ORIGINAL ARTICLE

Hearing Screening Protocols of Babies with Hearing Loss Risk Factors in Turkey

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Objectives: Undetected congenital hearing loss negatively affects the development of child's speech, language, social and cognitive skills. Children who are identified early as having hearing loss and receive intensive early intervention perform better. In our study the objective was to compare hearing screening protocols for infants who has risk factors for hearing loss.

Materials and Methods: In this study, infants who have risk factors for hearing loss, hospitalized in Hacettepe University Newborn Intensive Care Unit, included regarding the criteria issued by Joint Committee on Infant Hearing Position Statement 2007. Control group was comprised infants born in Hacettepe University and not having those risk factors for hearing loss. A hundred infants in each group, totally 200 (400 ears) were screened by three different protocols. First protocol used Transient Evoked Otoacoustic Emission, second protocol used Automated Auditory Brainstem Response and the third protocol used two tools in combination. Tympanometric assessment was done by multi frequency tympanometry in each protocol.

Results: Following the statistical comparison of protocols, it has been found that the 1st and 2nd protocols and also the 1st and 3rd protocols cannot be used in place of the other while the 2nd and 3rd protocols can be used in place of one another (p<0,05).

Conclusion: It is more effective to use the 3rd protocol which consists of Transient Evoked Otoacoustic Emissions, Automated Auditory Brainstem Response in combination and tympanometric measurements.

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Introduction

Oral communication is rather significant in interpersonal relationship. The most significant factor in learning to speak is having a normal hearing.^[1:4] Congenital hearing loss not only affects adversely speaking and language skills of children but also their social, emotional and mental development. The level of this effect increases with the level of hearing loss and the age diagnosis.^[3, 5-7]

Bilateral congenital hearing loss incidence varies between 1/1,000 and 6/1,000. It has been reported that this rate is between 1/1,000 and 3/1,000 in healthy newborns and between 20/1,000 and 40/1,000 of Newborn Intensive Care Unit (NICU) infants. ^[7-10].

In newborn hearing screening, two methods are validated; Evoked Otoacoustic Emissions (EOAEs) and Auditory Brainstem Response (ABR). ^[11,12]

Automated models of those methods can be used separately or in combination. Those methods are non-invasive, fast (shorter than five minutes), easily applicable and do not necessitate the employment of skilled personnel. In addition to those methods, evaluating middle ear conditions of newborns and infants whose middle ears are under mass system, high frequency probe tone tympanometry, also gives valuable data to the clinician as a reliable, objective method. ^[13,14]

In Turkey, newborn hearing screening implementation is an ongoing process since 2004. The present study aims to compare different hearing screening protocols regarding the risk factors for hearing loss.

Materials and Methods

This present study approved by Hacettepe University Ethical Board (LUT 07/87) conducted at Hacettepe

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University Faculty of Medicine, Otorhinolaryngology Department, Audiology and Speech Pathology Unit for one and a half year.

In this study, healthy infants (n=100) and infants (n=100) who had risk factors for hearing loss, hospitalized in NICU, enrolled regarding the criteria of reports issued by Joint Committee Infant Hearing (JCIH) 2007 position statement.^[15] Initial screening of all the infants were done before the infants were discharged from the hospital. Totally 200 infants (400 ears) were screened.

Chronological age and birth weight rates of groups are given in Table 1.

Infants' communication and demographic information were obtained from their parents and recorded in forms specific to each infant.

Equipments

Hearing screening was performed while infants were sleeping either on their baby beds or on their parents' laps with full stomach and relaxed. After recording the communication and demographic information in the forms specific to each baby, the measurements were done bilaterally in a quiet environment by applying automated TEOAE and/or AABR depending on the protocol used and middle ear pressure measured using multifrequency tympanometry.

TEOAE

Automated TEOAE measurements were done using GN Otometrics MADSEN Accuscreen PRO Screening emission equipment with 3 mm or 4 mm probe tip according to the external ear canal size of infants. After placing suitable probe tip in the ear canal, the measurement results were automatically obtained as pass or refer. Emission measurements were done with a non-linear 60 Hz click square wave stimulus of 40 dB SPL intensity by using TEOAE form of the tool between 1.4 and 4 kHz frequency range.

