

ORIGINAL RESEARCH

Validity of otoacoustic emission test as screening test for assessment of hearing in newborns

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ABSTRACT

Late identification of hearing loss presents a significant public health concern. However, without screening, children with hearing loss are usually not identified until 2 years of age, which results in significant delays in speech, language, social, cognitive and emotional development. Detailed history was taken about the baby and noted. Babies are brought to a noise free room for examination. With babies comfortably lying on mother's lap, a soft pediatric probe tip is placed in the ear canal to obtain a tight seal. A miniature speaker within the probe assembly generates in the ear canal sound stimuli at a moderate intensity level. Among this population 1244 babies (90%) passed in the first screening, 136(10%) were failed (refer). Out of 136 babies, 6 were unilateral and 130 were bilateral. Of 136 babies 6 babies were lost follow up and second screening test was done for 130 babies. Among them 10 babies (0.7%) failed in the second screening test. Of these 10 babies 4 lost follow up and BERA was done for 6 babies, 5 of them were confirmed to have sensorineural hearing loss.

Key words: Otoacoustic emission test, assessment of hearing, newborns

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INTRODUCTION

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.

The prevalence of newborn and infant hearing loss is estimated to range from 1.5-6.0 per 1000 live births^{1,2}. According to the 2005 estimates of World Health Organization (WHO), 78 million people have disabling hearing impairment. Incidence of congenital sensorineural hearing loss (SNHL), averages approximately 3/1000^{3,4}. In India, 63 million people (6.3%) suffer from significant auditory loss⁵, and hearing loss is seen with an average of four per 1000

newborn children in India⁶. In US current prevalence is 1.4 per 1,000.

The prevalence of deafness in Southeast Asia ranges from 4.6% to 8.8%⁵ (Garget *et al.*, 2009). Among 6.5 billion in world, 5.3 billion live in developing countries like Africa, Asia and Latin America⁷ where no newborn hearing screening programs exist. The above data clearly indicate the critical need to develop the hearing screening program in the developing countries to combat the detrimental effects of hearing loss on all babies born with hearing loss.

Substantial proportion of infants with congenital hearing loss has no identified risk factors. Risk factor screening identifies only 50% of infants with significant hearing loss^{8,9}.

42-70% of children with hearing loss will be missed if only risk factor screening is performed¹⁰.

Failure to identify the remaining infants with hearing loss results in diagnosis and intervention at an unacceptably late age.

Late identification of hearing loss presents a significant public health concern. However, without screening, children with hearing loss are usually not identified until 2 years of age, which results in significant delays in speech, language, social, cognitive and emotional development.

A critical period exists for optimal language development and earlier intervention may produce better results.

Treatment of hearing defect will improve communication and alleviate parental frustration.

In contrast, early identification and intervention prior to 6 months of age has a significant positive impact on development.

A universal screening program has to be developed to identify infants with hearing loss at the earliest^{11,12}.

METHODOLOGY

STUDY SITE: The study was conducted in the Department of Pediatrics and ENT department.

STUDY POPULATION: The study group comprised of all newborns at Hospital during study period.

STUDY DESIGN: Prospective study

SAMPLE SIZE: 1380.

STATISTICAL FORMULA

$$n = [(Z_{1-\alpha/2})(1-p)p] / \xi^2 p$$

RESULTS

Table 1: Result of Initial Screening

	Number	Percentage (%)
OAE present in both ears	1244	90
OAE present in any one ear	6	1
OAE absent in both ears	130	9
Total	1380	100

Among this population 1244 babies (90%) passed in the first screening, 136(10%) were failed (refer). Out

EXCLUSION CRITERIA

- Infants with atresia of External Auditory Canal.
- Infants with middle ear pathology.

This proposed study was undertaken by department of pediatrics and ENT, in order to detect the validity of Distortion Product Otoacoustic Emissions as a screening test.

DPOAE testing of infants will be done at 24-72 hours. For "pass" cases no further testing to be done. For "refer" cases repeat DPOAE testing will be done at 15-30 days.

