ORIGINAL ARTICLE

Automated Auditory Brainstem Response: A Proposal for an Initial Test for Healthy Newborn Hearing Screening with a Focus on the Test Time

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Objective: Some researchers recommend the use of Automated Auditory Brainstem Response as an initial screening test for healthy newborns due to its lower false-positive and referral rates, high specificity, and also its' ability to diagnose auditory neuropathy spectrum disorder combination with Transient Evoked Otoacoustic Emissions test. On the other hand, the test time can be a disadvantage. With technological advancements, a new generation Automated Auditory Brainstem Response has been developed which is faster. The new design of the Automated Auditory Brainstem Response is designed with a coupler that does not contain disposable electrodes is available at an acceptable cost. The aim of this study was comparing the new generation's Automated Auditory Brainstem Response and Transient Evoked Otoacoustic Emissions test by regarding to their test times. The results were then compared with those in previously published literature.

Methods: Two hundred and sixty healthy infants were included in the study. The hearing screening of all infants was performed using Transient Evoked Otoacoustic Emissions and Automated Auditory Brainstem Response test devices with new, improved technology. The Ero-ScanTM (Maico, Berlin, Germany) test system was used for the Transient Evoked Otoacoustic Emissions, and the newly designed Maico MB11 BERAphone (Maico-Berlin, Germany) Auditory Brainstem Response screening device with three electrodes in one cap was used for the Automated Auditory Brainstem Response test.

Results: Mean age of babies was 60.7±51.3 hours, and age range was 4hours-312hours. The test times for the Transient Evoked Otoacoustic Emissions were 13.68±9.2s and 14.04±9.4s, and for the Automated Auditory Brainstem Response, they were 39.15±22.2s and 45,25±23,9s for the right and left ears respectively.

Conclusions: Although the Automated Auditory Brainstem Response test time is statistically longer than the Transient Evoked Otoacoustic Emissions, the amount of time it takes has been significantly shortened by the new technology. This finding enhances the value of the new generation Automated Auditory Brainstem Response technology usage as an initial test for newborn hearing screening.

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Introduction

The transient (automated) evoked otoacoustic emission (TEOAE) and automated auditory brainstem response (AABR) screening methods are used for newborn hearing screening [1-8]. While the TEOAE is used for the measurement of outer hair cell function, the AABR is used for the measurement of the inner ear, auditory nerve, and brainstem responses [2].

Both screening methods have certain advantages and disadvantages. The target population (healthy infants or infants in the intensive care unit), test time, basic materials, and cost are important factors to be considered in choosing a newborn hearing test [2,4,9]. Since the TEOAE test method does not require electrodes and its test time is shorter than the AABR test, it has been suggested as the initial screening test for healthy newborns. The AABR has only been

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suggested for infants with a hearing loss risk factor since its test time and preparation for the infant (cleaning of the area for the electrodes and attaching them) is longer [2]. However, with advances in technology, this test time has decreased, and there is no longer a need for electrodes in the AABR test [10,11].

Some studies in the literature reported that AABR is higher specificity than TEOAE, however, it is not clear about sensitivity (especially for the mild-moderate hearing loss) [12,13,14]. On the other hand, in our previous study it was declared that the sensitivity and specificity of the AABR test compared with the TEOAE test and it has been higher for the initial stage of newborn hearing screening [9]. With the low false-positive rates of the AABR test, the newborns are no longer misdiagnosed with hearing loss, and the loss of time and cost caused by unnecessary test repetitions are decreased both for the parents and the clinician. . Additionally, since patients with Auditory Neuropathy Spectrum Disorder (ANSD) can only be diagnosed by combination with AABR and TEOAE tests, the legitimate question of whether the AABR test should be used for all newborn hearing screening has been raised.

With all this information we had, sequentially research was undertaken by the authors. In the first part of this, the sensitivity, specificity, and false-positive rates were analyzed, and the findings revealed that the AABR test should be considered as the initial test for newborn hearing screening [9].

We planned this study as the second part of the sequentially research mentioned above. With the advances of AABR technology, decrease in the test time, and outomes of the previous study led us to plan this research. The aim of this study was to determine the test time of the AABR test with the new technology and to decide whether that test could be used as the initial test for all newborn hearing screening.

Methods

All the steps of this study were planned and done according to the principles outlined in the Declaration of Helsinki [15].

