Referral Rates of Transient Evoked Otoacoustic Emission and Distortion Product Otoacoustic Emission in Neonatal Hearing Screening: Two-step Protocol in Chennai

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Background: The present study is aimed at finding the referral rates in Transient Evoked Otoacoustic Emission (TEOAE) and Distortion Product Otoacoustic Emission (DPOAE) in well- born and high-risk infants, using two-step hearing screening protocol with TEOAE and DPOAE, and to compare and contrast the referral rates in the first screening. **Subjects and Methods:** A prospective study design was carried out on 404 neonates (808 ears) who were screened between June 2019 and February 2021 at Voluntary Health Services, Chennai. All subjects were randomly selected with inclusion and exclusion criteria. All newborns were screened with both TEOAE and DPOAE. 'Pass' and 'refer' were tabulated to calculate the referral rates and Chi-square test was done to find the significance between the groups. **Results:** Among 404 (100%) neonates screened, 364 (90.14%) were well-born and 40 (9.90%) were high-risk babies. The total referral rate for TEOAE was 88 (10.90%) among which 77 (21.15%) were well-born babies and 11 (27.50%) were high-risk infants. Total referral rate in DPOAE was 91 (11.27%) among which 75 (20.06%) were well-born and 16 (40%) were high-risk infants. Statistical analysis revealed no significant difference between the groups (p=0.000). **Conclusion:** TEOAE is a rapid test with low referral rates and more acceptability. DPOAE, with greater sensitivity, frequency specificity and better SNR, is more accurately used for infants with high-risk registers. Both the OAEs can be used for all the infants as a screening procedure in a two-step protocol.

Keywords: Hearing Screening, Referral Rate, Otoacoustic Emissions, High-Risk Registers.

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Introduction

Congenital hearing loss has been estimated to be 1.2 to 5.7 per 1000 live births.^[1] With greater incidences of hearing impairment in newborns, hearing screening becomes a warranted need. Early the detection, earlier the treatment provided so that there is an optimum chance for utilizing the critical period. Ideal resources for improving oral communication skills can be availed. Thus, Newborn Hearing Screening (NHS) programs have been executed in almost all over India's hospitals and Institutions for categorizing the status of hearing ability.

The purpose of screening programs is to identify the presence or absence of loss due to congenital or perinatal factors and to intervene before 6 months of age.^[2] To successfully employ the hearing screening, physiological tests such as Evoked Otoacoustic Emissions (EOAE) and Automated Auditory Brainstem Response (AABR) has been prevalently used. Both OAEs and AABR are non-invasive and involves recording the physiologic activities, which provides a higher degree of peripheral sensitivity. The Otoacoustic Emission measures sound waves that are generated by the hair cells of the cochlea. These are measured using microphones placed in the ear canals.^[3] Even though, OAE screening is easier and quicker to perform than AABR, OAEs are affected by vernix caseosa in newborns, external ear debris, or fluid.^[4] Therefore, the referral rate with OAEs has been reported to be high (5-20%), if screening is performed during the first 24 hours after birth.^[5]

The two widely used OAEs for screening include Transient-Evoked Oto-acoustic Emissions (TEOAEs) and Distortion Product Oto-acoustic Emissions (DPOAEs). TEOAEs are simpler than DPOAE on the subject of technical complexity and the time required for testing.^[6] Thus, TEOAEs are more useful for UNHS as the duration for the testing is less and has adequate accuracy, whereas DPOAEs are more useful for screening infants with high-risk registers. The DPOAE uses high intensity signals with more concentration in narrow regions of cochlea.^[7]

With more frequency specificity, DPOAE has an upper hand than TEOAE. JCIH, 2007 suggests that both the OAEs are shown to be effective for newborn hearing screening and AABR becomes a requisite only when it is performed for high-risk neonates.^[2] These procedures are easily performed on infants, which gives us the information underlying the auditory status with the help of physiological activity recorded noninvasively. The previously established protocols by many Indian hospitals and institutes state that the first and second stages of hearing screening are TEOAE or DPOAE and AABR is used in the third stage of hearing screening. Other combinations have been reported as well.^[8] When comparing both the OAEs, TEOAE is noted to have high referral rate than that of DPOAE. By keeping track of these variables, we have drawn a comparison between TEOAE and DPOAE. Thus, this study aims to find the significance of TEOAE matched with DPOAE in the Neonatal Hearing Screening program. The objectives are to find the referral rates in DPOAE and TEOAE, and to compare and contrast the DPOAE and TEOAE referral rates.

