Role of Two Stage Otoacoustic Emissions Test for Screening of Hearing Impairment in High Risk Neonates - A Prospective Observational Study

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ABSTRACT

BACKGROUND

Hearing is one of the most important senses which constitutes the basis for acquiring language, communication, cognitive and psychosocial development. Hearing impairment in infants should be recognized as soon as possible after birth for early interventions. Hearing status of a newborn in this study is being assessed by two subsequent tests with Oto-Acoustic Emissions (OAE) followed by Brain stem Evoked Response Audiometry (BERA). We wanted to study the efficacy and role of two stage Otoacoustic Emission (OAE) test for screening high risk new-borns to detect hearing impairment.

METHODS

A prospective observational study was conducted from July 2014 to July 2017 at Govt. Medical College, Thrissur, Kerala. OAE screening was done in two stages for 500 high risk infants admitted in newborn intensive care unit (NBICU) during the study period. First OAE test was done on the day of admission and 2nd test was done after one month. All the infants underwent Brainstem Evoked Response Audiometry (BERA) test, a month after the second OAE test. Data was analysed for efficacy of the tests.

RESULTS

First OAE was passed by 290 babies i.e. 58 % whereas 210 babies (42 %) showed a result of 'refer' in both the ears. Second OAE tests were done after 1 month which showed a result of 'pass' by 460 babies (92 %) and a 'refer' by 40 babies (8 %). All babies which underwent BERA 1 month after second OAE were included in the study; out of those babies, 10 babies showed impaired hearing and they were referred for further evaluation and intervention. In our study, OAE was 100 % sensitive in the first and second tests. Specificity of OAE was 59.1 % and 93.87 % in the first and second tests respectively. The study showed 2 % permanent congenital hearing impairment (PCHI).

CONCLUSIONS

OAE is an effective tool providing a quick, harmless and less expensive method for screening of hearing loss in infants, irrespective of comorbidities. No single test can detect all defects in the auditory pathway. As a primary option, a two-stage evaluation with OAE can easily detect infants who need further evaluation and early intervention. A two-stage screening with OAE will give a highly sensitive and reasonably specific test which can be easily implemented in all levels of the healthcare system.

KEYWORDS

High Risk Neonates, Hearing Impairment, OAE, BERA

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BACKGROUND

Hearing is one of the most important senses which acts as the basis for acquiring language and communication, which serves as the foundation of all forms of development. Hence hearing loss definitely limits an infant's access to spoken language. It should be diagnosed as early as possible after birth. Any delay in its detection will lead to damage and improper development and functioning of the central auditory pathway due to lack of its stimulation. Ideally, the diagnosis of hearing impairment must be made by 3 months of age and auditory intervention should begin before 6 months and surgery if needed at a later age. Infants with other congenital anomalies are at higher risk of developing hearing loss than normal infants. It is ideal for all high-risk babies to undergo auditory screening within the first 2 months of life, preferably before hospital discharge.

In most of the developed countries, routine new-born screening for hearing has been implemented with different outcome and varied success[1,2] but in India, there is no such dedicated program available for the same, especially in majority of the villages and semi urban areas. Studies in this field have shown that 4 out of every 1000 new-borns have got severe to profound hearing loss.[3] The prevalence of permanent congenital deafness is found to be 5 % in high risk new-borns and 0.5 % in well nursing babies.[4]

OAE and BERA are considered to be indirect objective measures of peripheral auditory status. OAEs are biological phenomena generated as mechanical activity in the outer hair cells of normal cochlea. OAEs were first confirmed, reported and brought into clinical use by David Kemp in 1978. Recording of sounds that are produced by outer hair cells of cochlea is done in OAE testing. Those sounds are small but potentially audible, and detected by microphones instead of electrodes. OAE based neonatal screening is used in most of the centers as it is a non-invasive, rapid, simple, easily repeatable and a low cost. BERA, which was first described by Jewett and Williston in 1971 is an objective electro-physiological test which studies the electrical potential generated at the various levels of the auditory system starting from cochlea to auditory area in cortex. The stimulus is either in the form of clicks or tone pips which are transmitted to the ear via a transducer placed in the insert earphone or headphone. The waves of impulses generated are recorded by the placing electrodes over the scalp. It does not require active conscious participation of the patient. It can be used to predict the approximate hearing threshold indirectly. Since BERA is an expensive test, it is not feasible for all neonates in our country.

We wanted to study the efficacy and role of two stage OAE screening for hearing impairment in high risk newborns.

METHODS

A prospective observational study was conducted in the Department of Otorhinolaryngology of Government Medical College Hospital, Thrissur, Kerala for a period of three years from July 2014 to June 2017. Sample size was calculated using the formula zα2 x pq / d.2 500 infants, who were admitted to New-Born Intensive Care Unit (NBICU) were included in the study. Informed consent was obtained from the parents of all babies.

