Original Article

Iran J Pediatr
Apr 2013; Vol 23 (No 2), Pp: 199-204

The Specificity and Sensitivity of Transient Otoacustic Emission in Neonatal Hearing Screening Compared with Diagnostic Test of Auditory Brain Stem Response in Tehran Hospitals

Jaleh Yousefi*, MD; Mohammad Ajalloueyan, MD; Susan Amirsalari, MD; Mahdieh Hassanali Fard, MS

New Hearing Technologies Research Center, Baqiyatallah University of Medical Sciences, Tehran, Iran

Received: *Oct 14, 2012*; Accepted: *Jan 14, 2013;* First Online Available: *Feb 07, 2013*

Abstract

Objective: Since early detection (specially before 6 months of age) of deaf people leads to better hearing and speech outcome after treatment, several clinical trials have been performed in order to find a cost effective, short duration screening test for diagnosis of neonatal hearing impairment. The aim of this study was to assess the sensitivity and specificity of Transient Otoacustic Emission (TEOAE) test in newborns comparing with auditory brain stem response (ABR) in the age of 3 months and to analyze the association between risk factors and hearing loss in neonates.

Methods: A cross-sectional study was conducted January2008 - May 2009 in Tehran. 1000 newborns (526 boys and 474 girls) were assessed. First, all of neonates were evaluated by TEOAE 24h after birth. If responses of OAE were failing, they were retested 10 to 15 days after birth by TEOAE. Also, All Neonates were assessed by ABR in the age of 3 months. Descriptive Statistics was used to analyze data.

Findings: Eighteen out of 1000 neonates failed double–checked TEOAE tests, of which 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 results). From these 9 patients 2 had profound hearing loss and received cochlear implantation. We found that OAE has 66.7% sensitivity and 98.8% specificity in diagnosis of neonatal hearing impairment. Its positive and negative predictive value was 33.3% and 99.7% respectively. Also we did not find statistically significant relationship between hearing loss and risk factors.

Conclusion: TEOAE as a simple, non-invasive, short duration and cost effective method, is a suitable test for neonatal hearing screening. Even though only two thirds of patients were detected by this method, 99.7% negative predictive value makes it a good screening test. We recommend OAE as a suitable primary neonatal hearing screening all over the country.

Iranian Journal of Pediatrics, Volume 23 (Number 2), April 2013, Pages: 199-204

Key Words: Hearing Loss; Sensitivity; Specificity; Auditory Brain Stem Response; Otoacustic Emission

Introduction

The initial signs of hearing loss are very subtle and systematic neonatal hearing screening is the most effective tool for early detection of it. Hearing loss affects around 3 out of every 1000 live births[1]. In Iran, the studies have shown different incidence of hearing impairment. For example, Lotfy et al (2007) found that in hearing screening of neonates born in Hedayat and Milad hospital in Tehran, 1 in 1000 neonates had hearing impairment[2], while Ghasemi et al found an incidence of

*** Corresponding Author;**
Address: New Hearing Technologies Research Center, Baqiyatallah University of Medical Sciences, Mollasadra Ave., Vanak Sq., Tehran, Iran
E-mail: yousefidr@yahoo.com

2 out of every 1000 neonates[3].

Early diagnosis and immediate intervention play important role in the development and prognosis of children with hearing loss and decrease the impact of the condition on the child's social, emotional, intellectual and linguistic development[2,4].

There are many behavioral and electrophysiological assessment methods for screening of hearing in neonates. Behavioral techniques have a high number of false negative results[2,4]. As electrophysiologic methods with greater sensitivity and specificity, the following may be used: auditory brainstem response (ABR) automated auditory brainstem response (AABR) and evoked oto-acoustic emissions (EOAE). ABR and OAE are used for universal hearing screening. However, it is better to minimize false-positive results in developing a more reliable newborn hearing screening program. OAE and ABR tools are evolving and becoming more and more automated. Determining which of them is most effective is interesting[5].

