Journal of Cardiovascular Disease Research

ISSN: 0975-3583,0976-2833 VOL13, ISSUE 10, 2022

STUDY OF NEWBORN HEARING SCREENING BY TRANSIENT EVOKED OTOACOUSTIC EMISSION TEST AT A TERTIARY HOSPITAL

Parag Mahankar[1], Nisha Deshpande[2], Disha Padalkar[3], Priyanka Badjate[4]

[1]Assistant Professor, Department of Pediatrics, Bharati vidyapeeth Medical College and Hospital, Pune, India.
[2]Consultant, Department of Pediatrics, Jupiter Hospital, Pune, India.
[3]Assistant Professor, Department of Pediatrics, Bharati vidyapeeth Medical College and Hospital, Pune, India.
[4]Associate Professor, Department of Pediatrics, Bharati vidyapeeth Medical College and Hospital, Pune, India.

Received Date: 15/09/2022 Acceptance Date: 12/11/2022

Corresponding Author: Dr Priyanka Badjate, Associate Professor, Department of Pediatrics, Bharati vidyapeeth Medical College and Hospital, Pune, India.
Email: dr.priyanka_b@yahoo.com

Abstract

Background: Congenital bilateral hearing impairment occurs in approximately 1 to 5 per 1000 live births and when permanent unilateral hearing loss is included, the incidence increases to 8 per 1000 live births. Present study was aimed to study newborn hearing screening by transient evoked otoacoustic emission test at a tertiary hospital. **Material and Methods:** Present study was single-center, prospective observational study, conducted in newborns (with or without risk factors for hearing impairment) born at our hospital. Handheld TEOAE device, Inter-Acoustic-EP-15 TEOAE, manufactured by Eclipse was used for Initial Screening and First Follow-Up Screening. **Results:** In present study, out of 734 newborns, 449 (59.9%) were males and 294 (40.1%) were females. 667 (90.87%) were in the "no risk" group and 67 (9.12%) were in the high-risk group. Among 734 newborns, 2 were confirmed to have hearing loss by AABR. The incidence of hearing impairment in this study is 2.7 per 1000 newborns with a 95% confidence interval between -0.74 to 1.28. 0.27% of newborns failed the 2 staged screening tests by TEOAE. This 0.27 % was confirmed to be hearing impaired with AABR. Considering all the limitations of the test, in the present study the sensitivity of TEOAE was found to be 75% and the specificity was 100%. The accuracy of TEOAE was found to be 15%. **Conclusion:** In present study, incidence of hearing impairment of 2.7 /1000 screened, with incidence of 29.8/1000 in at risk group, warrant implementation of neonatal hearing screening in India.

Keywords: newborn hearing screening, transient evoked otoacoustic emission test, hearing impairment, AABR

Introduction

Hearing impairment is a condition wherein the ability to detect certain frequencies of sound is completely or partially impaired.[1] The ability to hear during the early years of life is critical for development of speech, language, and cognition. Congenital bilateral hearing impairment occurs in approximately 1 to 5 per 1000 live births and when permanent unilateral hearing loss is included, the incidence increases to 8 per 1000 live births. [2,3]

ISSN: 0975-3583,0976-2833 VOL13, ISSUE 10, 2022

Early identification and intervention in an infant with hearing impairment can prevent severe psychological, educational, and linguistic repercussions. Intervention at or before six months of age allows a child with impaired hearing to develop normal speech and language, alongside his or her hearing peers.[4]

Various diagnostic modalities are available for diagnosis of hearing loss like Otoacoustic emissions (OAE), tympanometry and automated auditory brainstem response (AABR).[4] The current protocol recommended by Joint Committee on Infant Hearing (JCIH) in their Position statement 2000 is defined as universal screening with objective technology by 1 month of age, identification by 3 months of age, and intervention by 6 months of age.[5] India being a developing country, it is very important to screen maximum number of neonates for hearing loss and give them treatment at the earliest for the better development for future of the child and the country. Present study was aimed to study newborn hearing screening by transient evoked otoacoustic emission test at a tertiary hospital

Material And Methods

Present study was single-center, prospective observational study, conducted in department of paediatrics & neonatology, at Aditya Birla Memorial Hospital, Pune, India. Study duration was of 19 months (1st January 2014 to 31st July 2015). Study approval was obtained from institutional ethical committee.

