

ACCURACY OF OAE AND BERA TO DETECT THE INCIDENCE OF HEARING LOSS IN NEWBORN

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ABSTRACT: OBJECTIVE: The aim of this study was to assess the sensitivity and specificity of otoacoustic emission (OAE) test in newborns comparing with auditory brain stem response (ABR) in the age of 3 months and 6 month to analyzed the incidence of hearing loss in newborn. **METHOD:** A prospective study was conducted between October 2012-October 2014 in Govt. Medical College, Haldwani. 500 newborns were assessed. First, all of neonates were evaluated by OAE in 24hrs after birth. If responses of OAE were failing, they were retested in 3 month after birth by OAE. Also, All Neonates were assessed by ABR in the age of 3month and 6 months. Descriptive Statistics was used to analyze data. **FINDINGS:** The incidence of permanent congenital hearing loss according to diagnostic testing, Five out of hundred newborn with risk factors (5%). And in well nursing baby it display 0.5% which is 10 times less than high risk population. In our study Otoacoustic emission screening was conducted for 400 normal babies on day 1 after birth in most case, 250 babies (62%) passed the first screening test. 150 babies (38%) referred in both the ears. second test were screened again within a period of three month. The second OAE testing was conducted in all 400 babies. 398 babies (99.5%) passed the second OAE screening, and 2 baby (0.5%) failed the second OAE test. Brainstem Evoked Response Audiometry was done at 3 month and 6month showing 2 impaired, 398 normal. In our study Otoacoustic emission screening was conducted for 100 high risk babies on day 1 after birth, 55 babies (55%) passed the first screening test. 45 babies (45%) referred in both the ears. second test were screened again within a period of three month. The second OAE testing was conducted in all 100 babies.92 babies (92%) passed the second OAE screening, and 8 baby (8%) failed the second OAE test. Brainstem Evoked Response Audiometry was done at 3mt and 6mt showing 9 impaired 91normal.In 9 impaired 2 showing normal hearing on FFA and one showing conductive HL on tympanometry. In our study sensitivity & specificity of OAE 70% and 61% at 0 month and 70% and 99% at 3 month and BERA sensitivity and specificity at 3 month 90% and 99% and at 6 month 100% and 99%.

KEYWORDS: OAE, BERA, HL.

INTRODUCTION: Early detection of hearing loss has been a long-standing priority in the field of audiology. Hearing screening tests have been used for the last 60 years to identify children of school going age who require further audiological evaluation, and ultimately to identify those children who require further audiological and educational intervention (White, 2003:79).¹ However, owing to the fact that hearing loss is an invisible disability, it may often go undetected until school age, especially in children with no additional disabilities. The identification of hearing loss in developing countries is often passive, and poor reactions of a child to acoustic stimuli are ignored or only identified following an underlying disease, such as suppurative Otitis Media (Olusanya, Luxon & Wirz, 2004:295; Olusanya, 2001:142).² This late identification of hearing loss leads to delays in speech, language,

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reading and writing, academic achievement, and personal and social development (Yoshinaga-Itano & Gravel, 2001:62).³

The last 35 years have therefore seen the implementation and development of infant hearing screening (IHS) programs in order to identify hearing loss as early in life as possible. If hearing loss is identified early, early intervention services can be provided, in order to prevent developmental delays in children with hearing loss (Yoshinaga-Itano, 2004:454).⁴ IHS programs have evolved from early behavioural observation techniques to sophisticated, screening technologies relying on physiologic measurements, such as oto- acoustic emissions (OAEs) and brainstem responses evoke audiometry (BERA) (Diefendorf, 2002:469; Northern & Downs, 2002).⁵

AIMS & OBJECTIVEA: Accuracy of OAE & BERA to detect the incidence of hearing loss in newborn.

METHOD & MATERIAL: STUDY DESIGN: Hospital Based Prospective longitudinal Study. (Follow up)

Study Place: Audiology department of ENT, department of Paediatric (NICU) and Obstetrics & Gynaecology department under of the Government Medical College, Haldwani.

Study Population: The newborns admitted in the NICU of the STH and well nursing care newborn (n=800) during the entire study period.

Study Sample/Subjects: All those newborns (n=500) from the above study population whose mothers gave consent for screening tests to be done on their newborns and also they were not lost to follow up upto 6 months from the birth of the child during the entire study period.