Screening ABR

Two different brand name equipments (GN Otometrics MADSEN Accuscreen Pro Automatic

ABR and Maico MB 11 screening ABR) were applied to 80 infants (40% of total number of current study). The results were found to be matched with each other. Therefore, GN Otometrics MADSEN Accuscreen Pro screening ABR equipment and Maico MB 11 screening ABR equipment were both used in our study. In both measurements 35 dB HL narrow band click stimulus was used.

During ABR testing, done by GN Otometrics MADSEN Accuscreen Pro screening equipment, the infants' foreheads and mastoid bone areas behind both ears were cleaned; disposable electrodes were placed on those areas. Three electrode entries specified with three separate colors, white pointed electrode (active electrode) on the forehead, red pointed electrode (passive electrode) on the mastoid bone of the tested ear and black pointed electrode (ground electrode) was placed on the mastoid bone of the opposite ear. Measurements were done using insert earphones. Examination of the opposite ear was done after the places of passive and ground electrodes were changed. The measurement results were automatically obtained as pass or refer.

During the measurements conducted by Maico MB 11 screening ABR equipment, the test was done by BERA phone after applying conductive gel below part and vertex of the ear. The measurement results were automatically obtained as pass or refer.

Tympanometry

GSI TympStar Version 2 Middle Ear Analyzer was applied for tympanometric evaluation using 678 Hz probe tone. The results are classified as normal, negative and positive middle ear pressure. ^[16]

Screening Protocols

In this study hearing screenings of infants were done within the scope of three basic protocols.

Protocol I: Screening was performed using TEOAE and tympanometric measurements.

Protocol II: Screening was done using AABR and tympanometric measurements.

Table 1. Demographic information of infants

| Groups | Sex | Chronolo | gical age | Birth | weight |
|----------------------|---------------|-----------|---------------|-----------|------------------|
| | Female / Male | (day) | | (| gr) |
| | | Min - Max | Mean±sd | Min - Max | Mean±sd |
| Infants with HLRF | 41 / 59 | 2-500 | 21,19 ± 50,98 | 920-4200 | 2596,61 ± 879,07 |
| Infants without HLRF | 42 / 58 | 1-10 | 3,31 ± 2,17 | 2030-4800 | 3239,85 ± 427,58 |

sd: Standard deviation

Protocol III: Screening was conducted using TEOAE and AABR in combination, and tympanometric measurements.

The results of the first and second protocols considered to be positive (normal hearing) if the infants pass the screening bilaterally. If the infants pass with AABR alone or in combination with TEOAE bilaterally for the third protocol, the result considered to be positive (normal hearing).

In all those protocols, infants who failed the initial screening were asked for follow-up in ten days. Infants who failed the second screening were directed to the Otorhinolaryngology Department for examination of probable external ear canal or middle ear problems. Infants who received medical treatment were rescreened following their intervention, and then as like the infants with normal ENT findings, referred for further diagnostic evaluation if they fail the screening.

Data Analysis

Statistical analysis was done using "SPSS 10.0 for windows" package program. Descriptive statistical method was used to determine frequency and percentages while Kappa coefficient tests were used to evaluate inter-protocol compatibility. If p < 0.05, the difference was accepted to be statistically significant.

Results

Protocol I

Infants without HLRF had 1% fail rate for right ear and 2% for left ear (Table 2). Infants with HLRF had 24% fail rate for right ear and 17% for left ear (Table 3).

Infants without HLRF passed the second hearing screening while infants with HLRF failed the second hearing screening 44.8% and 20.7% respectively for right and left ears (Tables 4 and 5).

Protocol II

Infants without HLRF had 100% pass rate for both right and left ears (Table 2). Infants with HLRF had 14% fail rate for right ear and 7% for left ear (Table 3).

Infants with HLRF failed the second hearing screening 33.3% for both right and left ears (Tables 4 and 5).

Protocol III

Infants without HLRF all passed the initial screening while infants with HLRF had 14% fail rate for right ear and 7% for left ear. The results of the initial screening and tympanometric evaluation are shown in Tables 2 and 3.

Infants with HLRF failed the second hearing screening 33.3% for right and left ears (Tables 4 and 5).

