The impact of pass/refer criteria in the use of otoacoustic emission technology for newborn hearing screening

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Conflict of interest

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ABSTRACT

Purpose: The current study aimed to compare the specificity of transient evoked otoacoustic emissions (TEOAEs) and distortion product otoacoustic emissions (DPOAEs) in isolation and in combination, with varying pass/refer criteria for DPOAE technology.

Method: A longitudinal, repeated measures design was employed. The current study sample comprised 91 of the initial 325 participants who returned for the repeat screening and diagnostic audiological assessment within a risk-based NHS programme.

Results: TEOAE screening had the highest specificity in comparison to DPOAE screening at the initial and repeat screening, irrespective of differences in DPOAE pass/refer criteria. DPOAE screening had a slightly higher specificity, with a three out of six rather than the four out of six frequency pass criteria.

Conclusions: Pass/refer criteria alone do not influence referral rates and specificity. Instead, consideration of other factors in combination with these criteria is important. More research is required in terms of the sensitivity and specificity of OAE screening technology using repeated measures and diagnostic audiological evaluation as the gold standard.

Keywords: pass, refer, criteria, otoacoustic emissions, newborn hearing screening, sensitivity, specificity

INTRODUCTION

Newborn hearing screening (NHS) is the first stage of any early hearing detection and intervention (EHDI) programme. Two objective measures are generally used in NHS programmes, either in isolation or in combination. These objective measures comprise otoacoustic emissions (OAEs) and automated auditory brainstem response (AABR), with notable differences between them. While OAEs reflect cochlear status at the level of outer hair cells (OHCs), the AABR measurement extends beyond this to reflect auditory neural function up to the level of the brainstem (JCIH, 2019). Although both AABR and OAE screening technologies are unable to identify slight or mild hearing impairment (Young et al., 2011), there is evidence suggesting that OAEs, specifically transient evoked otoacoustic emissions (TEOAEs), are more sensitive to mild hearing impairment than AABR (JCIH, 2019).

Evoked OAEs, namely TEOAEs, and distortion product otoacoustic emissions (DPOAEs) are of greater clinical significance than spontaneous OAEs (Baiduc et al., 2013). TEOAEs are low-intensity sounds originating from active amplification of OHCs of the cochlea, whereas DPOAEs are generated by two continuous pure tones presented simultaneously into the ear canal (Hall, 2000). There are a few advantages of DPOAEs over TEOAEs. Firstly, DPOAEs assess higher frequencies which are the frequencies to be affected first in instances such as ototoxicity and are the frequencies of concern with permanent congenital hearing loss that is screened for in the neonatal and infant population. Secondly, it can be recorded with a greater degree of hearing loss in comparison to TEOAEs (American Academy of Audiology, 2009). Thirdly, DPOAEs demonstrate better frequency specificity in comparison to TEOAEs, resulting in a variety of clinical applications including difficult to test populations and monitoring cochlear changes (Glattke & Kujawa, 1991; Lonsbury-Martin et al., 1993; Martin et al., 1990) Lastly, one may limit the screen frequencies within the pass/refer criterion in noisy settings (Hall, 2015). With regard to OAE technology, TEOAEs are used more commonly in NHS programmes, either in isolation or combination with AABR (Kanji et al., 2018). This is in line with a systematic review of NHS protocols and their outcomes, indicating that most protocols make use of TEOAE as opposed to DPOAE (Kanji et al., 2018). Only two of the 15 programmes noted in this review documented the inclusion of DPOAEs in NHS protocols. These authors concluded that

there is variation in terms of screening protocols globally, and that this may be due to what is considered feasible for particular contexts.

