Section: Otorhinolaryngology

Original Research Article

A HOSPITAL BASED PROSPECTIVE STUDY TO EMPHASIZES THE IMPORTANCE OF USING BRAIN STEM EVOKED RESPONSE AUDIOMETRY (BERA) & OTO ACOUSTIC EMISSION (OAE) AS A SCREENING TEST FOR THE EARLY DETECTION OF HEARING LOSS IN NEWBORN ADMITTED AT TERTIARY CARE CENTER

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ABSTRACT

Background: Hearing loss is the most common congenital factor seen in 0.1–0.2% infants. Many healthcare settings use both OAEs and BERA in a two-step screening process to maximize the detection of potential hearing impairments. There are very few studies from India, which have compared OAE and BERA as a screening modality for detection of hearing loss in children. With the aim of establishing some guidelines regarding the protocols for hearing loss assessment and preventive measures, the present study has been undertaken to compare OAE with BERA done simultaneously, in the diagnosis of pediatric hearing loss.

Materials and Methods: This is a hospital based observational descriptive study conducted on 300 newborn infants of NICU and indoor and outdoor infants in SP Medical College & Hospital, Bikaner during one-year period. In the present study, DPOAEs were used to screen for the presence of normal versus abnormal hearing [pass/refer]. If the results were "pass" [OAEs are present ≥ 6 dB above the noise floor for the majority of test frequencies] then no follow up OAE was done. The absence of emissions with DPOAE was considered as "refer" result. Irrespective of "pass" or "refer" result children were subjected for BERA test.

Results: Among 300 infants, the first stage of screening was conducted for 236 babies with distortion product otoacoustic emission who did not have any risk factors. Out of 236 infants, 22 had a 'refer' in 1st OAE screening. 2 patients had type B tympanogram depicting that middle ear effusion was present. One patient was lost to follow up. 11 infants had 'refer' in the 1st OAE screening out of 64 infants who had risk factors. 3 patients had type B tympanogram depicting that middle ear effusion was present. Out of 11 patients 3 had refer in the 2nd OAE. Among 64 high risk babies, 3 (4.68%) babies were deaf and among 236 babies with no associated risk factors 1 (0.43%) was deaf. On application of Chi-Square Test this difference was significant statistically with a p value of 0.0064, thus making strong the need for a screening process for deafness in high risk associated births.

Conclusion: All high-risk children should be screened with BERA early so that children with hearing loss identified and taken care for that. Screening programs should not only include newborn screening, but also screening in later periods based on the risk factors.

Keywords: BERA, OAE, Infants, NICU, Hearing loss.

INTRODUCTION

Hearing is an important sense humans have; it is very important for speech and language development, communication, and learning. Hearing loss in children constitutes a considerable disability because it is an invisible disability that can compromise their optimal development and personal achievement. The prevalence of congenital hearing loss has been estimated to be 1.2–5.7 per 1000 live births.[1]

Newborn hearing screening (NHS) has been recognized globally as a critical early intervention measure. Its primary objective is the early identification of hearing loss, which, if undetected, can severely impact the linguistic, social, and cognitive development of children.[2] The importance of NHS lies in its potential to detect hearing impairments before they can affect these critical areas of development, thus facilitating timely medical or surgical interventions that can significantly improve the quality of life and developmental outcomes for affected infants.[3]

There are many causes of neonatal hearing loss like antenatal/maternal Causes—Genetic defects are thought to be responsible for about half of the cases.[4,5] Aminoglycosides and loop diuretics have long been recognized to have the potential for ototoxicity.[4,6] CMV, rubella virus, HIV are other prenatal causes of hearing loss. Perinatal/intra-natal Causes –Meconium-stained liquor, birth asphyxia, etc. causes hearing loss. Postnatal Causes for neonatal hearing loss include noise exposure, hyperbilirubinaemia, cytomegalovirus [CMV] infection, low birth weight, prematurity, hypoxia, etc.[4,7,8]

With the ever-growing number of candidates for hearing screening, especially in a country like India, due to high birth rate, there is a need for screening modality for hearing assessment, which is reliable, but at the same time requires less time and expertise. Brainstem Evoked Response Audiometry [BERA]/Auditory Brainstem response [ABR] has been established as the most reliable screening tool for hearing assessment in neonates since its first use in 1978 for this purpose. However, technical expertise required and time consumed in performing BERA in a neonate or a child makes this modality fall short of being an ideal screening tool. Otoacoustic Emission [OAE] is another screening test which is fast and easy test and can be conducted without sedation to new-born. OAE is generated at the outer hair cells, it does not detect Eighth nerve or auditory brainstem pathology which is detected by ABR test.