All newborns (with or without risk factors for hearing impairment) born at our hospital during the study period, parents willing to participate in present study were considered in present study. There were no exclusion criteria in present study. All newborn babies born in our hospital were enrolled into the study with prior informed consent obtained from the parents. The enrolled subjects were grouped into ‘at risk’ and ‘not at risk’ group based on the presence or absence of the risk factors included in the ‘HRR’ of JCIH 2007 respectively.[6]

Study was conducted in a noiseless environment, on a sleeping baby after ensuring no obstruction in external auditory canal. All subjects underwent the audiological tests as per the Screening-Rescreening Protocol.

The study protocol was carried out in three steps.

1. Initial Screening- All newborns enrolled in the study were screened by TEOAE within first 3 days of life / as soon as the babies were fit enough to undergo the test in case of very sick babies.
2. First follow-up screening was done at 4 to 6 weeks of age by TEOAE for-
   I. All babies of “At risk” group
   II. Babies of “No risk” group who failed the first test screening (‘refer’ category)
2. Second follow-up screening was done at 3 months age to confirm the hearing impairment by AABR test for
   I. All babies of “At risk” group
   II. Babies of “No risk” group who failed the first follow-up screening (‘refer’ category)

Handheld TEOAE device, Inter-Acoustic-EP-15 TEOAE, manufactured by Eclipse was used for Initial Screening and First Follow-Up Screening. The AccuScreen OAE detection scheme is based upon signal statistical analysis which guarantees high specificity and sensitivity, with minimal impact of background noise and recording conditions. It has a clinical sensitivity of more than 99%, without requiring decisions or equipment adjustment by the user. It has a TEOAE testing frequency range from 1.4 to 4 kHz. Sound stimulus is by non- linear click sequence with stimulus level 45-60 dB hearing loss.

ISSN: 0975-3583,0976-2833 VOL13, ISSUE 10, 2022

The display shows statistical waveforms, measurement progress, TEOAE detection level, noise level, and the results- PASS or REFER. PASS, determined by statistical algorithm, based on binomial statistics, indicates that the patient has normal outer cell function at the time of testing. A REFER result suggests a possibility of a sensorineural hearing loss or indicates the requirement of further diagnostic hearing evaluation. It also shows 'A' (artificial reject) and 'S' (stimulus stability) values where in, the 'A' value greater than 20%, indicates a noisy test and ear probe mal-position. When test result shows an 'A' value of > 20% and 'S' value of < 80%, a repeat test is advocated.

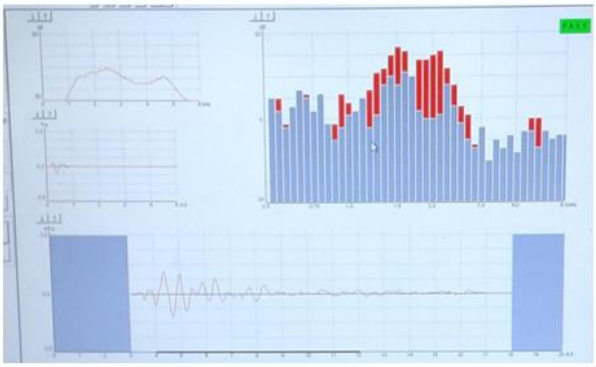

Figure 1: Display of result – Pass;