ABR is a standard and very precise test in determining the average threshold of frequencies at 2000-4000 Hz. The differences in the size of the external auditory canal and in the placement and type of earphone can produce small differences in the stimulus and therefore can lead to false negative results in mild hearing losses. False positive results of it seem to be fewer[6,7].

OAE tests are generally thought to be easier to administer and faster. The time needed for screening test is variable. However, the average time to carry out automated ABR testing ranges from 8 to 15 min, and conventional OAE tests take 2 to 13 min[6,7].

In one study, AABR and OAE were used as most important hearing screening tests. The aim of this study was the comparison of AABR and OAE results. All 2454 neonates born in 2001-2003, were assessed by OAE and 3117 neonates born in 2004-2006, by AABR. Screening by AABR had less false positive responses but it had high cost and needed more time for assessment. However, AABR and OAE usually are used for screening, not for precise identifying of late hearing disorders. For precise identifying of hearing loss, complete ABR tests (frequency specific air and bone conduction) should be used [8].

According to Iran Statistics Center, 1286000 neonates were born in Iran in 2008. If incidence of hearing loss is 2 per 1000 neonates, there will be 2500 neonates with hearing loss per year. Without hearing screening tests, hearing loss will be identified and treated at the age of 2-3 years[3]. Therefore, it is necessary to secure holistic development of the child by detecting hearing loss at birth and providing remedial measures at the earliest.

In our study, neonatal hearing screening is carried out on 1200 neonates born in Baqiyatallah and Najmiye Hospitals in Tehran, by TEOAE January 2008 - May 2009. Two hundred neonates were excluded from the study because they did not returned for ABR test in the age of 3 months, so 1000 neonates completed the study.

The sensitivity and specificity of TEOAE was compared with ABR by statistic analyzes. Also, the relationship between hearing loss and some risk factors (age of parents, hyperbilirubinemia, hearing loss history in siblings or other family members, mother's drug consuming during pregnancy, NICU stay, history of disease in other children, convulsion, antibiotics) were studied in the two groups of impaired and normal ABR. The goal of this study was to compare the results of a two-step screening process of TEOAE with diagnostic test of ABR in a population of newborns.

Subjects and Methods

This research was observational cross-sectional study carried out between January 2008 and May 2009. The hearing screening program was done in two hospitals (Baqiyatallah and Najmiye) in Tehran. The population consisted of 1200 neonates born in these hospitals.

The TEOAE recordings were performed by Echochek ECN06/07/4138 device (Auto Dynamics Co, England) and ABR by Madsen ICS-Chartr ep, GN-Otometrics Co. (version 5.4) (table 1).

The parents filled a questionnaire concerning biography and hearing loss history of their children. The audiologist conducted TEOAE and ABR results in a non-sound silent room with the child in state of natural sleep in a common crib. The pass or fail responses of TEOAE and ABR were

Table 1: Auditory brain stem response recording parameters

Parameter	Characteristics	
Electrodes	Non inverting / Positive electrode Inverting / Negative electrode Common/ ground electrode	Frontal mastoid of test ear mastoid of non test ear
Filters	High pass filter Low pass filter Notch filter	30Hz 3000 Hz off
Transducer	Ear phone (TDH 39)	
Stimulus parameters	Click 0/1 ms Polarity: Rate: 21.7/s Masking	 alternative off
Time window	15 ms	

recorded by audiologist and analyzed later by SPSS software. The average time for the total TEOAE measurement (placement of electrodes and headphones not included), was 5 min in the initial screening test and 4 minutes in the rescreening test. ABR in infants lasted 11 minutes.

For the initial screening, infants were tested with TEOAE 24h after birth. Another screening was conducted for infants who failed in the first-stage screening. They were retested in 10-15 days after birth by TEOAE and again all neonates were evaluated in the age of 3 months by ABR. In other words, all neonates (abnormal and safe neonates tested by OAE at birth) were tested by ABR in the age of 3 months.

