RESEARCH ARTICLE

Transitory evoked otoacoustic emission (TEOAE) and distortion product otoacoustic emission (DPOAE) outcomes from a three-stage newborn hearing screening protocol

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Abstract

Objective: Comparison of the efficacy of Transitory Evoked Otoacoustic Emissions (TEOAEs) and Distortion Product Otoacoustic Emissions (DPOAEs) in a neonatal hearing screening protocol, based on a three-stage strategy.

Methods: In the first stage, a hearing screening using both evoked emissions was conducted in 3,480 neonates from March 2006 through January 2012. Both TEOAEs and DPOAEs were recorded. Neonates, who did not undergo the test before being discharged, were examined within 30 days at a scheduled appointment. Follow-up of the referred newborns (second-stage screening) was performed as an outpatient re-screening, within a month. The third-stage evaluation, i.e., the diagnostic testing, included a clinical otolaryngological examination, high-frequency tympanometry at 1,000 Hz and Auditory Brainstem Response (ABR) measurements.

Results: A total of 3,480 (97%) newborns (n =1,765 males) out of 3,595 infants were enrolled in the study. In the first-stage evaluation, 8.9 % of the infants were referred according to TEOAEs, while the percentage of the referred infants for DPOAEs was 25.7 %. At this initial assessment stage, the specificity of TEOAES and DPOAEs were determined as 92% and 75%, while positive predictive values (PPV) were 3.8 % and 1.3 %, respectively. In the second stage of evaluation, the specificity of TEOAES and DPOAEs were 86 % and 76 %, while the PPV increased to 18 % and 15 %, respectively.

Conclusions: With a lower follow-up rate, TEOAEs testing was significantly easier to perform and more reliable compared to the DPOAEs test. Hippokratia 2016, 20(2): 104-109

Keywords: Newborn hearing screening, distortion product otoacoustic emissions, transient evoked otoacoustic emissions, hearing loss

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Introduction

Hearing loss is likely to be the most common congenital abnormality in humans, with severe bilateral sensorineural hearing loss affecting up to three children in 1,000 live births in the well-baby nursery population[1]. Over 50% of congenital hearing loss is of genetic origin. In addition to the hereditary hearing loss, a number of in utero and neonatal complications (e.g. infections, immaturity, asphyxia, ototoxic medications and hyperbilirubinemia) have been implicated as risk factors in neonatal hearing disorders[2].

There is a general agreement that the early detection of hearing impairment is warranted and should lead to early intervention[3]. Universal Newborn Hearing Screening (UNHS) has been suggested as a tool to speed up diagnosis, initiate treatment, and thus maximize linguistic competence and literacy development for deaf or hard of hearing children[4]. The general recommendation is to perform hearing screening in neonates within the first month of life, preferably in the delivery centers. Such an approach would enable a diagnosis and treatment before the sixth month of life for children with proven hearing impairment and would give the best possible opportunity for early hearing amplification and speech and language development[5].

The use of otoacoustic emissions (OAEs) during the first few days after birth has proven to be a simple, rapid, accurate and cost-effective neonatal hearing screen-

ing. OAEs provide a non-invasive objective indicator of healthy cochlear function and are widely used in universal newborn hearing screening programs[6].

There is evidence that Transitory Evoked OAEs (TEOAEs) result from contributions that are distributed over a large frequency region of the cochlea that is modified by individual structural differences. Therefore, their detection and frequency content are influenced by the status of the whole cochlea, making the analysis of a specific area of the cochlea more difficult. In contrast, Distortion Product OAEs (DPOAEs) appear to be generated by more specific regions of the cochlea and have the potential to test micro-mechanical properties of the outer hair cells in frequency specific regions. Another important difference is the frequency range in which TEOAEs and DPOAEs are most effective. TEOAEs are effective in sampling cochlear function in the mid-frequency region. On the other hand, DPOAEs can be measured over a broad range of frequencies, but they perform better than TEOAEs at 4 kHz or more[7]. Nevertheless, according to mechanism-based taxonomy, TEOAEs represent reflection source emissions, which arise through a process equivalent to linear reflection while DPOAEs arise by nonlinear distortion[8].

A Universal Newborn Hearing Screening program, funded by the European Union, was implemented in Greece last November. Until then only sporadic, independent screening programs were held in several hospitals in Greece and were lacking a National Coordination Committee[9]. The objective of the present study was to compare the efficacy of TEOAEs and DPOAEs in a neonatal hearing screening protocol based on a two-stage screening, and a third diagnostic stage. To our knowledge, there are only a few studies comparing TEOAEs and DPOAEs in infant hearing screening by means of time consumption, referral rates, and predictive values[10]. Subjects' risk factors and their relation to screening outcomes were also evaluated. The current study provides the first hospital-based report on the island of Crete with preliminary data to guide future programs and investigations.