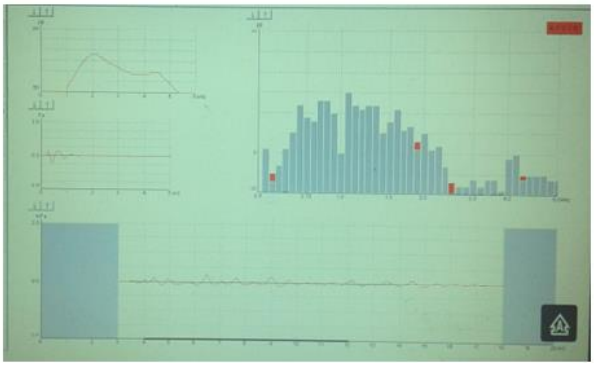

Figure 2: Display of result- Refer

The OAE screening conducted in a quiet environment with the baby in mother's lap or lying comfortably on a bed, ideally in sleeping state. Probe tip of sizes varying from 4 mm to 12 mm were used for different neonates to obtain an adequate seal. A suitable probe tip was selected and coupled to the OAE probe. The same was inserted sufficiently deep in to the ear canal to ensure a good seal in the ear canal

All infants who failed the 'second follow-up screening' were referred to audiologist for detailed evaluation and early intervention. As per JCIH 2007 Position Statement, separate protocols are recommended for NICU and well-infant nurseries. NICU infants admitted for more than 5 days are to have AABR included as part of their screening so that neural hearing loss will not be missed.[6] Hence as a part of clinical care, babies from "at risk" group who were referred on initial screening were screened by AABR at 3 months of age or at the time of neurodevelopmental assessment follow up irrespective of their status on 1st screening.

The results of audiological evaluation were recorded in a standardized proforma. Data was collected and compiled using Microsoft Excel, analyzed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi-square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

Results

In present study, out of 734 newborns, 449 (59.9%) were males and 294 (40.1%) were females. According to JCIH 2007, birth weight < 1.5 kg is one of the risk factors for hearing impairment. Out of the study sample of 734, 42 babies i.e. 5.8% weighed < 1.5 kg. Out of these neonates, 2 failed 2nd TEOAE test and were confirmed to have hearing impairment by BERA. 29 newborns had gestational age of < 34 weeks; 51 newborns were between 34 to 37 weeks of gestational age. 2 neonates with gestational age of < 34 weeks were observed to have hearing impairment. In our study group, 734 newborns were screened, out of which 667

ISSN: 0975-3583,0976-2833 VOL13, ISSUE 10, 2022

(90.87%) were in the "no risk" group and 67 (9.12%) were in the high-risk group.

Table 1: General characteristics

Characteristics	No of cases	Percentage
Gender		
Male	440	59.9
Female	294	40.1
Birth weight (Kg)		
>1.5	692	94.2
≤ 1.5	42	5.8
GA (weeks)		
Full term	654	89.1
34-<37	51	6.9
<34	29	4
Risk factors		
Present	67	9.12
Absent	667	90.87

Distribution of risk factors in our study among "at risk" babies was as follows- family history of hearing loss (2.98%), history of intrauterine infection (13.43%), craniofacial abnormalities (19.4%), hyperbilirubinemia of exchange level (8.95%), culture positive postnatal infection (17.91%), and birth asphyxia (50.74%). There were 36 neonates who had more than 1 risk factor according to JCIH.

Table 2: Assessment of risk factors

Risk factors*	No of cases	Percentage (n=67)	Percentage (n=734)
Family H/O hearing loss	2	2.98	0.27
H/O in utero infection	9	13.43	1.23
Craniofacial anomalies	13	19.4	1.77
Hyperbilirubinemia exchange level	6	8.95	0.82
Culture positive postnatal infection	12	17.91	1.63
Birth asphyxia (APGAR at 1 min<4/ 5min <6)	34	50.74	4.63
NICU stay >5day/mechanical ventilation/ birth weight <1.5/ ototoxic medication	50	74.62	6.81

*Some of the newborns had more than one risk factors.

In the study, 13 infants had craniofacial anomalies. Among them 4 newborns had cleft lip, 1 infant had congenital cataract and 8 newborns had abnormal ear feature in the form of preauricular ear tag or sinus. None of these failed the hearing screening test.