Individuals

Two hundred and sixty infants (520 ears) who passed the newborn hearing screening test were included in

this study. The test time was determined for the right and left ears of all sex types of infants. Our aim was to compare only the test times of the equipment excluding the preparation time and data which are dependent on the non specialist experience and the babies awake or not. In addition, in order to establish this, the screening tests performed within 48 hours and after 48 hours of the time of birth, if the infant's age was influent in terms of ear debris or not,. The hearing screening of the first group consisted of 196 infants (392 ears) and was performed within 48 hours of the time of birth while the second group was composed of 64 babies (128 ears) whose hearing screening was performed 48 hours after the time of birth.

Procedure

The hearing screening of all infants was performed using TEOAE and AABR test devices with developed technology. The Ero-Scan™ (Maico, Berlin, Germany) test system was used for the TEOAE, and the newly designed AABR screening device with three electrodes in one cap, Maico MB11 BERAphone (Maico-Berlin, Germany), was used in the AABR test.

The MB 11 BERAphone includes the speaker, the electronic and the measuring electrodes in one unit. The data transfer are made through USB connection. As the stainless steel electrodes are integrated in the BERAphone without any application of disposable electrodes which are necessary. The BERAphone is placed onto the baby's head, after just some application of electrode gel. If a response was observed at 35 dBnHL, the test result will be passed. Stimulus type was CE-Chirp with stimulus rate of 93/s and stimulus level of 35 dB nHL. The new CE-Chirp stimulates all regions of the cochlea at the same time and thus generates much higher responses and consequently faster results than a standard click.

The Ero-Scan™ system has been designed for a fast automatic testing of newborn. The test result will be passed or referred together with the frequency specific test result TEOAE 0.7 to 4 kHz. Stimulus intensity range and peak equivalent were 83 dB nHL and ± 3 dB respectively. Microphone system noise was -20 dB$_{SPL}$ at 2 kHz (1 Hz BW)- 13 dB$_{SPL}$ at 1 KHz (1Hz BW).

Since the aim of the study was to evaluate the test times of newer, technologically more advanced

screening devices, the period from the initiation of the test to the receiving the responses was taken into consideration. Other factors including the experience of the clinician performing the test, the preparation of the infant for the test, the placement of the probe and electrode, and the duration of the recording of information related to the infant were not considered.

For reliability, the tests were performed by the same audiologist and audiometrist. In order to avoid factors which might influence the test results (noise, activity of the infant, nursing behavior of the infant, etc.), the tests were performed during the infants' natural sleep and in a standard soundproof room. Before the TEOAE tests, the cleanliness of the probe filter was checked for each infant. The test time was measured with a chronometer.

Statistical Analysis

Student's t-test was used in the statistical analysis, and a blind approach was used. $p < 0.01$ was considered as statistically significant.

Results

The TEOAE and AABR test times for both ears (520 ears) for all 260 infants were determined, and the data is presented in Table 1.

In the comparison of TEOAE and AABR test times, AABR test time was obtained statistically ($p < 0.01$).

The results regarding the time of the tests were evaluated according to two separate groups: those tested within the first 48 hours of being born and those tested 48 hours after being born. The group of 196 infants (392 ears) tested within the first 48 hours had a mean age of 27 hours (19 ± 20.09 hours; age range 7-48 hours). The data of the TEOAE and AABR test times for each ear of the infants in this group is shown in Table 2.

For the second group consisting of 64 infants (128 ears) who were tested after the first 48 hours, the mean age was 94 hours (19 ± 85.22 hours: age range 49-312 hours). This data is shown in Table 2.

While no significant difference was observed in the comparison of TEOAE and AABR test times according to age (test hours after birth) ($p > 0.01$), the same comparison showed that the AABR test time was significantly longer ($p < 0.01$).

In addition, the differences in right and left ear test times were also evaluated with no statistically significant difference between the two ears. ($p > 0.01$)

Discussion

In our study, the tests performed with developing screening devices had average TEOAE test time that was statistically shorter compared with the AABR test time. However, according to the literature related to

Table 1. The test times of infants' TEAOE and AABR tests.

