

ORIGINAL ARTICLE

## Comparison of Hearing Screening Protocols for Universal Newborn Hearing Screening In Turkey

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**Objective:** Congenital hearing loss is one of the most common major abnormalities present at birth. Early diagnose is very important. In this study a comparison of five different newborn hearing screening protocols are made to determine the most suitable screening protocol which can form a model for newborn hearing screenings in Turkey's maternity hospitals.

**Methods:** Newborn hearing screening tests (TEOAE and AABR) were performed on 500 newborns. Five test protocols were used and compared. In the first protocol, TEOAE was only used. In the second protocol AABR was only used. In the third protocol automatic tympanometry, TEOAE and AABR were used. In the fourth protocol TEOAE and AABR were used. In the fifth protocol automatic tympanometry and TEOAE were used.

**Results:** Congenital bilateral hearing loss is found 2/1000 in this study. There was high consistency among second (A-ABR used only), the third (Automatic tympanometry TEOAE and A-ABR were used) and the fourth (TEOAE and AABR were used) protocols. On accounts of high population number and rapid population growth, it is vital to conduct national newborn hearing screening in Turkey.

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### Introduction

The development of speaking and language ability in infants improves quickly in the first few months of lives. Congenital hearing loss negatively affects children's speech, language and social and cognitive development. For this reason, if hearing loss is diagnosed late, negative effects become more than important in early diagnose.<sup>[1-3]</sup>

Congenital hearing loss is one of the most common major abnormalities present at birth. Significant bilateral hearing loss is present in about 1 to 6 per 1,000 newborns.<sup>[3-5]</sup> Congenital bilateral hearing loss is seen 1/1,000 and 3/1,000 in healthy newborns and 20/1,000 and 40/1,000 in NICU(Neonatal Intensive Care Unit) baby.<sup>[6,7]</sup>

Two techniques (EOAEs-Evoked Otoacoustic Emissions- and AABR-Automated Auditory Evoked Response-) are highly acceptable in newborn hearing screening programs.<sup>[6-8]</sup>

Successful application of national newborn hearing screening requires the coordination of numerous factors affecting the program. The three protocols are used in newborn hearing screening programs are;

Hearing screening with TEOAE, AABR and TEOAE with AABR to be applied together.<sup>[5,9,10]</sup>

The method or methods preferred in newborn hearing screening programs differ., In our study a comparison of five different hearing screening protocols are made to determine the most suitable screening protocol which can form a model for newborn hearing screenings in Turkey's maternity hospitals. Besides; the objective is to ascertain the most suitable, economic and easily applicable screening model that is fit for our country's conditions.

### Methods

Our study is conducted in a public maternity hospital in Ankara. Parents are informed about the screening procedure and received their approval. Five hundreds newborns are studied within the scope of this research.

### Subjects

Between the dates November 2002 and April 2003, 500 physically healthy (1,000 ears), 2 to 220 hour-old and ready to be discharged newborns are included in the study. Table 1 shows gender, age average, birth weight average and age ranges of the newborns. To ensure measurement reliability and applicability while

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conducting the study, newborns are studied when they are full, relaxed, asleep on their beds or on their mothers' laps.

**Hearing Screening with TEOAE**

Otodynamics Echocheck and Madsen Accuscreen Pro handheld devices were used in TEOAEs screening. Non-linear and click stimulus were used. As a stimulus level, in Otodynamics Echocheck, Otodynamics, England and Madsen Accuscreen Pro handheld, GN Otometrics, Denmark devices, 84 dB SPL and 60 Hz stimulus were used respectively. According to size of external auditory meatus of newborn, 3mm or 4mm probe tips with 4 gr probe were used. Results were given pass or refer automatically by these devices.

**Hearing Screening with Automatic ABR**

All automatic ABR measurements are conducted under 2.000 Hz – 4.000 Hz frequency range with Madsen Accuscreen Pro screening device by using 35 dB nHL tightband click stimulus. Measurement results are obtained through automatic evaluation as Pass or Refer .

**Hearing Screening via Automatic Tympanometry**

Tympanometric measurements of newborns are conducted by using 226 Hz probe tone Madsen Tympano-Screen screening tympanometry which has 226 Hz probe tone only.

