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A PROSPECTIVE STUDY TO SCREEN FOR HEARING IMPAIRMENT IN ALL NEWBORNS BORN AT TERTIARY CARE CENTER IN TUMKUR

Paediatrics

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ABSTRACT

Hearing impairment is one of the most prevalent congenital disorders observed in newborns. Identifying hearing impairment early and acting on that identification is essential to an infant's ability to develop normal speech, language and cognitive development. Universal Newborn Hearing Screening (UNHS) is a vital public health effort to reduce the burden of unrecognized hearing loss. To screen every newborn admitted to the tertiary care hospital in Tumkur for hearing impairment and to look for high-risk factors for hearing impairment in those newborns. A prospective observational study was carried out over a period of 24 months in a unit of 306 newborns. All newborns underwent hearing screening using a two-stage Otoacoustic Emissions (OAE) protocol. Newborns who failed both stages underwent confirmatory Brainstem Evoked Response Audiometry (BERA). Demographic data and potential high-risk factors were recorded. All statistical analysis was done using Epi Info version 7.2.5. Out of 306 newborns, 6 (1.96%) were diagnosed with hearing impairment based on the BERA results. Hyperbilirubinemia was the most frequently noted risk factor (36.93%), followed by birth asphyxia, meningitis, and prematurity. However, no statistically significant association was found with any of the high-risk factors present with hearing loss occurrence. This study illustrates the importance of universal newborn hearing screening in a clinical verification context, regardless of risk factors. Early identification of hearing loss using OAE and BERA tests allows for intervention as soon as possible, which is vital for the most favorable neurodevelopmental outcomes.

KEYWORDS

Newborn hearing screening, Otoacoustic emissions (OAE), Brainstem evoked response audiometry (BERA), Sensorineural hearing loss (SNHL), Hyperbilirubinemia, Risk factors, Universal screening, Early intervention

INTRODUCTION

Hearing is crucial for speech, language, social skills, and cognitive development in children. Hearing is necessary for developing spoken language, interacting with other people, and ultimately learning and achieving academically. Hearing loss, and possibly hearing impairment, can cause irreversible development delays and psychosocial issues if not detected early in life (Yoshinaga-Itano et al., 1998). Studies consistently document that language and cognitive outcomes were substantially better, even years later, for children who were identified and received intervention for hearing loss during the first six months of life than for children who were identified later (JCIH, 2007).

Congenital hearing loss is one of the most prevalent birth disabilities worldwide. It is estimated that approximately 1 to 3 of every 1,000 births will result in permanent bilateral hearing impairment (WHO, 2021). The incidence of hearing impairment in neonatal intensive care units (NICUs) is even more severe, and documented incidences are approximately 2 to 4 of every 100 infants because of the multitude of risk factors that discontinuity of care may have exposed them to (American Academy of Paediatrics, 2007).

Hearing loss plays a significant role in childhood disability in India, with estimates indicating that every year nearly 18,000 babies are born with congenital hearing impairment—with approximately two babies born every hour (National Programme for Prevention and Control of Deafness, Government of India, 2014). The estimated prevalence of congenital hearing loss in India is 5.82 per lakh population (Satish et al., 2019).

The implications of untreated or undiagnosed hearing loss can be severe and life-long. Children who are diagnosed after one year of age are more likely to miss out on opportunities for normal language development, have poorer academic performance, have social difficulties, and develop maladaptive behaviors. Hearing loss is a "silent disability" and nearly always goes undetected until the speech delay gives rise for more investigation— usually after two years when the opportune time for neurodevelopmental intervention has passed, (Olusanya et al., 2008).

Understanding the seriousness of the problem, global health organizations like the World Health Organization (WHO) and the Joint Committee on Infant Hearing (JCIH) strongly recommend Universal Newborn Hearing Screening (UNHS). JCIH has a "1-3-6" protocol: all babies should be hearing screened by 1 month of age; diagnosis should be validated by 3 months, if the screening did not pass; and early intervention services should start no later than 6 months of age (JCIH, 2007). WHO also recommends making the hearing screening programs include in national health policies for the purpose of reducing the disability caused by hearing impairment (WHO, 2021).

Although international recommendations exist, the implementation of hearing screening services in low- and middle-income countries (LMIC) like India has been fragmentary and often only available to high-risk neonates or in acute care settings. Solutions to hearing loss remain particularly challenging in rural areas where there is a lack of awareness, capacity and existing structure for providing care. In Karnataka, Tumkur district offers a semi-urban environment where evaluating the adaptation and outcomes of universal hearing screening services is necessary.