Mean test time (s±SD)		Min-max time (s)		Mean test time (s±SD)		Min-max time (s)	
TEOAE		TEOAE		AABR		AABR	
Right	Left	Right	Left	Right	Left	Right	Left
13,68±9,2	14,04±9,4	11-35	4-23	39,15±22,2	45,25±23,9	15-101	14-110

Table 2. The TEOAE and AABR test times for the groups

Mean Age (min-max)	Mean test time (s±SD)		min-max time (s)		Mean test time (s±SD)		min-max time (s)	
	TEOAE		TEOAE		AABR		AABR	
	Right	Left	Right	Left	Right	Left	Right	Left
27,19±20,09 (7-48) (First group)	13,84±8,2	14,17±10,1	11-18	4-18	39,88±19,8	46,65±20,4	15-101	15-110
94,19±85,22 (49-312) (Second Group)	13,63±9,6	14±9,9	12-35	12-23	36,89±24	40,94±25,8	15-95	14-108

the TEOAE and AABR test times in hearing screenings [16,17,18] was compared with the findings of our study, the AABR test time within chronological development was shorter than the time previously indicated. Moreover, except for the study by Babac[17], it is noteworthy that the results we observed were even shorter than the TEOAE test times indicated in other studies. (Table 3)

When the literature of the previous ten years was analyzed, the effects of the improved technology in screening devices gained importance (Table 3). In the study by Hahn et al. (1999) in which they compared the clicked-evoked OAE and second generation AABR (Algo1-Algo2) devices in healthy infants, they indicated that the AABR test times, which lasted for an average of three minutes, were shorter than clicked-evoked OAE test time [10]. In the study by Meier et. al (2004) in which they compared the advanced TEOAE with three other more advanced AABR devices, they observed that with its new design and practical cap with three electrodes, the MB11 BERAphone AABR had a shorter test preparation time compared with the Algo3 AABR. Also, the Algo 3 AABR device had a shorter test time compared with the previous Algo model due to its ability to screen both hearing pathways at the same time. They also stated that since the TEOAE is a hand-held screening device, it could be opened and closed in a shorter time, while the Algo3 and MB11, which are computerized screening devices, had a longer test time due to the time it took to start up and shut down [18]. However, since the computer was started and shut down only once per day, we believe this should not have been a factor in their evaluation.

Babac et al. (2007) stated that the AABR test time is shorter than those previously indicated in the literature[17]. Pedersen et al. (2008) suggested that although the test time is longer, the AABR test should be done initially due to its low failure rate and cost[16]. Van den Berg et al. (2010) emphasized that, not only the M11 BERAphone, AABR device's test times are statistically and significantly shorter than ALGO™, but it is also more reliable and applicable in the noisy environment of neonatal intensive care units (NICUs). Additionally, it is potentially more cost effective compared with the ALGO device [19].

As verified by the studies mentioned above, different test times for the TEOAE and ABBR tests have been obtained, even from devices that are the same brand[16,20]. Factors which might cause differences among test times could be listed as follows: 1- The differences of the recording algorithm of screening device 2- Test preparation time (It could be ranged according to the experience of the clinician) 3- The differences of the selected population (healthy and/or newborns in the risk group) 4- The timing of the screening test (before or after 48 hours); 5- The test conditions (with noisy or quiet environment) 6- Refer rate.

Table 3. Studies of Related Literature

Research	Baby	Number of Baby	Screening Test TEOAE	Device AABR	Test Time TEOAE	Test Time AABR	Preperation Time Included	Referral Rate TEOAE	Referral Rate AABR
VanderBerg (2010) Holland	NICU	54	-	MB11Beraphone ALGO™(NATUS)portable	-	11.4 min 13.9 min	+	-	16
Freitas(2009) Brasil	Well baby	100	Capella Madsen	ABaer Biologic	6.75 min	9.22 min	+	2	0.5
Pedersen (2008) Denmark	Well baby	1627	?	ABaer Biologic	3.8 min	6.6 min	+	11	4
Babac(2007) Sırbian	NICU and well baby	907	?	?	21.3 s	135.3 s	-	-	-
Meier (2004) Switzerland	Well baby	150	EchoscreenTDA (Fisher-Zoth)	EchoscreenTDA (Fisher-Zoth) The Algo 3 (NATUS) MB11 BERAphone	30 s	4-5 min	-	-	-
Hahn(1999) Germany	Well baby	55	ILO 288 Echoport Version	Algo 1 (NATUS) Algo 2(NATUS)	5.30 min	3.23 min 3.08 min	-	-	0
Doyle et.al (1997) USA	Well baby	?	ILO 88	Algo 2(NATUS)	5.2 min	5.7 min	-	21	11.5

