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Original Article

Paediatrics Section

Comparison of Hearing Impairment among Healthy and High-risk Neonates at a Tertiary Care Hospital, Rajasthan, India: A Cross-sectional Study

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ABSTRACT

Introduction: Hearing impairment is caused by damage in the inner ear (can be even birth defect), ear infection, ruptured eardrum and so on. It can be prevented using early detection thus, helps in avoiding severe psychosocial, educational, and linguistic repercussions. It is necessary to diagnose hearing impairment before six months of age to prevent future delays in speech and language development.

Aim: To determine the prevalence of hearing impairment in high-risk neonates and to establish the fact that, these neonates have higher prevalence of hearing impairment as compared to normal population.

Materials and Methods: A cross-sectional study was conducted in the Department of Paediatrics at Jawaharlal Nehru Medical College and Hospital, Ajmer, Rajasthan, India. The duration of the study was six months, from December 2012 to May 2013. A total of 500 babies including 297 normal and 203 high-risk babies were enrolled into the study. All the neonates were screened using Behavioural Observation Audiometry (BOA) and Distortion Product Oto-acoustic Emission (DPOAE) preferably within three days of life. Those, who failed under this test, underwent for Brain stem Evoked Response Audiometry (BERA). Data was collected in the Microsoft Excel and analysis done by Statistical Package for Social Sciences (SPSS) version 23.0.

Results: The mean age of the newborns on admission, was 3.86±4.25 days and the mean weight was 2560±510 g. Out of 500 newborns screened, 58 babies had abnormal results with the first screening test. When these 58 babies subjected to BERA, eight babies showed Hearing Loss (HL). Sepsis, Neonatal Intensive Care Unit (NICU) stay more than five days and use of aminoglycosides more than seven days were the important risk factors associated with hearing impairment. Prevalence of hearing impairment in the present study was came out to be 16/1000. This finding was statistically significant with p-value <0.05.

Conclusion: There was high prevalence of hearing impairment in high-risk newborns, majority of which were bilateral. The authors recommend multistage screening in all newborns at birth or within month's time at all level of healthcare facility. Newborns with sepsis, NICU stay more than five days and use of aminoglycosides more than seven days should have mandatory audiologic evaluation at discharge.

Keywords: Behavioural observation audiometry, Brain stem evoked response, Distortion product oto-acoustic emission, Hearing loss

INTRODUCTION

Significant HL is one of the most common birth related congenital illnesses, that occur in about 1 to 3 in 1,000 healthy neonates and of 100 neonates, 2 to 4 will be reported in the Neonatal Intensive Care Unit (NICU) [1-3]. Although, the prevalence of hearing impairment varies with the age group surveyed and the testing methods used [4]. There are many aetiological factors which results in severe HL in neonates. Among the various factors, genetic causes responsible for atleast 50% to 60% of childhood HL [5]. Environmental causes of HL include rubella embryopathy, prematurity, bacterial meningitis, and head trauma [5]. The initial signs of HL are very subtle, and systematic neonatal hearing screening is the most effective means of early detection. The early identification of HL is necessary to minimise the consequences of hearing impairment on the future communication skills of a baby [6,7].

The following are the various methods that assess HL in neonates i.e., electrophysiological and behavioural assessment methods. Behavioural techniques have been noted with high number of false negative results [8,9]. As electrophysiologic methods have greater sensitivity and specificity, the following may be used: Auditory Brainstem Response (ABR), Automated Auditory Brainstem Response (AABR) and Evoked Oto-Acoustic Emissions (EOAE). ABR and EOAE are mostly used for universal hearing screening tools for neonates. However, it is better to minimise false-positive results and developing a more reliable newborn hearing screening program. EOAE and ABR tools are evolving and becoming more and more automated [10].

The present study was aimed to determine the prevalence of hearing impairment in high-risk neonates and to establish the fact that, high-risk neonates have higher prevalence of hearing impairment as compared to normal population.

MATERIALS AND METHODS

This cross-sectional study was conducted in the Department of Paediatrics in Jawaharlal Nehru Medical College (JLN Medical College and Hospital), Ajmer, Rajasthan, India. The duration of the study was six months, from December 2012 to May 2013. Ethical clearance for the present study was obtained from Institutional Ethical Committee (IEC). Informed written consent was taken from parents/guardian of the neonates after fully explaining the nature and purpose of the study.

