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ORIGINAL ARTICLE

Can Automated Auditory Brainstem Response be Used as an Initial Stage Screening Test in Newborn Hearing Screening Programs?

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Objectives: Generally, newborns have been tested according to the method recommended by the Joint Committee on Infant Hearing all around the world: a two-stage automated transient evoked oto-acoustic emissions (ATEOAE) program, completed by an automated auditory brainstem response (AABR) for the positive diagnosis of hearing impairment. However, there are still some controversies on this two-stage method. In this study, we used ATEOAE and AABR in combination as an initial stage screening protocol to investigate if we could reduce the disadvantages of routinely performed screening procedure.

Materials and Methods: A total of 1,978 neonates were screened for hearing impairment during the study period prospectively. 1,917 of them were tested with both ATEOAE and AABR in the first day of their life. If newborns did not meet pass criteria for any of the tests, both tests were repeated in 10-day period.

Results: Out of 1,917 neonates, 202 (10.53%) were failed the initial ATEOAE, and 37 (1.97%) failed the initial AABR. 158 of the 202 neonates that failed the ATEOAE and all neonates that failed AABR was subjected to the second test. Four (2.5%) neonates failed second ATEOAE, and three (1,89%) failed second AABR. All four neonates were referred for further audiologic evaluation, and three of them, whose AABR were negative, were diagnosed as having congenital hearing loss.

Conclusion: As a first stage screening method AABR has the lowest false positive rate, referral rate and high specificity. Therefore, we recommend that all universal newborn hearing screening programs should consider revising their protocols to decrease expenses in terms of time and money.

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Introduction

Two screening tests used in most universal hearing-screening programs (UNHS) are automated OAEs and AABR all around the world, which are also suggested by Joint Committee on Infant Hearing (JCIH).[1,2]

Otoacoustic emissions are used to assess cochlear integrity and are physiologic measurements of the response of the outer hair cells to acoustic stimuli. Provided that the patient's middle ear function is normal, these measurements can be used to assess cochlear function for the 1,000-4,000 Hz frequency range. The presence of evoked OAE responses indicates hearing sensitivity in the normal to near-normal range(35 dB hearing level [HL].[3,4] Since a pass outcome rules out serious degrees of hearing loss, the presence of ATEOAE does not always indicate normal hearing sensitivity.[5]

AABR is an electrophysiologic measurement that is used to evaluate auditory function from the eighth nerve through the auditory brainstem. AABR measurements are obtained with the click stimulus usually set at 35 dB HL. When a click is used to evoke the ABR, information regarding hearing sensitivity is restricted to approximately 1,000-4,000 Hz. The AABR method produces a simple pass or fail result without requiring interpretation and the test can be conducted in the presence of background noise due to the features of a device which attenuates background noise. it lacks frequency-specific information and requires increased preparation time prior to testing because of placement of the electrodes.[4,6] However, due to the advancements of technology and development of automatic fast AABR without electrodes, these disadvantages have been overcome.

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Usually the two step screening test is performed by using ATEOAE in the first stage, which is thought to be a more economical and fast test, and automated ABR, takes longer to perform due to the placement of electrodes, is a complete test in the second stage. [1,3,4] Since it is faster and was the first one,Kemp discovered OAE in 1978 then ABR was modified as a screening test called AABR in 1987, to be used traditionally as an automated screening test, ATEOAE is usually the test of choice in screening programmes. [1,2,7,8] However, the effectiveness of ATEOAE is reduced by contamination with low-frequency ambient noise in a busy nursery, vernix in the ear canal, or any middle ear pathology.Therefore referral rate for ATEOAE is usually higher especially if performed during the first 24 hours of life. [4,9]

Referral rates always vary depending on the method of screening test used in the program. [4,10] This variation must be kept in mind when a protocol for screening is established. Although OAE screening continues to be cost effective in the well-baby nursery, there are still some controversies on this two-stage screening protocol due to the high false-positive and referral rate of ATEOAE testing. [4,9,11,12] Furthermore, due to the increased understanding and identification of auditory neuropathy, an AABR screening protocol is discussed to be used for healthy newborns, not only in the NICU setting. [4,8,10]

Another issue discussed in literature for choosing a screening protocol takes into consideration the target population, birth rate, the price of devices and distance to diagnostic audiology centers, it has not yet been determined which methods of hearing screening is the most effective. [4,8,10]

In this study, we used ATEOAE and AABR in combination as an initial stage screening method to investigate if we could reduce the disadvantages of routinely performed screening procedure by comparing their outcomes.

