

FEASIBILITY OF TWO STAGED NEWBORN HEARING SCREENING AND IDENTIFICATION OF RISK FACTORS FOR HEARING LOSS OTHER THAN THOSE INCLUDED IN HIGH RISK REGISTRY (HRR) GIVEN BY JOINT COMMITTEE ON INFANT HEARING (JCIH)

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ABSTRACT

Background: Hearing impairment in neonates is a hidden disability, which is usually detected around 2 years of age. Crucial speech and language development begins during first six months of life. Undetected hearing loss present from an early age can impede acquisition of speech language, communication, cognitive and social-emotional development of a child. Across the globe, there is an evolving consensus that all infants should be screened for hearing impairment and appropriate interventions should be instituted in those found to have the problem by six months of age. Most developed countries have introduced mandatory screening and interventional programme with strategies appropriate for their public health concerns. Unfortunately, in developing countries, due to the paucity of resources, infant hearing screening programme has not been introduced as national programme. There have been very few large scale hearing screening studies done in India, to know the feasibility of universal hearing screening or high risk neonate hearing screening. The present study is taken to fill in the lacune in this aspect.

Aims & Objective: To study the feasibility of using two staged Transient Evoked Otoacoustic Emissions (TEOAE) followed by confirmation with Auditory Brainstem Response (ABR) in hearing screening of newborns along with an attempt to identify additional risk factors, other than those included in "High Risk Registry (HRR)" given by Joint Committee on Infant Hearing (JCIH) in 2007.

Material and Methods: A prospective observational study of hearing impairment screening was conducted on 800 newborns, who were screened with two staged Transient Evoked Otoacoustic Emissions TEOAE, using handheld TEOAE device, followed by confirmation with Auditory Brainstem Response (ABR). The study was done in Command Hospital Air Force, Bangalore, during Jan 2010 to May 2011, where in all new born, born during the study period were screened, which included 757 healthy neonates and remaining 43 high risk neonates as per HRR of JCIH 2007. Additional risk factors that could affect the hearing in the normal neonates was also studied.

Results: At the end of the two TEOAE tests, 15 (1.8%) neonates of the 800 cohort screened were suspected of hearing impairment and referred for ABR test. Sensorineural hearing loss was confirmed by ABR in 5 (0.6%) of those 15 referred, with a 1.2% false positive rate at the end of 2nd TEOAE. 2 of the hearing impaired infants belonged to "at risk group" neonates with remaining 3 not having any risk factor as per "High Risk Registry (HRR)" of Joint Committee on Infant Hearing (JCIH). This study showed the presence of medical conditions like maternal Urinary Tract Infection (UTI), Gestational Diabetes Mellitus (GDM) or maternal Diabetes Mellitus (DM) and Pregnancy Induced Hypertension (PIH) along with the well-known risk factors of HRR in the infants with hearing loss. But a strong association between these maternal conditions and hearing impairment could not be established due to small sample size, warranting a detailed study of these other possible risk factor.

Conclusion: This study has shown that two-stage hearing screening with TEOAE & ABR is a feasible method that can be successfully implemented for newborn hearing screening, for early detection of hearing impaired, on a large scale, in hospital, to achieve the high quality standard of screening programs. 3 of the 5 hearing impaired detected in the study had no known risk factor for hearing loss, advocating universal hearing screening and an extensive efforts are required to find additional risk factors that can be included in the HRR of JCIH so as to make high risk screening more effective.

Key-Words: Neonate; Universal Hearing Screening; Joint Committee on Infant Hearing; Transient Evoked Otoacoustic Emissions

Introduction

Neonatal medicine has advanced by leaps and bounds with advent of modern technology and application science. The focus of modern newborn care is not mere survival of preterm and critically ill neonate but an intellectual outcome with a qualitative life, which can be achieved by identify and treat the hidden morbidities such as hearing loss with screening methods. Hearing loss is a multifaceted condition with profound medical, social, and cultural

ramifications. It is the most prevalent disability across nations often referred to as the hidden disability.^[1] Deafness is one of the most common congenital anomaly in the newborn. Incidence of congenital sensorineural hearing loss (SNHL), averages approximately 3/1000.^[2,3] In India, 4 out of every 1000 children born are found to have severe, to profound hearing loss.^[4]

Though most developed countries have accepted hearing impairment as a major public health problem and have

introduced mandatory screening and interventional programme, there is a huge lacuna in implementation of hearing screening methods in developing nations due to lack of sensitization towards the magnanimity of problem or due to fear of applicability and feasibility of the study in resource poor health care setup. The study was undertaken to know the feasibility of two staged hearing screening method in finding the incidence of hearing impairment in newborns and its applicability for early diagnosis of hearing impaired, in addition to identifying risk factors not enlisted in HRR of JCIH.