Therefore, the present study was carried out to screen all newborns attending a tertiary care facility in Tumkur and to determine the prevalence of hearing impairment, along with the associated high risk factors. It is hoped that the prospective study would add to data of the same nature as the establishment of region-specific knowledge would be of value in advancing local health policy, and in advocating for adding UNHS to standard care for neonates at the same sites, or in similar contexts in India.

Objectives Of This Study

- To determine the occurrence of hearing impairment among newborns
- To evaluate high-risk factors associated with neonatal hearing loss

2. Review Of Literature

Hearing loss (HL) is one of the most frequent congenital anomalies in newborns, and, if undetected, results in significant consequences regarding language development, education and psychosocial wellness. Neonatal hearing disability is emerging as a public health issue with significant consequences in terms of population size; with this being particularly noted in low- and middle-income countries lacking consistent newborn screening programs.

WHO estimates based on its World Report on Hearing (2021) indicates that 1.5 billion people experience some level of hearing loss, with over 430 million needing rehabilitative services, which includes approximately 34 million children under age 15. Congenital hearing impairment occurs in a rate of 1-3 per 1000 live births in developed countries which is dramatically higher in neonatal intensive care units (NICUs), where factors are more likely to occur (WHO, 2021).

In India, the burden is great. Based on the National Programme for Prevention and Control of Deafness (NPPCD) data, approximately 5.82 per lakh population are affected with congenital hearing loss, translating to approximately 18,000 infants with hearing impairment born annually (MoHFW, 2022). Many of these infants will go unidentified until they are at least 2–3 years old, when they can no longer access the critical time window for language development which can never be recovered (Olusanya et al., 2014).

Language and the ability to communicate rely on access to auditory input early in life. Yoshinaga-Itano et al. (1998) found that infants who received early intervention prior to 6 months had significantly improved language compared to infants who received intervention later. More recent research is also consistent with early induction and amplification being effective in preventing delays in speech and language development and ensured improved social-emotional and academic outcomes (Ching et al., 2013; Moeller & Tomblin, 2015).

Children with undetected HL may also demonstrate delayed developmental milestones, poor academic performance, social isolation and behavioral problems (Sininger et al., 2010). As HL can be "hidden" or "invisible", diagnosis is often delayed as parents identify difficulties with hearing due to their observation of developmental milestones and performance.

The Joint Committee on Infant Hearing (JCIH) has put forth its "1-3-6 guideline": screening by 1 month, diagnosis by 3 months, and intervention by 6 months (JCIH, 2007; 2019). WHO also suggests that hearing screening should be part of newborn care packages, particularly in countries with high neonatal morbidity (WHO, 2021).

A few countries, including the United States, UK, and Australia have mandatory universal-newborn hearing screening (UNHS) programs with coverage of over 95%. In contrast, many low and middle-income countries including India rely on risk-based screening, which misses almost 50% of the cases and especially cases where there are no identifiable risk factors (Korver et al., 2017).

Two of the most commonly used neonatal hearing screening methods are Otoacoustic Emissions (OAE), and Brainstem Evoked Response Audiometry (BERA). OAE is easy to apply, rapid to administer, and inexpensive with high sensitivity and specificity to different degrees (Kemp, 2002), however OAE may not pick up auditory neuropathy, and this would be better detected using BERA. As a result, and in practice, combined protocols where OAE is used first and BERA used to confirm cases yield a high degree of diagnostic accuracy (Norton et al., 2000; Sharma et al., 2018).

Multiple Indian studies underline the emerging push for universal screening.

- Kumar et al. (2015) conducted a study with 500 infants screened at a tertiary care hospital in India, and found 11 (2.2%), had significant HL, where NICU admission, LBW, and hypoxia were also significant.
- Anand et al. (2016), screened 1052 newborns and found that 7.8% of those with risk factors had HL, while 1.12% of those without risk factors had impairment, indicating that adequate screening cannot be solely risk-based.
- Singh et al. (2017) screened 4356 neonates and showed an HL prevalence of 2.07 per 1000, with higher prevalence reported in rural and tribal populations and in cesarean deliveries.
- Manjunath et al. (2018) used a two-step TEOAE screening, prior to ABR, with 977 low-risk newborns and found a HL prevalence rate if 6.1 per 1000, confirming that screening has value for all neonates, even without identifiable risk.
- Satish et al. (2019) implemented a four-stage OAE-BERA protocol and screened 26,487 newborns, identifying 19 with confirmed HL (0.717 per 1000) to emphasize the feasibility of UNHS in busy government hospitals.
- Balasubramanian et al. (2020) studied 100 high-risk neonate in his study and reported HL in 3.06% of the sample framed their arguments strongly in favor of OAE plus AABR testing for early identification.
- Mahmood et al. (2020, Pakistan) assessed 108 newborns with OAE and BERA tests and detected HL in 7 patients (6.5%). They highlighted the importance of identifying HL even in asymptomatic infants.