Materials and Methods

This is a prospective cohort study of neonates which includes the program of National Newborn Hearing Screening Program (NNHSP), conducted in Turkey.
The study included 1917 healthy term non neonatal intensive care unit (NICU) newborns who were subjected to NNHSP during the period between October 2007 and October 2009 at our tertiary audiology center. All neonates were tested with both ATEOAE and AABR in the first 48 hours of life prior to their discharge. If newborns did not meet the pass criteria for neither of the tests, both tests were repeated ten days later when they were scheduled for the first pediatric follow -up as well.

The ATEOAE search was conducted with Ero-scan TM (Maico, Berlin, German). The default settings of the ATEOAE protocol were as follows; number of bands reported: 6, frequency range: 1.5kHz to 4 kHz, click presentation level: 83 dB SPL, peak equvialent averaging time: 64 seconds, pass SNR (signal-to-noise ratio): 4.dB, number of passing frequencies for overall test pass: 3. The test was done after the appropriate mushroom-shaped eartip size was selected and gently placed into the ear canal. The results were automatically obtained as pass or refer. The result pass was considered in the presence of TEOAE response. Refer indicates a possibility of hearing loss of 30 dB HL or more.

Automatic ABR measurements were done using Maico MB 11 screening ABR (Maico, Berlin, German). Default protocol of the test settings were as follows; EEG filter: 125-1.25 kHz, Stimulus rate 93 Hz, Test intensity level: 40 dB HL, Test signal: Click (125 μs). During the test, conductive gel was applied on the below part and vertex of the ear. If the baby's head skin is greasy, where the electrodes come into contact, the greasy skin was cleaned prior to testing. Optimising the conduction, electrolytic conductive paste (Ten20) was used. Automated ABR was performed by BERAphone which can be used with built-in-automatic ABR-Fast Steady State (FSS) algorithm. Before begining the test, impedence measurement was performed. The measurement results were automatically obtained as pass or refer. Refer indicates a possibility of a hearing loss of 40 dB HL or more in the tested ear.

Hearing screening was conducted in a Faraday cage which has a feature of the sound room, accompanied by their parents, in a naturel sleep or somnolence state.

The order of procedures application was alternated, that is, sometimes the ATEOAE was applied first and sometimes the AABR was the first, in order to control the variable sequence of procedures. As a result, the newborn who did not pass the screening test, even if just in one ear, was called for a hearing screening retest. Newborns who passed the screening test were

discharged and parents were instructed to follow their hearing and the development of their oral language.

On the hearing screening retest, the procedure which the newborn has not previously passed was repeated. When the "pass" result was obtained, the same procedure that has been described above was followed. In case of "refer", the newborn was referred for further audiological evaluation.

In the audiological evaluation, the process of diagnosis, which was done before three months of age, involved otorhinolaryngological evaluation; anamnesis on the overall development of the child; and behavioral, electrophysiological and electroacoustic procedures. The newborns and their families were assisted by a team of professionals, involving audiologist, otorhinolaryngologist and psychologist .

To determine the sensitivity and specificity of any hearing screening, it would be required that all newborns made complete diagnostic evaluation after the hearing screening, which is not feasable in practice, once the prevalence of hearing impairment is 1/1000 alive newborns. [17] However, the combined use of evoked OAEs and AABR allows one test to evaluate the other and thus, to establish sensitivity and specificity values close to a true result. The true negative was considered when the two procedures showed the presence of response on hearing screening in both ears, determining the false-negative rate equal to zero and consequently 100% sensitivity. [18] The estimated rate of false-positive and specificity was also determined.