EXCLUSION CRITERIA: Unstable newborns needing urgent referral to higher centers were excluded.

Sample Size: n=500 (Using Purposive sampling).

Study Period: 2 years (October 2012-October 2014).

Study Tools:

- a) A semi structured questionnaire.
- b) For hearing tests in the newborn: Screening tests like OAE and BERA.

Description of the Study Sample 800 newborn and their caregivers enrolled in the NHS program between October 2012 to April 2014 were selected for participation in the study, based on participants meeting the predetermined participant selection criteria. 300 are lost from follow up and newborn that received their initial hearing screening within 72 hour of birth. Routine follow-up visits were scheduled three monthly, in order to enable the identification of late-onset or progressive hearing loss.

Again all they were requested to return in three months time. Either they were Pass or Refer. Follow-up visits for infants participating in the NHS (Newborn health screening) program were scheduled until infants reached 6months of age. Records of visits to the NHS were complete for all 500 newborn in terms of demographic information for each newborn and their caregiver; auditory tests conducted and their results; risk factors for hearing loss and number of visits to the NHS.

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DATA COLLECTION PROCEDURE:

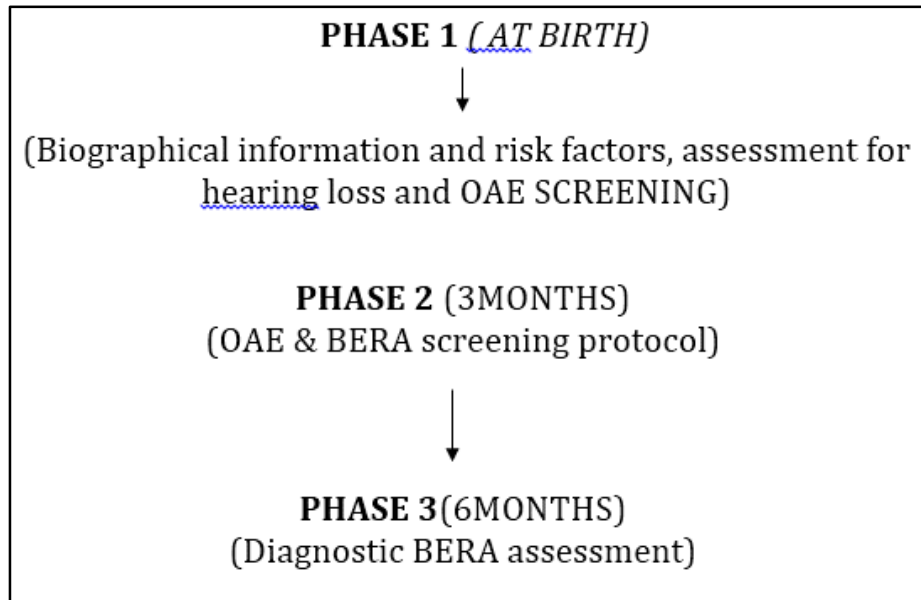
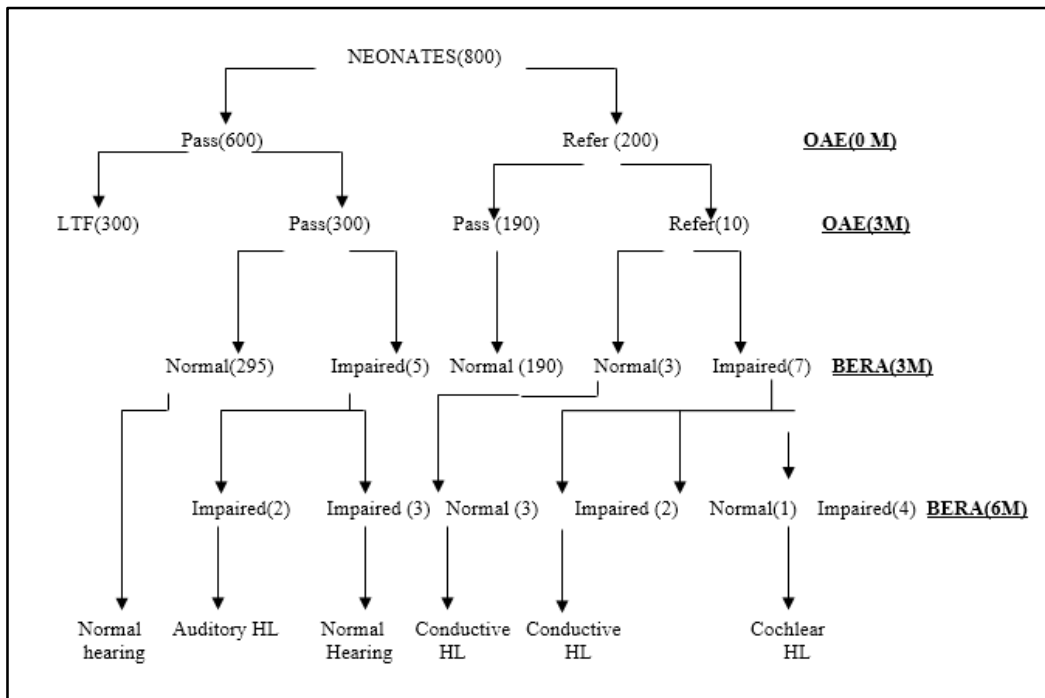