Materials and Methods

All newborn babies born in Command Hospital Air Force, Bangalore [CHAF (B)], were enrolled into the study during the study period of Jan 2010 to May 2011, with prior informed verbal consent obtained from the parents. The enrolled subjects were grouped into 'at risk' and 'no risk' group based on the presence or absence of the risk factors included in the 'HRR' of JCIH 2007 respectively.^[5]

The Risk indicators included: (i) Family history of permanent childhood hearing loss. (ii) Neonatal intensive care of more than 5 days or any of the following regardless of length of stay: Extracorporeal Membrane Oxygenation (ECMO) therapy, assisted ventilation, exposure to ototoxic medications or loop diuretics and hyperbilirubinemia that requires exchange transfusion. (iii) In utero infections, such as Cytomegalovirus (CMV), herpes, rubella, syphilis, and toxoplasmosis. (iv) Craniofacial anomalies, including those that involve the pinna, ear canal, ear tags, ear pits, and temporal bone anomalies. (v) Physical findings, such as white forelock, that is associated with a syndrome known to include a sensorineural or permanent conductive hearing loss. (vi) Culture-positive postnatal infections associated with sensorineural hearing loss, including confirmed bacterial and viral (especially herpes viruses and varicella) meningitis. (vii) Head trauma, especially basal skull/temporal bone fracture that requires hospitalization.

Technique and Tool - Handheld TEOAE device, "MADSEN AccuScreen PRO" OAE Screener, manufactured by Fischer-Zoth Diagnosesysteme GmbH, Germany, was used in Initial Screening and First Follow-Up Screening. It has a clinical sensitivity of more than 99%, without requiring decisions or equipment adjustment by the user. Sound stimulus is by non-linear click sequence with stimulus level 45-60 dB HL and TEOAE testing frequency range from 1.4 to 4 kHz. Evaluation of results is by AccuScreen binomial statistics and the results are displayed as 'PASS' - , indicating that the

patient has normal outer hair cell function, and 'REFER'- suggest a possibility of a sensorineural hearing loss or indicates requirement of further diagnostic hearing evaluation. Study was conducted in a noiseless environment, on a sleeping baby after ensuring no obstruction in external auditory canal. Two-stage protocol of OAE and ABR was used to improve positive predictive value of the screening programme, as the refer rates at time of hospital discharge from such programs were reported to be much lower than those in programs that used just OAE screening.^[6] All subjects underwent the audiology tests as per the Screening-Rescreening Protocol and hearing deficit confirmed with ABR. (figure 1).

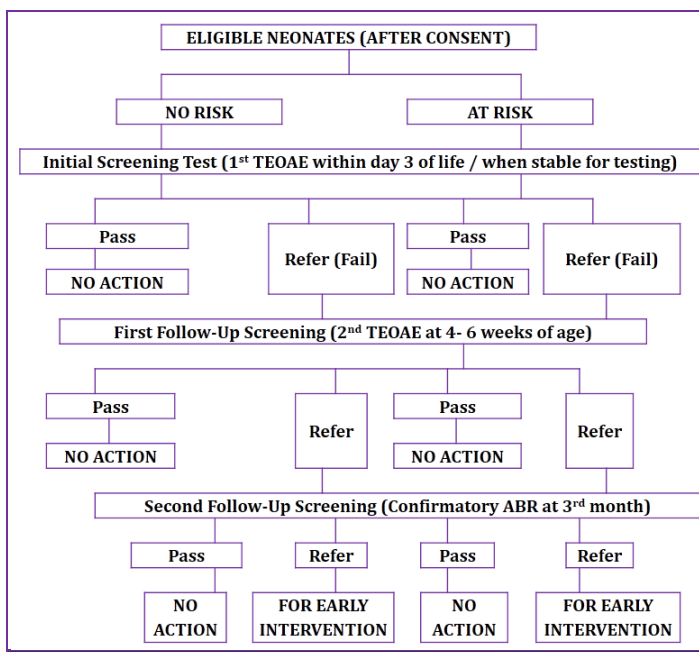


Figure-1: Screening and re-screening protocol

Screening / Re-screening Protocol: The study protocol was carried out in three steps. (1) Initial screening (1st TEOAE): All newborns enrolled into 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 (2nd TEOAE) was done at 4 to 6 weeks of age by TEOAE for: (a) All babies of "At risk" group; (b) Babies of "No risk" group who failed the first test screening ('refer' category). (3) Second follow-up (confirmatory ABR) was done at 3 months age to confirm the hearing impairment by ABR/ BERA test for: (a) All babies of "At risk" group; (b) Babies of "No risk" group who failed the first follow-up screening ('refer' category).