The Global Burden of Disease Study (Haile et al., 2021) found that the number of persons with HL in 2050 will rise to 2.45 billion, with the greatest burden suffered in South Asia and Sub-Saharan Africa. The study linked poor Healthcare Access and Quality (HAQ) index with increased disability due to untreated HL, noting the significant need for investments into early detection services.

Chadha et al. (2021) informed The Lancet Public Health that programs for newborn hearing screening should be included in essential newborn care, especially in LMICs, and evaluate cost-effectiveness of PSA, with public-private partnerships and digital health initiatives.

The literature highlights that hearing loss is a prevalent and serious pediatric issue, but early identification with screening and intervention can significantly change the outcome. It is evident that clinically effective guidelines for universal hearing screening are available internationally (supported by multiple sources and technological advances) although India has been inconsistent in its approach to universal hearing screening. There is enough evidence to justify universal OAE-BERA protocol discrimination, including semi-urban sites like Tumkur being included. This research has contributed to the limited regional information, but it encourages screening to be extended as newborn care for all newborns.

2.1 Gaps Identified In Existing Literature

Although there is plentiful evidence from around the world on the case for early hearing screening, there are still significant gaps in the Indian and broader Low- and Middle-income Country (LMIC) context. First, almost all studies that have considered hearing screening in India have focused on high risk newborns, meaning many infants with hearing loss WHO may have no identifiable risk factors at birth are not included in the available literature. By focused on high risk newborns, this underestimates the burden of congenital hearing impairment. Second, we have no specific data for some regions, particularly semi-urban and rural regions like Tumkur, where limited healthcare infrastructure and limited awareness prevails. The vast majority of the available studies suffer from small sample sizes, single stage screening, and little follow-up investigation decreasing the generalizability and reliability of the outcomes. Third, the association of risk factors as they have been statistically considered to be associated with confirmed hearing loss are also considered in very few studies. Therefore, these gaps also demonstrate that a prospective study should be more rigorous and include both screening and risk, or screening without risk assessment, to develop strategies using the results the intervention at a local and national level.

3. MATERIALS AND METHODS

3.1 Study Design And Setting

This study was a hospital-based prospective observational study to determine the incidence of hearing impairment among newborns and to examine related high-risk factors. A prospective design was selected to carefully observe subsequent outcomes over time following exposure to suspected risk factors. A prospective design allowed for more diligent recording of data and follow-up over time. The data was collected from the Department of Paediatrics at Sri Siddhartha Medical College and Hospital which is a well-known tertiary care center situated in Tumkur, Karnataka and a well-established center for many deliveries from an urban and rural backgrounds.

3.2 Duration Of Study

The study spanned a timeline of 24 months, allowing ample time for participant recruitment, two-stage hearing screening, confirmatory testing and data analysis. The longer duration also limited seasonal bias and allowed researchers to include a representative sample of newborns.

3.3 Sample Size

The study was conducted on 306 newborns; Based on previous studies done in India, the sample size was calculated using the prevalence data

available. In their study, Balasubramanian et al. (2020) had noted that the prevalence of hearing loss in high-risk neonates was approximately 3.06%. Based on this prevalence, and using the well-known formula for sample size calculations, and 95% confidence interval (Z = 1.96) and 2% margin of error (d = 0.02), the final sample size was calculated to be 285. To maintain robustness and cover for potential dropouts, 306 neonates were screened.

3.4 Inclusion And Exclusion Criteria

All live-born infants (including both regular and high-risk newborns) who were delivered at the tertiary care center within the specified study period were included in the study to provide a more representative evaluation of the population included. High-risk newborns included newborns with clinical factors such as hyperbilirubinemia, prematurity, low birth weight, birth asphyxia, and suspected meningitis.

Newborns were excluded from the study if newborns were discharged prior to screening being completed, did not return for follow-up OAE testing, or if the parents or guardians of the newborn refused permission for the hearing assessments.

3.5 Hearing Screening Protocol

The screening followed a two-stage hearing screening protocol recommended by the Joint Committee on Infant Hearing (JCIH, 2007).