Data of all newborns were entered in central database of Ministry of Health. Statistical analysis was performed with SPSS 14.0 statistical software (SPSS Inc, Chicago, Illinois). A descriptive statistical analysis was performed to estimate the specificity and the percentage of tests false-positive and the confidence interval of 95% was calculated for specificity. The chi-square test was performed to compare the referral rates, specificities and false positive rates of ATEAOE and AABR.

Results

During the study period, 1,917 healthy term newborns from the well-baby clinics were included in the study. They were tested with both ATEOAE and AABR in the first 48 hours of their life. If newborns did not meet the pass criteria for either of tests, both tests were repeated ten days later. A hundred and two infants failed one or other of the tests in the first attempt, 44 (21.78%) of them didn't show up for the second attempt. Thus, 158 newborns were subjected to a second test. Population characteristics were not taken into consideration.

In the initial stage, 1,715 (89.47%) newborns were found to have normal hearing and were discharged without scheduling a control evaluation. Out of 1,917 newborns, while 202 (10.53%) failed the initial ATEOAE, 37 (1.97%) failed the initial AABR. In the second stage, four (2.5%) neonates failed the second ATEOAE, and three (1.89%) failed the second AABR. All four neonates were referred for further audiological evaluation, and three of them, whose AABR were negative, were diagnosed as having some degree of bilateral congenital sensorineural hearing loss. There were no known risk factors for those newborns. The results are summarized in Table 1.

When considering the false-positive and the specificity of applied ATEOAE and AABR in the initial stage, there was no statistically significant difference between the two tests ($p=0.122$ and $p=0.140$, respectively). However, the failure (referral) rate of ATEOAE performed in the first 48 hours was approximately five times higher than AABR failure rate and there was a statistically significant difference among them ($p=0.004$). In the second stage, the difference between failure rates of ATEOAE and AABR was not statistically significant ($p=0.170$), but the AABR's false-positive rate and specificity was 0% and 100%, respectively, as seen in Table 1.

The change in failure rate of ATEOAE between two stages was statistically significant ($p<0.05$). Also, there was a statistically significant difference between the initial and second stages' ATEOAE specificities and false- positive rates ($p<0.05$). (Table 1)

There were no statistically significant differences between failure rates and specificities of AABR among the initial and second stages ($p=0.177$). However the change was statistically significant when false-positive rates of AABR were compared ($p<0.05$).

In the initial and second stages, the false-positive rates and the specificities with confidence intervals for ATEOAE and AABR are described in Tables 2 and 3.

Discussion

Retrospective studies of large scale UNHS have shown that permanent hearing loss is one of the most common

Table 1. The number of newborns that passed and failed after performing TEOAE and AABR in collaboration, also the false- positive rates and specifities of both tests.

TEOAE+AABR		Test results (%)			
		Pass (%)	Fail (% Referral rate)	False -positive rate (%)	Specificity (%)
Initial stage 1917 infant	ATEOAE	1715 (89,47)	202 (10,53)	0.98	89
	AABR	1880 (98,3)	37 (1,97)	0.91	98
Second stage 158 infant	ATEOAE	154 (97,47)	4 (2,53)	0.25	98
	AABR	154 (98,97)	3 (1,93)	0	100

Table 2. The false positive rates and the specificities with a confidence interval for ATEOAE and AABR in the initial stage

Inıtial Stage	Estimated value	Confidence İnterval	
		Lower limit	Upper limit
ATOAE sensitivity	1	0.30	1
ATOAE specitivity	0.89	0.88	0.90
ATOAE False - Positive	0.98 %	0.95	0.99
AABR sensitivity	1	0.30	1
AABR specitivity	0.98	0.97	0.98
AABR False - Positive	0.91 %	0.76	0.97

Table 3. The false positive rates and the specificity with a confidence intervals for ATEOAE and AABR in second stage