Data were presented as general numbers and percentage of positive or negative results obtained by newborn hearing screening and were collected in a central database and analyzed with SPSS version 17.0. Also, we analyzed the relationship between hearing loss incidence and risk factors by the methods of t-test and Chi-square.

After assessment of all neonates in 3 months by ABR, if they had auditory disorders, were referred to an academic rehabilitation center for receiving appropriate treatment for speech and language skills. All parents were informed before OAE hearing screening. In addition, parents were informed for the need to return for rescreening in case of a first failure.

Findings

The average age of the subjects at the initial screening test was 24h. 1000 neonates (526 boys and 474 girls) were assessed.

Out of the total population of 1000 newborns screened using TEOAE, 982 (98.2%) had normal and 18 (1.8%) impaired two-step TEOAE. Tested with ABR in 3 months, 991 (99.1%) had normal and 9 (0.09%) had impaired ABR. Hearing loss in 6 neonates, detected by TEOAE, was confirmed by ABR in the age of 3 months. In other words, 12 responses of TEOAE were false positive.

Therefore, the false-positive rate of TEOAE was 1.2% in the initial newborn hearing screening. In the age of 3 months, out of the 1000 neonates, 9 showed hearing loss using ABR of which 6 were identified by OAE. Therefore, 3 responses of OAE were false negative. The results of TEOAE and ABR tests have been shown in Table 2.

Table 2: Newborn Infants Tested by Two-stage TEOAE and ABR (n=1000)

Result of tests	n	%
Impaired OAE result	18	1.8
Impaired ABR result	9	.09
Impaired results indentified by OAE and ABR	6	.06
False-positive rates by OAE	12	1.2
False-negative rates by OAE	3	0.3

Out of 9 neonates with hearing loss using ABR, 2 had bilateral profound hearing loss, they received cochlear implantation. 7 babies had mild or moderate hearing loss and did not need cochlear implantation. Two of these 7 babies had cleft palate and serous otitis media.

Also, in this study, the sensitivity of TEOAE for identifying hearing loss was 66.7% and the specificity of it 98.8%.

Comparison of the effects of risk factors on the results of impaired ABR and normal ABR showed that in our study there is no difference between these two groups (P>0.05). Table 3 shows the comparison of results of impaired ABR and normal ABR in these two groups.

Discussion

The incidence of hearing loss is different in various studies. According to Wrightson (2007), the incidence of hearing loss was 2 to 3 in every 1000 newborns [9]. De Michele (2010) found it 2 to 4 out of every 1000 newborns [10]. In Iran, Lotfy et al (2007), in hearing screening of neonates showed that among 1000 neonates born in Tehran, only 1 had hearing impairment[2] and Ghasemi et al (2008) in Mashhad city, found that the incidence was 2 per 1000 neonates[3]. In our study the rate of hearing disorders was 9 out of 1000 neonates and deafness rate was 2 out of 1000 neonates. Therefore, the early identification of hearing loss is very important for following auditory training and speech and language treatments in hearing impaired children[11].

Various tools with high sensitivity and specificity are available. If a screening tool detects the majority of people with the same disorder, has validity and high sensitivity, and if it excludes most people without the disorder, has high specificity. OAE and ABR have now been tested in various centers. ABR is not affected by external ear wax or fluid and has high sensitivity and specificity[12]. However, according to the American Academy of Family Physicians, the sensitivity of OAE in identification of hearing loss was 84% and its specificity 90%. In our study, the sensitivity (66.7%) and specificity (98.8%) of TEOAE for detecting hearing loss were high; therefore, it is an effective tool for screening of neonates at birth.