Material and Methods

From March 2006 through December 2012, 3,480 newborns were consecutively enrolled in this prospective study. A total of 3,595 deliveries took place during the same period at the General Hospital of Chania. Thus, our screening population constituted 97% of the total number of newborns in our hospital. The Ethics Committee approved this neonatal screening protocol (Ethics Committee of the General Hospital of Chania, decision number 24/8-2-2006).

A data checklist containing demographic data (name, gender, gestational age, labor method and test age), as well as, information for possible hearing loss risk factors (i.e. family history of sensorineural hearing loss, hyperbilirubinemia, low birth weight, ototoxic medication, low APGAR score, craniofacial abnormalities, in utero infections, mechanical ventilation for five days or more, head trauma), was completed for every neonate. A parent or caregiver provided written consent on the same checklist.

During the first stage of screening and according to protocol, neonates were screened in a quiet environment with acceptably low noise levels. The hearing screening was conducted every day of the week. Infants were examined before they were discharged or within 30 days at a scheduled appointment. OAEs were recorded with the use of the Accuscreen-Pro TDA device (Madsen, GN-Otometrics, Copenhagen, Denmark).

Starting with TEOAE testing, both TEOAEs and DPOAEs were measured by a resident physician enrolled in an otolaryngology training program who was experienced in neonatal screening techniques. The results obtained, were documented as either "Pass" or "Refer". TEOAEs were recorded with a non-linear click sequence stimulus type, with a click rate of approximately 60 Hz and a frequency range between 1.4 to 4 kHz. The signal bandwidth ranged from 500 Hz to 4,500 Hz, with a maximum sound pressure of 85 dB. DPOAEs stimulus was a primary tone pair, f2/f1 =1.24, with a sampling rate of 12.8 kHz. The frequencies examined were 2, 2.5, 3.2, and 4 kHz. The DPOAEs test was completed successfully with a "Pass" if DPOAEs could be registered on at least three frequencies. A successful outcome was a "Pass" result on both sides for either TEOAEs or DPOAEs.

In the second stage screening, follow-up of the referred newborns was performed as an outpatient re-screening, within one month of the initial evaluation. If the result in both TEOAEs and DPOAEs on the follow-up screening was "Refer" in either ear or if there was the presence of at least one known risk factor, the neonate was further evaluated at the Audiology-Neurotology Laboratory of the ENT Department during the diagnostic third stage.

The third-stage evaluation included a clinical ENT examination, tympanometry (probe-tone 1,000 Hz), and Auditory Brainstem Response (ABR). ABR measurements were performed using the platform EP25 Eclipse (Interacoustics, Copenhagen, Denmark). Normal hearing was defined on the basis of a tympanogram type A and wave V presence at 30 dB normal Hearing Level (nHL) on the ABR. Children with abnormal ABR recordings (sensorineural hearing loss) received further evaluation which included imaging techniques, behavioral audiometry methods and specialist consultation (i.e., pediatrician, geneticist). TEOAE and DPOAE recordings obtained were compared by means of duration and reliability. The relationship between outcomes and the presence of any known risk factor was also evaluated.

Data Analysis

Quantitative variables are present as mean plus standard deviation (SD) or median values and interquartile range (IQR). Qualitative variables are presented as absolute and relative frequencies. Mean duration time of both TEOAEs and DPOAEs was not normally distributed and

the comparison between them performed with Wilcoxon matched paired test, a non-parametric equivalent of the student's t-test. Specificity and positive predictive values were based on the observed true positive (TP), true negative (TN), and false positive (FP) cases. All reported p values are two-tailed. Statistical significance was set at $p < 0.05$ and analyses were conducted using the Statistical Package for Social Sciences (SPSS) statistical software, version 17.0 (SPSS Inc., Chicago, IL, USA). Post- hoc power analysis revealed that a sample size of 3,480 subjects had 90 % power at 5 % alfa level, with a large effect size of 0.5.

Results

A total of 1,765 (50.7 %) males and 1,715 (49.3 %) females were enrolled in the study. There were 118 (3.4 %) preterm subjects, 97 (2.8 %) had a family history of hearing loss, and 16 infants (0.5 %) had been mechanically ventilated for more than five days. Nineteen (0.5 %) newborns had a birth weight lower than 1,500 gr and 24 (0.7 %) newborns had minor auricular abnormalities (ear tags, isolated microtia). No syndrome had been identified in any neonate (Table 1). Three hundred twenty-eight (9.4 %) mothers reported that they smoked during pregnancy, and four (0.1 %) had received medical treatments that are implicated as a risk factor for hearing loss.