In addition antenatal and perinatal factors and events that could have influenced the hearing impairment in the "no risk group" was looked for to find any association with the hearing impairment.

Study protocol was approved by the ethical committee of our institution. The results of audiology evaluation were

recorded in a standardized pro-forma. The data was entered into Microsoft Excel and analyzed using S.P.S.S package version 12.0.

Results

A total of 800 neonates were included into the study, of which 43 had risk factors for hearing impairment as per 'HRR' of as JCIH 2007 ("at risk group"). Results at different stages of the study are show in Table 1 and Figure 2. In the initial screening (end of 1st TEOAE) 93 of the 800 study cohort, failed the initial TEOAE test, accounting to an 11.6% positive for hearing impairment. (Table 1 & Figure 2). In the 1st follow-up screening (end of 2nd TEOAE) 15 neonates failed TEOAE with 1.8 % testing positive for hearing impairment. (Table 1 & Figure 2). Of the 15 neonates who were suspected to be hearing impaired at end of two staged TEOAE only 5 were confirmed to be hearing impaired by ABR on 2nd follow up evaluation, decreasing the hearing impairment of cohort to 0.62%.

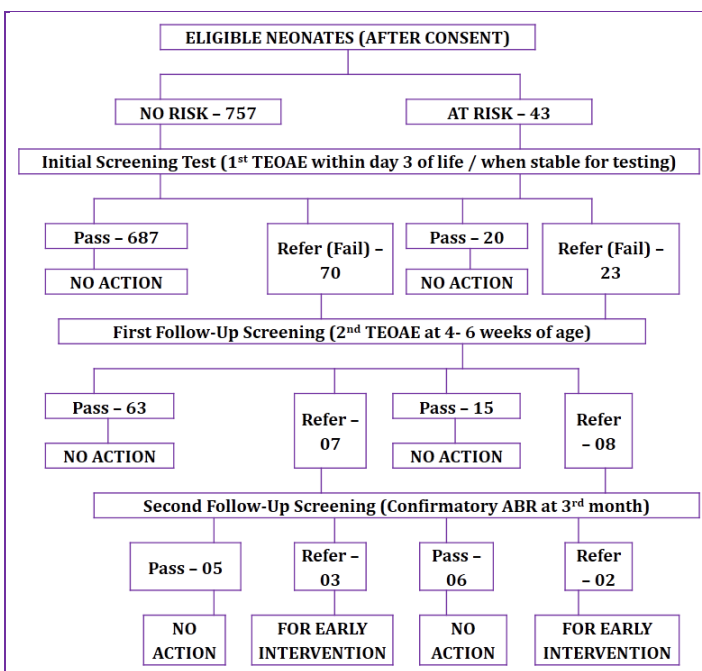


Figure-2: Results of screening and re-screening

Table-1: Result of Screening Protocol

	Screened	Test 1*	Test 2**	Test 3***	Incidence of Hearing Impaired
Total	800	93 (11.6%)	15 (1.875 %)	05 (0.62 %)	6.25/1000
At Risk	43	23 (53.4%)	08 (18.6%)	02 (4.6 %)	46.5/1000
No Risk	757	70 (9.2%)	07(0.92%)	03 (0.3 %)	3.96/1000

* Test 1: Test Positive for hearing loss in Initial Screening (1st TEOAE); ** Test 2: Test Positive for hearing loss in 1st Follow-up Screening (2nd TEOAE); *** Test 3: Confirmed positive by ABR in 2nd Follow-Up Screening (True positive)

Table-2: Incidence of Hearing Impaired

	Screened	Incidence in the Cohort	Incidence Expressed /1000 screened	95% CI
Total Screened		5 / 800	6.25	4.28 - 11.62
At Risk		2 / 43	46.5	2.01 - 4.66
No Risk		3 / 757	3.96	1.96 - 10.32

Table-3: Distribution of Risk Factors among At Risk Infants And The Hearing Impairment

Risk Factor	Screened	Hearing Impairment
Family history of childhood hearing loss.	1	0
Hyperbilirubinemia exchange level	1	0
In utero infections,	11	1*
Craniofacial anomalies	1	1**
Syndromes associated	2	1**
Culture positive postnatal infections	6	0
Birth asphyxia (APGAR at 1min <4/ 5 min <6)	10	1***
NICU stay >5d/ mechanical ventilation / birth weight <1.5/ ototoxic medication	11	0
Total	43	2

* Also suffered sepsis; ** expired; *** also weight <1.5 kg + ventilated

The overall incidence of hearing impairment was 6.25/1000 screened with a 95% confidence interval of 4.28-11.62. (Table 2). Incidence of hearing impaired in no risk group was 3.96/1000 with a 95 % confidence interval between 2.01- 4.66. (Table 2). Whereas Incidence in at risk newborns was 46.5/1000 with 95 % confidence interval is of 1.96-10.32. (Table 2) The distribution of 'at risk' infants screened as per their risk factors and the hearing impaired in various groups of infants with risk factors is shown in Table 3.