Inclusion criteria: The subjects were divided into two groups:

- Normal newborns: Newborns included in this group had no risk factor for HL. Out of 297 newborns, four were from Special Neonatal Care Unit (SNCU) and 293 were those, who born in the JLN Hospital, were included in the study.

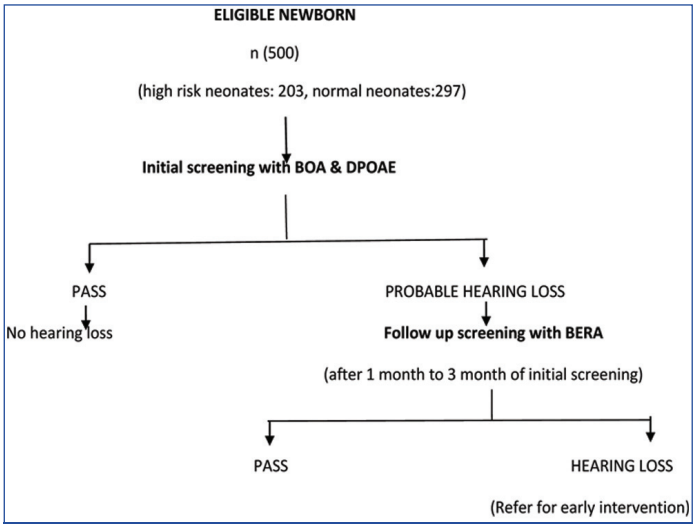
- High-risk newborns: Newborns included in this group had one or more risk factors for HL. Out of 203 newborns, 147 were from SNCU suffering from diseases having risk for HL. The remaining 56 babies were from JLN hospital having one or more maternal risk factors (elderly pregnancy, high/low blood pressure, viral & bacterial infections, oto-toxic medications, history of sibling death and diabetes mellitus), family history of permanent hearing, history of NICU admission more than five days, preterm babies having weight >1.8 kg and neonatal seizures. Neonates with the following risk factors were enrolled for the study i.e., family history of permanent HL, neonatal intensive care of more than five days. Exposure to oto-toxic medication more than seven days, hyperbilirubinemia requiring exchange transfusion, infection, maternal risk factors, birth asphyxia, prematurity, congenital anomaly, Very Low Birth Weight (VLBW) and neonatal seizures [7].

Exclusion criteria: Upon considering the aspect of the research study, neonates with the following characteristics were not considered for the study- neonates, who were on ventilator support from birth to death, active ear infection and parents of neonate not willing to give informed consent to participate were excluded from the study.

Sample size calculation: With 95% confidence level and 5% absolute precision, the required sample size came out to be 122 high-risk subjects, but to be on better side, 203 high-risk samples were included [11-13]. Along with that, 297 normal newborns were also included in the study to establish the fact that, high-risk babies have higher prevalence of hearing impairment as compared to normal population.

Study Procedure

History regarding demographic details, gestational history of mother, family history of deafness, any complication during pregnancy was taken. All eligible newborns enrolled in the present study, were screened by BOA and DPOAE preferably within three days of life in both risk factor group and normal newborns group. The study was deferred for few days in very sick babies. These babies were screened after discharge from SNCU and were fit enough to undergo the test within one month of age. The babies, who had probable HL in initial screening was subjected to ABR to confirm and grading the degree of HL after one month of initial screening [Table/Fig-1].



[Table/Fig-1]: Hearing screening procedure flowchart (N=500). A total of 58 neonates had probable hearing loss with initial screening test. Eight neonates failed in the follow-up screening with BERA.

Behavioural Observation Audiometry (BOA): Stimuli like pure tones at 500 Hz or 4 kHz, narrow band noise or white noise were presented in a well lit, noise free environment at a level of 80 decibel (dB) HL using paediatric audiometer PA5 device (interacoustics) such that, the distance between the loudspeaker and the ear of the infant was around 50 cm and the loudspeaker of the device facing the infant's ear. The response was observed in the form of any change in the behaviour such as startle reflex, auropalpebral reflex, arousal from sleep or cessation of the activity. The result of the test was recorded as 'pass' or 'probable HL' based on the presence or absence of the response.

