Original Research Article

DOI: http://dx.doi.org/10.18203/issn.2454-5929.ijohns20172654

Efficacy of TEOAEs and BERA as screening tools for deafness in newborn

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Received: 29 May 2017 Accepted: 14 June 2017

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ABSTRACT

Background: Hearing during the first 6 months of life is also considered as crucial for normal acquisition of language. Hence, infants with permanent congenital and early hearing loss identified by 6 months of age and given appropriate and timely support are reported to achieve better language outcomes than those identified later than 6 months of age.

Methods: The study group constituted of 200 ears of 100 neonates (0-28 days) that were randomly selected. The neonates were taken from immunization clinic, newborn nursery, neonatal ward and intensive care unit of our hospital and also those referred from other hospitals.

Results: There were 4 neonates (8 ears) with high risk factors of hyperbilirubinemia, prematurity and preterm born. These were subjected to Transient Evoked Oto-acoustic Emission (TEOAE) as well as BERA. Out of the 8 ears, 3 ears showed TEOAE fail, one had bilateral and the other had unilateral TEOAE fail. 5 ears passed TEOAE test.

Conclusions: TEOAE cannot completely replace BERA as screening modality for hearing impairment in neonates, however can complement it.

Keywords: BERA, TEOAE, Deafness, Newborn

INTRODUCTION

An important aspect in child's development is the acquisition of and production of spoken language. Language is the key to express our thoughts, feelings and needs and by which we understand others. According to UNICEF analysis each year approximately 1,26,000 - 5,00,000 babies are born with significant hearing loss and about 90% of them live in developing countries. ¹

Hearing loss has been reported as the commonest congenital abnormality in newborn, more than twice as prevalent as other conditions which are screened for at birth such as phenylketonuria, sickle cell anemia, hypothyroidism and galactosemia.² Permanent congenital hearing loss could occur during or shortly after birth as early onset or manifest postnatally as late onset,

progressive or acquired hearing loss with varying degrees of severity. EARLY onset refers to first 28 days of life .Hearing loss is considered as significant if it is such degree that would interfere with normal speech and language development.

Moderate permanent bilateral hearing loss (>40 dB) in early childhood canimpede speech, language and cognitive development.^{3,4} It also has adverse effect on social, emotional and academic development with a high cost to society.^{5,6} Even children with a mild or unilateral permanent hearing loss may experience difficulties with speech, language, educational and psycho social development.⁶⁻⁸ The period from birth to 5 years is often viewed as the critical phase for the development of language.⁹

Hearing during the first 6 months of life is also considered as crucial for normal acquisition of language. Hence, infants with permanent congenital and early hearing loss identified by 6 months of age and given appropriate and timely support are reported to achieve better language outcomes than those identified later than 6 months of age. ¹⁰

Technological advancement in screening instrumentation within the last two decades have resulted in the introduction of two new objective tests namely Otoacoustic Emission and Auditory Brain Stem Response/ Brainstem Evoked Response Audiometry (BERA).

Universal newborn hearing screening; the goal is to achieve the highest possible yield from a wide screening coverage that is associated with a low referral rate. When only OAE is used babies with auditory neuropathy will be missed while ABR may miss babies with mild SNHL or with high frequency hearing loss. The most preferred option is to combine both the tests in a two stage screening programme. ¹¹

To justify universal screening, at least five criteria must be met: An easy to use that possesses a high degree of sensitivity and specificity to minimize referral for additional assessment is available.

- 1. The condition being screened for is otherwise is not detectable by clinical parameter.
- 2. Interventions are available to correct the conditions detected by screening.
- 3. Early screening, detection and intervention result in improved outcomes.
- 4. The screening programme is documented to be in an acceptable cost effective range. 12

The identification of all newborns with hearing loss before the age of six months has now become an attainable realistic goal .In the past parents and pediatrician often did not suspect a hearing loss until the age of 2-3 years, after important milestones have not been met. By the time these milestones are missed, the hearing impaired child has already experienced irreversible delays in speech and language development .Technology allows for the development of screening tools that are reliable and that can be used to identify infants with hearing loss.

With the ability to detect and diagnose an infant with hearing loss soon after birth, there is now no reason why any infant born with a hearing loss should experience anything but normal speech and language development as a result of early intervention. ¹³

METHODS

This is a prospective study to compare the efficacy of Transient Evoked Oto-acoustic Emission (TEOAE) and

BERA as screening tools to detect hearing impairment in neonates during newborn hearing screening programme. The study was conducted between October 2008 to October 2009 at Manipal Hospital Bangalore.

The study group constituted of 200 ears of 100 neonates (0-28 days) that were randomly selected. The neonates were taken from immunization clinic, newborn nursery, neonatal ward and intensive care unit of our hospital and also those referred from other hospitals.

An informed consent for both the tests BERA and TEOAE were taken from one of the parents after explaining them the methods of testing in their own language.