Figure 1: Graphic representation of the research

STATISTICAL ANALYSIS: The elicited socio-demographic information from the mothers of the newborns along with obtaining different exposure profile of at risk newborns for hearing loss and the results of the screening hearing tests was checked properly for any missing information. After ensured checking for data cleaning, the data entered in the MS excel after proper coding of data to prepare master chart. Appropriate analysis was carried out like percentage for descriptive information and fisher's exact test/chi-square to find the association between established risk factors & hearing loss, relationship of mother age, education with hearing loss in the newborns. By comparing the results of screening tests with confirmatory BERA at 6 months, the percentages of false positive, false negative, true positive and true negative was find out so as to calculate the accuracy (Sensitivity/Specificity) of the used screening test.

OBSERVATION & RESULT: The present study was carried over a period of almost 2 years in the department of Otorhinolaryngology, Sushila Tiwari Hospital, Haldwani. The study included 500 newborn that were born in this hospital and follow up for next 6 months by applying OAE at 0mt 3mt and BERA at 3mt & 6mt.

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| Exposure/Established Risk Factors | Frequency | Percent |
|-----------------------------------|------------|--------------|
| Absent | 400 | 80.0 |
| Present | 100 | 20.0 |
| Total | 500 | 100.0 |

Table 1: Risk factor Exposure/Non exposure profile of the newborn

The 100 newborn were found to be exposed to different causes which can lead to neonatal hearing loss. While the remaining 400 newborns were free from different exposures responsible for neonatal hearing loss.

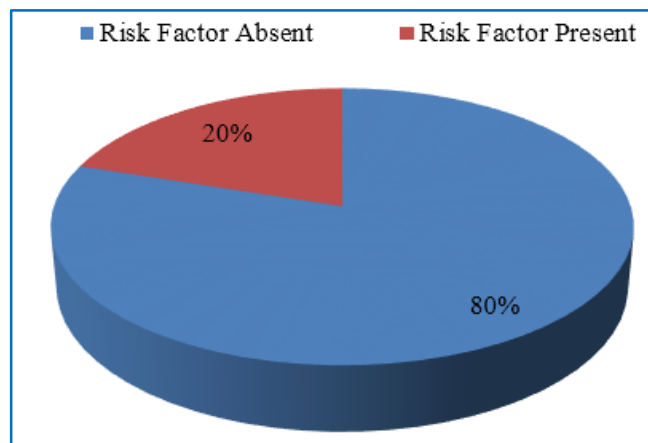


Fig. 1: Exposure to Risk Factor

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| Risk factor | SNHL + | SNHL - | Total |
|--------------|----------|------------|------------|
| Present | 5 | 95 | 100 |
| Absent | 2 | 398 | 400 |
| Total | 7 | 493 | 500 |

Table 2: Sensorineural hearing Loss in Children With and Without Risk Factors

- Incidence of SNHL in high risk newborn in this hospital based study = 5%.
- Incidence of SNHL in well nursing newborn = 0.5%.
- Incidence of hearing loss in high risk newborn is 10 time higher than normal newborn.
- Fisher Exact test showing p value 0.004 statistical significant.