The mean age in the first-stage examination was 16 days (median 11, IQR: 3-22), while the mean age in the second-stage examination was 32 days (median 24, IQR: 6-42). In the first-stage screening, the mean duration of the TEOAEs test was 30.3 seconds (SD =32.1) on each ear, and the mean length of the DPOAEs testing was 29.4 seconds (SD =34.9) (p =0.36). Similarly, in the second-stage screening session, the mean duration of TEOAEs was 47.5 seconds (SD =42.6) was not statistical different (p =0.93) from the mean length of DPOAEs at 47.14 seconds (SD =33.3).

Screening outcomes per evaluation stage are shown in Table 2. At the first screening stage, 8.9 % of the infants were referred according to TEOAE outcomes, while the percentage of the referred infants for DPOAE testing was 25.7 %. All TEOAEs recordings were performed without any test - performance problems, while a "Noise" or "Leak" screen indication existed for 441 (12.6 %) DPOAE measurements, in the first-stage evaluation. Ten infants, who failed the first-stage screening, did not return for follow-up. Fifty-five subjects (1.6 %) were admitted to the diagnostic stage of the program with ABR evaluation, due to second-stage referral. Mean age at the diagnostic stage was 96 days (median 92, IQR: 42-162). ABR hearing thresholds were abnormal in 12 (22 %) cases. Unilateral hearing loss was diagnosed in seven (14 %) infants (two with mild, four with moderate and one with profound hearing loss), while five (9 %) infants were found with bilateral hearing loss (two with moderate, and three with profound hearing loss). In total, the prevalence of hearing loss was estimated as 3.4 per 1,000 infants. The incidence of bilateral hearing loss >60 dB nHL was

Table 1: Characteristics of the 3,480 newborns who were enrolled in the hearing screening from March 2006 through January 2012 at the General Hospital of Chania and consisted this study population.

	n	%
Sex		
Males	1,765	50.7
Females	1,715	49.3
Gestational weeks, median (IQR range)	40 (38-40)	
Birth weight (g), median (IQR range)	3300 (3020-3600)	
Birth weight (g)		
>1,500	3,461	99.5
≤1,500	19	0.5
Preterm delivery		
No	3,362	96.6
Yes	118	3.4
Delivery		
Caesarian section	1,882	54.0
Vaginal	1,598	46.0
Smoking during pregnancy		
No	3,152	90.6
Yes	328	9.4
Infection (Rubella, CMV, Toxoplasma, Syphilis, Herpes)		
No	3,443	98.9
Yes	37	1.1
Family history of hearing loss		
No	3,383	97.2
Yes	97	2.8
Minor auricular abnormalities		
No	3,456	99.3
Yes	24	0.7
Hyperbilirubinemia		
No	3,298	94.8
Yes	182	5.2
Medication		
No	3,476	99.9
Yes	4	0.1
Syndromes		
No	3,480	100
Yes	0	0.0
Mechanical ventilation (>5 days)		
No	3,464	99.5
Yes	16	0.5

n: number of infants, IQR: interquartile range

Table 2: Screening results per stage of the neonatal hearing screening protocol, based on a three-stage strategy that enrolled 3,480 newborns from March 2006 through January 2012 at the General Hospital of Chania.

	Total screened	Pass	Refer	Unilateral Refer	Bilateral Refer	Refer Both TEOAE & DPOAE
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
First-stage						
TEOAE	3,480 (100.0)	3,169 (91.0)	311 (8.9)	216 (6.2)	95 (2.7)	212 (6.0)
DPOAE	3,480 (100.0)	2,586 (74.3)	894 (25.7)	586 (16.8)	308(8.9)	
Second- stage*						
TEOAE	201 (5.8)	137 (3.9)	64 (1.8)	51 (1.4)	13 (0.4)	
DPOAE	201 (5.8)	121 (3.5)	80 (2.3)	68 (2.0)	12 (0.3)	55 (1.6)
Third- stage						
ABR**	55 (1.6)	43 (1.2)	12 (0.3)	7 (0.2)	5 (0.1)	

n: number of infants, TEOAE: Transitory Evoked Otoacoustic Emissions, DPOAE: Distortion Product Otoacoustic Emissions, ABR: Auditory Brainstem Response, *: Ten infants were lost on follow-up (0.3%), **: ABR due to screening outcome.

1.3 per 1,000, while 0.8 per 1,000 were diagnosed with profound hearing loss.