 Table 2. Initial screening and tympanometric results of protocols (without HLRF)

| Procedures | | Screen | ing(%) | | Tympanometry(%) | | | | | | | |
|------------------------------|-----|--------|--------|-----|-----------------|-----|-----|-------|----|--------|--|--|
| (Without | Pas | s | Fa | ail | Nor | mal | Neg | ative | Po | sitive | | |
| HLRF) Initial test | R | L | R | L | R | L | R | L | R | L | | |
| Protocol I (TEOAE) | 99 | 99 | 1 | 2 | 95 | 98 | 4 | 1 | 1 | 1 | | |
| Protocol II (AABR) | 100 | 100 | | _ | 95 | 98 | 4 | 1 | 1 | 1 | | |
| Protocol III (TEOAE+AABR) | 100 | 100 | | _ | 95 | 98 | 4 | 1 | 1 | 1 | | |

Table 3. Initial screening and tympanometric results of protocols (with HLRF)

| Procedures | | Scre | ening(%) | | Tympanometry(%) | | | | | | |
|------------------------------|----|------|----------|----|-----------------|------|-----|-------|-----|--------|--|
| (Without HLRF) | Pa | iss | Fa | il | No | rmal | Neg | ative | Pos | sitive | |
| Initial test | R | L | R | L | R | L | R | L | R | L | |
| Protocol I (TEOAE) | 76 | 83 | 24 | 17 | 75 | 81 | 19 | 15 | 6 | 4 | |
| Protocol II (AABR) | 86 | 93 | 14 | 7 | 75 | 81 | 19 | 15 | 6 | 4 | |
| Protocol III (TEOAE+AABR) | 86 | 93 | 14 | 7 | 75 | 81 | 19 | 15 | 6 | 4 | |

| Procedures | | Screer | ning(%) | | Tympanometry(%) | | | | | | |
|-----------------------|-----|--------|---------|-----|-----------------|------|------|-------|-----|-------|--|
| (Without HLRF) | Pas | SS | F | ail | Norm | nal | Nega | ative | Pos | itive | |
| Initial test | R | L | R | L | R | L | R | L | R | L | |
| Protocol I (TEOAE) | 100 | 100 | — | — | 33.3 | 66.7 | 66.7 | 33.3 | _ | _ | |

Table 4. Second screening and tympanometric results of Protocol I (without HLRF)

Table 5. Second screening and tympanometric results of protocols (with HLRF)

| Procedures | rocedures Screening(%) | | | | Tympanometry(%) | | | | | | | |
|------------------------------|------------------------|------|------|------|-----------------|-------|-------|-------|--------|----|--|--|
| (Without HLRF) | Pas | s | Fa | il | Norm | al | Nega | tive | Positi | ve | | |
| Initial test | R | L | R | L | R | L | R | L | R | L | | |
| Protocol I (TEOAE) | 55.2 | 79.3 | 44.8 | 20.7 | 62.06 | 72.41 | 31.03 | 31.03 | 10.34 | - | | |
| Protocol II (AABR) | 66.7 | 66.7 | 33.3 | 33.3 | 86.67 | 86.67 | 13.03 | 13.03 | _ | - | | |
| Protocol III (TEOAE+AABR) | 66.7 | 66.7 | 33.3 | 33.3 | 86.67 | 86.67 | 13.03 | 13.03 | _ | - | | |

Comparison of Protocols

Kappa coefficient was used for agreement among all protocols. Regarding the initial screening, Kappa coefficient among the first and second protocols, the first and third protocols was found to be 0.681 indicating high ratio agreement among those protocols (p<0.05). Also, Kappa coefficient among the second and third protocols was found to be 1.000 for the initial screening. This finding supports the perfect agreement among the second and third protocols (p<0.05) (Table 6). This data demonstrates that there is 100% agreement among those protocols (the second and third) and they can be used in place of one another (p<0.05).

The results of second screening showed that Kappa coefficient among the first and second protocols was found to be 0.727 like the Kappa coefficient among the first and third protocols. Those results indicate high ratio agreement among those protocols (p<0,05). This finding shows that the first and the second protocols cannot be used in place of one another like the first and the third protocols (p<0.05). Also, Kappa coefficient among the second and third protocols was found to be 1.000 for the second screening. This finding supports the perfect agreement among those protocols (p<0.05)

(Table 7). This data demonstrates that there is 100% agreement among those protocols (the second and third) and they can be used in place of one another (p<0.05).

Correlation between negative middle ear pressure and TEOAE was found to be statistically significant in case TEOAE response was not acquired (Protocols I and III) (p<0.005).

Comparing all the protocols, the findings support the use of AABR to screen infants with HLRF.

As a result of all three protocols, three infants with HLRF diagnosed having hearing loss, 1 bilaterally and 2 unilaterally.