The OAE screening is quicker and easier to perform than ABR; but it is affected by external ear wax or fluid. Sometimes, in various studies, OAE test is performed twice. An initial OAE test is performed at birth and an OAE retest performed 2-3 weeks later to decline referral rate for ABR[12-14]. For the initial screening in our study, infants were tested with TEOAE 24h after birth. Other screening was conducted for infants who failed in the first-stage screening. They were evaluated 10-15 days after birth by TEOAE. All neonates (hearing impaired and safe neonates tested by OAE) were tested by ABR 3 months after birth. In Iran, In a two-stage screening program using repeat screening with OAE described by Lotfy et al (2007), the referral rate for OAE is reported to be 7.7% when screening was performed within the first 24h after birth, and during second step it has been reported to be 1.67%[2]. This rate was similar to our referral rate after second TEOAE (1.8%).

Table 3: Comparison of variables in impaired ABR and normal ABR

Risk factors	Impaired ABR result	Normal ABR result	*P*-value
Sex (male)	44.4	52.7	0.7
Age of father (mean+SD)	30.4 (4.0)	32.5 (5.5)	0.3
The age of mother(mean+SD)	26.8 (5.0)	28.2 (5.0)	0.4
Mild hyperbilirubinemia	33.3	41.4	0.7
Severe hyperbilirubinemia	0.00	1.0	1.0
Hearing loss history in siblings	0.00	1.1	1.0
Hearing loss history in family	11.1	4.0	0.3
Drug consuming during pregnancy	2.22	12.8	0.3
NICU history	11.0	10.0	1.0
History of disease in other children	12.5	2.5	0.2
History of convulsion	0.00	1.7	1.0
Antibiotic consuming	11.1	18.7	1.0

Out of 1000 neonates, 18 (1.8%) had hearing loss by two TEOAE tests. hearing loss by OAE in 6 neonates, was confirmed by ABR. Therefore, 12 responses of TEOAE were false positive. In the age of 3 months, out of 1000 neonates 9 had hearing loss by ABR of whom 6 were identified by TEOAE. Therefore, 3 responses of TEOAE were false negative. Out of 9 neonates, 2 had profound hearing loss and received cochlear implants. None of 2 neonates had high risk registry. Also, the relationship between hearing loss and risk factors was not statistically significant. It means that neonates may have hearing loss without a history of risk factors. According to the Joint Committee on Infant Hearing (JCIH), only 2-5% of neonates with high risk registry have moderate or severe hearing loss and also 50% of neonates with congenital hearing loss have no evidence of risk factors. Therefore, JCIH suggested that hearing screening should be done in all neonates with or without high risk registry and also it is recommended to evaluate perfectly in 3 months hearing of neonates who failed in screening test[15,16]. In our study, out of 9 neonates, 2 had NICU history, 1 had hearing loss history in family and 2 had history of mother's drug consuming during pregnancy, the remaining 5 neonates had no risk factors. Therefore, it is suggested that audiologists use hearing screening for all neonates not just for high risk babies. In other words, all babies should be screened at birth. If the result of screening fails, complete hearing tests several weeks after birth should be done. In our study, ABR was a very precise test for hearing of children and TEOAE results have shown various false negative and false positive rates, but the sensitivity and specificity of TEOAE was relatively high. Therefore, TEOAE test can be used for the screening of neonates. According to these results, the importance of early diagnosis of hearing loss, high sensitivity, high specificity and easiness of TEOAE for implementation (simple, non-invasive, short duration and cost effective method), we advise to use TEOAE as screening test for all neonates (whether normal or high risk babies).

Although we evaluated TEOAE at birth for neonatal hearing screening and compared it with ABR results in 3 months, it was carried out in two hospitals in Tehran; in a country like Iran, which presents large ethnic differences, the same type of analysis should be performed in several regions.

Conclusion

It is necessary to study generalized development of children by detecting hearing loss at birth and providing a screening test for assessment of them. In our study, we compared the results of TEOAE (screening test) with the results of ABR (diagnostic test) and found sensitivity of TEOAE to be 66.7% and its specificity 98.8%.