Infants with hearing loss were all term deliveries born by caesarean section with a birth weight greater than 1,500 g. They had no perinatal infections, facial abnormalities or positive family history.

In the first stage of evaluation, the specificity of TEOAEs and DPOAEs were found at 92 % and 75 % respectively, while positive predictive values (PPVs) were 3.8 % and 1.3 %, respectively. In the second stage of evaluation, the specificity of TEOAEs and DPOAEs were 86 % and 76 %, respectively, while PPVs increased to 18 % and 15 %, respectively.

Out of 182 newborns with hyperbilirubinemia (>18 mg/dL), 134 (74 %) passed the first-stage evaluation. One baby failed the second- stage evaluation and was referred for ABR testing (Table 3). There were 97 (2.8 %) newborns who had a family history of hearing loss, although it wasn't possible to certify that all of these cases were hereditary forms of hearing loss. Only one baby with a birth weight less than 1,500 g was referred for ABR testing due to an OAE referral, while none of the 19 low-weight newborns were found with hearing loss in the diagnostic stage evaluation.

During the study, 379 neonates with a risk factor underwent ABR testing. Of these, 182 (48 %) had hyperbilirubinemia, 97 (25.5 %) had a positive family history, 19 (5.1 %) had low birth weight, 37 (9.8 %) had intrauterine infections, 16 (4.3 %) received mechanical ventilation for more than five days, 24 (6.3 %) had craniofacial abnormalities, and four (1.2 %) received ototoxic medical treatments (Table 3). Abnormal ABR recordings were not related to any risk factor, although those children were followed-up regularly for two years in four-month intervals.

Table 3: Screening results per risk factor of the neonatal hearing screening protocol from March 2006 through January 2012 at the General Hospital of Chania.

Risk Factor	n	2nd Stage OAEs' Refer	ABR	
			Normal	Abnormal
Birth weight <1500 g	19	1	19	0
Infection	37	6	37	0
Positive Family History	97	7	97	0
Hyperbilirubinemia	182	1	182	0
Medication	4	0	4	0
Syndromes	-	-	-	-
Mechanical Ventilation> 5 days	16	3	16	0
Craniofacial Abnormalities	24	3	24	0

n: number of infants, OAEs: Otoacoustic Emissions, ABR: Auditory Brainstem Response.

Discussion

Hearing screening programs utilizing TEOAE or DPOAE protocols are accepted worldwide, and in all centers efforts are implicated to use a screening protocol with low false-negative results and low referral rates. It is documented that false-positive results cause unnecessary diagnostic testing and emotional distress. Therefore, minimizing false-positive results is critical for a successful hearing-screening program[11].

The total occurrence of hearing loss in our screened population was 3.4 per 1,000 newborns. The prevalence of severe bilateral sensorineural hearing loss was found to be 0.8 per 1,000 infants, which concurs with other reported series[12].

The main cause for examining the neonates on an outpatient basis after they were discharged from the maternity department was the high referral rate and the lack of strict protocol during the initial phase of the program. Thus, the mean age of neonates in the first stage screening was relatively high.

The sensitivity of TEOAE screening is reported as high as >90 % and the specificity on the two-test TEOAEs screening, or a two-stage screening program combining TEOAEs and ABRs, is >99 %[13]. When DPOAEs are used, reported referral rates in hearing screening programs range from 4% to 15 %, and from 3 % to 12 % with the use of TEOAEs[14]. In the present study, 311 (8.9 %) of the infants failed the TEOAE exam in the first-stage, while 894 (25.7 %) failed the DPOAE test. Still, only 212 (6 %) did not meet both the TEOAE and DPOAE "Pass" criteria and were subsequently admitted to the second-stage evaluation. During the second-stage, only 55 (1.6 %) failed both TEOAE and DPOAE tests. They were then admitted for evaluation in the diagnostic third-stage. The "Pass" rate for the TEOAE test was 91 % with a false-positive rate of 9 %.

During the second-stage evaluation a "Refer" result for the TEOAE and DPOAE tests was obtained in 64 (1.8 %) and 80 (2.3 %) of the infants, respectively. The high false-positive rate during the first-stage might be attributed due to the presence of debris in the ear canal. Incomplete clearance of normal fetal middle ear fluid can cause artifacts of otoacoustic emissions[15].

Akinpelu et al noticed that when there was liquid in the middle ear, significant reductions of DPOAE levels occurred across all frequencies. These changes became greater for increased volumes of liquid. Changes in the noise level had important effects on the OAE signal-to-noise ratio at the three lowest frequencies[16].