**Screening Protocols**

In this study newborn hearing screening was done by using five protocols. We compared the output of these five protocols.

Protocol 1; Only TEOAE was used. When baby passed both ear, screening was accepted as a pass.

Protocol 2; A-ABR was only used. When baby passed both ear, screening was accepted as a pass.

Protocol 3; Automatic tympanometry, TEOAE and AABR were used. When positive TEOAE and A-ABR responses or only A-ABR responses were obtained, screening was accepted as a pass. Babies who pass only A-ABR test, referred to ENT examination in

order to eliminate external and/or middle ear problems. Babies who pass only TEOAE test, were followed up in order to eliminate possible central auditory disorder.

Protocol 4; TEOAE and A-ABR were used. When positive TEOAE and A-ABR responses or only A-ABR responses were obtained, screening was accepted as a pass. Babies who pass only A-ABR test, referred to ENT examination in order to eliminate external and/or middle ear problems. Babies who pass only TEOAE test, were followed up in order to eliminate possible central auditory disorder.

Protocol 5; Automatic tympanometry and TEOAE were used. When bilateral positive TEOAE responses were obtained, screening was accepted as a pass. In this protocol, whether or not tympanometric finding supports TEOAE result was searched.

In all these protocols babies who failed according to screening results were recalled for a second examination three weeks later. Babies who failed after second examination were asked to perform diagnostic audiological tests after their ear, nose and throat examinations were completed.

Statistical evaluation was accomplished by using Kappa Coefficient Tests.

**Results**

The results related to the hearing screening of 500 babies (1,000 ears) included in the study are given below.

By using the first protocol (TEOAE) 14 babies were asked to be rechecked for a second TEOAE test, 3 of them did not come while 11 babies came for check up. Findings obtained from the first and second tests in this protocol are indicated in Table 2.

Diagnostic audiological tests of the 3 babies who failed in the second test were conducted when they were 2 months old. Babies' hearing tests in TEOAE, ABR and soundfield tests were examined. The results showed that 2 of these babies had normal hearing, 1 had profound hearing loss. False positive ratio was found as 2% in this protocol.

**Table 1.** Symptoms, signs and therapy of different groups of posttraumatic facial palsy

GROUP	Sex	Age Range (hour)	Mean Age (hour)	Birth Weight (gr)	Mean Birth Weight (gr)
	Female/ Male				
N = 500	228 / 272	2-220	36.1± 20.7	1,650-4.650	3,141± 467

Within the second protocol made by using automated ABR 9 babies were asked to be rechecked. Except one baby 8 babies came for check up. Findings obtained from the first and second tests in this protocol are indicated in Table 3.

Diagnostic audiological tests of one baby who failed in the second test were conducted when s/he was 2 months old. Baby's hearing tests in TEOAE, ABR and soundfield tests were examined. The results showed that this baby had profound sensory-neural hearing loss. False positive ratio was found as 1.4 %.

The third Protocol was accomplished by using TEOAE, automatic tympanometry and A-ABR and 9 babies were asked to be rechecked for a second test. Except one baby 8 babies came for check up. Findings obtained from the first and second tests in this protocol are indicated in Table 4.

Although 5 of the 491 babies failed TEOAE, they passed automatic ABR test. The distribution of the results of 5 babies who failed TEOAE indicates that 3 babies' automatic tympanometry results were normal while 2 of them were abnormal. The fact that tympanometric measurement of 3 babies who did not give emission response was within normal values increased hearing loss suspicions of these babies. However evaluating via A-ABR in this protocol and their positive results of A-ABR test, the babies were accepted as passed the hearing screening. On the other hand 2 babies who did not give emission response and whose tympanometry result was abnormal values responded via A-ABR. Since this condition meant conductive pathology (milk otitis, otitis media etc.), their families were given more detailed information and they were directed.