There are a number of factors that may influence the variations in the type of technology used in NHS programme protocols, such as the availability of equipment and consumables, personnel conducting the screening and their training, cost and time efficiency. While these are noteworthy considerations, the Joint Committee on Infant Hearing (JCIH) asserts that evidence-based research is needed to support the reliability and validity of all screening equipment used, whether OAE or AABR. Hence, the choice of screening measure should also be based on sensitivity and specificity, which may also relate to the population being screened. For example, some literature and guidelines recommend the use of AABR when screening neonatal intensive care (NICU) graduates, as they may be considered to be at a higher risk for auditory neuropathy, whereas OAEs have been recommended for well babies who are discharged soon after birth (ASHA, 2020; HPCSA, 2007; Jayagobi et al., 2020; JCIH, 2007, 2019; van den Berg et al., 2010). Sensitivity refers to the ability of a measure to correctly identify individuals as having a condition whereas specificity refers to the ability of a measure to correctly identify individuals without the condition. Sensitivity is calculated by dividing the number of individuals with true positive results over the sum total of true positive and false negative results in individuals suspected to have the condition. Specificity is calculated by dividing the number of true negative results by the sum total of false positive and true negative results in individuals suspected to not have the condition (Parikh et al., 2008). Various specificity rates have been reported for OAEs, with some literature indicating a higher specificity for TEOAEs (Shetty et al., 2016; Tzanakakis et al., 2016) and others indicating s higher specificity for DPOAEs (Iwanicka-Pronicka et al., 2008; Maung et al., 2016). Specificity rates have been reported to be between 79.7% and 99% for TEOAE and 37% to 95% for DPOAE (Iwanicka-Pronicka et al., 2008; Maung et al., 2016; Shetty et al., 2016). Apart from screening procedure and population being screened, manufacturer specifications may also contribute to the sensitivity and specificity as a result of varying algorithms and test settings or parameters. The JCIH recommends AABR screening and rescreening protocols in the NICU to allow for detection of auditory neuropathy (JCIH, 2019). A lack of consideration of aspects related to

sensitivity and specificity may result in missed cases of hearing loss or false positive findings (Kanji et al., 2018), which in turn have an impact on refer rates within programmes.

Refer rates are one of the key benchmark indicators documented in relevant EHDI position statements and guidelines in order to measure the success of NHS programmes (JCIH, 2007; JCIH, 2019; HPCSA, 2018). These guidelines suggest that the referral rate from NHS for audiological or medical evaluation should be less than 5% within one year of programme commencement irrespective of the population being screened (well babies or NICU graduates).

Sensitivity, specificity as well as refer rates may be influenced by specific test parameters, such as the response criteria used during TEOAE and DPOAE as well as the pass/refer criteria used for DPOAE screening based on the number of frequencies included in the protocol. Some manufacturers programme the response criteria into the OAE unit, with at least three frequencies evaluated during screening (2 kilohertz-kHz, 3 kHz and 4 kHz), and a signal-to-noise ratio (SNR) of at least 6 decibel (dB). However, some manufacturers may set their own SNR, which may vary for DPOAE and TEOAE. A minimum absolute DPOAE amplitude level of 5 decibel sound pressure level (dB SPL) is generally accepted (ASHA, 2020). TEOAE screening results are usually dependent on the minimum number of averages collected before the test is terminated, which is typically 50 averages, whereas DPOAE screening is often terminated on the basis of SNR or a combination of SNR and DPOAE minimum amplitude (ASHA, 2020).

Although test parameters have been reported and compared, an overall standardized *pass/refer* criteria for screening measures has not been specified in the literature (Gulati et al., 2020; Nishad et al., 2020; Yousefi et al., 2013) which limits the comparison between programmes. A study using TEOAE technology specified the use of an automated pass criterion of two bands based on TEOAE SNR (max. noise 60 dB and max. signal 70 dB) and reproducibility within 128 to 2048 frames. A reproducibility value of 60 to 80% was required for the band response to be considered a *pass* (Van Dyk et al., 2015). An earlier study comparing the ergonomic performance of commercially available devices for NHS specified the pass criterion based on manufacturer settings

for both OAE and AABR (Meier et al., 2004). Earlier studies using DPOAE measures have indicated varying overall *pass/refer* criteria, with some literature defining an overall *pass* criterion as a *pass* result at four out of five frequencies screened (Swanepoel, et al.2006), and other literature defining it as a *pass* at two frequency bands (Hatzopoulos et al., 2007). More recent studies have specified the use of a three out of four frequency pass criterion (de Kock et al., 2016; Tzanakakis et al., 2016). However, none of these recent studies have explored the sensitivity and specificity in relation to differences in pass/refer criteria. A previous study explored the pass rate and false positive findings in relation to four DPOAE pass criteria. Findings from this study revealed varying pass/refer rates based on the inclusion or exclusion of 2 kHz and whether replication was required. A higher pass rate (88.94%) was obtained for the least stringent criterion (present emission at any two frequencies, without replication and a response at 2 kHz not required) versus the most stringent criterion of a present emission at two of the three frequencies including 2 kHz and with replication (64.4%). With regard to false positive findings, data indicated a lower false positive rate with the least stringent criterion (11%) versus the most stringent criterion (35%) (Barker et al., 2000). Korres et al. (2003) compared the pre-discharge screening results using two different signal to noise ratios (3dB and ≥6dB) within the same frequency range of 1-4 kHz, for statistically significant difference was noted, suggesting that both signal to noise ratios were valid. Specification of pass/refer criteria is particularly important in order to ensure the accurate reporting and fair comparison of findings from NHS programmes in countries when the success of implementation as well as outcomes is determined.