Many healthcare settings use both OAEs and BERA in a two-step screening process to maximize the detection of potential hearing impairments. Initially, all newborns undergo OAE screening; those who refer or fail proceed to the more detailed BERA test.[9] This combined approach ensures a high detection rate while maintaining efficiency and cost-effectiveness. The use of both tests in tandem accommodates the strengths and limitations of each method, providing a comprehensive assessment of a newborn's auditory health.[10]

There are very few studies from India, which have compared OAE and BERA as a screening modality for detection of hearing loss in children. With the aim of establishing some guidelines regarding the protocols for hearing loss assessment and preventive measures, the present study has been undertaken to compare OAE with BERA done simultaneously, in the diagnosis of pediatric hearing loss.

MATERIALS AND METHODS

This is a hospital based observational descriptive study conducted on 300 new born infants of NICU and indoor and outdoor infants in the department of Otorhinolaryngology and Department of Paediatrics at SP Medical College & Hospital, Bikaner, Rajasthan, india during one-year period.

Inclusion Criteria

1. Babies who delivered in this hospital were included in the study.
2. Those babies who required intensive care were not included in the study during the acute phase. However, they were included after stabilization or before discharge.

Exclusion Criteria

1. Babies whose mother (parents) not give consented.
2. Babies with acute illness admitted to NICU.

Methods

Procedure of the test

The parents were counseled regarding congenital hearing loss and the need for early diagnosis and intervention prior to the test. Written informed consent was obtained from the parents.

In all the 300 children a detailed history, including antenatal/maternal, perinatal/intra-natal, postnatal history for any risk factors and delayed milestones of the child, was elicited from the parents preferably from the mother.

The babies underwent a routine ENT examination consisting of inspection of the pre-aural, pinna, and post aural region. Occluding wax or debris was gently cleaned using cotton tipped swab and otoscopic examination of the tympanic membrane was conducted using welch allyn 05259-M series otoscope with plastic speculums.

In the present study, DPOAEs were used to screen for the presence of normal versus abnormal hearing [pass/refer]. If the results were “pass” [OAEs are present $\geq$ 6 dB above the noise floor for the majority of test frequencies] then no follow up OAE was done. The absence of emissions with DPOAE was considered as “refer” result. Irrespective of “pass” or “refer” result children were subjected for BERA test.

Neonates diagnosed with auditory disorders were advised to seek early hearing aid amplification and were referred to a rehabilitation center for appropriate management.

PROTOCOL

First stage: Neonates were tested within first week of birth. They were tested with Distortion Product Otoacoustic Emissions. Those babies who passed this test were considered passed. Those babies who had 'refer' in this test were tested after one month.

Second stage: The babies who had 'refer' in the first stage screening were subjected to tympanometry and rescreened with DPOAE. Babies who had 'refer' in the second stage test also underwent a diagnostic brainstem evoked response audiometry and workup for the etiology of congenital hearing loss.

Those babies who passed this were not re-screened and were considered pass.

RESULTS

The present study was conducted on 300 newborn babies among whom 50.33 percent (151 babies) were females and 49.66 percent (149 babies) were males. The birth weight of were varied from a minimum of 1.4 kg to 4.2 kg. Majority of the patients (238/300) weighed between 2.6 to 3.5kg. 64 patients had been identified with risk factors according to the JCIH guidelines 2007 (table 1).

The first stage of screening was conducted for 236 babies with distortion product otoacoustic emission who did not have any risk factors. Out of 236 infants, 22 had a 'refer' in 1st OAE screening. 2 patients had type B tympanogram depicting that middle ear effusion was present. One patient was lost to follow up (table 2). 11 infants had 'refer' in the 1st OAE screening out of 64 infants who had risk factors. 3 patients had type B tympanogram depicting that middle ear effusion was present. One patient was lost to follow up. Out of 11 patients 3 had refer in the 2nd OAE (table 3).

Table 4, where the findings of first OAE screening was compared between high risk infants and normal infants, shows that 9.32% of the normal babies had 'refer' and 17.18 % of the babies with high risk factor had 'refer' as hearing impairment causes a deleterious effect on the life of a child, a timely diagnosis drastically changes the quality of life of even a single patient and his parents who has been diagnosed early by the screening schedule. Our study shows those babies who were subjected to second OAE screening with no middle ear pathology in tympanometry. Among the normal babies, 4 (18.18%) babies had 'refer' and 81.82% passed whereas 3 (27.27%) out of the 11 high risk babies had 'refer' and 72.72% of the babies passed.

