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**Research Article** 

# ASSOCIATION BETWEEN HIGH RISK FACTORS AND INITIAL SCREENING RESULTS OF NEWBORN HEARING SCREENING

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# ABSTRACT

Joint Committee on Infant Hearing (JCIH, 2007) has recommended the High-Risk Register (HRR) which includes the specific risk indicators that are often associated with infant and childhood hearing loss. High false positive results in initial screening of NHS has been reported. Therefore, a second screening is always recommended before a diagnostic evaluation. The reasons attributed for high false positive results are fluid/debris in the ear canal which usually subsides within a week's time. The refer results warrants for another visit that increases the anxiety of parents. Thus, there is a great need to analyse the factors associated with the 'refer' result in the initial screening. Though the risk factors are known to influence referral rates (JCIH, 2007), there is a need to measure the strength of association. The aim of this study is to do a retrospective analysis and find the association of high risk factors with the initial screening results of newborn hearing screening. The study was conducted at Department of Paediatrics, Chettinad Medical College and Research Institute, Chennai, Tamilnadu and Institutional ethics committee approval was taken. From an ongoing newborn hearing screening program in our OP, medical records of all the babies who underwent hearing screening between the month of April 2017-August 2018 were extracted and analysed in our college. All babies have been subjected to the following screening protocol. Screening was done using DP-OAE (Distortion product otoacoustic emissions) or A-ABR (Automated-Auditory Brainstem Response) after 10 days of birth but within 1 month of age. DP-OAE screening was done for all babies except for babies with hyperbilirubenemia ( $\geq 18$ mg/dL) and NICU stay >5 days. Babies who do not pass the initial screening, a re-screening is carried out after 2 weeks. Passing criteria is >4 dB SNR for at least 3 frequencies in both ears. Among the total number of babies screened (1653), 147 (9%) obtained 'refer' results in the screening. 753 (45.5%) had one or more high risk factors. Among the babies screened, 85 babies with high risk factors and 62 without risk factors got 'refer' results in the initial screening. Initial screening results were compared across risk factors to see the strength of association. There is a significant association between refer results and overall high-risk factors in initial hearing screening. Within the high-risk factor group, individual risk factors like craniofacial anomalies, preterm, low birth weight and NICU stay seem to be the most important risk factors influencing referrals in the initial screening. Among the combined high-risk factors, preterm and low birth weight combination was more commonly seen in babies with refer results and it has a highly significant association. Since, refer results are twice more often obtained in high risk babies, it is important to have a system in place and a logistic plan for the follow up of these babies.

# Keywords: - Congenital Hearing Loss, Microphone, Neonatal Intensive Care Unit, Hearing Screening

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# INTRODUCTION

Congenital hearing loss has recently been recognized as one of the most common birth defects in newborns with a prevalence of permanent hearing loss ranging from 2-3/1000 live births (Vohr, 2003). Universal Newborn Hearing Screening (UNHS) is the most effective means to ensure early identification, habilitation and a satisfactory outcome for normal language development in children. According to the Joint Committee on Infant Hearing (JCIH, 2000), UNHS is mandatory for all babies and should identify newborns at risk for specifically defined hearing loss. Almost all of the developed countries have made UNHS mandatory (National Centre for Hearing Assessment and Management, 2006), thus making UNHS the standard of care across developed countries.

National efforts in preventing the delay in the identification of hearing loss began in 1969 (Northern & Downs, 1991) when a national committee was formed, which later became the JCIH. Initially, the committee recommended screening newborns for hearing loss by using high-risk criteria. The JCIH expanded the high-risk criteria from five factors (JCIH, 1973) to seven factors (JCIH, 1982) and then to ten factors (JCIH, 1990). The JCIH, 2000 defines the target population for infant screening programs as unilateral or bilateral permanent hearing loss averaging 30-40 dB in the speech frequency range. With specific reference to newborn hearing screening (JCIH, 2000) position statements and (JCIH, 2007) updates of position statement had set the following benchmarks.