In the first stage, Newborns underwent Otoacoustic Emissions (OAE) screening (Transient Evoked OAE [TEOAE] or Distortion Product OAE [DPOAE]) at 72 hours of life or prior to hospital discharge. The temporal proximity was used to minimize false positives due to the presence of vernix or amniotic fluid remaining in the ear canal immediately after gestation (Prieve et al., 2000).

Participants failing the first OAE screening were recalled for a second-stage OAE, between 15 - 30 days. Newborns who passed the screening were considered to have normal hearing while those who failed were referred for Brainstem Evoked Response Audiometry (BERA).

BERA was used as a confirming diagnosis particularly for infants who failed both OAE, or infants where OAE could not be performed due to anomalies of the external ear or ongoing middle ear problems. BERA has known high sensitivity and additionally ability to screen for auditory neuropathy otherwise not picked up by OAE alone (Sininger, 2002).

Overall, this multi-stage approach is what we hoped would reduce likelihood of false positives while balancing both specificity and accuracy.

3.6 Data Collection And Statistical Analysis

Demographic and clinical data regarding birth weight, gestational age, birth order, sex, mode of delivery, and presence of risk factors (hyperbilirubinemia, birth asphyxia, meningitis, prematurity, mechanical ventilation, and family history of SNHL) was collected using a structured proforma. The collected data was entered into Microsoft Excel and analyzed using Epi Info software version 7.2.5, which was developed by the Centers for Disease Control and Prevention (CDC). Descriptive statistics (frequency, mean, and standard deviation) were used to summarize the demographic and clinical variables. Chi-square (χ^2) tests were utilized to assess associations and determine overall significance between individual risk factors and occurrence of hearing loss. A p-value < 0.05 was considered statistically significant.

3.7 Variables Collected

To achieve the aims of the study, an extensive list of demographic, perinatal and clinical variables were recorded for each enrolled newborn, using a pre-tested structured proforma. These variables were used as they were identified as possible risk factors or correlates of neonatal hearing loss in the literature.

Demographic Variables:

The Demographic Profile Included:

- Sex of newborn (male/female)
- Birth order (first, second, third, or fourth)
- Mode of delivery (vaginal or cesarean)
- Gestational age (defined term or preterm)
- Birth weight in kg divided into:

<1.5 kg (very low birth weight)
1.5-2.5 kg (low birth weight)
2.5 kg (normal birth weight)

Perinatal And Clinical Variables:

To assess any risk associations, the following clinical variables were noted:

- Hyperbilirubinemia if any, with phototherapy or exchange transfusion,
- Birth asphyxia, with low Apgar scores or resuscitation at delivery,
- Neonatal meningitis, clinically or lab confirmed,
- Prematurity with gestational age <37 completed weeks,
- Mechanical ventilation, with prolonged ventilation (>5 day),
- Family history of hearing loss (i.e., of sensorineural hearing loss (SNHL)),
- History of intrauterine infections, craniofacial anomalies or exposure to ototoxic drugs, however, these were prevent in this population.

Screening Outcome Variables:

At each point of diagnosis, hearing screening results were documented:

- First OAE screening result (Pass/Fail),
- Second OAE screening result (Pass/Fail),
- BERA test result used as our diagnostic outcome (Normal/Hearing Impairment).

These variables allowed the researchers to calculate the prevalence of hearing loss, characterize other based distributions of the risk factors, and perform bivariate analysis on the association of the independent risk variables on the dependent variable which was confirmed hearing impairment.

3.8 Ethical Considerations

This study followed the ethical principles set forth in the Declaration of Helsinki. Prior to study initiation, ethical approval was obtained through the Institutional Ethics Committee of Sri Siddhartha Medical College and Hospital, Tumkur. The parents or legally authorized guardians of all the newborns who participated in the study provided written informed consent, after they were provided the purpose, procedures, possible benefits, and risks of the screening before signing the consent documents.

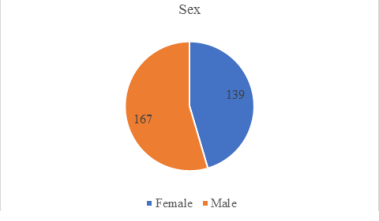
The confidentiality and anonymity of the participants were upheld throughout the study. There were no invasive procedures performed, OAE, and BERA are non-invasive, safe, and well tolerated in newborns. Participation in the study did not compromise the standard care provided to any infant. The parents were informed of the results of the screening and were provided with advice regarding further evaluation or intervention, if warranted.