METHOD

Purpose

The current study aimed to compare the specificity of TEOAEs and DPOAEs in isolation and in combination, with varying pass/refer criteria for DPOAE technology.

Design

A longitudinal, repeated measures design was employed.

Participants

A nonprobability, purposive sampling method was used. All participants in the current study sample had to undergo a diagnostic audiological assessment, either soon after a refer outcome on the repeat hearing screening or at six months corrected age if a pass screening outcome was obtained. In order to determine sensitivity and specificity of measures, screening results need to be compared to diagnostic assessment findings or findings from a test that is considered an appropriate reference or gold standard for verification of the individual's true status (ASHA, 1997, 2013).

The current study sample comprised 91 of the initial 325 participants who returned for the repeat screening and diagnostic audiological assessment within a risk-based NHS programme. There was a high loss to follow-up return rate for the repeat hearing screening and diagnostic audiological assessment which contributed to the small sample size in the current study. Sensitivity could not be calculated as none of the participants presented with hearing loss.

With regard to the demographic profile of the 91 participants, the mean length of NICU stay was 1.5 days. Forty six participants were female and 45 were male. Eighty nine participants were preterm, one was full term and one was early term with a mean gestational age of 31 weeks. One participant has a normal birthweight, 23 were low birth weight, 60 were very low birth weight and seven were extremely low birth weight. Of the 91 participants 78 had neonatal jaundice and two had hyperbilirubinemia for which they received phototherapy and an exchange blood transfusion. Twenty six participants received ventilation and all but 12 received ototoxic medication. With regard to neurological conditions, one had mixed cerebral palsy, four had an intraventricular haemorrhage, three had perinatal asphyxia and one had mild ventriculomegaly.

Procedures

The current study formed part of a larger study that made use of TEOAE, DPOAE and AABR screening, with an overall DPOAE *pass* for each ear determined by a *pass* result for four or more of the frequencies screened (1-6 kHz). TEOAE, DPOAE, and AABR screening were conducted using the Madsen Accuscreen handheld combination OAE/ABR screener at two different time intervals,

namely prior to discharge as well as six weeks after discharge (Kanji & Khoza-Shangase, 2018). Participants who passed the repeat hearing screening were booked for visual reinforcement audiometry at six months (corrected age), whereas those who referred were booked for a diagnostic ABR soon after the repeat screen. The initial screening was conducted in "step down" and Kangaroo Mother Care wards following discharge from the NICU and high care wards. The repeat hearing screening was conducted in the Audiology department which was located in close proximity to the neonatal follow-up clinic. The mean ambient sound level was 50.4 A-weighted decibels (dBA) at the initial hearing screening and 46.0 dBA at the repeat hearing screening (Kanji, 2019).The current study comprised a secondary analysis of the frequency specific data related to OAE screening results, using both a three and four out of six pass criterion for DPOAE screening within the 1-6 kHz frequency range, with L1/L2 at 60/50 dBSPL. For TEOAE, a total of at least eight registered, valid peaks in alternating directions (both above and below the median line), in the temporal waveform of the emissions had to be obtained for *pass* result within a 1.5-4.5 kHz frequency range at a stimulus level of 70-84 dBSPL.

Data analysis

Due to the absence of participants with hearing loss in the current study sample, analysis could be conducted only in relation to specificity (% TN findings). In order to establish which tests or combinations of tests had the highest specificity (% True Negative (TN)) for behavioural HL at six months, the participant was classed as 'Refer' if the outcome for any one test was 'Refer'. Proportions across different test combinations were compared by the z-test for proportions (Agresti & Kateri, 2011), with critical p-values adjusted (to 0.020) for multiple comparisons.