**Table 2.** Outcomes of I. Protocol

<b>The First Protocol (TEOAE)</b>	<b>Total number</b>	<b>Percent (%)</b>
The first test		
Subject	500	100
Pass	486	97.2
Bilateral Refer	8	1.6
Unilateral Refer	6	1.2
The second test		
Subject	11	100
Pass	8	72.7
Bilateral Refer	2	18.2
Unilateral Refer	1	9.1
Baby referred diagnostic test	3	0.6
Baby diagnosed hearing loss	1	0.2

**Table 3.** Outcomes of II. Protocol

<b>The Second Protocol (AABR)</b>	<b>Total number</b>	<b>Percent (%)</b>
The first test		
Subject	500	100
Pass	491	98.2
Bilateral Refer	5	1.0
Unilateral Refer	4	0.8
The second test		
Subject	8	100
Pass	7	87.5
Bilateral Refer	1	12.5
Unilateral Refer	–	
Baby referred diagnostic test	1	0.2
Baby diagnosed hearing loss	1	0.2

**Table 4.** Outcomes of II. Protocol

The Third Protocol (Tymp+TEOAE+AABR)	Total number	Percent (%)
The first test		
Subject	500	100
Pass	491	98.2
Bilateral Refer	5	1.0
Unilateral Refer	4	0.8
The second test		
Subject	8	100
Pass	7	87.5
Bilateral Refer	1	12.5
Unilateral Refer	–	
Baby		
Fail TEOAE and pass AABR	5	
Had abnormal tympanogram	2	
Had normal tympanogram	3	
Baby		
Diagnosed conductive pathology according to tympanometric test	2	
Baby referred diagnostic test	1	0.2
Baby diagnosed hearing loss	1	0.2

Diagnostic audiological tests of one baby who failed in the second test were conducted when she was 2 months old. Baby’s hearing tests in TEOAE, ABR and soundfield tests were examined. The results showed that this baby had profound bilateral sensory-neural hearing loss. False positive ratio was found as 1.4 %.

The fourth protocol was realized by using TEOAE and A-AABR and 9 babies were asked to be rechecked for a second test. Except one baby 8 babies came for check up. Findings obtained from the first and second tests in this protocol are indicated in Table 5.

Diagnostic audiological tests of 1 baby who failed in the second test were conducted when she was 2 months old. Baby’s hearing tests in TEOAE, ABR and soundfield tests were examined. The results showed that this baby had profound hearing loss. False positive ratio was found as 1.4 %.

The last protocol was the combination of TEOAE and Automatic Tympanometry. Four of the 14 babies who failed had abnormal tympanometry values, 10 of them had normal values. In this protocol 14 babies were asked to be rechecked for a second test. Three of them did not come while 11 babies came for check up. Findings obtained from the first and second tests in this protocol are indicated in Table 6.

Diagnostic audiological tests of 3 babies who failed in the second test were conducted when they were 2 months old. Babies’ hearing tests in TEOAE, ABR and soundfield tests were examined. The results showed that 2 babies had normal hearing, 1 had bilateral profound sensory-neural hearing loss. False positive ratio was found as 2%.

**Comparison of the Protocols**

In the protocols, defining statistics is used to determine pass or fail ratios of the babies.

**Agreement among protocols**

Kappa coefficient was used for agreement among all protocols in the first screening test results. Kappa coefficient among the first and second protocols, the first and fourth protocols, the second and fifth protocols was found to be 0.795. Kappa coefficient among the first and fifth protocols, the second and fourth protocols was found to be 1.000. Kappa coefficient among the second and third protocols, the third and fourth protocols was found to be 0.898. This finding proves the perfect agreement among these protocols (p<0.05). Kappa coefficient among the first and third protocols, the third and fifth protocols, fourth and fifth protocols was found to be 0.778. This finding indicates the high ratio of agreement among these protocols (p< 0.05).

**Table 5.** Outcomes of IV. Protocol

The Fourth Protocol (TEOAE+AABR)	Total number	Percent (%)
The first test		
Subject	500	100
Pass	491	98.2
Bilateral Refer	5	1.0
Unilateral Refer	4	0.8
The second test		
Subject	8	100
Pass	7	87.5
Bilateral Refer	1	12.5
Unilateral Refer	–	
Baby		
Fail TEOAE and pass AABR	6	
Baby referred diagnostic test	1	0.2
Baby diagnosed hearing loss	1	0.2