OAEs have been reported to have a high false-positive rate of about 15 % in the first screening on day one and then reduce by about 50 % with each retest. Gabbard et al, showed a significant difference in the age-related effect during the OAE screening test, while Vohr et al, also reported that the age of the patients might affect the OAE results[17,18].

The high referral rate of DPOAEs is partly attributed to the fact that the equipment used (Accuscreen, GN-Otometrics, Copenhagen, Denmark) could not perform a calibration check, even in the screening mode, if noise was present, or if the probe fitting was not absolutely perfect in the ear canal. Under such conditions, the "Leak" or "Noise" indication appeared and the test could not be performed. After several trials, all of these cases were considered "Refers". Probe fitting and noise level are important factors for a successful OAE test. We decided to take into consideration the rapidity and easiness of the two tests and compare the results. We did not face any problems due to probe fitting while performing the TEOAE tests but did report a number (n =360 or 10.5 %) of cases in which the DPOAE test could not be performed in, at least, one ear due to a "Leak" indication on the device's screen. For certain, TEOAE testing was significantly easier to perform and more reliable in comparison to the DPOAE test, which, moreover, proved to be unreliable under certain conditions such as high baby arousal states and noise levels. Even though there was not a significant statistical difference between the performance duration of the two methods, DPOAEs were considered more time-consuming due to the repeated efforts of trying to overcome the problems associated with the probe fitting. Achieving ideal noise levels for testing was not always possible. Although the vast majority of newborns are typically in quiet states, it is possible to have a baby who is alert and active or crying. Performing a hearing-screening test on a baby in these states should not be attempted. It is suggested to return at a later time to test the baby. Perhaps soon after feeding, and under reasonable clinical conditions.

On the other hand, we have to keep in mind the existing differences between the two methods according to the mechanism-based taxonomy, which provides an improved interpretive framework that promises to enhance the clinical utility of OAEs[8]. Therefore, in the future the concurrent use of both TEOAEs and DPOAEs may be recommended for infant hearing screenings, while until now protocols usually have been based on one test.

The main problems for implementing a universal newborn hearing screening were Greece's geography and the fact that the majority of children are delivered in private hospitals. This represents a great disadvantage concerning the control of the total number of deliveries and cannot be easily used to implement population screening programs, especially when it is not supported by legal regulations. In November 2015, a national program, which includes 17 hospitals throughout the country, started under the auspices of the Hellenic Center for Disease Control and Prevention and the 1st Otolaryngology Department of the University of Athens. Parental awareness regarding the importance of early identification of hearing loss depends mainly on neonatologists and pediatricians since such regulations do not exist.

Nowadays it is also important to consider the economic impact of a UNHS program. Recent studies regarding ''generated evidence'' show that for each testing site the initial investment can be recovered within the first two years of the ongoing project, through the various clinical and administration premises within the European Union[19].

Our study limitations included: a) testing of the neonates delivered only in the public hospital of Chania, b) the timing of the first-stage examination during the initial phase of the study.

Maintaining positive parental attitudes is an essential prerequisite for a viable and efficient neonatal screening program[15]. In our series, only 33 out of 115 (28.5 %) newborns that missed the test before discharge from the hospital, presented at the scheduled appointment time. This low rate contrasts significantly with the 88 % compliance rate for babies scheduled to return for a follow-up test after discharge, which was referred to their hearing screening test before discharge during the same period. The low compliance rate observed here is not exceptional. For example, in the first year of the universal NHS demonstration project in New York State in the USA, the compliance rate for infants not screened before hospital discharge, who were meant to undergo a post-discharge screening test was only 17 %[20]. These results lead us to the conclusion that in order to achieve higher compliance rates, funding and the presence of secretarial support are very important[21].

Infants who pass the neonatal screening but have a risk factor for sensorineural hearing loss should have at least one diagnostic audiology assessment by six to ten months of age. In our study population, no abnormal ABR was recorded in any child with a risk factor. This is a controversial finding regarding the current literature. Indeed we have examined children with risk factors who suffered from hearing loss, especially those with positive family history, but these children were tested at an older age and were not included in the study population. Our findings confirm the necessity of hearing screening implementation in all neonates and not only those with risk factors. Providing hearing screening evaluation to every newborn and not only newborns with risk factors is mandatory for diagnosing delayed hearing impairment[22].

Conclusions

Hearing screening tests were welcomed by the parents and did not cause notable maternal concerns. TEOAEs testing was significantly easier to perform and more reliable compared to the DPOAEs test, in which the equipment used has proven to not be reliable in certain test conditions such as the baby's arousal state and excessive environmental noise.

We found that all cases with abnormal ABR were not related to any risk factor, justifying the application of a screening program to all newborns.

Conflict of interest

Authors declare no conflict of interest.

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