- 1. Minimum of 95% of infants should be screened during birth admission or before 1 month of age.
- 2. Referral rate after the screening process should be 4% or less within one year of program initiation.
- 3. Screening program should receive a follow-up of 70% of infants or more.

JCIH, 2007 has recommended the High-Risk Register (HRR) which includes the specific risk indicators that are often associated with infant and childhood hearing loss. It enlists the suggestive factors of hearing loss and it alerts concerned personnel to investigate those neonates who have increased probability of hearing loss (DeMello, 1995). The use of HRR includes two purposes. First to identify infants who should receive audiological evaluation and especially who live in developing nations or remote areas where universal hearing screening is not available. Secondly, it is important to track babies who have normal hearing at birth but may develop hearing loss at later age. Hence, risk indicators help to identify infants who should receive on-going audiological and medical monitoring and surveillance (JCIH, 2000).

Approximately 10-12% of the new born population have one or more risk factors during birth that may impact hearing (Alpiner & McCarthy, 1999). Studies have shown that prevalence of congenital hearing loss in children with HRR is greater than in general population (Mehl & Thomson, 2002). Estimates of hearing loss among high risk infants, however, range from 2 to 4 per 100 or approximately ten times greater than the general population (Prieve & Stevens, 2000).

# Need for the study:

High false positive results in initial screening of NHS has been reported (Mehl & Thomson, 1998; Nagapoornima et al., 2007). Therefore, a second screening is always recommended before a diagnostic evaluation. The reasons attributed for high false positive results are fluid/debris in the ear canal which usually subsides within a week's time. The refer results warrants for another visit that increases the anxiety of parents. Thus, there is a great need to analyse the factors associated with the 'refer' result in the initial screening. Though the risk factors are known to influence referral rates (JCIH, 2007), there is a need to measure the strength of association.

The aim of this study is to determine the association of initial screening results of newborn hearing screening with high risk factors.

# Material and Methods:

The study was conducted at Department of Paediatrics, Chettinad Medical College and Research Institute, Chennai, Tamilnadu and Institutional ethics committee approval was taken. A retrospective cohort design was used in the study. From an ongoing newborn hearing screening program in a Hearing Out Patient Clinic, medical records of all the babies who underwent hearing screening between the months of April 2017-August 2018 were extracted and analysed in our hospital. Initial hearing screening was done after 10 days of birth but within 1 month of age. Distortion product otoacoustic emissions (DPOAE) were used as the first level of screening except for babies with Hyperbilirubinemia ( $\geq$ 13mg/dL) and NICU stay >5 days for whom ABR screening was done. Information on high risk factors was collected from the hospital records and through parent interview. High risk register was adapted from the American Joint Committee statement on Infant hearing screening (JCIH, 2000). Consanguinity was added in the list as it is pertinent in south India. High-risk register included in the study are family history of childhood impairment, consanguinity, craniofacial hearing anomalies, in-utero infections, preterm birth <32 weeks, low birth weight <2.5 kgs, NICU stay for >5 days, low APGAR score <8 at 5 minutes, hyperbilirubinemia, neonatal seizures, ototoxicity, congenital perinatal infection, and mechanical ventilation for >5 days.

# Screening environment and equipment:

Hearing screening was carried out by audiologists in a sound treated room. DPOAE screening was done using Intelligent Hearing Screening system 2.32 version and GSI Audera version 1.0.3.4. DPOAEs at 2f1-f2 were evoked with two tones f1 and f2 at each of the 6 frequencies with L1 set at 65 dBSPL and L2 at 55 dBSPL. Signals were presented and DPOAE's were detected with a probe assembly that contained a microphone and two miniature loudspeakers. For all the babies, prior to the presentation of stimulus a complete probe fit was determined. A pass outcome for DPOAE screening was defined as a minimum signal to noise ratio of 3 dB at 3 frequencies.

Auditory brain stem response (ABR) screening was done using MAICO MB 11 BERA phone version 1.1 with the implemented chirp stimulus and an automated response detection method. Pass/refer status were based on the response observed at 35 dBnHL.