Distortion Product Oto-Acoustic Emission (DPOAE): It was conducted using Oto-read device (interacoustics) in a noise free environment, on a calm baby after ensuring no debris or other obstruction in the external auditory canal. A miniature earphone and microphone were placed in ear. Two sounds of simultaneous pure tones 65 dB and 55 dB were produced and response was measured by microphone in the ear canal with the frequency range of 2 kHz to 5 kHz. Result of test was indicated as 'pass' or 'refer (probable HL)' such that, pass indicated patient having normal outer hair cells functioning and probable HL suggesting possibility of a sensory neural HL or any conductive HL, which indicates requirement of further diagnostic hearing evaluation.

Brainstem Evoked Response Audiometry (BERA): In order to carry out the further diagnostic procedure, this was performed in a quiet room for about 30-45 minutes, post feeding and while they were in natural deep sleep. Those, who remained awake were being done sedation with oral Triclofos. The placement of the electrodes was such that, the negative electrode was kept at the mastoid process of the test ear, positive electrode placed at the forehead and ground electrode at the mastoid process of the non testing ear. It was made sure that, the resistance should be kept below 5000 ohms (Ω). The stimulus was presented individually to the right and left ears with refraction clicks of 0.1 millisecond (msec) duration administered at the rate of 30.1/second using EAR-3A 10 Ω insert earphones, inserted into the test ear. Four thousand responses were averaged with filter setting of 30-3000 Hz on the non destructive interventions. Minimum of two sets were performed for reproducibility. Auditory brain stem response developed within 15 msec time and was seen at a gain of 200 nanovolt/division (nv/div). Initially the high intensity of 70 dB normal hearing level (nHL) was administered. Then the intensity was decreased insteps of 10 dB till 30 dBnHL, which was taken to be the normal threshold for producing wave V. This was a prominent trough like deflection crossing well below the baseline on the oscilloscope after seven msec. An infant was considered to have normal hearing threshold if, wave V is present at 30 dBnHL in both ears or in one ear at 45 dBnHL.

STATISTICAL ANALYSIS

Data of the present study was compiled in Microsoft Excel-2007 and the statistical analysis done by SPSS version 23.0. The descriptive analysis of the screening procedures outcome and the prevalence of HL were calculated. Chi-square test was used to analyse the data, $p<0.05$ considered to be statistically significant in the study.

RESULTS

A total of 500 eligible newborns with 203 high-risk and 297 normal newborns were included in the study. Total 280 (56%) of the study population were male child and 220 (44%) were female child, giving a male:female ratio of 1.27:1. Their age ranges from one day to 28 days [Table/Fig-2]. The majority of newborns were term (n=441, 88.2%) while 57 (11.4%) were preterm. In the present study, maximum newborns (61%), had >2.5 kg weight, 4.4% had VLBW [Table/Fig-3]. The mean age±SD on admission was 3.86±4.25 days in the study group. The mean weight±SD of the newborns was 2560±510 g. Fifty-eight newborns out of total 500 newborns had

High-risk newborns						Normal newborns				
Age group (in days)	Male (n=122) n (%)	Female (n=81) n (%)	Total (n=203) n (%)	Mean age±SD (in days)	p-value	Male (n=158) n (%)	Female (n=139) n (%)	Total (n=297) n (%)	Mean age±SD (in days)	p-value
0-3	38 (18.7)	18 (8.9)	56 (27.6)	5.45±4.45	0.24	155 (52.2)	139 (46.8)	294 (98.9)	1.98±0.84	0.10
4-7	52 (25.6)	34 (16.7)	86 (42.4)			3 (1.0)	0	3 (1.0)		
8-28	32 (15.7)	29 (14.3)	61 (30)			0	0	0		

[Table/Fig-2]: Age and sex distribution in study subjects (N=500).