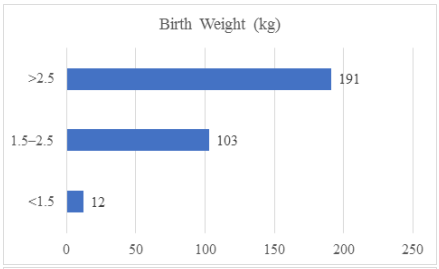
4. RESULTS

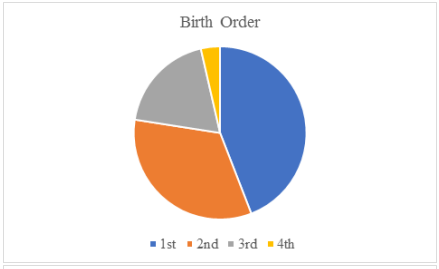
4.1 Demographic Profile Of The Study Population

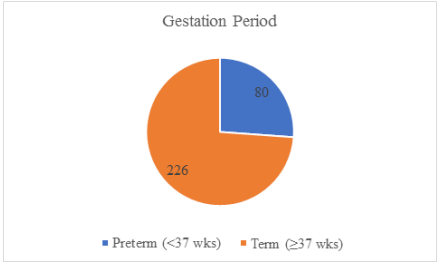
Table 1: Distribution of Newborns by Demographic Characteristics (N = 306)

Variable	Category	Frequency (n)	Percentage (%)
Sex	Female	139	45.42
	Male	167	54.58
Birth Weight (kg)	<1.5	12	3.92
	1.5–2.5	103	33.66
	>2.5	191	62.42
Birth Order	1st	135	44.12
	2nd	102	33.33
	3rd	58	18.95
	4th	11	3.59
Gestation Period	Preterm (<37 wks)	80	26.14
	Term (≥37 wks)	226	73.86









Interpretation Of Demographic Variables

Sex: From the total 306 newborns screened, 167 (54.58%) were male, while 139 (45.42%) that were female demonstrate a male dominant population for this study, which is consistent with the distribution of a general birth cohort and does not appear to introduce any selection bias. The almost equal representation helps ensure generalizability of the sample from both sexes.

Birth Weight: The analysis showed many newborns (191; 62.42%) had a birth weight above 2.5 kg, which designates them to be normal birth weight infants. The remaining 103 babies resembled low-birth-weight infants (33.66%); and 12 infants (3.92%) that were classified as very low birth weight (<1.5 kg). Given the substantial low and very low birth weight population in addition to the larger proportion of low and very low birth weight, we feel justified in considering birth weight as a potential risk factor for hearing loss.

Birth Order: Of the newborns screened, there were the most first-born infants (135; 44.12%). The next cohort made up second-born babies (102; 33.33%) followed with third-born toddlers (58; 18.95%) and few fourth-born children (11; 3.59%). This birth order distribution reflects the natural distribution of births one would expect for a population in the Indian context and offers a chance to examine whether birth order contributes to perinatal risks and auditory outcomes.

Gestational Age: Overall, 226 infants (73.86%) attended full-term and 80 infants (26.14%) were delivered prematurely (<37 weeks). Including a substantial percentage of preterm infants is important, as preterm birth is a known risk for sensorineural hearing loss. The distribution allows for sufficient comparisons in the term and preterm groups in later discussions of the study.

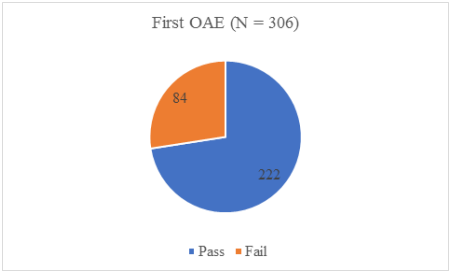
4.2 Hearing Screening Results

Table 2: Distribution of Newborns Based on Hearing Screening Outcomes

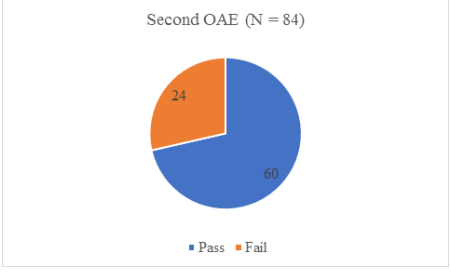
Screening Stage	Result	Frequency (n)	Percentage (%)
First OAE (N = 306)	Pass	222	72.55
	Fail	84	27.45
Second OAE (N = 84)	Pass	60	71.43
	Fail	24	28.57
BERA (N = 24)	Positive (Hearing Loss)	6	25
	Negative	18	75