Table 5 shows BERA findings in the whole sample size after stepwise OAE1-TYMP-OAE2-ABR screening. Among 64 high risk babies, 3 (4.68%) babies were deaf and among 236 babies with no associated risk factors 1 (0.43%) was deaf.

Table 1: Demographic characteristics in study population

Characteristics	Number of Infants (N=300)	High Risk babies (HRB) (N=64)
Gender		
Female	151	34
Male	149	30
Birth weight		
1 to 2.5	57	44
2.6 to 3.5	238	20
>3.5	5	0
Risk factors		
Present	64	-
Absent	236	-

Table 2: Results of Screening in Normal Babies (Without Any Risk factors)

Result of OAE 1	Number of Infants (N=236)	Result of OAE 2 (N=22)
Pass	214	18
B/L Fail	13	2
Left Fail	4	1
Right Fail	5	1
Tympanometry 1st (N=22)		
Normal	19	
Middle ear pathology	2	
Lost of Follow-up	1	

Table 3: Results of Screening in High-Risk Babies

Result of OAE 1	Number of Infants (N=64)	Result of OAE 2 (N=11)
Pass	53	8
B/L Fail	6	2
Left Fail	3	0
Right Fail	2	1
Tympanometry 1st (N=11)		
Normal	7	
Middle ear pathology	3	

Lost of Follow-up	1	

Table 4: Comparison of findings of OAE 1st and OAE 2nd Screening in HRF and Normal Babies

OAE Finding	HRF Infants	Normal Infants	Total
First OAE Finding			
Failed	11 (17.18%)	22 (9.32%)	33 (11%)
Passed	53 (82.81%)	214 (90.67%)	267 (89%)
Total	64 (21.33%)	236 (78.66%)	300 (100%)
Second OAE Findings			
Failed	3 (27.27%)	4 (18.18%)	7 (21.21%)
Passed	8 (72.72%)	18 (81.82%)	26 (78.78%)
Total	11 (33.33%)	22 (66.66%)	33 (100%)

Table 5: Comparison of BERA findings among total infants (n=300)

BERA Results	High Risk Infants	Normal Infants	Total
Failures	3 (4.68%)	1 (0.43%)	4 (1.33%)
Passed	61 (95.31%)	235 (99.57%)	296 (98.66%)
Total	64 (21.33%)	236 (78.66%)	300 (100%)

Chi- Square =6.283with 1 degree of freedom; p= 0.0065

DISCUSSION

Hearing loss in early life hampers development of children, early detection of hearing loss in paediatric age group gives opportunity to treat it and good speech and overall development of children. Our study evaluated risk babies using OAE. The SNR for 2kHz, 3kHz, 4kHz and 6kHz is deduced to be 8,10,8,6 dB SPL respectively. These sound to noise ratio values were similar for both high risk and normal babies in our study. Micheal P Gorga,[11] concluded that DPOAE levels, noise levels and SNRs were similar for well babies without risk indicators, well babies with risk indicators, and Neonatal Intensive Care Unit babies. Our findings were similar to this study.

We have found male-to-female ratio to be 1:1.01 among patients having hearing loss, so there is no gross difference in male-to-female ratio. Saikat Samaddar et al,[12] conducted a study on 1182 infants out of which 613(51.3%) were females and 569(48.1%) were males.

In our study 236 (78.66%) babies out of 300 did not have any risk factors whereas 64 (21.33%) patients had been identified with risk factors according to the JCIH guidelines 2007. Similar results found by Abraham K Paul et al,[13] & Saikat Samaddar et al,[12] high risk factors was 20.01% & 28.4% respectively.

The birth weights of babies varied from 1.5 kg to 4.1kg. No significant correlation was found between the occurrence of hearing loss and low birth weight in our study. Jewel et al,[14] Abraham et al,[13] Saikat Samddar et al,[12] also did not found any significant co-relation between birth weight and prevalence of hearing loss.

We used a two stage OAE protocol, where in neonates were subjected to 2 stages of otoacoustic emission screening and tympanometry. One of which was performed at one week of birth and the other was conducted for only those who had ‘refer’ in the first screening programme. Tympanometry was done to assess the middle ear pathology. Those babies who had ‘refer’ in the second stage were subjected to diagnostic Brainstem Evoked Response Audiometry. This protocol was put forward by the American Academy of Audiology Childhood Hearing Screening Guidelines,[15] in September 2011 which mentions a hearing screening guideline wherein they have stated that tympanometry must be included in hearing screening of newborns who have had ‘refer’ in the first screening test.