High-risk newborns							Normal newborns					
Gestational age group (in weeks)	Birth weight groups						Birth weight groups					
	1000-1499 gm (n=22)	1500-2499 gm (n=86)	2500-3500 gm (n=95)	Total (n=203) (%)	Mean weight±SD	p-value	1000-1499 gm (n=0)	1500-2499 gm (n=87))	2500-3500 gm (n=210)	Total (n=297) (%)	Mean weight±SD	p-value
<37	16	36	1	53 (26.1)	2.40±0.58	0.0001*	0	2	2	4 (1.4)	2.66±0.42	0.99
37-41	6	50	94	150 (73.9)			0	85	206	291 (97.9)		
≥42	0	0	0	0			0	0	2	2 (0.7)		

[Table/Fig-3]: Distribution of cases according to gestational age and birth weight.
*Represent the p-value significant (<0.05)

abnormal testing when subjected to hearing screening with BOA and DPOAE test. 8 (1.6%) neonates had abnormal finding, when those 58 newborns with abnormal testing screened with BERA [Table/Fig-4]. Prevalence of hearing impairment in the present study, was came out to be 16/1000. This finding was significant with p<0.05. In the present study, hearing impairment was found to be associated with sepsis, prematurity, VLBW, NICU stay more than five days, use of aminoglycoside more than seven days and hyperbilirubinemia requiring exchange transfusion.

Parameters	High-risk newborns (n=203) n (%)	Normal newborns (n=297) n (%)	Chi-square	p-value
BOA and DPOAE (first screening test) (N=500)				
Pass	153 (30.6)	289 (57.8)	56.58	0.0001*
Refer	50 (10)	8 (1.6)		
BERA (second screening test) (n=58)	50	8		
Pass	43 (74.1)	7 (12)	7.415	0.006*
Refer	7 (12)	1 (1.7)		
Prevalence of hearing loss	34.48/1000	3.37/1000		
Confidence interval	(0.0089-0.0601)	(0.0-0.0101)		

[Table/Fig-4]: Comparison of prevalence of hearing loss in high-risk and normal newborns.
BERA: Brainstem evoked response audiometry; BOA: Behavioural observation audiometry; DPOAE: Distortion product oto-acoustic emission test. *Represent the p-value significant (<0.05)

DISCUSSION

The effect of hearing impairment on the newborn, the family and the society is lifelong if, timely intervention not sought. Diagnosis in early phase and timely intervention remains the only way to reduce its effect on speech, language, and cognitive development. In the present study, hearing impairment was found in 58 newborns following the initial screening by BOA and DPOAE. These 58 newborns when screened with BERA, only eight newborns (seven high-risk neonates, one normal newborn) were found to have HL. The high prevalence of abnormal results during initial screening test may be due to presence of amniotic fluid or debris in the middle ear, which is expected during early age, but it improved with time as it gets cleared naturally. In the present study, the prevalence of failed results reduced with time that supports the use of multistage screening for hearing impairment in newborns. In the present study, the prevalence of hearing impairment was 3.37/1000 in normal newborns and 34.48/1000 in high-risk newborns. In the present study, the authors noted, there was an increased prevalence of hearing loss among high-risk newborns which had also been seen in various other studies in the past. In a study, done by Nagapoornima P et al., the incidence of hearing loss in normal (4.7/1000) and high-risk (10.75/1000) [11]. According to study done by Paul AK reported the incidence of 0.98/1000 and 10.3/1000 in normal and high-risk babies group respectively after a study period of seven years [14]. In the present study, hearing impairment was found to be associated with sepsis, prematurity, VLBW, NICU stay more than five days, use of aminoglycoside more than seven days and hyperbilirubinemia requiring exchange transfusion. [Table/Fig-5] shows comparative chart of various studies done in the past [4,12,13,15-19]. According to the study done by Balasubramanian J et al., main risk factor associated with hearing impairment was severe birth asphyxia [15]. In the present study, there was no role of birth asphyxia, neonatal seizures, maternal risk factors, congenital and history of hearing