### Statistical analysis:

The otoacoustic emission analyzer and auditory brain stem response equipment was calibrated and the protocol driven measurement ensured internal validity. Odds ratio (OR) and 95% confidence interval (CI) was used to estimate (association) the risk of getting 'refer' results in babies with risk factor. Chi square test was used to calculate the statistical significance of association. Significance was set to p=0.005.

#### **Results:**

The total number of babies screened was 1653 of which 753 (45.5%) babies had one or more high risk factors. Among the babies screened, 147 (9%) babies obtained 'refer' results in the initial screening of whom 85 were with high risk factors and 62 were without risk factors. Initial screening refer results were compared across the risk factors to analyse the strength of association of risk factor which is depicted in the table 1.

Risk factors	<b>Refer results</b>	Odds ratio	95% Confidence	P value
(No. of babies)	(No. of babies)	( <b>OR</b> )	interval (CI)	
Hyperbilirubinemia (N=376)	32	0.95	0.69, 1.31	0.767
Preterm (N=412)	62	1.81	1.47, 2.24	0.000*
Low birth weight (N=352)	54	1.86	1.47, 2.36	0.000*
NICU (N=294)	48	2.02	1.56, 2.62	0.000*
Consanguinity (N=81)	8	1.13	0.55, 2.30	0.734
Ototoxicity (N=31)	5	1.98	0.77, 5.09	0.148
Craniofacial anomalies (N=20)	12	15.48	6.43, 37.26	0.000*
Low APGAR score (N=42)	7	2.06	0.93, 4.56	0.070
Preterm & low birth weight (N=276)	42	2.03	1.55, 2.65	0.000*
Preterm, low birth weight &	16	1.55	0.97, 2.49	0.071
hyperbilirubinemia (N=138)				
Preterm, low birth weight, hyperbilirubinemia	12	1.87	1.06, 3.29	0.032
& NICU (N=86)				

Table 1: Association between high risk factors and initial screening results of Newborn Hearing Screening

P value < 0.001- statistically significant

On analysis, the overall risk factor for hearing loss had significant association with the referrals (OR: 2; p=0.002). Babies with risk factor are prone to get refer result in initial screening twice more often than babies without high risk factor.

For further analysis, babies with high risk factor are divided into two groups- with individual risk factor and with combination of risk factor (More than one risk factor).

# Individual risk factor Craniofacial anomalies:

Among the babies screened, twenty babies had craniofacial anomalies of which 8 (0.5%) babies passed the initial hearing screening whereas twelve babies (8.2%) obtained 'refer' results. The odds ratio for babies

with craniofacial anomaly was 15.48 (95% CI= 6.43, 37.26) which is statistically significant (p =0.000). Babies with craniofacial anomaly had 15 times more chances of getting 'refer' results in initial screening than those without that risk factor.

#### **Preterm:**

Among the babies screened, 412 babies had preterm births of which 62 babies got refer results. The odds ratio is 1.81 (95% CI= 1.47, 2.24) which is statistically significant (p=0.000). Preterm babies are prone to get 'refer' result in initial screening twice more often than babies without that risk factor.

### Low birth weight:

Low birth weight is commonly seen in preterm babies. 352 babies were born with birth weight less than 2.5 kgs of which 54 babies obtained 'refer' results. The odds ratio is 1.86 (95% CI= 1.47, 2.36) which is statistically significant p=0.001. Babies with low birth weight get 'refer' results twice more often than babies with normal birth weight.

# Neonatal Intensive Care Unit admission (NICU):

The other high risk factor that had significant (p=0.000) 'refer' result in hearing screening is NICU stay. Infants admitted to the neonatal intensive care unit (NICU) have a higher incidence of congenital hearing loss as compared to the healthy newborn (Vohr et al., 2000). On analysis, the number of babies who had NICU admission for greater than 5 days is 294. Among them, 48 babies had 'refer' in initial hearing screening test. The odds ratio is 2.02 (95% CI: 1.56, 2.62) and it is statistically significant (p= 0.000). The risk estimates of NICU babies for 'refer' results is twice than babies without this risk factor.