Table 3: Craniofacial anomalies wise distribution of cases in study group

Craniofacial anomalies	No of cases	Percentage
Cleft lip and cleft palate	4	0.5
Abnormal eye features	1	0.1
Abnormal ear features	8	1.1
No anomalies	721	98.2

In the 1st screening, out of 734 newborns, total 44 newborn babies did not PASS the initial screening test, so, accordingly referral rate was 5.99% and passing rate was 94.01%. Of the 44 who failed, 12 belonged to "at risk" group and 32 were of "no risk" group. The referral rate in "at risk" neonates was 17.91% and that in "no risk" neonates was 4.79% at the

ISSN: 0975-3583,0976-2833 VOL13, ISSUE 10, 2022

end of 1st stage TEOAE.

Among "at risk" group, there were 2 deaths and 2 were lost to follow up. So, we could screen only 40 newborns at 1st follow up by TEOAE i.e. 2nd screening test. In 1st follow up TEOAE, 32 normal newborns and 8 high risk newborns were screened. All "no risk" neonates passed the 2nd TEOAE. Among "at risk", 6 passed the test and 2 were referred. Among the "at risk" group though whole group was subjected to TEOAE screening for 2nd time, no failures were found among the infants who had already passed the initial screening. The referral rate in first follow-up screening (end of 2 staged TEOAE) was 0.27% of the total study cohort, with 2.98% referral rate among the "at risk" group and 0% referral among the "no risk" group.

The 2nd follow-up screening which was done to confirm hearing deficit using AABR showed 2 neonates with hearing impairment among the total study population of 734. Here again though whole of 'at risk' group was subjected to AABR, no failures were found among the infants who had already passed the TEOAE (Flow Chart 2). These 2 newborns had risk factors for hearing loss as per JCIH.

Table 4: Result of screening protocol

	Total Number Screened	**Refer In 1st Screening (Refer Rate)**	**Refer In 2nd Screening (Refer Rate)**	**Confirmatory test (BERA)**	**Incidence Of Hearing Impaired**
TOTAL SCREENED	734	44(5.99%)	2(0.27%)	2(0.27%)	2.7 per 1000
AT RISK	67	12(17.91%)	2(2.98%)	2(2.98%)	29.8 per 1000
NO RISK	667	32(4.79%)	0	0	0

*2 cases were lost to follow up and 2 cases died from "at risk" group

Among 734 newborns, 2 were confirmed to have hearing loss by AABR. The incidence of hearing impairment in this study is 2.7 per 1000 newborns with a 95% confidence interval between -0.74 to 1.28. 0.27% of newborns failed the 2 staged screening tests by TEOAE. This 0.27 % was confirmed to be hearing impaired with AABR.

Total 67 at risk newborns were screened. Among them 2 were detected to have hearing impairment by BERA. The incidence of hearing loss in newborns with risk factors was observed to be 29 per 1000 newborns. 95% of confidence interval is between -0.37 to 6.17. 29.8% of newborns failed the 2 staged screening tests by TEOAE. All these newborns were confirmed to have hearing loss later by AABR. Not a single newborn in the no risk group was found to have hearing loss.

Table 5: Incidence of hearing impairment in the study

Children Screened	**Incidence in the cohort**	**Incidence expressed /1000 screened**	**95% confidence interval per 1000 screened**
Total screened	2/734	2.7	-0.74 to 1.28
At risk screened	2/67	29.8	-0.37 to 6.17

Discussion

Hearing loss is an etiologically heterogeneous trait with many known genetic and environmental causes.[7] The identification, assessment and management of hearing impairment in the pediatric population can be a challenging endeavor. Nevertheless, newer technology, improved techniques, and the cooperative efforts of various professional organizations and their constituencies have made significant strides towards achieving this goal.

