pISSN 2349-3283 | eISSN 2349-3291

Original Research Article

DOI: http://dx.doi.org/10.18203/2349-3291.ijcp20184183

Universal hearing screening of newborn to detect hearing loss and aid in early intervention: multicentre study

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Received: 08 September 2018 **Accepted:** 14 September 2018

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ABSTRACT

Background: Significant hearing loss is one of the most common major abnormalities present at birth. Screening for hearing loss in new-born is based on two concepts. First, a critical period exists for optimal language skills to develop, and Second, earlier intervention produces better outcomes.

Methods: A two-stage screening protocol, in which new-born are screened first with two staged Transient Evoked Oto-acoustic Emissions TEOAE, using handheld TEOAE device, followed by confirmation with Auditory Brainstem Response (ABR). The objective was to study the incidence of hearing impairment in "healthy" and "high risk" newborns. A prospective observational study of hearing impairment screening was conducted on 4400 newborns, the study was done as a multi-centre study in 3 different hospitals during January 10 - December 14.

Results: 4400 new born, born during the study period were screened, which included 4162(94.7%) healthy neonates and remaining 238(5.3%) high risk neonates. 24 newborn among the cohort of 4400, had hearing impairment confirmed by ABR. The overall incidence of hearing impairment is 5.45/1000 screened with 95 % confidence interval between 4.28-11.6. Incidence of hearing impairment in the "no risk" group was 2.4/1000 with 95 % confidence interval between 2.01-4.66. Whereas incidence of 58.8/1000 with 95 % confidence interval is between 1.96-10.32 was seen in "at risk" group. Also, this study shows Universal hearing screening of newborns with a two staged screening protocol using TEOAE followed by confirmation with ABR is not only cost effective for detection of hearing loss but also aids in early intervention.

Conclusions: The incidence of hearing impairment in our study (5.45 per 1000) is much higher than results shown in previous studies and national average of 4/1000.

Keywords: Neonate, Universal hearing screening, Transient evoked otoacoustic emissions

INTRODUCTION

It is well recognized that unidentified hearing loss can adversely affect optimal speech and language development, acquisition of literacy skills, and academic, social and emotional development. The risk is even more in a country like India where infrastructure is abysmally inadequate for prevention and remediation. Neonatal hearing loss and its developmental consequences are measurable, before 6 months of age for newborn infants who are hard of hearing, enables them to perform significantly higher on vocabulary, communication,

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intelligence, social skills and behavior necessary for a successful later life.¹⁻³ American Academy of Pediatrics (AAP) in 1999 advocated universal new-born hearing screening programme (UNHSP) and remedial intervention which is being practiced in most of the developed countries.⁴

The advances in critical neonatal care, has led to increased survival of preterm and critically ill newborns, making it more important, to monitor and detect hearing loss early in Neonatal Intensive Care Units (NICUs).

Incidence of hearing impairment in at risk and not at-risk infants range from 6-60 per 1000 neonates with an average of 4 per 1000 neonates (Northern and Hayes).⁵

The paucity of large-scale studies on new born hearing screening in developing countries leaves a lacunae in real incidence of hearing impairment in the new born babies and the early detection methods. In a developing country like India, the risk of infants to develop these disabilities is obviously more.

The study was undertaken to know the realistic incidence of hearing impairment and applicability of hearing screening methods for diagnosis of hearing loss and aid in early intervention.

METHODS

All newborn babies born in two tertiary care hospitals at Delhi and Bangalore and zonal hospital in Kanpur between Jan 2010 to Dec 2014, were enrolled 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 (Joint Committee on Infant Hearing, 2007).

The Risk indicators included-Family history of permanent childhood hearing loss. 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 hyper bilirubinemia that requires exchange transfusion.

In utero infections, such as Cytomegalovirus (CMV), herpes, rubella, syphilis etc. Craniofacial anomalies, including those that involve the pinna, ear canal, ear tags, ear pits, and temporal bone anomalies.

Physical findings, such as white forelock, that is associated with a syndrome known to include a sensorineural or permanent conductive hearing loss.

Culture-positive postnatal infections associated with sensori-neural hearing loss, including confirmed bacterial and viral (especially Herpes and Varicella) meningitis. Head trauma, especially basal skull/temporal bone fracture.

At risk group included neonates who had distinct and significant associations with risk factors included in the HRR of as JCIH 2007.2 No risk group included neonates who did not fulfill the criteria mentioned in the HRR of as JCIH 2007.

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 sensori-neural 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.

All subjects underwent the audiological tests as per the Screening - Rescreening Protocol and hearing deficit confirmed with ABR. Screening / Re-screening Protocol The study protocol was carried out in three steps.

Initial screening

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.

First follow-up screening was done at 4 to 6 weeks of age by TEOAE for:

All babies of "At risk" group ii. Babies of "No risk" group who failed the first test screening ("refer" category)

Second follow-up screening was done at 3 months age to confirm the hearing impairment by ABR/BERA test for:

All babies of "At risk" group ii. Babies of "No risk" group who failed the first follow-up screening ("refer" category) Study protocol was approved by the ethical committee of our institution. The results of audiological evaluation were recorded in a standardized Performa. The

data was entered into Microsoft Excel and analyzed using S.P.S.S package version 17.0.

