OAE			
	+ve	-ve	Total	Test value	+ve	-ve	Total	Test value
No	6	137	143	$\chi^2=0$	25	118	143	$\chi^2=0$
Yes	0	1	1	df=1	1	0	1	df=1
Total	6	138	144	p=1.00	26	118	144	p=1.00

Table 9: Association between hearing loss and birth weight.

Birth weight	AABR 90 dB				OAE			
	+ve	-ve	Total	Test value	+ve	-ve	Total	Test value
Normal	6	131	137	$\chi^2=0$	24	113	137	$\chi^2=0$
Abnormal	0	7	7	df=1	2	5	7	df=1
Total	6	138	144	p=1.00	26	118	108	p=1.00

Table 10: Association between gestational age and hearing loss.

Gestational age	AABR 90 dB				OAE			
	+ve	-ve	Total	Test value	+ve	-ve	Total	Test value
Full term	6	131	137	$\chi^2=0$	24	113	137	$\chi^2=0$
Pre-term	0	7	7	df=1	2	5	7	df=1
Total	6	138	144	p=1.00	26	82	144	p=1.00

DISCUSSION

In the present study, OAE had a higher referral rate compared to AABR and since overall prevalence of deafness was 1.4 %, false positive results are significantly more with OAE. Since referral leads to unwanted parental anxiety and additional visits to higher institution for confirmatory audiometric investigation, AABR is a better tool for screening. All 6 babies identified with AABR failed with behaviour response audiometry too. But AABR was significantly difficult to perform and more expensive. These findings are similar to the study done by Benito-Orejas where TEOAE screening yielded 10.2% fail results from the first screening step; AABR gave 2.6%.[10] In the second screening step, 2% of the newborns screened with TEOAE were referred, whereas 0.32% of those screened with AABR were referred. These differences were statistically significant. Although AABR screening tests involve a slightly higher cost in time and money than TEOAE, the results obtained compensate this difference. Further in that study AABR gave fewer false positives and a lower referral rate; the percent of infants lost during follow-up was consequently smaller.

In our study, sensitivity of OAE was 17% and the specificity was 81.9%. Positive likelihood ratio with OAE was 0.923. Negative likelihood ratio with OAE was 1.02. Since the sensitivity is low the false negative response is higher which accounts for 17% (infants who have passed in OAE even though they have hearing loss). The reason could be because is OAE unable to detect the neural pathology. Yousefi et al did a study of comparing specificity and sensitivity of TEOAE and BERA. In their study, 18 cases out of 1000 neonates had failed double checked TEOAE tests.[11] From these 18 failed cases, 6 were confirmed by ABR test (12 false positive results). 9 out of 1000 neonates had impaired ABR tests, from these patients, 6 had failed OAE as well, but 3 had normal OAE (3 false negative results). From these 9 patients 2 had profound hearing loss so cochlear implantation was scheduled for them. They found that OAE has 66.7% sensitivity and 98.8% specificity in diagnosis of neonatal hearing impairment. In a study done by Fa-Lin et al on 600 neonates (1,200 ears), the incidence of ABR abnormality (78.6%, 943/1,200) was remarkably higher than that of DPOAE abnormality (22.3%, 268/1,200). Two hundred and forty-one ears (20.8%) were negative and 252 (21%) were positive in both DPOAE and ABR

tests. A total of 707 ears (58.9%) presented with a discordant result in DPOAE and ABR. The false positive and false negative rates of the DPOAE test were 6.0% (16/268) and 74.1% (691/932) respectively.[12]

Limitations

Limitations inherent to cross-sectional study exists in this study. Hearing screening needs proper follow-up and repeated testing at 3 months and 6 months as AABR findings have been proven to be reversible in neonatal jaundice. Since prevalence of deafness is 1.6%, identification of risk factors for deafness requires a larger study with wider set of inclusion criteria.

CONCLUSION

It is concluded that in high-risk neonates the diagnostic value of DPOAE for identification of hearing loss, when used alone, was limited since OAE has higher referral rate and lower specificity compared to AABR. The AABR test appears to be more reliable for hearing screening in high-risk neonates. Babies with higher duration of NICU stay had greater probability of hearing loss.

Recommendations

Data regarding universal hearing screening and prevalence of deafness among healthy newborn is lacking in South Indian population. A cohort study with complete follow up till audiological recovery could be done with emphasis on the importance of early screening. This can be compared with cohort of unscreened babies with late audiological intervention and their handicaps. Larger sample size can be studied to analyse all the risk factors for hearing loss. Previous data has shown significant association between low-birth-weight birth asphyxia and neonatal jaundice. Extreme premature neonates should be studied separately owing to neurological immaturity of evoked responses. Importance of behaviour response audiometry and possibility of training paediatricians and NICU nurses in hearing assessment could be studied. This is essential in SNCUs and primary care set-up where proper audiological facility is a luxury. Multiple protocols could be studied in randomised controlled study comparing 2 stage (OAE and BERA) and single stage screening. ABR and confirmatory BERA could be done and studied at various levels.

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