The newborn were subjected to TEOAE and BERA measurements while they were under natural Sleep. The TEOAE was done using Maico-ERO scan and BERA by HIS (Intelligent hearing systems). The well born babies were initially subjected to TEOAE and those which were passed in the test were discharged from the hospital. The well born neonates which failed in the test were followed after 6-8 weeks and were subjected to diagnostic BERA. The neonates with risk factors underwent both TEOAE and BERA and the results noted.

BERA testing procedures

The mother was instructed to hold the baby still and soothe the baby if he/she woke up or stirred.

Electrode placement

Rubbing the surface with cotton soaked in saline, the area of electrode placement is cleaned. The pasting electrodes are used to stick the electrodes in their respective positions. Stimulus is given through insert ear phones. Click stimulus is given at 40dBHL and if there was no response, stimulus is increased by 20 dB and reduced by 10 dB if response is obtained (1024 clicks @19.3/second).

OAE testing procedures

A soft pediatric probe tip in the ear canal was inserted to obtain a tight seal. Multiple responses were averaged. All TEOAE were analyzed to the noise floor. Therefore, a reduction of physiologic and acoustic ambient noise is critical for good recordings. The test usually was completed in less than 5 minutes. The ears were checked before inserting the probe tip to make sure that they were free of vernix or debris. The mother was instructed to hold the baby still. The test was conducted in a quiet room. The test was done for both ears and recording were obtained for each ear.

RESULTS

The pass and fail rate for TEOAE as a function of test shows that 182 Neonates passed TEOAE and 18 ears

failed TEOAE in the initial testing (Table 1). Finally comparing the TEOAE with BERA, using BERA as the gold standard the pass and fail rate obtained by using the above screening tools are tabulated as shown (Table 2).

Table 1: OAE findings.

| OAE | Number | % | 95% CI |
|----------------------|--------|-------|-------------|
| Passed | 182 | 91.0 | 86.22-94.23 |
| Failed | 18 | 14.0 | 9.87-19.49 |
| Total number of ears | 200 | 100.0 | - |

Table 2: Evaluation of OAE test in relation to BERA/ABR.

| Diagnostic statistics (OAE vs. BERA/ABR) | | | |
|------------------------------------------|----------|--|--|
| True positive (no) | 4 (ears) | | |
| False Positive (no) | 14 | | |
| False Negative (no) | 2 | | |
| True negative (no) | 180 | | |
| Sensitivity (%) | 66.67 | | |
| Specificity (%) | 92.78 | | |
| FN (%) | 33.33 | | |
| FP (%) | 7.21 | | |
| PPV (%) | 22.22 | | |
| NPV (%) | 98.90 | | |
| Accuracy (%) | 92.00 | | |
| Significance | <0.001** | | |

Screening of 192 ears of well born neonates with TEOAE, 180 ears were pass and these were discharged from the study.

There were 4 neonates (8 ears) with high risk factors of hyperbilirubinemia, prematurity and preterm born. These were subjected to TEOAE as well as BERA. Out of the 8 ears, 3 ears showed TEOAE fail, one had bilateral and the other had unilateral TEOAE fail. 5 ears passed TEOAE test. These neonates were subjected to BERA. One neonate with hyperbilirubinemia had bilateral absent BERA with normal TEOAE recordings giving a false negative result. Of the 2 neonates with low birth weight and preterm, one neonate had both TEOAE as well as BERA pass recordings while other neonate had bilateral TEOAE as well as BERA recorded fail. Unilateral ear of a neonate with hyperbilirubinemia recorded TEOAE as well as BERA fail. These neonates were followed up.

The premature neonate with bilateral failed TEOAE and BERA passed after the completion of the gestational age. However the neonate with false negative result was lost to the follow up. The other ears still failed on repeat BERA. There were 15 ears of well born neonates which showed TEOAE fail. These were followed up after 6-8 weeks and were subjected to BERA. Out of them 14 ears passed BERA and one ear failed in BERA.

DISCUSSION

In our present study 100 neonates (200 ears) were taken up for the study in a prospective manner .The pass rates of TEOAE was 91% and the pass rate for BERA was 98%. The number of false positive ness obtained from TEOAE was 7% and the sensitivity of TEOAE was 92.7% and specificity of 66%.The referral rate in our study was 9% when TEOAE was used alone and when combined with BERA the referral rate is reduced to 2%.