RESULTS

A total of 4400 neonates were included into the study during the study period, of which 119(5.3%) had risk

factors for hearing impairment as per "HRR" of as JCIH 2007 ("at risk group"), as shown in Table 1.In the initial screening 502 of the 4400 study cohort screened, failed the initial TEOAE test, accounting to a referral rate of 11.6% and pass rate of 88.4%. Of the 502 who failed, 128 belonged to "at risk" group and 374 were of "no risk" group (Table 1).

Table 1: Result of screening protocol.

	Total No. screened	Refer in initial screening (refer rate)	Refer in 1st follow-up screening (refer rate)	Refer in 2 nd follow- up screening (refer rate)	Incidence of hearing impaired
Total screened	4400	502(11.4%)	82(1.86%)	24 (0.54 %)	5.45/1000
At risk	238	128(53.4%)	44(18.5%)	14 (5.88%)	58.8/1000
No risk	4162	374(9.0%)	38(0.91%)	10(0.24%)	2.40/1000

The referral rate in "at risk" neonates was 53.4% and that in no risk neonates was 9.0% (Table 2). In the 1st follow-up TEOAE 86 neonates failed the TEOAE for the 2nd time of which 44 belonged to "at risk" group and remaining 19 belonged to "no risk" group.

Table 2: Incidence of hearing impaired.

Children screened	Incidence in the cohort	Incidence expressed/ 1000 screened	95% confidence interval/1000 screened
Total screened	24/4400	5.45	4.28-11.62
At risk	14/238	58.8	2.01-4.66
No risk	10/4162	2.40	1.96-10.32

Among the "at Risk" group though whole group was subjected to TEOAE screening for 2nd time, no failures were found among infants who had already passed initial screening (Table 1). The referral rate in the first follow-up screening (end of 2nd staged TEOAE) was 1.8% in the total study cohort with 18% referral rate among the "at risk" group and 0.92% referral among the "no risk" (Table 1).

The 2nd follow-up screening which was done to confirm hearing deficit, using BERA showed 10 neonates with hearing impairment among the total study population of 800. Here again though whole of at-risk group were subjected for BERA no failures were found among the infants who had already passed the TEOAE. Of the 10 who failed BERA, 4 newborn had risk factor for hearing loss as per JICH and the rest 6 had no risk factor for hearing impairment.

Incidence hearing impaired in the total study cohort- 24 newborn among the study cohort of 4400 screened had hearing impairment confirmed by BERA. The overall incidence of hearing impairment is 5.45/ 1000 screened

with a 95 % confidence interval between 4.28-11.62 (Table 2). Among the 1.8% of newborns who failed screening (refer rate) at the end of two staged TEOAE 0.6% were confirmed to be hearing impaired with BERA.

Incidence hearing impaired in no risk newborns- Among 4162 infants with no risk factors screened only 14 had hearing impairment, showing an incidence of 2.4/1000 in the no risk group with a 95 % confidence interval is between 2.01-4.66 (Table 4).

The two staged TEOAE had shown a refer rate of 0.9% (failed) at the end of 2nd screening, of which 0.3% were confirmed to have hearing deficit by BERA.

Table 3: Distribution of risk factors among at risk neonates and hearing loss.

Risk factor	No. screened	No. of infants with hearing impairment
Family history of childhood hearing loss	4	0
Exchange transfusion level hyperbilirubinemia	4	0
In- utero infections (early onset sepsis)	60	4
Cranio-facial anomalies	4	Expired
Syndromes associated	10	2- expired
Culture positive post- natal infections	38	2
Birth asphyxia (apgar at 1min<4/5 min<6)	54	4
Nicu stay >5 days/ mechanical ventilation/ birth weight <1.5/ oto- toxic medication	64	2 (mechanical ventilation and weight <1 kg)
Total	238	14

Incidence of hearing impairment in at risk newborns- 238 at risk neonates were screened and 14 were detected to be hearing impaired, which is an incidence of 58.8/1000 (95% confidence interval is between 1.96-10.32) (Table 3). The two staged TEOAE screening had shown a fail (refer

rate) of 18% at the end of 2nd stage of which 4% were confirmed to have hearing impairment by BERA. The distribution of at-risk infants screened as per risk their risk factors are shown in Table 3.

Table 4: Risk factors other than those in HRR of JCIH 2007.

Medical conditions	No. screened	No. Of infants with hearing impairment	Other risk factors in association
Maternal gdm/dm	428	4	Uti (culture positive)
Maternal pih	256	4	Birth asphyxia+mechanical ventilation, weight<1.5kg
Maternaluti (culture positive)	24	4	Gdm

And the incidence of hearing impairment in various groups of infants with risk factors is shown in Table 3. In this study 14 hearing impaired infants were detected in at risk group with risk factors given in Table 3. Among the hearing-impaired newborns confirmed by BERA, risk factors other than those mentioned in "HRR" of as JCIH 2007, (Table 4) were identified, but a correlation with the hearing defect and these risk factors could not be made as the sample size was small and with multiple risk factors.