Inclusion Criteria

Babies admitted to NBICU during the study period were evaluated. High risk neonates having risk factors like craniofacial abnormalities, low birth weight, preterm, low APGAR score, hyperbilirubinemia, family history of hearing loss, and intrauterine infections with TORCH were included in the study. Also included those who were in ventilator and having syndromes associated with sensory neural and conductive hearing loss.

Exclusion Criteria

Babies not coming under high risk group and the babies whose parents didn't give consent were excluded from our study. High risk neonates who died or lost follow up were later excluded from the study.

Parents were explained about the study, and written informed consent was taken. The demographic data and detailed clinical history were collected from them in a predesigned proforma. General, systemic and ENT examination findings were recorded.

Extrapolated Distortion Product OAE and Transient Evoked OAE were used for screening the infants to differentiate permanent childhood hearing impairment (PCHI) from the conductive hearing loss.

Infants were screened with OAE on admission. Retest with OAE was done a month later. All babies underwent a diagnostic BERA test after a month of second OAE. Babies with absent wave 5 at 40 dB were taken as 'refer' result. They were referred for further evaluation and intervention.

Statistical Analysis

A comparative assessment of the results of OAE screening tests and confirmatory BERA was done. The percentages of true positive (TP), true negative (TN), false positive (FP) and false negative (FN) were determined. This data was analysed to find the efficacy of OAE as a screening test.

RESULTS

In this study, two stage OAE screenings were conducted for babies admitted to NBICU with various neonatal problems. Among 500 infants, 54 % were males and 46 % were females. 2 % had family history of SNHL and 2 % had craniofacial anomalies. 56 % had very low birth weight (< 1500 g) and 44 % infants were born before 37 weeks (preterm). 290 babies (58 %) passed the first screening test. 210 babies (42 %) gave the result as 'refer' in both the ears.

The second OAE testing was conducted after 1 month in all 500 babies. 460 babies (92 %) passed and 40 babies (8 %) failed. BERA was done for all babies 1 month after the 2nd OAE test. 10 babies (2 %) showed impaired hearing and were referred for further evaluation and intervention and followed up for 1 year for confirmation of results.

Age of Baby	Frequency	Percent
0 - 7 days	170	34 %
8 - 14 days	140	28 %
15 - 21 days	115	23 %
22 - 28 days	75	15 %
Total	**500**	**100 %**

Table 1. Age Distribution

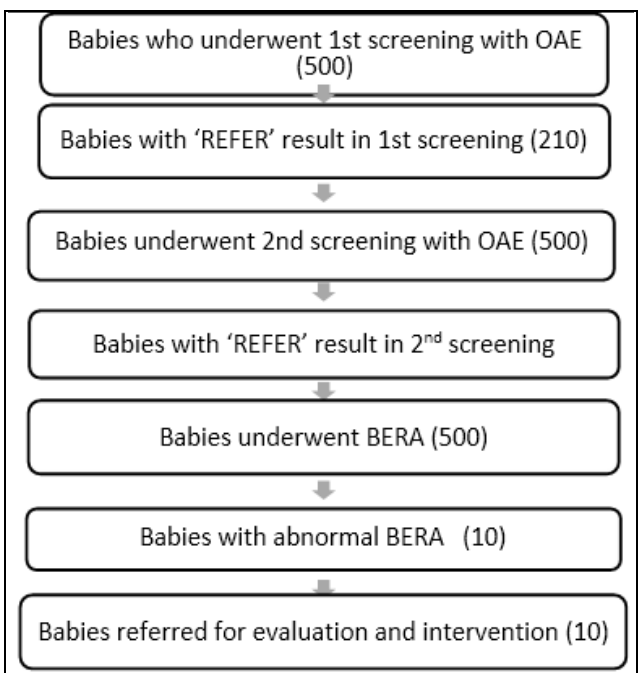

Figure 1. Algorithm of Present Study & Results

Taking BERA as a standard diagnostic tool, we analysed the sensitivity and specificity of OAE tests.

	BERA-Hearing Loss Detected	BERA Hearing Loss Not Detected	Total
OAE 1st month hearing loss detected	10 (TP)	200 (FP)	210
OAE 1st month hearing loss not detected	0 (FN)	290 (TN)	290
	10	490	500

Table 2. Efficacy of OAE 1 with BERA

Sensitivity = TP / (TP + FN) X 100 = 10 / 10 X 100 = 100 %.

Specificity = TN / (TN + FP) X 100 = 290 / 490 X 100 = 59.1 %.

	BERA-Hearing Loss Detected	BERA-Hearing Loss Not Detected	Total
OAE 2nd month hearing loss detected	10 (TP)	30 (FP)	40
OAE 2nd month hearing loss not detected	0 (FN)	460 (TN)	460
	10	490	500

Table 3. Efficacy of OAE 2 with BERA

Sensitivity = TP / (TP + FN) X100 = 10 / 10 X 100 = 100 %.

Specificity = TN / (TN + FP) X 100 = 460 / 490 X 100 = 93.8 %.

In our study OAE was 100 % sensitive in both the first and second sittings. Specificity of OAE was 59.1 % and 93.8 % in the first and second sittings respectively.