The first stage of screening was conducted for 236 babies with distortion product otoacoustic emission who did not have any risk factors. Out of 236 infants, 22 had a ‘refer’ in 1st OAE screening. 2 patients had type B tympanogram depicting that middle ear effusion was present. One patient was lost to follow up in our study. In a study conducted by Abraham K Paul,[13] 724 (9.0%) babies out of 8134 babies had ‘refer’ in the first screening test, which is almost equal to what we had in our study. Another study done by Saikat Samaddar et al,[12] had refer in 7.8% neonates which is quite lower than what we had in our study.

In a study conducted by Kurt A Stone, Brian D Smith et al,[16] of 1002 infants, 111 failed the initial screen (11.2%). When screening was repeated, only 2 infants failed. One infant failed the second screen and a tympanogram. He was treated and he passed a third use of DPOAE. An additional infant failed the repeat screen but passed the tympanogram. Hence doing tympanometry could save cost in screening procedures for hearing loss as it may exclude the patients who failed OAE due to middle ear pathology.

Abraham et al,[13] found that out of 2031 babies who had risk factors 234 had ‘refer’ in the first screen and finally 78 patients had ‘refer’ in the second screen. This study can be compared to our study as the results are similar.

In the high-risk group Saikat Samaddar et al,[12] 1ststage TEOAE screening yielded 7.40% ‘Refer’, declining to 2.97% in the 2ndstage TEOAE screening.

BERA was conducted for those babies who had refer in OAE2.So a total of 4 babies were subjected

to BERA. Abraham et al conducted BERA in 159 patients who had 'refer' in the second screen. Out of these 159 patients, 21 patients with risk factors failed and 8 out of 81 without any risk factor failed.
Saikat Samaddar et al,[12] had BERA fail in 0.35% infants in the non-high-risk group and 1.79% in the high-risk group.
Katheleen Billings et al,[17] studied 301 children, in whom 68.1% had a definite orprobable cause of their SNHL identified 18.9% had 1 or more possible causes; 31.9%, no obvious cause. A family history of SNHL or prematurity and/or complicated perinatal course was found in 28.6% of patients. Named syndromes, multiple congenital anomalies, meningitis, or prenatal maternal factors, including maternal prenatal substance abuse was present in another 38.5%. However, syndromes commonly reported to be associated with SNHL, such as Waardenburg syndrome, were seen in less than 1% of patients.
B De Capua, De Felice et al,[18] noted that two babies (3.8 per1000 live births) were detected to have bilateral hearing loss and one (1.9 per 1000 live births) was detected to have unilateral hearing loss.
Prieve et al,[19] used a protocol that included Otoacoustic Emission screening at birth. Second stage screening was conducted with OAE, ABR at 4-6 weeks after the first stage scan. They screened 69,766 neonates of which, 4,699 failed the screening test. Diagnostic ABR and OAE were repeated after 4-6 weeks. Thirty-three well babies (1 in every 2041) were confirmed to have hearing loss in comparison to fifty-two NICU babies (1 in 208).
Brainstem Evoked Response Audiometery was done for the babies who failed both the OAE tests. B De Capua, De Felice et al,[18] screened 532 newborns using OAE. The first test was carried out within 4 days of delivery. Those babies who failed were retested within 15 days, and a diagnostic ABR was done after two consecutive failed OAE within one month. They noted that of the 532 babies screened, 62(11.65%) babies failed the first test. They also noted that 13 (11.65%) failed to retest with OAE.
Our study shows that the BERA findings in the whole sample size after stepwise OAE1-TYMP-OAE2-ABR screening. Among 64 high risk babies, 3 (4.68%) babies were deaf and among 236 babies with no associated risk factors 1 (0.43%) was deaf. On application of Chi-Square Test this difference was significant statistically with a p value of 0.0064, thus making strong the need for a screening process for deafness in high risk associated births. Kanan S and Pensi CA,[20] reported a prevalence of 10.42 per 1000 births for Central nervous system anomalies, 3.17 per 1000 births for multiple congenital anomalies, 2.95 per 1000 births for musculoskeletal anomalies, 2.49 per 1000 births for gastrointestinal system anomalies and 2.27 per 1000 births for cardiovascular anomalies. In our study, the prevalence for deafness was 3.5 per 1000 births thus warranting a need for screening programme for hearing.

CONCLUSION

Hearing is not a visible disability. It commonly goes undetected until it affects the child's communication in the form of speech and language. This emphasizes the need for newborn screening. Though congenital hearing loss contributes to a majority of hearing loss in children, it can also occur in the later periods due to meningitis, encephalitis, complications of prematurity, etc. Screening programs should not only include newborn screening, but also screening in later periods based on the risk factors. All high-risk children should be screened with BERA early so that children with hearing loss identified and taken care for that.

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