



Original Research Article

ROLE OF TWO STAGE OTOACOUSTIC EMISSION TEST FOR SCREENING OF HEARING ASSESSMENT IN HIGH RISK NEWBORNS AT TERTIARY CARE MEDICAL COLLEGE HOSPITAL

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ABSTRACT

Background: Hearing is one of the most important senses which acts as the basis for developing speech, language and communication, which serves as the foundation of all forms of development. Hearing is necessary to learn languages and speech and to develop cognitive skills. As hearing is important for normal educational and social development, hearing loss can be devastating. 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. Hearing status of a newborn can be assessed by two subsequent tests with Oto-Acoustic Emissions (OAE) followed by Brain stem Evoked Response Audiometry (BERA). So, this study is taken to know the efficacy and role of two stage Otoacoustic Emission (OAE) test for screening high risk new-borns to detect hearing impairment.

Aims and objective: is to evaluate the hearing of the newborns with two stage Otoacoustic emission test and access the outcome.

Materials and Methods: The present prospective observational study was conducted on 250 high risk infants admitted in neonatal intensive care unit (NICU). OAE screening was done in two stages, First OAE test was done on the day of admission and 2nd test was done after one month.

Results: First OAE was passed by 160 babies i.e. 64 % whereas 90 babies (36 %) showed a result of 'refer' in both the ears. Second OAE tests were done after 1 month which showed a result of 'pass' by 220 babies (88 %) and a 'refer' by 30 babies (12 %). All babies which underwent BERA 1 month after second OAE were included in the study; out of those babies, 5(2%) 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 65.3 % and 89.7 % in the first and second tests respectively.

Conclusion: The 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.

INTRODUCTION

Hearing is one of the important senses. Normal speech and language development depend upon a child's ability to hear spoken language. Early infancy is the most appropriate time for a child to acquire the foundation of language and communication. The most important period for language and speech development is generally regarded as the first three years of life. Early intervention by hearing rehabilitation contributes to positive outcomes in language development. Children undergoing hearing rehabilitation before 11 months of age have a stronger vocabulary and verbal reasoning skills at 5 years of age than those intervened later.^[1] Different studies have indicated that early identification followed by proper intervention as early as six months of age results in essentially normal language acquisition later on and minimizes the negative effects of hearing loss.^[2,3]

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.^[4,5] Studies in this field have shown that 4 out of every 1000 new-borns have got severe to profound hearing loss.^[6] The prevalence of permanent congenital deafness is found to be 5 % in high risk new-borns and 0.5 % in well nursing babies.^[7]

India launched the national programme for prevention and control of deafness in 2006. The implemented program uses a two-part protocol for screening infant hearing. Institution-based screening to screen every baby born in a hospital or admitted there soon after both using OAE. Those who fail the test are re-tested after 4 weeks. Those who fail the second screening are referred for ABR (auditory brainstem response) testing at the tertiary-level centres. Community-based screening involves screening newborns who are not born in hospitals. This screening is done through a brief questionnaire and behavioral testing. The screening is conducted when the baby attends immunization at six weeks of age and beyond. If any baby fails the screening, they are referred for formal OAE screening at the district hospital. If they fail OAE, they are then sent for ABR testing. Thomas et al found DPOAE to be an effective method for neonatal hearing screening.^[8]

It is important to note that many risk factors can potentially cause neonatal hearing loss: Intrauterine infections, known as TORCH infections, may include cytomegalovirus (CMV), herpes, rubella, syphilis, and toxoplasmosis. Craniofacial anomalies, including those involving the pinna, ear canal, ear

tags, ear pits, and temporal bone anomalies, may also be present. Hyperbilirubinemia requiring exchange transfusion or kernicterus, an APGAR score of less than four at one minute, or less than seven at five minutes, very low birth weight (VLBW) below 1.5 KG, and gestational age less than 32 weeks are additional risk factors for hearing loss. Manifestations of congenital anomalies or syndromes with hearing loss, such as Usher-refsum syndrome, fetal alcohol syndrome (FAS), Waardenburg syndrome, Alport syndrome, Pendred syndrome, and Jervell and Lange Nielsen syndrome, may also lead to hearing loss. Neurodegenerative disorders such as Hunter syndrome or sensory motor neuropathies such as Friedreich's ataxia and Charcot-Marie-Tooth syndrome, ventricular hemorrhage, respiratory distress requiring mechanical ventilation, faintly history of hearing loss, and medication use of ototoxic medications (mostly aminoglycoside antibiotics) are other factors that may cause hearing loss.^[9]

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 electrophysiological 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.

OAE is an effective tool providing a quick, harmless and less expensive method for screening of hearing loss in infants, irrespective of comorbidities. So, this study is taken to know the efficacy and role of two stage Otoacoustic Emission (OAE) test for screening high risk new-borns to detect hearing impairment.

MATERIALS AND METHODS

A prospective observational study was conducted in the Department of ENT, Gulbarga Institute of Medical Sciences, Kalaburagi for a period of 6months from July 2024 to Jan 2025. Sample size

was calculated using the formula $2\alpha \times p/q$ / d.2 250 infants, who were admitted to Neonatal Intensive Care Unit (NICU) were included in the study. Informed consent was obtained from the parents of all babies.

Inclusion Criteria

Babies admitted to NICU 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 NICU with various neonatal problems.

Among 250 infants, 56 % were males and 44 % were females. 2% had family history of SNHL and 2 % had craniofacial anomalies. 58% had very low birth weight (< 1500 g) and 42 % infants were born before 37 weeks (preterm). 160 babies (64 %) passed the first screening test. 90 babies (36 %) gave the result as 'refer' in both the ears.

The second OAE testing was conducted after 1 month in all 250 babies. 220 babies (88 %) passed and 30 babies (12 %) failed. BERA was done for all babies 1 month after the 2nd OAE test. 05 babies (2 %) showed impaired hearing and were referred for further evaluation and intervention and followed up for 1 year for confirmation of results.

Table 1: Age Distribution

Age of Baby	Frequency	Percent
0 - 7 days	88	35%
8 - 14 days	67	27%
15 - 21 days	55	22%
22 - 28 days	40	16%
Total	250	100 %

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

Table 2: Efficacy of OAE 1 with BERA

	BERA-Hearing Loss Detected	BERA Hearing Loss Not Detected	Total
OAE 1st month hearing loss detected	5(TP)	85(FP)	90
OAE 1st month hearing loss not detected	0(FN)	160(TN)	160
	05	245	250

Sensitivity = $TP / (TP + FN) \times 100 = 05 / 05 \times 100 = 100 \%$.

Specificity = $TN / (TN + FP) \times 100 = 160 / 245 \times 100 = 65.3 \%$.

Table 3: Efficacy of OAE 2 with BERA

	BERA-Hearing Loss Detected	BERA-Hearing Loss Not Detected	Total
OAE 2nd month hearing loss detected	5(TP)	25(FP)	30
OAE 2nd month hearing loss not detected	0(FN)	220(TN)	220
	5	245	250

Sensitivity = $TP / (TP + FN) \times 100 = 05 / 05 \times 100 = 100\%$.

Specificity = $TN / (TN + FP) \times 100 = 220 / 245 \times 100 = 89.7\%$.

In our study OAE was 100 % sensitive in both the first and second sittings. Specificity of OAE was 65.3% and 89.7 % 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 AS⁹ 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, Saklani 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 65.3 % and 89.7 % 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).

CONCLUSION

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.

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