Interpretation of Screening Stages

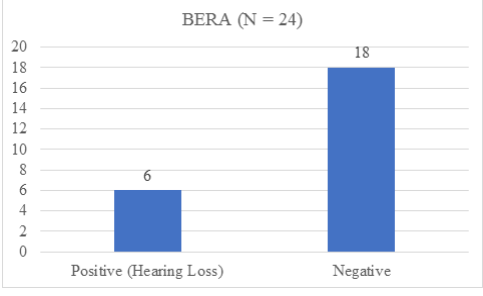
First OAE Screening: Of the 306 newborns screened, 222 infants (72.55%) passed the first OAE (Otoacoustic Emissions) test, whereas 84 infants (27.45%) failed OAE tests. A higher fail rate in the initial stage of screening is not unexpected given that early postnatal OAE screening is susceptible to transient conditions of the middle ear such as fluid, vernix or noise interference that may falsely results in passing the OAE test (Prieve et al., 2000). This underscores the importance of a second stage screening to eliminate unnecessary referrals while decreasing anxiety for parents.



Second OAE Screening: Of the 84 infants who failed the first OAE, 60 infants (71.43%) and 24 infants (28.57%) were able to pass and fail the second-stage OAE after responding to a recall after 15–30 days. The drop in failure rate at the second screening suggested that many of the failures at stage one were the result of temporary conductive problems that resolved spontaneously over the intervening days. This supports the recommendation for a two-stage global OAE protocol, producing increased specificity and reduced risk for over-referral (JCIH, 2007).



BERA Testing (Confirmatory Stage): The 24 infants who failed both OAE screenings had Google Brainstem Evoked Response Audiometry (BERA) testing completed. Out of these infants, 6 (25%) were confirmed to have hearing loss, yielding an overall prevalence rate of 1.96% (6 out of 306). The other 18 infants (75%) had normal hearing even though they failed both OAE tests. This further illustrates the importance of BERA as a confirmatory measure, and as a helpful tool to assess sounds from auditory neuropathy spectrum disorders (ANSD) that OAE alone may overlook (Sininger, 2002).



These results, when taken together, support the use of universal newborn hearing screening (UNHS) through a series of steps-- using OAE as the first step and BERA as the last step-- for accurate diagnosis. Given that this population had almost 2% confirmed hearing loss, the evidence also supports the inclusion of hearing evaluations in the routine care of all neonates, even in the absence of risk factors.

4.3 Distribution Of High-Risk Factors Among Newborns

The study group's population was assessed for multiple clinical risk factors that are established associations with neonatal hearing loss. The table below provides a frequency and percentage distribution of these high-risk conditions for the 306 newborns.

Table 3: Distribution of High-Risk Factors (N = 306)

High-Risk Factor	Frequency (n)	Percentage (%)
Hyperbilirubinemia	113	36.93
Birth Asphyxia	70	22.88
Meningitis	14	4.58
Prematurity	80	26.14
Low Birth Weight (<2.5kg)	115	37.58
Mechanical Ventilation (>5 days)	6	1.96
Family History of SNHL	3	0.98
Ototoxic Drug Exposure	0	0
Craniofacial anomalies	0	0

Interpretation Of Risk Factor Distribution

Of the many risk factors identified, hyperbilirubinemia emerged as the most frequently documented risk factor with 113 newborns (36.93%). This finding aligns with previous studies that have indicated elevated bilirubin levels can be associated with toxicity to the auditory nerve pathways and cochlear damage especially when the bilirubin values surpass the neurotoxic range or an exchange transfusion is needed (Maisels & Watchko, 2003). Birth asphyxia was documented in 70 newborns (22.88%) which is clinically important, as perinatal hypoxia may challenge vital cochlear oxygenation and neural transmission, increasing the risk of sensorineural hearing loss (Berg et al., 2005). Prematurity, which was noted in 80 of the infants (26.14%), is also a well-recognized risk factor that may be involved with an immature auditory pathways, underdeveloped structures of the middle ear, and they may have Low birth weight (LBW) (i.e., < 2.5 kg) was present in 115 newborns (37.58%), often with the overlap of preterm gestational age. These infants had multiple neonatal conditions and potential complications as a result of LBW (i.e., respiratory distress and hyperbilirubinemia) combined with sudden risk factors for hearing loss.