Second Stage	Estimated value	Confidencel İnterval	
		Lower limit	Upper limit
ATOAE sensitivity	1	0.30	1
ATOAE specitivity	0.99	0.95	0.99
ATOAE False - Positive	0.25%	0.01	0.78
AABR sensitivity	1	0.30	1
AABR specitivity	1	0.96	1
AABR False - Positive	0%	0	0.03

abnormalities present at birth. In 1999, the American Academy of Pediatrics Task Force on Newborn and Infant Hearing stated, "significant bilateral hearing loss has been shown to be present in approximately 1 to 3 per 1,000 newborns in the well-baby clinic population, and in approximately 2 to 4 per 1,000 infants in the intensive care unit population".[13] Data from the newborn hearing screening programs in Rhode Island, and Texas show that 2-3 of every 1,000 neonates have hearing loss.[14,15] A retrospective study conducted by Connolly et al.[16] in 2005 found that 1 of every 811 infants without risk factors and 1 of every 75 infants with risk factors have hearing loss. The prevalence of hearing loss may continue to change as more data becomes available from UNHS. In Turkey, data obtained from NNHSP showed that 17 out of every 10,000 have hearing loss in healthy newborns.[17] In our study, this congenital hearing loss ratio was 0.15% consistent with the previous results.

The goal of any newborn hearing screening (NHS) program is to achieve a high level of both sensitivity and specificity. The ideal program should permit the identification of as many newborns as possible who do have a hearing loss (high sensitivity) and also to exclude as many newborns as possible who do not have a hearing loss (high specificity).[4] In our study, in the initial and second stage both ATEOAE and AABR sensitivity were 100% meaning both screening tests can determine the status of hearing accurately. The specificity for AABR in the initial and second

stages were 98% and 100 % while for ATEOAE it was 89% and 98%, respectively. As a result, it is concluded that AABR is more specific to elicit the newborn with hearing loss. This data also shows that ATEOAE is less reliable then AAABR, especially if performed during the first 48 hours of life.

In view of findings in the literature, when the newborn hearing screening was performed using ATEOAE, the referral rate ranged from 0.6% to 12.03%[18,19], the false-positive rate from 0.64% to 5.8%[19] and the specificity from 91.8% to 99.7%.[6,14,20]. With AABR the rate of referral ranged from 0.2% to 5.3%, [6,16,20] the false-positive rate from 0.34% to 3.9%,[5,6,16,20] and the specificity from 93% to 99.7%.[2,6,16] Using ATEOAE and AABR in combination, the rate of referral ranged from 1.8% to 8.6%,[19,21,22] the false-positive rate reported was 9%.[23] However, no study describing the specificity of the protocol was found. As seen on Table 1, our results were consistent with the published literature.

Recent studies focused on minimizing the false-positive rate.[5,6,16,19] Clemens and Davis [5] found that the false-positive rate of 0.8% after two screening tests before hospital discharge. In the present study, the false-positive rate of ATEOAE in the initial stage was 0.9%. In the second stage using ATEOAE, the false-positive rate decreased to 0.2% ($p > 0.05$). False-positive rates of AABR in both stages were 0.91% and 0%, respectively ($p > 0.05$). Our false-positive rate was high in the first two days, but it was lower about the 10th day. The high false-positive rate in the beginning of life may be due to vernix or debris in the ear canal.[5] On the other hand, to our knowledge, these false-positive rates (0.9%-0%) for both tests were significantly lower than any other reported in the literature.[5,6,20]

The false-positive rates previously reported by UNHS program range between 2.5% and 8%.[5,9] Critics of UNHS programs have claimed that this rate is too high and might lead to a number of the negative effects produced by false-positive screening tests, namely emotional trauma, disease labeling, iatrogenesis from unnecessary testing and increased expense in terms of time and money. [4,5]

In our study, although no statistically significant data was found between AABR and ATEOAE when comparing false-positivite rates and specificities, referral rates of ATEOAE were approximately five times higher in the first stage. As seen in Table 4, this has to be kept in mind while deciding which procedure should be implemented in a screening program.