Discussion

The goal of initial early detection of hearing loss programs comprised infants with HLRF.^[17] The procedure of hearing screening has changed through the years.^[15]

Although commonly, hearing screening programs are applied bilaterally there are clinics applying hearing screening unilaterally.^[18,19] In 2007 report issued by Joint Committee on Infant Hearing, it was noted that unilateral response in infants should not be accepted as success criteria but rather bilateral response should be considered. ^[15] Following those criteria, in this study, 2 infants having HLRF were diagnosed with unilateral hearing loss. We argue that since it is significant to follow those infants' both speech-language development and amplification^[7,20] newborn hearing screenings should be applied bilaterally.

In this present study bilateral responses were considered to be pass criteria. In literature as well, it is

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Table 6. Agreement of protocols according to initial screening

| Protocols | Kappa coefficient among the protocols |
|--------------------------------|---------------------------------------|
| The first and second protocols | 0.681 |
| The first and third protocols | 0.681 |
| The second and third protocols | 1.000 |

emphasized that infants with normal hearing, the protocols where AABR test is used alone or in combination with TEOAE, the necessity for a recheck is lower than protocols where only TEOAE test is used.^[21,22] The results of the present study are compatible with literature findings.

In some studies it is advocated that as part of hearing screening program, the best method is to implement both AABR and TEOAE tests together in order to determine auditory neuropathy spectrum disorder (ANSD).^[23-26] Timely and successful treatment results can be achieved in hiperbilirubinemia regarding ANSD by using AABR and TEOAE in combination. ^[27,28] Joint Committee on Infant Hearing 2007 Position Statement indicated that infants who stay in NICU longer than 5 days should be screened not only with TEOAE test but also with ABR so as to detect neural problem as early as possible. ^[15]

None of the infants were diagnosed with ANSD in the present study. We think that the infant number comprised in the study can be insufficient. However, we believe that in order to detect this disorder as early as possible hearing screening protocol should include AABR and TEOAE in combination, especially for infants having HLRF.

As TEOAE and AABR test results are affected by debris in the external ear canal and milk otitis media in the middle ear of a newborn, false positive ratio of hearing screening tests increases. ^[15,18] In our study, in order to interpret the false positive ratio in all of the three protocols, tympanometric evaluation was done as well.^[29] Many researchers advocate the significance of using high probe tone stimuli for the tympanometric evaluation of infants. ^[30]

In literature, there are various approaches concerning the follow-up procedure of infants with or without HLRF. $^{\scriptscriptstyle [31,32]}$

As we compared different hearing screening protocols in this study, infants screened merely by TEOAE failed the initial screening if they had negative tympanometric results which increases the probability of retest. This result is consistent with the literature. ^[13,29] Comparison Table 7. Agreement of protocols according to second screening

| Protocols | Kappa coefficient among the protocols |
|---|---------------------------------------|
| The first and second protocols The first and third protocols | 0.727 0.727 |
| The second and third protocols | 1.000 |

of the second and the third protocol suggests that those protocols are compatible with each other and appropriate for infants with HLRF. Pass ratio of the second and the third protocol was found to be higher than the first protocol. So, those two protocols are more advantegous than the first protocol. However, the cochlear function is not evaluated particularly in the second protocol. As the third protocol assesses both the central and peripheral auditory system, and has benefits to diagnose ANSD during early infancy, it has more advantages than the other two protocols for newborns with HLRFs.

It is concluded that the high pass rate of the present study in the initial screening attributed to the time the infants screened (at least 48 hours after birth).^[33]

Newborn Hearing Screening which has an active role on early detection of congenital hearing loss is becoming more widespread in Turkey as it is in the whole world. In newborn hearing screening, it is quite important to use the approriate test method and protocol in order to attain target population and get result quickly. In addition, conducting a hearing screening on infants with HLRF, it is important to set the follow-up process for early diagnosis. In the light of the results, in order to interpret false positive ratio, decrease referral rate and evaluate the whole auditory system, the third protocol is more instructive. It is rather important to inform the families about the importance and necessity of this procedure in order to achieve regular controls of infants with HLRF. The success of hearing follow-up procedure is closely related with the way families are informed about the content.

In view of current results and literature data concerning this subject, we suggest that infants with HLRF should be screened with TEOAE and AABR methods in combination or AABR alone in Turkey. Also, audiological follow-up of infants should continue till they are 3 years of age once a year even if they pass the hearing screening. The follow-up procedure should be compatible with their age and cooperation.

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