The test time shows differences according to the function and application principles of the screening device. Higher test reliability, shorter test times, and lower costs have been made possible through technological advances, including the production of devices with easier applications. These advances are also responsible for the different test times encountered in the literature. Innovations in recording methods, such as noise filtering and algorithms, and first, second, and third generations of devices are constantly being produced, for example Algo1, Algo2, Algo3, and Algo™, along with MB11 and MB11 Beraphone. The differences in these devices and test methods should be considered when comparing the literature related to test time. (Table 3)

Besides evaluating the test time in studies related to test duration, time spent preparing the infant, the placement of the probe and electrode in the AABR test, and the test time itself have to also be considered[16,17,18,19]. However, as seen in Table 3, different test times, including preparation time, have been obtained from devices of the same brand from clinics[16,20]. Because of the experience of clinician[18] it is very difficult to form a standard. For this reason, in our study, the preparation time was not taken into account. Only the test time is reflected in the results.

The selected population also influences the test time. Like Van den Berg et al. in their 2010 study (Table 3), we think that the late maturation of the infants who graduate from the intensive care units may be another cause for the longer test times in the literature[19]. Therefore, healthy infants were selected as our study group in order to avoid test times being influenced by this factor. On the other hand, further studies are needed to compare NICU and healthy newborns in terms of the late maturation with the current technological devices.

The refer rate influences the test times of both the TEOAE and the AABR such as taking a longer time with excessive measurement noise and/or hearing impaired infant. For this reason, only infants who had passed the screening test were included in our study; the test times of those infants who had failed were not included.

Freitas et al. (2009) stated that the high refer rate, possibly caused by vernix, may extend the average test time, so if the results include all the test times in the 1st and 2nd controls, a much more balanced result can be achieved[20]. However, only stating the refer rates to prove the vernix effect is not sufficient. Determining the test times of infants who have passed or failed the test and comparing these results with those of their control tests of ten days later should be more accurate to show the effect of vernix on the test time. Therefore, we searched to find comparative studies related to the test times of infants who passed or failed, but we could not reach.

Meier et al. (2004) suggested that a high refer rate is achieved from the TEOAE tests when it is performed within the first 24 hours under the influence of the vernix and that the screening should be done after 30 hours[18]. Doyle et al. (1997) stated in their study conducted with infants ranging from five to 120 hours old that while the infants being younger or older than 24 hours had no effect on the refer rate in the AABR test, it significantly increases this rate in the TEOAE test[21]. In our previous study[9], the refer rates of the TEOAE and AABR tests conducted within the first 48 hours (first group) and 10 days after birth (second group) were compared, it was obtained a significant difference in the first group whereas no meaningful difference in second group. It was speculated that this could have been the result of ear debris due to the vernix.

In this study, in order to establish the effects of debris on the test time, the TEOAE and AABR test times performed before and after 48 hours were compared, and there was no statistically meaningful difference between them. However, in the tests done after 48 hours, the test times for both tests became clinically shorter. This data supports the idea that ear debris can influence the results. It is also possible that the limited number of our cases may have been the reason for having no statistically difference.

Hall (2000) stated that the debris/vernix that is located in the ear canal has more influence on the TEOAE than AABR test in terms of the methodology, due to the TEOAE measurement being affected two times. One is the decrease in the intensity of the sound while transmitting the sound to the inner ear, the other is the decrease in the level of response while measuring the response from the inner ear. in the AABR test,[22].

Beniro-Orejas et al. (2008) stated that the refer rate for the first 48 hours for the TEOAE test is 10.2 % while it is 2.6 % for the AABR test and therefore, although the AABR test is more costly and the test time is longer, it is much more efficient for newborn hearing screenings [23].

When the new technology is evaluated, the high rate of failure has not been overcome on the TEOAE test [18]; however, the refer rate and test time have gradually decreased in the AABR test with new algorithmic measurement techniques (Algo3, Algo™ portable, and MB11 Beraphone) [22,24]. In terms of device costs with the new technology, the AABR's prices, previously four to five times more expensive than the TEOAE, have currently been lowered to only one and a half times higher. We think that in addition to the decrease in the costs, its success in diagnosing the babies with auditory neuropathy spectrum disorder, due to the lower refer rates and the lower stress felt by families, make the AABR test in hearing screenings a suitable initial test even in healthy infants.

Conclusion

Our study supports that the AABR test time has been decreased with developing technology. This result increases the usability of the AABR test as an initial test in newborn hearing screenings. Additionally, advantages such as a high test specificity, low false-positive rate, and the ability to diagnose auditory neuropathy cases were brought out the AABR test to the forefront as the best choice for the initial screening method for healthy infants in the Newborn Hearing Screening Protocol.

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