Those who have failed rescreening, will be subjected to Brainstem Evoked Response testing (BERA) within 3 months to confirm hearing loss.

Before the test it must be ensured that external auditory canal is free of debris and also middle ear pathology is to be ruled out. The test is conducted by a trained audiologist in a noise free room.

In our hospital 'OTOREAD', an automatic hand held device was used to screen the newborns. DPOAE test protocols can be set up with standard 'pass' or 'refer' criteria. The result is displayed on the screen, which is quick and accurate. A cradle is used to store the instrument and transfer the data to PC or thermal printer.

Detailed history was taken about the baby and noted. Babies are brought to a noise free room for examination. With babies comfortably lying on mother's lap, a soft pediatric probe tip is placed in the ear canal to obtain a tight seal. A miniature speaker within the probe assembly generates in the ear canal sound stimuli at a moderate intensity level.

of 136 babies, 6 were unilateral and 130 were bilateral.

Table 2: Result of Second Screening

	Number	Percentage (%)
Not done	1244	90
OAE present on repeat screening	120	9
OAE absent in both ears	10	1
Loss to follow up	6	
Total	1380	100

Of 136 babies 6 babies were lost follow up and second screening test was done for 130 babies. Among them 10 babies (0.7%) failed in the second screening test.

BERA-Brainstem evoked response audiometry.

Of these 10 babies 4 lost follow up and BERA was done for 6 babies, 5 of them were confirmed to have sensorineural hearing loss.

Table 3: Result of Bera

BERA	Number	Percentage (%)
Not done	1374	99.5
Normal	1	
Abnormal	5	0.36
Total	1380	100

Table 4: Characteristics of neonates with abnormal BERA

BERA abnormal	Birthweight	Gestation	Hyperbilirubinemia	Sepsis	Aminoglycosides	Perinatal depression	Use of Mechanical ventilator
1.	LBW	Preterm	Present	Present	Used	Absent	Not required (NR)
2.	Normal	Term	Absent	Absent	Not used	Absent	NR
3.	VLBW	Preterm	Absent	Absent	used	Present	Require d
4.	VLBW	Preterm	Absent	Absent	used	Absent	NR
5.	Normal	Term	Present	Present	used	Absent	NR

3 of the 5 babies were preterm and of low birth weight, one of them had perinatal depression and was mechanically ventilated for 5 days. A term baby with

meningitis was found to have hearing loss. One of the babies had no risk factors for hearing loss.

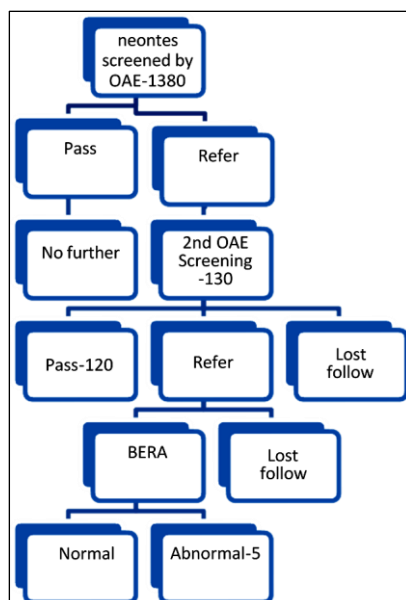


Figure 1: Flow Chart of Hearing Screening Result

DISCUSSION

Of 1380 babies 1245 babies passed in the initial screening, 136 were referred.

130 of them failed in both ears. Referral rate after first screening was found to be 10%.

5 babies lost for follow-up for OAE rescreening. Of the 125 babies, 115 passed on rescreening¹⁰.of them failed bilaterally. Referral rate was reduced to 0.7% from 9%. John *et al.* had shown refer rate of initial test of 6.4% was reduced to 1.6% on subsequent tests. OAE may be affected by debris or fluid in the external or middle ear resulting in referral rates of 5 to 20%, when screening is performed in the first 24 hours after birth. Referral rates less than 4% maybe achieved when OAE combined with automated BERA in a two-step screening system.