For a succesful UNHS program, it is essential to have a high rate of detection of moderate and severe hearing

Table 4. Referral rates and false-positive rates of screening programs. According to ongoing research common impression that there is no signicantly differences among false –positive rates of ATEOAE and AABR measurements. However , referal rates should be main criteria to compare screening test.

Author, Year	State/Test	Referal Rate %	False-Positive Rate %	Study Population
	ATEOAE			
Konukseven 2010	Turkey/ ATEOAE	10.5	0.98	1,917
Finitzo, 1998	Texas / ATEOAE	8.9	-	2,732
Vohr,	Rhode Island/ / ATEOAE	6.49	-	53,121
Lin, 2005	Taiwan/ATEOAE	5.8	-	18,260
Chapchap,2001	Brazil/ ATEOAE	1.8	-	4,186
	ATEOAE+AABR			
Finitzo, 1998	Texas / ATEOAE+AABR	3.1	-	11,350
Vohr,2001	Rhode Island / ATEOAE + AABR	3.1	-	
Lin, 2005	Taiwan/ ATEOAE + AABR	1.6	-	3,788
	AABR			
Conrad 2001	North Carolina/AABR	4,1	3.9	3,142
Connolly, 2005	Mississippi / AABR	4.1	3.6	17,602
Mason 1997	Hawai/AABR	4	3,5	10,372
Finitzo, 1998	Texas / AABR	3,4	-	3,016
Vohr,2001	Rhode Island / AABR	3.1	-	53,121
Stewart, 2000	Louisville/AABR	2	0.9 mean (0.3-2.5)	11,711
Konukseven 2010	Turkey/AABR	1.9	0.91	1,917
Lin 2005	Taiwan/AABR	0.8	-	3,540

losses and a low referral rate of babies with normal hearing.[4] With these goals in mind, the NIH Consensus Statement recommends that all screening programs should have a failure rate of no more than 5-7%, and the number of referrals be kept to a minimum.[12] Studies showed significantly higher referral rate when TEOAE is used alone.[9] De Freitas et al.[24] found that two step AABR has the best false-positive rate and specificity. In our study, the referral rate of 1.97% of AABR was much lower than the referral rate of 10.53% of ATEOAE in the initial stage ($p<0.05$). Using the example of an annual Turkey birth cohort of 1.378.000 and a conservative estimate of a 1.97 % and 10.53% referral rate of AABR and ATEOAE in the initial screening respectively could lead to referrals of 27.146 with AABR and 117.957 with ATEOAE. Therefore, instituting AABR as an initial screening in UNHSP could prevent 119.849(8.5%) refferral rate results per year and greatly reduce the expenses in terms of time and money.

Besides specificity, false-positive and referral rates of both test, to institute AABR as an initial screening test or to select the most cost-effective method, another point of view should consider AABR and ATEOAE as screening equipments and features (testing time, cost of device, easy to perform, noninvasive etc.) and detection the side of dysfunction on the auditory system.

Techniques currently used in newborn hearing screening can discriminate peripheral from central (ie, brainstem) auditory dsyfunction. Two-phase screening using 2 different electrophysiologic measures, OAEs and ABR, allows detection of various failure patterns and provides more complete information about auditory function.

However, OAEs are not a sufficient screening tool in infants who are at risk for neural hearing loss, auditory neuropathy spectrum disorder (ANSD).[25] Currently, according to JCIH [1,4] , any infant graduates from NICU or having risk factors should undergo an ABR screening so that the presence of ANSD is not missed. Cochlear function, and therefore OAE measurements, are usually normal in infants and children with this type of hearing loss. Therefore, if we screen the hearing of a newborn using ATEOAE in the initial screening, we may miss the diagnose ANSD. As the newborn with normal hearing, who pass the ATEOAE in the initial screening, are not referred or rechecked for the second stage.