Ethical considerations

Ethical clearance was obtained from the University Medical Ethics Committee prior to the commencement of the study and permission was also obtained from the relevant sites where the study was conducted. Participant codes were used instead of participant names to ensure anonymity.

RESULTS

All 91 participants in the current study sample underwent an initial hearing screening, a repeat hearing screening six weeks later, and a diagnostic audiological evaluation. Of the 91 participants, 67, 66 and 74 obtained a pass result for the initial DPOAE (4/6 frequency criterion), DPOAE (3/6 frequency criterion) and TEOAE screening respectively. A higher number of participants obtained a pass result at the repeat hearing screening, with 81 having obtained a pass for DPOAE (3/6 and 4/6 criteria) and 84 for TEOAE. With the 4/6 criterion, the most common frequency combination for which pass results were obtained was 3,4,5,6 kHz at the initial and repeat hearing screening. Whilst no specific frequency combination was noted for the 3/6 criterion, a refer result was consistently obtained at 1 kHz.

Specificity was determined using the diagnostic audiological assessment as the gold standard. An overall pass was considered as a bilateral 'pass' on both measures.

TEOAE screening had the highest specificity (81.3% TN) in comparison to DPOAE screening (72.5% for 4/6 or 73.6% TN for 3/6 criteria) at the initial screen, with DPOAE screening having a slightly higher specificity with a three out of six rather than the four out of six frequency pass criteria.

Similarly, results at the repeat hearing screening indicated the highest specificity for TEOAE screening (92.3% TN), with DPOAE screening in isolation and in combination having the same specificity (89.0% TN), irrespective of the differences in pass/refer criteria for DPOAE.

The %TNs (specificity) for the test combinations at the repeat screening were significantly higher than the %TNs for the test combinations at the initial hearing screening (z-test for proportions; critical p-value adjusted to 0.020 to allow for multiple comparisons) (Table 1 and Table 2).

DISCUSSION

Current study findings indicated a higher specificity at the repeat hearing screening when compared to the initial hearing screening, for both OAE measures in isolation or in combination. These findings correlate with those in the larger study by Kanji (2016) which included the use of AABR technology.

Findings from the larger study indicated lower specificity with all three measures combined at the initial screening (60.4%) in comparison to the repeat screening (89%). Percentage specificity noted in the current study with a combination of OAE technology (71.4%- 72.5%) was lower at the initial screening in comparison to the repeat screening (89%). A higher specificity at the repeat hearing screening may be a result of fewer false positive findings at the repeat hearing screening. One of the factors to consider when OAE technology is included in NHS programmes is a higher inpatient refer rate in comparison to AABR, resulting in the importance of a repeat outpatient hearing screening (ASHA, 2020), which was included in the current study for all participants irrespective of the initial screening outcome. These higher refer rates are consistent with the literature (de Kock et al., 2016; Vignesh et al., 2015), and this can be attributed to the presence of outer ear debris and middle ear fluid in the newborn population (ASHA, 2020) . Similar findings have been noted in literature, with specificity being higher in studies using TEOAEs for newborn hearing screening (Shetty et al., 2016) than those using DPOAE as a screening technology (Pasupathy & Kumar, 2018). Tzanakakis et al (2016) also reported a higher specificity for TEOAE at the initial and repeat screening (92% and 86%) in comparison to DPOAE (75% and 76%). Specificity of OAEs could not be calculated for any of the studies included in the systematic review by Akinpelu et al (2014) as none of the newborns that passed the screening were followed up with a diagnostic assessment. However, specificity of DPOAEs and TEOAEs was explored in high risk newborns by Maung et al (2016) using the same equipment as the current study. Contrary to current study findings, DPOAE had a slightly higher specificity (95.39%) than TEOAE (90.6%). Results from a polish universal newborn hearing screening programme revealed a higher DPOAE specificity rate than TEOAE, but with much lower percentages of 36.9% and 79.7% respectively (Iwanicka-Pronicka et al., 2008).