Material and Methods

Participants

The study group constituted of 404 neonates (i.e., total of 808 ears) born between June 2019 and February 2021, who were randomly selected. The neonates were taken from the Department of Pediatrics and Neonatology ward of Voluntary Health Services Hospital, a multispecialty hospital in the south Indian state of Tamil Nadu.

Inclusion and Exclusion criteria

The inclusion criteria for this study comprised of both wellborn and high-risk neonates. All neonates born through normal vaginal birth or cesarean delivery were included. The neonates categorized as high-risk, had at least one of the high-risk registers contributing to hearing loss.^[2]

The exclusion criteria included all neonates who were subjected to external ear anomalies (atresia, stenosis), vernix caseosa or fluid in the external auditory canal.

Diagnostic equipment and hearing screening procedure

The ambient noise levels of the test environment for the screening procedure were measured using Sound Level Meter VOLTCRAFT Schallpegelmessgerät 322 Data log. The noise levels measured in dBA ranged between 40 dBA and 55dBA.

A Natus Echo-Screen PLUS (TEOAE & amp; DPOAE) 010127TD (Natus Medical Inc., USA) hearing instrument

was used for DPOAE and TEOAE screening. The TEOAE screening uses click sequences covering the frequency range between 1.5 kHz and 3.5kHz. The test time for recording each ear was approximately 20 seconds. The DPOAE screening was recorded in frequencies 2000 Hz, 2500 Hz, 3200 Hz, and 4000 Hz. The test time for recording each ear was approximately 30 seconds. Automatic pass/refer results were obtained using preset screening parameters.

Before the screening procedure, all the parents were briefed on the importance and purpose of the hearing screening. An Informed consent was obtained after explaining the aim of the study with an assurance of their findings to remain anonymous.

The otoscopic examination was done before the testing to exclude neonates who had stenosis of the ear canal, debris, and vernix caseosa, etc. Then an appropriate ear probe tip was chosen following careful visual inspection of the ear canal size. Once a complete seal of the probe tip was achieved, OAEs recording was carried out. Adapting the two-technology screening protocol, both TEOAE and DPOAE testing was done sequentially in two steps for all infants. Ears with referral criteria, in either of the OAEs, were rescreened with both TEOAE and DPOAE after 1 month of the initial screening visit. Ears with failure criteria during the rescreening were referred for a detailed Audiologic evaluation within 3 months. The initial screening for all the neonates were screened within 72 hours of birth. Infants admitted to the NICU were screened before their discharge.

Analysis

The data for each OAE groups during the first visit were tabulated and keyed into Microsoft Office Excel 2010. Statistical analysis was carried out using the Statistical Package for Social Sciences (SPSS) version 20.0. The data were subjected to descriptive statistical measures. The correspondence and significant differences between the two groups were tested using Chi- square test for qualitative variables.

Results

Of 404 (100%) neonates, 364 (90.10%) were well-born neonates and 40 (9.90%) were high-risk neonates. The list of risk factors in our population is tabulated in [Table 1].

Pass and referral rates were calculated with the total number of ears because a 'refer' result in either of the ears was considered 'fail'. In the initial testing with TEOAE for 808 (100%) ears, the bilateral passing rate is 720 (89.10%). The total referral rate in TEOAE was 88 (10.90%). The referral rate in the groups of well-born and high-risk neonates was found to be 77 (21.15%) ears in well-born babies and 11 (27.50%) ears in high- risk neonates. Among 88 (10.90%) ears, 56 (63.64%) had bilateral referral rates, 15 (17.04%) had right ear 'refer', 17 (19.32%)

Table 1: Risk factors for hearing loss.					
Risk factors	N (%)				
Intrauterine growth restriction	4 (10%)				
Small for gestational age	2 (5%)				
Late pre term	6 (15%)				
Respiratory distress syndrome	2 (5%)				
Cephalopelvic disproportion	2 (5%)				
Fetal distress	4 (10%)				
Premature rupture of membranes	3 (7.5%)				
Meconium aspiration	1 (2.5%)				
Transient tachypnea	1 (2.5%)				
Gestational diabetes mellitus	2 (5%)				
Neonatal jaundice	9 (22.5%)				
Low birth weight	3 (7.5%)				
Umbilical hernia	1 (2.5%)				

had left ear 'refer'.