Meningitis was found to directly cause postnatal sensorineural hearing loss as a consequence of cochlear inflammation and ossification in 14 infants (4.58%). While being quite rare in the neonatal course of a hospitalization, meningitis represents a substantial perceived risk factor with the likelihood of permanent hearing loss (Durand et al., 2003).

While rare among this newborn cohort (6 infants; 1.96%), mechanical ventilation >5 days is a known auditory risk also because of the potential for prolonged hypoxia or exposure to ototoxic medications during critical care (American Academy of Pediatrics, 2007).

A family history of sensorineural hearing loss (SNHL) was present with 3 infants (0.98%) which remains pointedly relevant in all cases from a genetic factor, but these cases are often under reported based on lack of awareness and documentation.

No instances of ototoxic medication exposure or craniofacial anomalies were noted in this assessment, which could be related to the exclusionary criteria of this cohort, or be a function of the small sample size.

The data here underscores that although high-risk factors with NBHS, like hyperbilirubinemia, LBW, and prematurity, were viewed as relatively prevalent, there are still many newborns without apparent risk who underwent NBHS, justifying the need for universal, rather than selective, hearing screening protocols.

4.4 Statistical Analysis Of Risk Factors And Hearing Loss

After identifying clinical and perinatal risk factors of the study population, a bivariate analysis was performed to evaluate whether any of these individual risk factors presented a statistically significant association with confirmed hearing loss. BERA outcomes served as the dependent variable (hearing loss present or absent) and risk factors were evaluated as independent variables (risk factor present or absent). The statistical analysis was conducted using Epi Info version 7.2.5, and the Chi-square test (χ^2) was used to evaluate the significance of the associations between risk factors and BERA outcomes. The p-values <0.05 were regarded as statistically significant.

Table 4: Association Between Risk Factors And Hearing Loss (N = 306)

Risk Factor	Hearing Loss Present (n = 6)	Hearing Loss Absent (n = 300)	p-value
Hyperbilirubinemia	3	110	>0.05
Birth Asphyxia	2	68	>0.05
Meningitis	1	13	>0.05
Prematurity	2	78	>0.05
Low Birth Weight (<2.5kg)	2	113	>0.05
Mechanical Ventilation	1	5	>0.05
Family History of SNHL	0	3	>0.05

Interpretation Of Statistical Findings

There were no individual risk factors evaluated in this study that were significantly associated with confirmed hearing loss ($p > 0.05$). Although hyperbilirubinem kuvrrubin, birth asphyxia, prematurity, and low birth weight were common intrauterine factors among the infants who experienced hearing loss in this study, the association did not reach significance, due to the very small number of confirmed hearing loss cases (n = 6) in this study.

This is consistent with literature from India and abroad stating that a large number of infants identified with congenital hearing loss do not have any known risk factor (Anand et al., 2016; Olusanya et al., 2008). Thus, risk screening is philosophically insufficient and could potentially miss a high number of affected newborns.

The lack of statistically significant associations in this study supports the reason for undertaking universal newborn hearing screening (UNHS) rather than using targeted screening as outlined based on risk indicators. Targeted screening would not have identified many of the cases of hearing impairment encountered among this sample of babies.

5. DISCUSSION

This prospective study evaluated the number of all the newborn babies born in the tertiary hospital in Tumkur, Karnataka, India, for hearing loss as well as assess any associated risk factors. Because of BERA test results, we found an observed prevalence of confirmed hearing impairment was 1.96%, which is almost similar to other studies, both in India and elsewhere in the world. For example, Manjunath et al. (2018) found a prevalence of 6.1 per 1000 in low-risk babies, while Singh et al. (2017) reported at a prevalence of 2.07 per 1000 in a heterogeneous population. The World Health Organization (2021) estimates that 1–3 per 1000 live births are affected by hearing loss in developed contexts, while the prevalence is higher in neonatal intensive care units (NICU) of low- and middle-income nations. The higher prevalence identified in our study can be attributed to our inclusion of both low- and high-risk babies and the appropriateness of diagnostics due to confirmatory BERA testing.

Implementing a 2-stage OAE screening followed by BERA as a confirmatory test has been shown to be an important methodological strength. In our cohort, 27.45% of newborns failed the first OAE test but after the second-stage screening, it was determined that only 28.57% of these failed and ultimately we confirmed that only 6 were not hearing impaired as determined by BERA. This hierarchical multi-sequential approach in telling the difference between transient "failed" tests that could lead to anxiety and unnecessary referrals—usually due to some transient fluid in the external ear or vernix, is a great way to positively support our Health System. More specifically, through the findings of this current study, and as also shown by the Joint Committee on Infant Hearing (2007), it is clear that if we alter a multi-tiered screening protocol to manage false positives, it will provide more specific assessment, lower the rate of false positives, and elicit parental compliance by reducing uncertainty during the early post-natal period.