Study	Publication year	Place	Technology	Sample size (N)	Result
Present	2022	Ajmer	BOA, DPOAE, BERA	500 neonates	1st screening- 11.6% failed BERA -1.6% failed RF- VLBW, NICU stay > 5 days
Balasubramanian J et al., [15]	2020	Tamil Nadu	OAE, AABR	100 high-risk neonates	1st screening- 16.2% failed 2nd screening- 2.06% failed AABR- 3.06% failed RF- severe birth asphyxia, craniofacial anomaly
Panjiyar MM et al., [4]	2019	Mumbai	OAE, BERA	410 neonates	BERA- 1.21% failed Prevalence 12.20/1000 RF- severe birth asphyxia, prolonged NICU stay, VLBW
Bhatia R et al., [17]	2019	Udaipur	OAE, BERA	1114 neonates	1st screening-285 failed 2nd screening- 13 failed BERA- 1 failed RF- LBW
Gupta A et al., [18]	2019	Jodhpur	DPOAE, BERA	5000 neonates	Prevalence-high-risk (8.77/1000) at no risk (0.45/1000) RF-prematurity, VLBW, neonatal hyperbilirubinemia

Labaeka AA et al., [16]	2018	Nigeria	AABR	201 high-risk neonates	1st screening-41.3% failed 2nd screening-15.9% failed 3rd screening-9.5% RF-meningitis, vancomycin, amikacin administration more than five days
Vashistha I et al., [19]	2016	Ajmer	BOA, DPOAE, BERA	100 high-risk neonates	Prevalence- 15% Risk factor-prematurity, VLBW
Akinola MD et al., [12]	2014	Nigeria	EOAE	306 neonates	1st screening-29% failed 2nd screening/discharged-8.5% RF- prematurity
Lasisi AO et al., [13]	2014	Nigeria	AABR	453 neonates	1st screening- 49.4% failed 82.5% lost to follow-up 14/40 passed at follow-up RF- maternal preeclampsia

[Table/Fig-5]: Review of literature-prevalence of hearing impairment in neonates in various studies [4,12,13,15-19].
AABR: Automated auditory brainstem response; BERA: Brainstem evoked response audiometry; BOA: Behavioural observation audiometry; DPOAE: Distortion product oto-acoustic emission test; NICU: Neonatal intensive care unit; EOAE: Oto-acoustic emission test; RF: Risk factors; VLBW: Very low birth weight

loss. In the present study, bilateral hearing impairment 6 (1.2%) was more common than unilateral hearing loss 2 (0.4%). Labaeka AA et al., also reported predominance of bilateral hearing loss (5.45%) [16].

Congenital hearing loss affect 2-3 per 1000 newborns [20]. It is one of the most common sensorial deficits presenting at time of birth of a neonate [21]. Aetiology in almost 50% cases of congenital deafness follow genetic level and rest are due to environmental reasons [22,23]. The Joint Committee on Infant Hearing (JCIH) advises for universal hearing screening, soon after delivery or before their discharge from hospital. The guideline issued by JCIH in 2007 recommends screening within first month of life. Newborns, which are not able to pass the screening test, must undergo detailed hearing assessment before three months of age and if, confirmed must be provided with appropriate intervention within six months of age [7]. The goal of early diagnosis of hearing loss is to achieve better verbal and social communication. Delayed diagnosis may have a negative impact on the patient's verbal, educational, psychological and socioeconomic abilities.

In the present study, hearing loss was not only present in high-risk babies, but also seen in normal newborns although, the prevalence was low compared to them. Therefore, screening only those newborns, who are having one or more associated risk factors for hearing loss can miss many cases. Hence, universal screening of all the newborns must be done for hearing loss so that, it can be identified at early age and timely intervention can gives better response. It is universally accepted that, screening for hearing loss in all neonates is crucial. In a study by Farhat A et al., in his comparative study, identified neonates, those who were hospitalised in NICU, was more valuable to hearing impairment than screening just those, who were hospitalised in the NICU, when compared to that healthy neonates [24].

Limitation(s)

In the present study, congenital hearing loss cases of less severity and the progressive or late onset hearing impairment cases had not been detected by the screening methods.

CONCLUSION(S)

There was high prevalence of hearing impairment in high-risk newborns, majority of which were bilateral. Sepsis, prematurity, VLBW, NICU stay more than five days, use of aminoglycoside more than seven days and hyperbilirubinemia requiring exchange transfusion were important risk factors. Based on the present study, authors recommend for multistage screening in all newborns at birth or within month's time at all level of healthcare facility, as screening of only high-risk babies may led to missing of many cases of congenital deafness. Newborns, who fail on screening, should be given a diagnostic test and proper intervention within three months. Those, who have high-risk factor should be follow-up at interval of six months, even if they cleared the screening test.

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