With regard to OAE screening technology, more specifically pass/refer criteria related to DPOAE screening, the current study findings indicated little to no difference in the overall refer rate. However, the current authors argue that the frequencies screened and used within these pass/refer criteria need to be considered. Screening involving higher frequencies has been shown to decrease the referral rate (Akinpelu et al., 2014), which may be attributed to ambient noise levels and their influence on lower

frequencies and the subsequent signal-to-noise ratio (Kanji, 2019). A systematic review of OAE screening protocols and outcomes indicated that of the 11 studies that used DPOAE screening technology, most used four frequencies, ranging from 1-4 kHz, with only one study using five frequencies, and one using six frequencies (1-6 kHz) (Akinpelu et al., 2014). In these studies, the lowest refer rate (0.48%) and false positive rates (0.3%) was noted with a signal-to-noise ratio of 6dB for the 2-5 kHz frequency range (Attias et al., 2006). The highest refer rate (21%) and false positive rate (19.5%) was obtained with a signal-to-noise ratio of 3dB for a 1-4 kHz frequency range including 1.5 kHz. The timing of the screening differed in these studies, with Attias et al (2006) having screened newborns more than 48 hours after birth and Mathur and Dhawan (2007)having conducted screening at 48 hours or less. Similar to the current study, Ng et al. (2004) utilized a broad frequency range (1-6 kHz), with results yielding a 3.5% refer rate and a 3.1% false positive rate.

Although not explicitly related to specificity, studies using DPOAE screening technology revealed a higher refer rate with this technology as opposed to TEOAEs, which is consistent with the findings of the current study. In addition, Tzanakakis et al. (2016) indicated that the higher DPOAE referral rate may also be attributed to the equipment used as well as probe fit and noise levels. Findings related to specificity in this study, using the same equipment as in the current study, were 92% for TEOAE and 75% for DPOAE at the initial screening, and 86% and 76% at the second screening for TEOAE and DPOAE respectively. These authors recommend the use of both OAE measures as opposed to one or the other (Tzanakakis et al., 2016).Although the current study made use of both OAE screening measures in addition to the AABR, this may not be feasible in all contexts. While specificity is an important consideration, the measure or combination of measures yielding the best sensitivity and specificity needs to be considered. In comparison to DPOAE (51.9%), higher specificity has been noted for TEOAE (99%) and AABR (96%) (Institute of Health Economics, 2012; Pasupathy & Kumar, 2018; Shetty et al., 2016).

CONCLUSIONS

Referral rates decrease and specificity improves with repeat screening, which highlights the importance of a two-stage OAE or OAE/AABR screening protocol before referral for diagnostic evaluation. Pass/refer criteria as a stand-alone does not influence referral rates and specificity. Instead, consideration of other factors in combination with this criterion is important. These factors include the signal-to-noise ratio, frequencies included within the screening, and ambient noise levels. More research is required in terms of the sensitivity and specificity of OAE screening technology using repeated measures and diagnostic audiological evaluation as the gold standard.

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Table 1

Specificity for TEOAE and DPOAE measures in isolation and combination at two different time intervals (N=91)

Test(s)	DPOAE Frequency Pass/Refer Criterion	%TN		95% CI for %TN	
		Initial Screening	Repeat Screening	Initial Screening	Repeat Screening
DPOAE +TEOAE	4/6 frequencies	71.4%	89.0%	61.0-80.4%	80.9-93.9%
DPOAE	4/6 frequencies	72.5%	89.0%	62.2-81.4%	80.9-93.9%
DPOAE + TEOAE	3/6 frequencies	72.5%	89.0%	62.2-81.4%	80.9-93.9%
DPOAE	3/6 frequencies	73.6%	89.0%	63.8-81.6%	80.9-93.9%
TEOAE		81.3%	92.3%	72.1-88.0%	85.0-96.2%

Table 2

Significant p-values for measures in isolation and combination at two different time intervals

			Initial hearing screening			
			DPOAE + TEOAE	DPOAE	DPOAE + TEOAE	DPOAE
Repeat hearing screening	DPOAE Pass/Refer Criterion		4/6 frequencies		3/6 frequencies	
	4/6 frequencies	DPOAE	0.0029	0.0048	0.0048	0.0077
	3/6 frequencies	DPOAE	0.0029	0.0048	0.0048	0.0077
	4/6 frequencies	DPOAE + TEOAE	0.0029	0.0048	0.0048	0.0077
	3/6 frequencies	DPOAE + TEOAE	0.0029	0.0048	0.0048	0.0077
		TEOAE	0.0003	0.0005	0.0005	0.0008