The following risk factors did not have any significant association with the 'refer' results. The risk factors are consanguinity (odds ratio: 1.13, p: 0.73), ototoxicity (odds ratio: 1.98, p: 0.14), hyperbilirubinemia (odds ratio: 0.95, p: 0.76) and low APGAR score (odds ratio: 2.06, p: 0.70). None of the babies had family history of hearing loss and mechanical ventilation >5 days in the study population.

# **Combined risk factor:**

In the combination group, babies with the combination of preterm and low birth weight were 276. Out of which 42 obtained 'refer' result. The odds ratio is 2.03 (95% CI: 1.55, 2.65) which is statistically significant p = 0.000.

The other combination groups such as preterm + low birth weight + hyperbilirubinemia (odds ratio: 1.55; p= 0.071) and preterm + low birth weight + hyperbilirubinemia + NICU (odds ratio: 1.87; p= 0.032) did not have significant association with refer results.

#### **Discussion:**

It is not unexpected for parents to have apprehension when their babies have 'refer' result in hearing screening. It is the audiologist's role to effectively counsel the parents about the screening results and make them understand the importance of second screening. The present study indicates higher chance of referrals for high risk babies. This is in line with other literature (Bener, Eihakeem, & Abdulhadi, 2005; Saunders et al., 2007; Tiensoli, Goulart, Resende, & Colosimo, 2007) which supports this view.

In the current study, among the individual risk factors group, craniofacial anomalies, preterm, low birth weight and NICU stay babies had 'refer' results twice more often than babies without this risk factors. And among the combination group, the combination of preterm and low birth weight had 'refer' results twice more often than babies without this combination of risk factors.

Several researchers have associated various risk factors to the 'refer' result which are different from the current study. Zamani, Daneshjou, Ameni and Takand (2004) found craniofacial anomaly, hyperbilirubunemia, ototoxicity and mechanical ventilation to have significant relationship with newborn hearing loss. Pereira, Martins, Vieira and Azevedo (2007) found that among the term babies, a significant correlation was observed between the presence of risk factors such as family history and syndrome and the 'refer' results in hearing screening. It was reported that babies with syndrome had 37 times more chances of obtaining 'refer' in hearing screening. The lower the gestational age (< 30 weeks) and birth weight (< 2500 g), higher the chances of failing in the hearing screening test (3 times more). Tiensoli et al., 2007 found hyperbilirubinemia, low birth weight and ototoxicity as important risk factors to be associated with hearing impairment in newborns and infants. Chen, Zhang, Guo, Ye and Peng (2008) reported asphyxiation, very low birth weight (<1,500 g) and head and neck abnormality to be the significant risk factors for hearing loss.

There are inherent difficulties in obtaining the information on ototoxic drugs and length of mechanical ventilation due to lack of documentation in medical records. Due to these reasons there are chances that these risk factors are under-reported. The above literatures indicate that the association of risk factors differ with population. The medical care facilities, geographic location and incidence of risk factors often determine the association with hearing loss. When these variables change, it is expected to have changes in the association of risk factors. Hence, there is a great need to track these changes periodically and be informed to counsel parents and others about the risk factors. The knowledge of these factors also helps in keeping neonatologist and pediatrician aware about the etiology of hearing loss.

# **Conclusion:**

There is a significant association between refer results and overall high-risk factors in initial hearing screening. Within the high-risk factor group, individual risk factors like craniofacial anomalies, preterm, low birth weight and NICU stay seem to be the most important risk factors influencing referrals in the initial screening. Among the combined high-risk factors, preterm and low birth weight combination was more commonly seen in babies with refer results and it has a highly significant association. Since, refer results are twice more often obtained in high risk babies, it is important to have a system in place and a logistic plan for the follow up of these babies.

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