DISCUSSION

This study is one of the many steps towards evaluating the need and applicability of universal hearing screening in a developing nation like India. We looked into the incidence of hearing impairment in at risk and no risk group using two staged TEOAE followed by confirmation by BERA as per guidelines of American Academy of Pediatrics and recommendations of National Institutes of Health Consensus (NIHC) Development Conference Statement.

Screening the hearing loss at birth with TEOAEs and later confirming it at three to sixth months was taken as the standard. Deka et al studied the maturation of central auditory connections. ³ He proposed that though cochlea is fully developed at birth, the myelination of VIII nerve and maturation of brainstem takes nearly six months. This therefore forms the basis of screening and rescreening protocols where final confirmation of hearing loss is made only at around three to six months of age.

This accounts for any possible false positive results that may result from an immature central connection of cochlea. TEOAE was preferred as screening tool as it is cost effective, convenient, easy to use and time saving. ⁶⁻⁷ ABR was used to confirm the hearing defect in TEOAE failed infants to decrease the false alarm and unnecessary intervention. ABR was also done for all the at-risk infants with the aim of identifying false negative TEOAE (e.g. auditory neuropathy or auditory days-synchrony).

The incidence of hearing impairment in this cohort is 5.45/1000 with a 95 % confidence interval is between

4.28 -11.62. There are few surveys showing incidence of hearing impairment in India. In one of pilot studies conducted by Abraham K Paul at Cochin the incidence of hearing impairment is 10.3/1000 in high risk group and 0.98/1000 in well baby group.⁸ In another study, by P.Nagapoornima, et al. An incidence of hearing impairment of 5.6/1000 was demonstrated.⁹ The incidence of hearing impairment in our study (5.45 per 1000) is much higher than the national average of 4/1000. This may be because our hospital being a tertiary care centre has large number of high-risk deliveries leading to larger caseload of at-risk group.

The incidence of hearing impaired 5.45/1000 is very high in relation to other congenital defects for which cure can be provided, advocating for an early implementation of hearing screening in our nation. The incidence of hearing impaired 6.2/1000 is very high in relation to other congenital defects for which cure can be provided (Mehl and Thomson, 1998) advocating for an early implementation of hearing screening in our nation. ¹⁰ In this study a high incidence of hearing impairment of 58.8/1000 is seen in at risk group when compared 2.4/1000 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 17 times more than the no risk group. This finding is more than that of the literature reports of incidence in at risk infants being approximately 12 times greater than the incidence in normal population if one or more risk factors included in "High Risk Registry (HRR)" of Joint committee (JCIH), for infant hearing are present. ¹¹⁻¹³

It's worthwhile to note that among the 12-hearing impaired detected in the study 5 didn't have any risk factor. Hence just an at-risk hearing screen would have missed detection of 5 of the 12-hearing impaired (60% of total hearing impaired in the study cohort would be missed). Although the incidence of hearing impaired in no risk group (2.45/1000) is much less than the incidence in the at-risk group (58.8/1000), the magnanimity of newborn population in "no risk" group is huge, leading to

a large number hearing impaired missed by high risk screening.

Hence universal hearing screening is the ideal strategy of hearing screening for neonates. 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 two staged screening can be planned and the screening timing can be incorporated along with timing of discharge from hospital and timing of 1st dose of triple antigen vaccination (6 weeks) without extra burden on follow up. Those who fail this 2 staged screening and all of those who are having risk factors for hearing loss should undergo a confirmatory BERA and referred for detailed audiological evaluation if necessary. Creating awareness among parents regarding importance of hearing screening, available technology and benefits of detecting this hidden defect can itself decrease the burden of disease.

CONCLUSION

This study has shown that two-stage TEOAE hearing screening can be successfully implemented as newborn hearing screening method, for early detection of hearing impaired, on a large scale, in all hospitals to achieve the high-quality standard of screening programs. The finding is consistent with previous researches, which have indicated hearing loss to be the most frequently occurring birth defect. Though the incidence of hearing impaired in at risk newborns is higher than the no risk newborns, universal hearing screening is essential to detect large number of hearing impaired in the magnanimous no risk newborn population. Universal newborn hearing screening using two-stage TEOAEs proves to be a feasible method for early identification of congenital hearing loss in India. This method of universal screening of newborn for detection of hearing impairment is simple, reliable and cost effective and can be successfully implemented in all service hospitals.

Funding: No funding sources Conflict of interest: None declared

Ethical approval: The study was approved by the

Institutional Ethics Committee

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Cite this article as: Yenamandra KK, SahuPK, Kumar A, Rai N, Thakur PK. Universal hearing screening of newborn to detect hearing loss and aid in early intervention: multicentre study. Int J Contemp Pediatr 2018;5:2114-8.