DISCUSSION

The basic aim of all the new-born screening tests for hearing is early identification of any degree of deafness, followed by proper support and care with intervention to develop children with good speech and mental status. An improved outcome for children with congenital hearing impairment is achieved by diagnosis, confirmation and intervention by six months of age.[5]

In 1994, the' Joint Committee of Infant Hearing' recommended that all infants with hearing loss should be identified before the age of three months and should receive intervention through interdisciplinary programmes by the age of 6 months.[6,7] This screening should include all live births, with special attention to babies born out of high risk pregnancies.

OAE and BERA are the two important diagnostic assessments tests used. The aim of most of the neonatal screening programmes are to ensure that any hearing impairment with a threshold level of at least 40 dB HL in the better ear.[8] PCHI is considered to be present when it exceeds 40dB.

In our hospital-based study, the proportion of PCHI in high risk babies was 2 %. After reviewing literature on the same, it is seen that the prevalence of PCHI varies widely such as 18 % by Chadha S, Bais AS[9] and 1 % by Nagapoornima P, Ramesh A, Srilakshmi, Rao S, Patricia PL, Gore M et al.[10] The higher incidence may be due to the screening with only one OAE test.

In a study by Bhatt, Jaideep, Kuchhal, Vabhav, Saklanii and Kapil et al, it was found that 5 % of the high risk babies had sensory or neural impairment and in well nursing babies it was 0.5 %.[11] It is comparable with our result, i.e. 2 % hearing loss in high risk group.

Another literature estimates 0.15 % - 0.6 % of the general new-born population to be born with congenital hearing loss.[12] This incidence is reported to be 10 to 20 times higher in the high-risk NICU population.[13] Schulman–Galambos & Galambos studied 325 children for 1 year or more after discharge from their intensive care nursery and found 8 children (2.14 %) with severe hearing loss.[14] Roberts JL, Davis H, Phon GL et al in a recent large follow up study could confirm hearing loss in only 2.3 % which is very close to our result.[15]

Taking BERA as a standard diagnostic tool, we analysed the sensitivity and specificity of OAE tests in the first and second attempts. In our study OAE was 100 % sensitive in both the first and second sittings. Specificity of OAE was 59.1 % and 93.87 % in the first and second sittings respectively.

In a study by Bhatt et al, it was found that sensitivity & specificity of OAE was 70 % and 61 % respectively at 0

months and 70 % and 99 % respectively at 3 months which is again comparable to our results.[11] A higher 'refer' rate obtained in the first OAE of our study may be explained by the presence of amniotic fluid or vernix in external ear or middle ear effusion. Norton S J et al compared the accuracy of click evoked BERA, TOAE and DPOAE in his multi center longitudinal study to predict hearing status in children of 8 to 12 months of age.[16] The results indicated no significant difference between the three measures.

Diane C. Thompson, Heather Mc Philips, Robert L. Davis et al in their analytical study 'Universal Newborn Hearing Screening-Summary of Evidence', states that this tests have got a significant role in identification of new-borns with profound hearing loss but the efficacy to improve long-term language outcomes remains uncertain.[17] This again supports our results regarding the importance of early identification of hearing loss by sequential screening.

The OAE can detect the presence of middle ear fluid, damage to the outer hair cells and external canal block. Transient Evoked OAE and Distortion Product OAE are the most common forms of OAE used in infant screening. The demerit of TEOAE which uses intensity signals of 80Db SPL or greater is that it is not frequency specific as the stimulus is broadband click. It is found that the failure rate is higher with OAEs (7 - 10 %) than BERA (less than 2 - 4 %) due to the sensitivity of OAEs to outer and middle ear problems.

Though BERA is the gold standard for screening hearing impairments in infants, it is not feasible for all centers in developing nations like ours. This is because it is expensive. But at the same time, every step must be taken to prevent or minimize disabilities in children.

Hearing impairment is the most prevalent deficit among all sensory deficits. As per the 58th round of National Sample Survey Organization in 2002, 291 persons per 100,000 population fell into the category of severe to profound deafness.[18] It was found in the survey that major group belongs to the age group of 0 - 14 years. The survey also revealed that congenital deafness constitutes about 7 %. If undetected in earlier period, it will lead to inadequate development of communicative skills, thus access to education and finally social isolation of the child. At the end of study, we suggest that a two stage OAE can be a cost-effective primary option for screening even in peripheral centers as a part of the National Program for Prevention and Control of Deafness (NPPCD).

CONCLUSIONS

OAE is an effective tool for quick, harmless and less expensive screening of hearing impairment in babies, irrespective of age and comorbidity. The best process for early identification of deafness is either universal screening or high-risk screening of neonates. Both do not exist in majority of the hospitals in our country. In such a situation, the two stage OAE test can be considered as a cost-effective primary option in all rural centers of India as a part of the NPPCD. BERA, which is more expensive and time consuming, is required for only a few selected babies, making the program more suitable for clinical workup.

Limitations

We could not examine all the infants admitted in the NBICU of our hospital. Larger studies are needed for further evaluation.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.
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