Clarke et al compared two hearing screening methods in a well newborn infants within the post natal ward environment prior to discharge. The pass rate for two step screening using TEOAE and BERA was 91.4 % and 66.7% for TEOAE alone. They concluded that TEOAE alone for pre discharge hearing screening is associated with an excessively high false positive rates. ¹⁴

Mehl et al stated in their study stated that BERA can effectively reduce the referral rate to 1-2%. ¹⁵ Lin, Hung ching et al screened 21, 273 new born for hearing loss. The referral rate using TEOAE was 6.4 % (6.6 to 7. %) ABR significantly reduce the referral rate to 1 to 2. ¹⁶

Vohr et al, in an analysis of 3UNHS protocols the referral rate at discharge were 3.21%, 4.67%, and 6.49% for ABR, two step (TEOAE and ABR) and TEOAE protocols respectively.¹⁷

Our referral rate for those receiving successful screens is close to the reported average of 8-11% of initial TEOAE referral based on one or both ears referring. Our present study is similar to a 10 % referral rate reported by Vohr et al for initial OAE screening and falls within the range of 9-18% initial referral rate reported for DPOAE protocols by Norton et al. ^{18,19}

Decrease in referral rate is similar to a recent report using a combined OAE and ABR screening device which indicated improved refer rates using both technology in newborn Hall et al.²⁰ ABR therefore proved effective in reducing the referral rate. Mark Rhodes et al studied a total of 173 ears of 87 subjects, forty six were girls and forty seven were boys.²¹

Patient in NICU were tested using ABR, TEOAE and EOAE and acoustic stepidius reflex and by tympanometry and pneumatic otoscopy. Pass rates on hearing test were 75% to 89%. TEOAE produced lowest pass rate. TEOAE, DPOAE, followed by ABR testing of initial failures produced pass rates of about 90%. The most efficient combination was DPOAE with ABR.

Olusanya et al did a cross sectional pilot study based on a two stage UNHS by non specialist health workers using TEOAE and AABR in an inner city maternity hospital over 40 weeks. A total of 1330 babies were screened about 32.3% (371/1150) of babies in the well born nursery failed TEOAE and this referral rate was reduced

further to 3.1% after ABR screen. 31.7% (57/180) of special care baby unit babies failed TEOAE and the referral rate was reduced to 4.4% (8/180) with AABR screen.

He concluded that a second stage screening with AABR is effective in bringing the referral rates. Similarly in our study pass rates were increased by using BERA and also decrease in referral rates.

The initial OAE pass rates of 91% in the present study is similar to the previously reported results given by Watkins et al where the initial TEOAE pass rates are on average 89-92%. ¹⁹

Clemens et al did a retrospective analysis and 5010 infants were screened with an ABR. The false positive rate of Universal newborn hearing screening performed using ABR can be reduced to less than 1%. It has been shown to consistently produce lower false positive rates than the OAE test. ²²

It was observed in our study that using two technology screening programme there was significant decrease in false positive rate.

The sensitivity of OAE from our study is around 92.7% with specificity of 66%. This is similar to the study where White et al when screened on 1850 neonates showed a sensitivity of around 100% and a specificity of 73%, to conclude was moderately specific but very sensitive As we observed that using a two technology protocol reduces the referral rates, De Cristofaro, Joseph et al did a 3 year study of screening of well baby new born infants with one technology (TEOAE) and two technology (TEOAE)/ABR) reveal that failure rate of 2.4% for two technology 8.5% for one technology protocol. They conclude that two technology protocol resulted in low failure rate.

Betty et al in their retrospective study of 12081 new borns, referral rates with TEOAE was 6.49% when Combined with ABR was 4.67%. There was decrease in referral rates with two technology screening as similarly observed in our studies. Raijv Dhawan et al in his study of 200 neonates, had a pass rate of 87% for OAE and that for BERA 98%. He observed that the sensitivity of TE OAE being 80% and the specificity of TEOAE 92.85% with 7.14% false positive rate. Sensitivity of OAE calculated using BERA as the gold standard test was found to be 80% which means that TEOAE will miss out 20% hearing impaired neonates when used as an independent screening tool. This study made the status of BERA as "Gold Standard" screening tool. He concluded that TEOAE is a simple and rapid test with relatively higher acceptability and therefore has a major role as a screening tool especially in countries like India with very high birth rate. But, the low sensitivity and specificity are the main short comings that take away from the TEOAE, the status of independent screening tool for hearing impairment in neonates, therefore TEOAE cannot completely replace BERA as screening modality for hearing impairment in neonates, however can complement it. 23

Albert Mehl et al, during 1999 studied the referral rate of 52 hospitals that used ABR screening was 1.5% (49235 screened, 729 referred). The combined referral rate of 3 hospitals that used OAE screening was 11% (1957 screened, 216 referred) and the combined rate for the hospitals that used. 2nd stage screening was 8.4 % (4042 screened, 338 referred).²⁴

CONCLUSION

TEOAE was found to be simple and rapid test and relatively higher acceptability. TEOAE has a major role as a screening tool especially in the countries like India with very high birth rate, but the low sensitivity and specificity are the main short comings which take away the TEOAE, the status of independent screening modality.

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: Valse D, Nagarathna HK. Efficacy of TEOAEs and BERA as screening tools for deafness in newborn. Int J Otorhinolaryngol Head Neck Surg 2017;3:491-5.