We conclude from these results that TEOAE is a good screening test for hearing loss of neonates (whether normal or high risk babies), but because of false positive cases (12 cases out of 1000) its results must be confirmed with ABR as a diagnostic test at three months of age as mentioned in JCIH protocol.

Acknowledgment

The authors would like to thank personals of Baqiyatallah and Najmiyeh hospitals especially Mrs Sima Falak Aflaki for their constant efforts and supports.

Conflict of Interest: None

References

1. Lima GML, Marba STM, Santos MF. Hearing screening in a neonatal intensive care unit. *J Pediatr (Rio J)* 2006;82(2):110-4.
2. Lotfi Y, Movallali G. A universal newborn hearing screening in Iran. *Iran Rehabilitation J* 2007; 5(5-6):8-11.
3. Ghasemi MM, Zamanian A, Tale MR, et al. Neonatal hearing screening with TEOAE in mashhad city, Iran. *Iran J Otorhinolaryngol* 2006;18(1):15-21. [In Persian]
4. Taghdiri M, Eghbalian F, Emami F, et al. Auditory evaluation of high risk newborns by automated auditory brain stem response. *Iran J Pediatr* 2008;18(4):330-4.
5. Iwasaki S, Hayashi Y, Seki A, et al. A model of two-stage newborn hearing screening with automated auditory brainstem response. *Int J Pediatr Otorhinolaryngol* 2003;67(10):1099-104.
6. Meiera S, Narabayashib O, Probsta R, et al. Comparison of currently available devices designed for newborn hearing screening using automated auditory brainstem and/or otoacoustic emission measurements. *Int J Pediatr Otorhinolaryngol* 2004;68(7):927-34.

7. Erenberg A, Lemons J, Sia C, et al. Newborn and infant hearing loss: detection and intervention. American Academy of Pediatrics. Task Force on Newborn and Infant Hearing, 1998-1999. *Pediatrics* 1999;103(2):527-30.
8. Benito-Orejas JI, Ramı´rez B, Morais D, et al. Comparison of two-step transient evoked otoacoustic emissions (OAE) and automated auditory brainstem response (AABR) for universal newborn hearing screening programs. *Int J Pediatr Otorhinolaryngol* 2008;72(8):1193-201.
9. Wrightson AS. Universal newborn hearing screening. *Am Fam Physician* 2007;75(9):1349-52.
10. De Michele AM, Ruth RA. Newborn hearing screening. Available at: http://www.emedicine.com/ent/topic576.htm. Access date: Jun 15, 2010.
11. Mersch, J, Kibby JE. Newborn infant hearing screening, Available at: http://www.medicinenet.com/newborn_infant_hearing_screening/article.htm. Access date: Feb 19 2008.
12. Tanon-Anoh MJ, Sanogo-Gone D, Koussi KB. Newborn hearing screening in a developing country: Results of a pilot study in Abidjan, Côte d'Ivoire. *Int J Pediatr Otorhinolaryngol* 2010; 74(2):188-91.
13. De Capua B, Costantini D, Martufi C, et al. Universal neonatal hearing screening the Siena (Italy) experience on 19.700 newborns. *Early Hum Dev* 2007;83(9):601-6.
14. Bevilacqua MC, Alvarenga Kde F, Costa OA, Marel AL. The universal newborn hearing screening in Brazil: From identification to intervention. *Int J Pediatr Otorhinolaryngol* 2010;74(5):510-5.
15. Erenberg A, Lemons J, Sia C, et al. American Academy of Pediatrics task force on Newborn and infant hearing. Newborn and infant hearing loss: Detection and interventionl. *Pediatrics* 1999;103(2):527-30.
16. Joint Committee on Infant Hearing, American Academy of Audiology, American Academy of Pediatrics, American Speech-Language-Hearing Association, Directors of Speech and Hearing Programs in State Health and Welfare Agencies. Year 2000 position statement: Principles and guidelines for early hearing detection and intervention programs. *Pediatrics* 2000;106(4): 798-817.