**Table 6.** Outcomes of V. Protocol

The Fifth Protocol (Tymp+TEOAE)	Total number	Percent (%)
The first test		
Subject	500	100
Pass	486	97.2
Bilateral Refer	8	1.5
Unilateral Refer	6	1.2
The second test		
Subject	11	100
Pass	8	72.7
Bilateral Refer	2	18.2
Unilateral Refer	–	
Baby		
Had abnormal tympanogram	3	
Had normal tympanogram	2	
Baby referred diagnostic test	3	0.6
Baby diagnosed hearing loss	1	0.2

In comparing the protocols so as to verify hearing losses of the babies following their further examinations after the second screening test; Kappa coefficient among the first and second protocols, the first and third protocols, the first and fourth protocols, the second and fifth protocols, the third and fifth protocols, the fourth and fifth protocols was found to be 0.498. This result shows that these protocols cannot be used in place of one another ( $p>0.05$ ). On the other hand Kappa coefficient among the first and fifth protocols, the second and third protocols, the second and fourth protocols, the third and fourth protocols was found to be 1,000. This finding demonstrates that there

is 100% agreement among these protocols and they can be used in place of one another ( $p<0.05$ ). the first and second screening tests according to protocols were given in Tables 7 and 8 respectively.

### Discussion

Just as many other countries in the world, newborn hearing screening tests have recently become widespread in Turkey as well.<sup>[11]</sup> Increased attention to newborn hearing screenings led to innovations in screening devices and as time passed screening methods become more easily applicable. It is aimed to obtain maximum efficiency from broad population screenings by forming models of automatic screening

**Table 7.** Outcomes of first test according to protocols

Protocols	Pass		Refer	
	Number	Percent(%)	Number	Percent( %)
The first and fifth protocols	486	97.2	14	2.8
The second, third and fourth protocols	491	98.2	9	1.8

**Table 8.** Outcomes of second test according to protocols

Protocols	Pass		Refer	
	Number	Percent(%)	Number	Percent( %)
The first and fifth protocols	8	72.7	3	27.3
The second, third and fourth protocols	7	87.5	1	12.5

devices made out of objective audiologic diagnostic devices used in clinical atmosphere.<sup>[1,12]</sup>

A vast majority of Western countries are in search of a hearing screening procedure which is applicable in their national structure. In these procedures, the objective is to obtain maximum screening possibility with minimum cost. These procedures determine the means to reach newborns, tests that will be performed before babies are referred for diagnostic audiological tests and the types of re-tests.<sup>[10,13,14]</sup> Further goal of our study is to spread newborn hearing screenings in all of the maternity hospitals and Public hospitals in Turkey and to prepare the most applicable protocol.

In the early periods newborn hearing screening was performed, only babies having hearing loss risk were screened. Since many babies not having risk initially also showed serious hearing loss symptoms in the following years, it was recommended to perform hearing screening to all newborns.<sup>[15]</sup> In our study, we included only healthy newborns.

In newborn hearing screening protocols, hearing screening tests (OAE and AABR) can be used alone or together. Target population, birth rate, false positive rate, the cost of devices and consumption, distance to diagnostic audiology centers must be taken into consideration in deciding protocols. The aim of our study was to compare the screening protocols, to find protocols that can be used instead of the other one and also to decide the best protocol according to conditions of the maternity hospital. Comparing the screening tests is not subject of this study. Although tympanometric testing is not accepted as a screening method, it may help to comment on the TEOAE test results; for this reason tympanometric test was included in the third and fifth protocols.

It is projected that in order to ensure the success of newborn hearing screenings, applied test method should be practical and be able to respond in a short period. TEOAE and A-ABR methods are recommended for hearing screenings.<sup>[7]</sup> hearing screening pass ratios are higher in A-ABR measurement.<sup>[15-17]</sup> Comparison of different screening protocols showed that using multi-method approaches(the 3rd, 4th and 5th protocols) are better than one-method approach (either 1st protocol or 2nd protocol) because of low fail ratio.<sup>[18]</sup> The findings obtained in our study by comparing five different hearing screening protocols support the idea that when both methods are used, the number of babies called for test repetition and referred for diagnostic audiological examinations decreases. This situation can be seen in protocols that include A-ABR test (the 2nd, 3rd and 4th protocols) In the third and fourth protocols, although 5 babies failed from TEOAE tests, they passed from A-ABR. Babies who passed A-ABR were not retested and also not referred for diagnostic evaluation. The first and fifth protocols which include TEOAE test have higher false positive ratio than the protocols that include A-ABR. False positive ratios were 2% and 1.4% respectively. This data showed that TEOAE test causes higher refer rate and retest according to A-ABR. The A-ABR is accepted as gold standard test for newborn hearing screening. This means that if a baby fails TEOAE test and passes AABR, test screening result is accepted as passed. For this reason, the protocols in which A-ABR is used have less refer rate. It can be seen in the results of the second, third and fourth protocols; one baby who was referred to diagnostic audiological tests had profound