ISSN: 0975-3583,0976-2833 VOL13, ISSUE 10, 2022

As more precise objective technologies are introduced, there will be a tendency to rely more heavily on their application. OAEs have already made significant impact in pediatric practices because of their ease and simplicity. Within a short period of time, trained technical staff can become proficient in their usage and test interpretation.[8]

In this study, a total of 734 newborns were screened by TEOAE, out of which 667 were normal newborns and 67 were high risk newborns. Of these 440 (59.9%) were males and 294 (40.1%) were females. REFER result after the 2nd test of TEOAE was seen in 2 newborns belonging to high-risk group. These 2 newborns were confirmed to have hearing loss by AABR at 3 months of age. The incidence of hearing impairment in total study group was 2.7 per 1000 newborns.

In the study by P. Nagapoornima, incidence of hearing impairment was reported to be 5.6/1000.[9] Abraham K Paul carried out hearing screening by two staged OAE followed by AABR for confirmation in 10,165 newborns over the period of 7 years. 19.98% newborns were from high-risk group and 80.02% were without risk factors. The incidence of hearing loss was 10.3 per 1000 in the high-risk group and 0.98 per 1000 in the no risk group.[10] John Jewel *et al.*,[11] noted that 4 out of 1000 were detected with hearing loss.[11]

Ann Marry Augustine *et al.*,[12] carried out two stage sequential screening using the BERA, estimated prevalence of hearing loss among neonates in this study was 4.1 per 1000 babies screened. The distribution of risk factors in the newborns referred in this study groups was- family history of hearing loss (8.6%), H/o in utero infection (10.3%), Family H/o craniofacial anomalies (3.4%), Hyperbilirubinemia (> 20mg/dL) (5.2%), Very low birth weight <1500g (5.2%), prematurity (gestation <37weeks) (10.3%), Low Apgar score ≤4 at 1 min or ≤6 at 5 min) (3.4%), Mechanical ventilation (> 5 days) 1 (1.7%).[12]

The proportion of at-risk newborns ranges from 15.78%[9] to 24.75% [12] whereas the proportion of at-risk babies in the current study (9.12%) is lower than these studies. The distribution of at-risk babies according to various risk factors is uniformly lower than these studies. This low incidence rate could probably be explained by small number of sample size and lesser proportion of at-risk babies in this study. The different levels of quality of postnatal/neonatal care in the high-risk newborns in different tertiary care NICU set ups, awareness and avoidance of ototoxic medications in NICU and different socioeconomic status of study population as compared to population in other studies could also have contributed to the lower incidence in this study.

The referral rate in the current study in 1st screening test was 5.29% and 0.27% in the 2nd screening and confirmed hearing impairment of 0.27% in 2nd follow up by AABR. This shows false positive result of 95.2% by single TEOAE and 100% with 2nd screening TEOAE. This shows the importance of two-staged TEOAE screening followed by confirmatory BERA in reducing the unnecessary intervention and parental alarm and concern.

In 2006, India launched the National Program for prevention and Control of Deafness.[13] This program is currently running in over 192 districts of the country and its aim is to identify babies with severe-profound hearing loss by 6 months of age and initiate rehabilitation by 9 months of age.

It is necessary and high time to implement and incorporate universal neonatal screening in our country to secure normal, social and holistic development of the child by detecting hearing loss at birth and providing remedial services at the earliest. A child who receives early interventions for hearing loss requires less expensive special education in later part of life and has better chance to have a normal social life and improved quality of life.

All the high-risk infants are under constant follow-up at high-risk neonatal clinic and audiologist with the aim of early intervention and appropriate care. Considering all the

ISSN: 0975-3583,0976-2833 VOL13, ISSUE 10, 2022

limitations of the test, in the present study the sensitivity of TEOAE was found to be 75% and the specificity was 100%. The accuracy of TEOAE was found to be 15%.

OAE is cost effective and an easy-to-use screening tool. Thus, it is necessary to implement hearing screening in all newborns, but it is of utmost importance in those exposed to high risk factors. All infants with confirmed permanent hearing loss should receive early intervention services as soon as possible after diagnosis but preferably within 6 months of age. Appropriate interdisciplinary intervention program for infants with hearing loss and their families should be provided by professionals who are knowledgeable about childhood hearing loss. Continued assessment of communication development should be provided by appropriate professionals to all children with or without risk indicators for hearing loss.