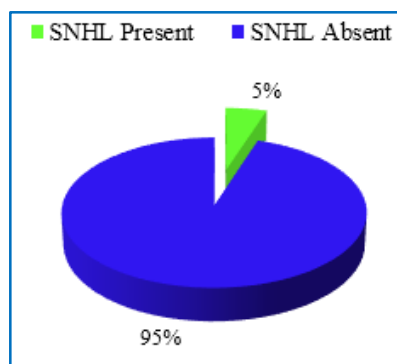


Fig. 2: Hearing Loss in Children Exposed to Risk Factor

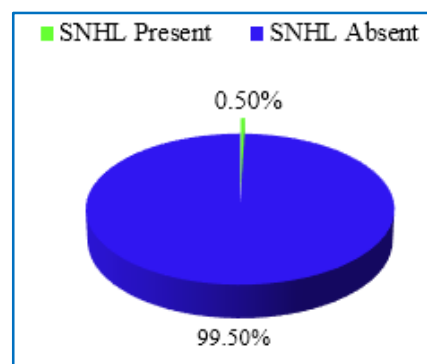


Fig. 3: Hearing Loss In Children not Exposed to Risk Factor

| Newborns | OAE at birth | OAE at birth |
|-----------------------------|--------------|--------------|
| | Positive | Negative |
| Hearing loss found (10) | 7 (TP) | 3 (FN) |
| No hearing loss found (490) | 188 (FP) | 302 (TN) |

Table 3: Accuracy of OAE at birth

On comparing the final hearing loss in the total 500 newborns confirmed by the final confirmatory test of BERA done at 1 year, it was found that only 10 newborns had confirmed hearing loss. Hence the false positivity by OAE at birth was more 1.e 188 newborns were falsely detected by OAE at birth to have hearing loss.

The sensitivity of OAE at birth.

$$= \frac{TP}{TP+FN} \text{ and whole multiplied by } 100.$$

$$= \frac{7}{7+3} = 70\%.$$

The specificity of OAE at birth.

$$= \frac{TN}{TN+FP} \text{ and whole multiplied by } 100.$$

$$= \frac{302}{302+188}.$$

$$= 61.63\%.$$

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| Newborn | OAE at 3 months | OAE at 3 months |
|-----------------------------|-----------------|-----------------|
| | Positive | Negative |
| Hearing loss found (10) | 7 (TP) | 3 (FN) |
| No hearing loss found (490) | 3 (FP) | 487 (TN) |

Table 4: Accuracy of OAE at 3 months

The false positivity decreased with OAE at 3 months.

The sensitivity of OAE at 3 months.

$$= TP/TP+FN \text{ and whole multiplied by } 100.$$

$$= 7/7+3=70\%.$$

The specificity of OAE at 3 months.

$$= TN/TN+FP.$$

$$= 487/487+3=99.39\%.$$

| Newborns | BERA at 3 months | BERA at 3 months |
|-----------------------------|------------------|------------------|
| | Positive | Negative |
| Hearing loss found (10) | 9 (TP) | 1 (FN) |
| No hearing loss found (490) | 3 (FP) | 487 (TN) |

Table 5: Accuracy of BERA at 3 months

The sensitivity of BERA at 3 months.

$$= TP/TP+FN \text{ and whole multiplied by } 100.$$

$$= 9/9+1=90\%.$$

The specificity of BERA at 3 months.

$$= TN/TN+FP \text{ and whole multiplied by } 100.$$

$$= 487/487+3=99.39\%.$$

| Newborns | BERA at 6 months | BERA at 6 months |
|-----------------------------|------------------|------------------|
| | Positive | Negative |
| Hearing loss found (10) | 10 (TP) | 0 (FN) |
| No hearing loss found (490) | 1 (FP) | 489 (TN) |

Table 6: Accuracy of BERA at 6 months

The sensitivity of BERA at 6 months.

$$= TP/TP+FN \text{ and whole multiplied by } 100.$$

$$= 10/10+0=100\%.$$

The specificity of BERA at 6 months.

$$= TN/TN+FP \text{ and whole multiplied by } 100.$$

$$= 489/489+1=99.8\%.$$

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DISCUSSION: Congenital hearing loss is one of the most common congenital anomalies which can be identified early in life. Its early recognition and intervention helps in the overall development of the child. The developed countries are aware of the burden of congenital hearing loss and have taken significant steps by way of government policies for identification and rehabilitation. On the other hand, in developing countries like India there is no estimate of the magnitude of this problem.