hearing loss. This data showed that these protocols were effective in newborn hearing screening.

The effect of otitis media with effusion (OME) is greater for infants with sensorineural hearing loss than for those with normal cochlear function.<sup>[13]</sup> In cases when fluid is available in middle ear TEOAE test result is negatively affected yet compared to TEOAE test, ABR test result is influenced less.<sup>[19]</sup> Thus in hearing screenings tympanometric measurement can also be performed.<sup>[20]</sup> Provided that debris is present on newborns' external ear and fluid in middle ear, hearing screening tests performed via TEOAE and ABR are affected and false positive ratio increases.<sup>[20]</sup> One reason for the inclination to decrease false positive ratio in universal newborn hearing screening is to prevent the families from feeling dismayed and another reason is to lessen the costs for post-screening evaluations. As the study results demonstrate, within the limits, it is suggested to perform 1,000 Hz probe tone tympanometric measurement prior to screening.

In order to support our study we included the screening tympanometry in our protocol. Using low frequency probe tone screening tympanometry is the limitation of our study but our results supported that tympanometric measurement is very important in newborn hearing screening protocols. Two of the 5 babies in the third protocol, and 4 of the 14 babies in the fifth protocol failed TEOAE test. Automatic tympanometric results of these babies were also abnormal. This condition informs us about conductive pathology that should be excluded before referring the baby for hearing loss. It is important for the clinician who follows the baby and gives information to the family. Tympanometric measurement will prevent unnecessary ABR test referral in the maternity hospitals that use protocols including TEOAE test. It will also prevent family anxiety and lessen transportation cost to distant centers.

Newborn hearing screening programs help to diagnose auditory neuropathy/auditory dys-synchrony (AN/AD) in their early phase. It is suggested to perform both methods simultaneously or conduct the screening with AABR especially in babies having risk potential.<sup>[21]</sup> We recommend protocols including A-ABR for maternity hospitals with high birth rate (40-50 birth in a day) and for babies in intensive care unit.

The birth rate of the hospital, cost of screening device and cost of transportation to the center for diagnostic audiological tests are very important factors in determining the most suitable screening protocol for the maternity hospitals in Turkey. According to findings obtained from our study the protocols with AABR measurement (the second, third and fourth protocols) have low referral rates. It is advocated to perform AABR measurement for screening protocol in maternity hospitals where birth rates are high and intensive care unit is available. As the hearing loss risk factors (consanguineous marriage, hyperbilirubinemia etc.) are high in these hospitals, congenital hearing loss and AN/AD ratio will be high as well.

All the same in the maternity hospitals with low birth rate and close to the diagnostic audiology center, the protocols without AABR measurement (the first and second protocols) can be performed. In case of one method used screening programs the parents should be informed and the baby should be sent for diagnostic audiological evaluation.

One of the topics under discussion is whether hearing screenings should be bilateral or unilateral.<sup>[20]</sup> It is believed that since consanguineous marriage ratio is high and it is possible to overlook unilateral hearing losses, bilateral screening is better for our country.

On accounts of high population number and rapid population growth, it is vital to conduct national newborn hearing screening in Turkey. This importance becomes even more vital once high amounts of consanguineous marriage are taken into account. In addition to financial conditions, difficulty in attending to diagnostic audiology centers is also significant in a country-wide screening program. Thus in terms of cost-effectiveness it is important to perform hearing screenings with the best protocol that minimizes the need for a baby's recheck. Consequently in selecting the protocol; birth rates, financial condition of the hospital, baby's potential risk factors, distance problem that might prevent baby's arrival for a second check up should all be considered.

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