In testing with DPOAE for 808 (100%) ears, the bilateral passing rate is 717 (88.73%). The total referral rate in DPOAE was found to be 91 (11.27%). The referral rate in the groups of well-born and high-risk neonates was found to be 75 (20.06%) ears in well-born babies and 16 (40%) ears in high- risk babies. Among 91 (11.27%) ears, 58 (63.74%) had bilateral referral rates, 13 (14.28%) had right ear 'refer', 20 (21.98%) had left ear 'refer'. These Referral rates among TEOAE and DPOAE has been summarized in [Table 2].

Comparison of TEOAE and DPOAE referral rate in Newborn Hearing Screening was carried out using Chi-square statistical analysis. The correspondence between the pass/refer rates from both the OAEs were not significantly different (p-value = 0.000). A nearly equivalent agreement was obtained with both methods.

Discussion

Universal Newborn Hearing Screening endorses early detection and intervention of children with hearing loss.^[2,9] This is followed to significantly improve communication skills and commensurate with typically developing children. To maximize optimum outcomes, in the long run, all infants should be screened no later than 1 month of age.^[2] Several screening protocols have been followed in various hospitals and institutions in India. An extensive review by Vidya Ramkumar revealed different protocol combinations of DPOAE, TEOAE and AABR.^[8] According to this review, our study does not follow any of the protocols that have been done before, as this new protocol includes Two-step: TEOAE and DPOAE. This combination has been used for low referral rates and false-negative results.^[10] Minimizing false-positive is also a matter of concern as its consequences to unnecessary detailed Audiologic testing. Maung et al., study on the diagnostic accuracy of TEOAE and DPOAE published results on sensitivity and specificity. DPOAE has a sensitivity of 97.57% and specificity of 95.39%, whereas, TEOAE has a sensitivity of 96.49% and specificity of 90.60%.^[11] Other studies such as Hall et al. on DPOAE and AABR screening show that, DPOAE has 100% sensitivity and 99.7% specificity.^[12]

Referral rates indicate the failure percentage in hearing screening. High referral rates in a group denote a greater incidence of hearing loss.^[13] Referral rates from the TEOAE screening in the first stage were high (32.2%), which was higher than the recommended benchmark by the JCIH (4%).^[14] In the DPOAE and AABR study of Vignesh S.S. et. al., total DPOAE referral rates were found to be 22.14%.^[15] Another study quoted that DPOAE referral rates fall between 4%- 15% and that of TEAOEs fall between 3%-12%.^[10]

These findings are similar to our study, where TEOAE referral rates are 10.90% and DPOAE referral rates are 11.27%. A judgment between referral rates and the hearing test reveals DPOAE to be more sensitive in the identification of hearing loss. It identifies ears from normal hearing from ears with moderate degrees and greater degree hearing losses.^[16] Presence of DPOAE indicates threshold better than 30dBHL.^[17] They also tend to have better signal-to-noise-ratios than TEOAEs. The concentration of energy higher in DPOAE (50-60 dB) than TEOAE (35-45 dB) allows detection of mild-moderate losses.^[7] The amplitude of OAE responses is higher in infants than adults, thus easing the detection of emissions.^[18] However, TEOAE testing was quicker, easy to

Table 2: Percentage of referral rates in TEOAE and DPOAE.							
Total no. of (100%)	Ears:	808	Referral rate among well- Born and high-risk infants	Bilateral Refer	Unilateral Refer		
TEOAE: Total referral (10.90%)	Rate:	88	Well-born-77 (21.15%) High-risk-11 (27.50%)	56 (63.64%)	R.E-15 (17.04%) L.E-17 (19.32%)		
DPOAE: Total referral (11.27%)	Rate:	91	Well-born– 75 (20.06%) High-risk-16 (40%)	58 (63.74%)	R.E-13 (14.28%) L.E-20 (21.98%)		