Abbey et al.[26] reported that, approximately one third (33.9%) of infants with the ANSD profile had a gestational age(GA) of $\geq$ 38 weeks. This finding suggests that, for all intents and purposes, those children were admitted to the NICU for reasons other than prematurity and may well have been missed if they had been admitted to the well-infant nursery, in which an OAE-screening technique is typically used for hearing screening. Of the 20 infants that Rance et al.[26] examined and ultimately diagnosed with ANSD, 13 (65%) had a GA of $\geq$ 38 weeks, also suggests us to use AABR in initial stage as we conclude.

Maxon et al. [10] describe the factors that can affect the referral rate for OAE-based NHS, the adequacy of probe fit, software options used, external ear conditions, screener training, and baby handling. The effect of the infant's age on screening outcomes is also discussed using results of screening for 1.328 regular nursery newborns, ranging in age from 6 to 60 hours, who were screened with TEOAE prior to hospital discharge. The youngest infants (6–9 hours old) were as likely to pass (90% pass rate) as the infants who were 24–27 hours old (94% pass rate). The results of this study are consistent with reports from many TEOAE-based screening programs that have demonstrated that acceptably low refer rates (mean=6.9%) can be obtained when appropriate screening procedures are followed.

In our study, we aimed to screen the newborns in the first 48 hours of life immediately prior to discharge. We did not take into consideration newborn's age while screening the hearing (the youngest newborn is 8-10 hours old due to the earliest discharge time of our birth clinic rule for healthy newborn) since testing time does not affect the comparison of the results of two screening tests, performed consecutively, as mentioned before our results for the initial stage ATEOAE referral rate was five times more than AABR. In the second stage those referral rates were 2.53% and 1.93%, respectively. Since there was no statistically singificant difference between AABR's referral rates in both stages, we may clearly say that AABR measurement is less affected from those factors explained above with respect to ATEOAE. One reason that can affect the referral rate of AABR may mostly be ear canal debris rather than other conditional factors, ambient noise, screener training, etc.as they are similar in both stages.

The only handicap for AABR seems to be longer testing time due to the placement of electrodes which is the reason why it is not widely used in UNHS. However, due to the advancements of technology and development of automatic fast ABR, this disadvantage has been overcome. [23] Also over a 10 to 15 year period, significantly decreased AABR prices led to more general usage.

In additon, while the preparation and the testing time are fast with ATEOAE, there is a a significant handicap because of insufficient specificity and higher referal rate. Unlike ATEOAE, AABR is more specific test.[9,22,23] Consistent with our data in the present study, false-positive rates 0.91 % and 0 % in the initial and second stage, respectively, is significantly lower than the rates of ATEOAE, becomes relevant in the decision of which procedure should be chosen in a program of NHS.

On the other hand, when AABR and ATEOAE are compared physiologically, ATEOAE evaluation goes as far as the inner ear, AABR goes beyond to the auditory brainstem. Therefore, it also makes sense physiologically to use AABR as an initial screening test in UNHS as AABR has high specificity and lower referral rate.

Several studies have described a combined AABR and ATEOAE screening technique as an effective device for maintaining low referral rates.[15,28] The authors believe that in the initial screening using only one screening device is more reasonable than two, as protocol with one device diminishes half of the test number performed with two devices. Furthermore, if AABR is chosen as an initial screening device, referral rate can be decreased below the rates acquired by using ATEOAE or both ATEOAE and AABR in combination.[11] Additionally, we can clearly say that the decision of referring to the second stage or rechecking is given according to the AABR's refer result by using AABR and ATEOAE in combination.

We also believe that to take into consideration the target population, birth rate, the price of devices and distance to diagnostic audiology centers in choosing protocols is not a valuable criteria while deciding which protocol is the most effective. It has been shown that because of the higher referral and false positive rate for ATEOAE in the initial stage, this higher cost is met through the years.

Conclusion

As an initial stage screening protocol, AABR has the lowest false positive and referral rate, high specificity and an acceptible testing time. Therefore, based on the significance of our results we recommend that all UNHS programs should consider revising their protocols so that the parent's emotional trauma, handicap labeling, iatrogenesis from unnecessary testing and increased expense in terms of time and money is decreased when the coverage of this screening program is extended.

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