In previously outlined studies/service reports, it also important to note that in this study there was no statistically significant association found between any of the individual high-risk factors—hyperbilirubinemia, prematurity, birth asphyxia, and meningitis—and confirmed hearing loss in our cohort of infants; ($p > 0.05$ for all). This is consistent with previous reports by Anand et al. (2016) and Olusanya et al. (2008) in finding that more than 50% of infants with congenital hearing loss may have no identifiable risk factors at the time of birth.

Consequently, reliance on risk-based screening solely is insufficient and may lead to delays in diagnosis and management in large numbers of infants. The lack of association in this study yet again supports the case for universal newborn hearing screening (UNHS) irrespective of clinical risk profile.

The implications for public health are poignant highlighting the

urgency and possible demand for UNHS to replace the current standard of practice within post-natal care routines offered within Indian tertiary hospitals. Early detection of hearing loss and provision of intervention services – ideally within the framework of the "1-3-6 guideline", that is, screening by 1 month, diagnosis by 3 months, and intervention by 6 months – can improve the language, cognitive, and social development outcomes of infants (Yoshinaga-Itano et al., 1998). The tests that were used in the current study are non-invasive, every professional who administers these tests does some of the screening in less than optimal conditions, which suggests that it is not a complicated procedure, and there is the foundation of neonatal care infrastructure that is becoming more aware with improved services like OAE and BERA testing in both urban and semi-urban areas like Tumkur, for instance.

Overall, the current study has confirmed that there is a high prevalence of neonatal hearing loss in this population and has further highlighted the ineffectiveness of selective hearing screening based on at-risk factors. The data argues strongly for hearing screening programs to be universalised as a standard of practice in all delivery settings, so that they will not miss undiagnosed infants with hearing loss in their critical period of development.

6. CONCLUSION

The goal of this study was to screen for hearing impairments in every newborn delivered at a tertiary care facility in Tumkur using a systematic, multistaged protocol incorporating both Otoacoustic Emissions (OAE) and Brainstem Evoked Response Audiometry (BERA). Six neonates out of the 306 screened were confirmed hearing losses with a prevalence of 1.96%. This represents a similar finding to the prevalence in the Indian context and globally. The study also shows that many of the infants identified with hearing loss did not have any identifiable risk factors, and there were no statistically significant associations found between markers of specific perinatal risk variables and confirmed hearing impairment. This would indicate strong support for universal newborn hearing screening (UNHS) at birth compared to selectively screening high risk infants.

Utilizing a two phased OAE protocol along with subsequent BERA for confirmation, was not only realistic, but the best method to reduce false positive cases along with providing accurate diagnosis. The study reiterates the idea that early identification of hearing loss, even if the newborn is asymptomatic, is vital for timely management and therefore leads to improved language development, cognitive development, and quality of life. Therefore, UNHS should be considered an integral part of holistic neonatal health care for all newborns regardless of the risk status.

7. Recommendations

Based on the above findings, the following recommendations are presented to enhance early detection and treatment of neonatal hearing loss:

- Incorporate newborn hearing screening (NHS) into all routine postnatal care in hospitals and healthcare set-ups, not only practice at tertiary settings.
- Improve referral and follow-up systems so infants who fail initial screening are retested with immediate promptness and referred to BERA confirmatory tests and early intervention if needed.
- Train the OAE and BERA screening ipsilateral healthcare professionals, including nurses, paediatricians and audiologists, and their respective interpretation of the results.
- Educate parents and caregivers about early hearing screening and consequences for the lack of follow-up from child health services.
- Advocate for governments to droup policy on newborn hearing screening which postulates across the state and national level as well as develop an efficient and integrated public health system and financial structure.

8. Limitations

Although the study provided useful information about the prevalence and detection of neonatal hearing loss, it has some limitations.

- Being a single-center study limits the extent to which findings can generalise, to say different regions or healthcare resources or even patients with different demographics.
- The number of screened newborns has been limited (N = 306), so detecting statistically significant associations or effect sizes related to risk factors and hearing loss may be limited.
- The study had a short follow-up duration, which limits long-term evaluative outcomes or late onset hearing impairment.

Future studies should conduct multi-center trials, with larger and more diverse populations as well as longer follow-up to consider the long-term consequences associated with identifying neonatal hearing loss early and apt intervention designs.

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