Due to variations in earphone placement among the, child behavior and hearing fluctuations from transient middle ear conditions, a 2-tiered hearing screening

program is recommended to reduce false positive results. This protocol would include the initial screen and same-day rescreen, failing which babies were called for rescreening 15-30 days later. Rescreening, preferably within the same session, has been found to reduce the number of failures by approximately one-half due to repositioning of earphones and reinstruction.

The data available from one Florida school district revealed that immediate rescreen reduced the total number of failures by 25%. A study in Beijing, the second inpatient OAE test showed the decrease in referral rate from 27.22% to 18.36%. In order to reduce the high over-referral rates, the ASHA (1997) guidelines revised the time between the initial screen and the rescreen to 6-8 weeks.

Of the 10 babies who failed rescreening, follow up was lost for 4 babies. 6 of them underwent BERA of which 1 was normal and 5 were abnormal i.e. they

had Bilateral sensorineural hearing loss. Sensitivity of BERA was found to be 100% which correlates with other studies. In a study done by James W Hall, The sensitivity of the BERA screening test (the percentage of neonates with actual hearing impairment who received a "Refer" outcome) was 100%. The specificity of the BERA screening test (the percentage of normal-hearing neonates who received a "Pass" outcome) was 99.7%. Hyde and associates reported BERA sensitivity of 98% and specificity of 96% if the average target hearing loss is 40 dB HL at 2 and 4kHz. If the target degree of hearing loss is 30 dB HL, sensitivity and specificity were 100% and 91%, respectively.

Galambos *et al.*¹³ in a more recent large follow up study continues to maintain a higher incidence of significant mileage to other studies. Yousefi, Jaleh *et al.*¹⁴ showed the prevalence of 0.9%. WK Low *et al.*¹⁵, had shown in their study in 2005, prevalence of hearing loss in newborns is 0.4%, while Downs *et al.*¹⁶ had shown prevalence of hearing loss in newborns is 0.32%. Our study matches most of the other study.

Incidence among the newborn with risk factors was found to be 1.5% and newborns without risk factors was found to be 0.09% which is 15 times lower than that with risk factors. A study was conducted between October 2012-October 2014 in Government medical college Haldwani. 500 newborns were assessed, 5% of high risk babies and 0.5% of were found to have hearing loss. Incidence of hearing loss was found to be 10 times more in babies with risk factors in this study. As per most of the western studies, incidence of congenital sensorineural hearing loss (SNHL) averages approximately 3/1000.

There are few surveys showing incidence of hearing impairment in India. In one such study, by Nagapoomma *et al.*, in 2006 an incidence of hearing impairment of 5.6/1000 was demonstrated (Nagapoomma *et al.*, 2007)¹¹. The incidence of hearing impairment in study at commando hospital was (6.25 per 1000). A study at tertiary hospital in southern India and in Christian medical college, Ludhiana showed prevalence of hearing loss of 0.4%. The prevalence of hearing loss in newborns of migrants in Beijing was found to be 0.32% (35 babies of 10983) in a study.

Incidence in our study was 3.6 per 1000 which is comparable to national average of 4/1000. Incidence in our study matches most of the other studies. The screening program was successful in detecting in detecting a baby without any risk factor. Hence OAE test is found to be valid and can be recommended for universal newborn hearing screening.

CONCLUSION

Incidence of the study was found to be 0.36%. This correlates well with national and international figures and therefore calls for UNHS to be made as national

practice. Hence the test was found to be valid for hearing screening.

With our limited data, it is too early to arrive at any conclusions or definite interpretations yet. Since the observations are correlating with previous studies and national data, OAE can be recommended for screening of hearing loss in newborns.

UNHS has become a national practice in most developed countries. The identification of all newborns with hearing loss before 6 months has now become an attainable realistic goal.

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