Limitations of present study were small sample size of the study; multiple follow ups are required since OAE needs to be conducted twice before the patient is referred for AABR which is considered to be the confirmative test. This adds to poor compliance. OAE is an inefficient tool for the diagnosis of neural dysfunction. Thus, neural conduction disorders or auditory neuropathy/ dys-synchrony without concomitant sensory dysfunction cannot be detected by OAE testing. Excessive debris in the ear canal and middle ear fluid, and cochlear hearing loss greater than 25-30 dB can affect the results of OAE.

Conclusion

In present study, incidence of hearing impairment of 2.7 /1000 screened, with incidence of 29.8/1000 in at risk group, warrant implementation of neonatal hearing screening in India. Two–stage TEOAE hearing screening can be successfully implemented as a newborn hearing screening method for early detection of hearing impaired on a large scale in hospitals to achieve high quality standard of screening programs.

Conflict of Interest: None to declare
Source of funding: Nil

References

1. Jane ES, Jeffrey WS. Hearing loss in neonatal intensive care unit graduates. In: John PC, Eric CE, Ann RS eds. Manual lf Neonatal Care. 6th Philadelphia: Lippencatt William and Wilkis: 2008.p.644-647.
2. Mehra S, Eavey RD, Keamy DG. The epidemiology of hearing impairment in the United States: newborns, children, and adolescents. Otolaryngology-Head and Neck Surgery. 2009 Apr 30; 140(4):461-72.
3. Stach BA, Ramachandran VS, Madell JR, Flexer C. Hearing disorders in children. Pediatric audiology: Diagnosis, technology, and management. 2008:3-12.
4. World Health Organization, The World Bank. World Report on Disability. Available from www.who.int/disabilities/world_report/2011/report.pdf. Accessed January 05,2014.
5. JCIH. Year 2000 Position Statement: principles and guidelines for early hearing detection and intervention programs. Joint Committee on Infant Hearing., American Academy of Audiology, American Academy of Pediatrics, American Speech- Language – Hearing-Association and Directors of Speech and Hearing Programs in State Health and Welfare Agencies. Pediatrics. 2000; 106(4): 798-81.
6. American Academy of Pediatrics. Year 2007 position statement: principles and guidelines for early hearing detection and intervention programs. Pediatrics. 2007 Oct; 120(4):898.
7. Nance WE. The genetics of deafness. Mental Retardation and Developmental Disabilities Research Reviews. 2003; 9(2):109–119.
8. Jacobson J, Jacobson C. Evaluation of hearing loss in infants and young children.

ISSN: 0975-3583,0976-2833 VOL13, ISSUE 10, 2022

Pediatric Annals. 2004 Dec 1; 33(12):811–821.
9. Nagapoornima P, Ramesh A, Srilakshmi, Rao S, Patrica PL, Gore *et al.* Universal Hwearing Screening. Indian J Pediatrics 2007; 74: 545-9.
10. Paul AK. Early identification of hearing loss and centralized newborn hearing screening facility-the Cochin experience. Indian pediatrics. 2011 May 1;48(5):355-9.
11. John Jewel, P. V. Vargese, Tejinder Singh, AshishVargeseNewborn Hearing Screening—Experience at a Tertiary Hospital in Northwest India.International Journal of Otolaryngology and Head & Neck Surgery, 2013; : 211-214.
12. Ann Augustine, Atanu Jana, Kurein Kuruvilla *et al.* Neonatal Hearing Screening – Experience from a Tertiary Care Hospital. Indian Pediatrics 2014; 51: 179-183.
13. World Health Organization. Newborn and infant hearing screening. Current issues and guiding principles for action. Available from http://www.whoint/blindness/publications/Newbornand InfantHeraing ScreeningReport.pdf. Accessed on December 06, 2013.