perform, and comparatively reliable.^[10] These referral rates also vary with a variety of factors. Sharma et al. emphasizes on trained health workers conducting the screening.^[19] These rates vary between first and second screening, where second screening rates adhere to the JCIH benchmark of 4%.^[8] Other aspects include the type of equipment used, inability to perform calibration check, the level of ambient noise, age, state, alertness and vegetative noises of the baby, the accuracy of probe tip fit, presence of fluid, debris, caseosa, etc. in the external auditory canal of the infant.^[2,4,10,11,20–24] Akinpelu O.V. et al. notices a significant reduction in DPOAE levels across all frequencies in the presence of middle ear fluid.^[19] It is equally important to consider the mechanism- based taxonomy differences as it improves the interpretation and clinical utility.^[25] Due to these factors, referral rates can vary between TEOAE and DPOAE in both well-born and high-risk infants.

Risk factors increase the probability of occurrence of hearing loss.^[26,27] Infants with risk factors who received 'pass' should undergo continuous monitoring beginning at 2 months of age.^[2] Authors such as Morzaria, Westerberg, and Kozak, suggest the set of risk factors and guidelines for infants who pass the hearing loss.^[28] It is mandatory that Audiologists who do the hearing screening provide factual counseling about follow-up and surveillance. Similar instructions were given to the parents of infants with risk-registers in our study. For infants with risk factors with a 'refer' result should be rescreened within 1 month of age.^[2] JCIH, 2019 lists 12 major risk factors that contribute to hearing loss, including delayed and progressive hearing losses. Risk factor information must be gathered and saved with easy access in medical records as the infant is prone to develop hearing loss, irrespective of initial hearing screening.^[17] The referral rate in high-risk infants was congruently high, compared to well-born infants. The referral rate in high-risk infants with TEOAE was 27.50%, higher than the 21.15% in well-born. DPOAE in high-risk infants are 40%, higher than the 20.06% in well-born. Our findings are favorable with Maung M. et. al. who has also suggested that DPOAE is more appropriate to use for infants with high-risk factors.^[11]

The estimation of hearing loss as unilateral or bilateral reported in the literature vary with many factors such as the protocol used, degree and type of hearing loss, etc.^[15,29–31] Bilateral 'refer' with TEOAE screening was 63.64% and, 63.74% with DPOAE screening. Unilateral 'refer' with the right ear in TEOAE is 17.04% and, 14.28% with DPOAE. Left ear 'refer' with TEOAE is 19.32% and, 21.98% in DPOAE. No drastic differences were noted as the reasons for referral rates are attributed here also.

Even though the Chi-square statistical significance test amongst the two methods, does not have any differences, minor qualitative variables make complimentary benefits. These quantitative results agree with our TEOAE and DPOAE referral rates. Therefore, concurrent use of both technologies is highly suggested.

Conclusion

Adapting a two-step protocol of TEOAE and DPOAE for hearing screening proves to be beneficial. TEOAE has low referral rates than DPOAE. TEOAE is a quick and an accurate screening tool to use in the first step, especially in India where birth rates are high. DPOAE has more sensitivity, frequency specificity and therefore, more appropriate to use with all infants, especially for high- risk infants. The referral criteria for the high-risk category was higher than the well-born neonates. Bilateral and unilateral referral rates were accounted for all the infants. Although, there were no significant differences between the OAEs, qualitative differences aid in complementary compatibility. Therefore, TEOAE and DPOAE can be used as screening tools for all categories of infants.

Future Directions

JCIH 2019 protocol updated the timeline of screening to be 1-2-3 months for those who meet the 1-3-6 benchmark. In order to adhere to this shorter time period, its crucial to have screening protocols that helps us to arrive at a faster diagnosis. In lieu of this, using DPOAE as one of the technologies, gives us more frequency specific information with better SNRs. To maximize the findings of the hearing status, AABR can also be used in later stages as rescreening procedures as it is specific in identifying conditions such as Auditory dysynchrony. Thus, the ultimate aim is to accelerate the process of diagnosis and intervention.

Limitations

A larger study sample could have been used for estimation of referral rates. Results obtained from rescreening was not considered for this study. AABR was not included in the rescreening and hence, chance of missing ANSD is high. Unable to show the accomplishment of 1-2-3 timeline because of parents' 'Loss-to-follow up' for rescreening settings. Audiologists with less experience were enrolled in the testing procedure.

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