The incidence of permanent congenital hearing loss as found in this sample of subjects is displayed above in figure 3 & 4.

Figure 3 & 4 displays the fact that 5% (n=5) of the high risk sample were found to have sensory or neural impairment. The literature estimates 0.15%-0.6% of the general newborn population to be born with congenital hearing loss (Northern & Downs, 2002: 267; Olusanya, Luxon & Wirz, 2004:288).⁶ This incidence is reported to be 10 to 20 times higher in the high-risk NICU population (Yoon et al., 2003:355; Yoshinaga-Itano, 2004:462).⁷ The sample of NICU infants in the current study displayed a 5% incidence rate of permanent congenital hearing loss, which is in keeping with the literature. And in well nursing baby it display 0.5% which is 10 times less than high risk population, which is Schulman – Galambos & Galambos⁸ studied 325 children for 1year or more after discharge from their intensive care nursery. They found 8 children (2.14%) with severe hearing loss. Galambos et al⁹ in a more recent large follow up study continues to maintain a higher incidence of significant milar to other studies.

Hearing loss of 4-9%. Roberts et al¹⁰ in another recent large follow up study could confirm hearing loss in only 2.3%. Therefore this issue remains Controversial.¹¹

The current study's incidence rate of permanent hearing loss is nevertheless still in accordance with reported incidence rates in the NICU population, although it is at the upper limit when taking the estimated actual who did not return for follow-up (Yoon et al., 2003:355; Yoshinaga-Itano, 2004:462; Northern & Downs, 2002:267).^{7, 4, 6}

Accuracy of Hearing Test (OAE and BERA): In summary, technologic advances now make it possible to assess auditory function in neonates and infants. These electrophysiologic and acoustic responses can be safely applied without reliance on a behavioral response. However, neither OAE nor BERA tests evaluate hearing or describe how a particular person will use available hearing. OAE and BERA are physiologic responses related to peripheral hearing status but constitute indirect measures of hearing.

To predict hearing status in children 0 to 12 months of age, a multicenter longitudinal study compared the accuracy of click-evoked BERA and TEOAEs. The results indicated no significant differences among the these measures.¹² However, a recent study comparing two-step TEOAEs and BERA found that BERA was more effective for NHS because it yields fewer false-positive results and a lower referral rate compared with TEOAE, resulting in a smaller percentage of infants lost during follow-up.¹³

Hyde and associates¹⁴ reported BERA sensitivity of 98% and specificity of 96% if the average target hearing loss is 40dBHL at 2 and 4kHz. If the target degree of hearing loss is 30dBHL, sensitivity and specificity were 100% and 91%, respectively.

Norton and coworkers held specificity at 80% and determined sensitivity for TEOAE, and BERA alone and in combination for a target loss of 30dBHL. Sensitivity ranged from 80% to 90%. If those infants with known progressive hearing loss were excluded, sensitivity improved.¹²

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In our study sensitivity & specificity of OAE 70% and 61% at 0 month and 70% and 99% at 3 month which is less than the above study and BERA sensitivity and specificity at 3 month 90% and 99% and at month 100% and 99% which is relatively similar to above study.

However, according to the American Academy of Family Physicians studies (2007), the sensitivity of OAE in identification of hearing loss was 84 % and the specificity of it was 90%. As well as, in our study, the sensitivity (70%) and specificity (99.3%) of TEOAE for detecting of hearing loss were high; therefore, it is effective tool for screening of neonates in birth.

Yousefi, Jaleh *¹, MD; Ajallouyeen et al.¹⁵ done a study of comparing specificity and sensitivity of TEOAE and compare it to BERA in there study they found: Eighteen cases out of 1000 neonates had failed double-checked TEOAE tests, from these 18 failed cases, 6 were confirmed by ABR test (12 false positive results). Nine out of 1000 neonates had impaired ABR tests, from these patients, 6 had failed OAE as well, but 3 had normal OAE (3 false negative result). From these 9 patients 2 had profound hearing loss so cochlear implantation was scheduled for them. They found that OAE has 66.7% sensitivity and 98.8% specificity in diagnosis of neonatal hearing impairment.

In our study showing same result for sensitivity and specificity of TEOAE for diagnosis of neonatal hearing impairment.

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