In this study two hearing impaired infants were detected in at risk group. One of the hearing impaired newborn suffered congenital rubella syndrome and sepsis in early neonatal period. The other newborn was a preterm, with weight <1.5kg along with Birth asphyxia (APGAR at 1min<4/ 5min<6) and respiratory distress requiring ventilator support for more than 5 days. No hearing impaired cases were detected in newborns with other risk factors.

Discussion

This study attempted to find the feasibility and need of implementing two staged hearing screening with TEOAE followed by confirmation with ABR in resource poor nation like India. As per the recommendations of National Institutes of Health Consensus (NIHC) Development Conference Statement^[7] we have tried to look into the incidence of hearing impairment in at risk and no risk neonates. The incidence of hearing impairment in this cohort is 6.25/1000 with a 95 % confidence interval is between 4.28-11.62, which is in par with few of the Indian studies like, P. Nagapoornima, et al in 2006 where in incidence of hearing impairment of 5.6/1000 was demonstrated.^[8] But this incidence is higher than the national average of 4/1000⁹ and more than the global average which is approximately 3/1000.^[9] This may be because our hospital being a tertiary care centre has large number of high risk deliveries leading to larger case load of at risk group. This incidence of hearing impairment

(6.25/1000) in newborns is very high in relation to other congenital defects for which cure can be provided^[10], advocating for an early implementation of hearing screening in every nation.

In this study a high incidence of hearing impairment of 46.5/1000 is seen in at risk group, when compared 3.96/1000 in no risk group. A huge disparity has been noticed in the incidence of hearing impairment in at risk and no risk groups, with incidence in at risk group being 11 times more than the no risk group. This finding is at par with the literature reports, which state, the incidence in at risk infants being approximately 10 times greater than the incidence in normal population.^[10] This supports the implementation of at risk screening and early intervention as a minimum compulsory measure to lessen the burden morbidity in these children.

It's worthwhile to note that among the five hearing impaired detected in the study three didn't have any risk factor. Hence just an 'at risk' hearing screen would have missed detection of 3 of the 5 hearing impaired (60% of total hearing impaired in the study cohort would be missed). Although the incidence of hearing impaired in no risk group (3.9/1000) is much less than the incidence in the at risk group (46.5/1000), the magnanimity of newborn population in 'no risk' group is huge, leading to a large number hearing impaired missed by high risk screening. Hence it's high time to take every measure to identify additional risk factor, other than those mentioned in HRR of JCIH 2007, so has to make high risk screening more effective or implement two staged TEOAE & ABR evaluation of all neonates (Universal hearing screening). Universal newborn hearing screening with two staged hearing screening programme is cost effective and feasible screening protocol which can yield realistic incidences. In our study, at the end of two TEOAE screening the suspected hearing impaired neonates were 1.8% of cohort, which decreased to 0.6% (that is 1/3rd result) on confirming with BERA testing (Table 1). This shows, two staged evaluation (TEOAE & BERA), with repeated TEOAE in early neonatal period, improves sensitivity and specificity of the screening protocol, giving realistic incidences. Considering the cost incurred on rehabilitation of a hearing impaired child in later part of life and the socio-economical impact on the child and the family, this two staged protocol of universal hearing screening and early interventions for hearing loss, will be less expensive and will give better chance for the neonate to have a normal social life and improved quality of living.

With the little efforts made to identify additional risk

factors, other than those mentioned in 'HRR' of as JCIH 2007, we found - maternal UTI (Urinary Tract Infection), PIH (Pregnancy Induced Hypertension), GDM (Gestational Diabetes Mellitus) and maternal DM (Diabetes Mellitus). (Table 3) to be associated with hearing impaired infants in no risk group. But a correlation with the hearing defect and these factors could not be made as the sample size was small and these hearing impaired infants had multiple risk factors.

Conclusion

This study has shown that two-stage TEOAE hearing screening followed by ABR to confirm the hearing deficit, is a feasible easily implementable and highly effective hearing screening protocol, for early detection of hearing impaired, on a large scale, to achieve the high quality standard of screening programs. Among the five hearing impaired detected in the study three didn't have any risk factor stressing the need of identifying, additional risk factors for hearing loss so as to improve the efficacy of high risk screening. And universal hearing screening is essential to detect the large number of hearing impaired in the magnanimous 'no risk' newborn population till the time High Risk Registry (HRR) is more effective.

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