Objective Hearing Screening Measures: An Exploration of a Suitable Combination for Risk-Based Newborn Hearing Screening

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Abstract

Background: The ideal hearing screening measure is yet to be defined, with various newborn hearing screening protocols currently being recommended for different contexts. Such diverse recommendations call for further exploration and definition of feasible and context-specific protocols.

Purpose: The aim of the study was to establish which combinations of audiological screening measures provide both true-positive (TP) and true-negative (TN) results for risk-based hearing screening, at and across time.

Research Design: A longitudinal, repeated-measures design was employed.

Study Sample: Three-hundred and twenty-five participants comprised the initial study sample. These participants comprised newborns and infants who were discharged from the neonatal intensive care unit and high care wards to “step down” wards at two public sector hospitals within an academic hospital complex.

Data Collection and Analysis: Transient evoked otoacoustic emissions (TEOAEs), distortion product otoacoustic emissions (DPOAEs), and automated auditory brainstem response (AABR) were conducted at the initial and repeat hearing screening. Diagnostic audiological assessments were also conducted. Results from combinations of audiological screening measures at the initial and repeat hearing screening were analyzed in relation to the final diagnostic outcome (n = 91). Participants were classified as presenting with an overall “refer” if the outcome for any one test was “refer.” The overall screening outcomes for different test combinations were compared using McNemar’s test for paired data. Proportions across different test combinations were compared by the z-test for proportions.

Results: Because of the absence of participants with hearing loss in the current study sample, analysis could only be conducted in relation to TN findings (specificity) and not TP findings (sensitivity). The percentage of TN findings was highest at the repeat hearing screening using any test or combination of tests when compared with findings from the initial hearing screening. TEOAE combined with AABR (TEOAE/AABR) (p < 0.0001), DPOAE combined with AABR (DPOAE/AABR) (p < 0.0001), and the combination of all three screening measures (p < 0.0001) yielded the highest percentage specificity at the repeat hearing screening when compared with the initial hearing screening.

Conclusions: The best specificity was noted at the repeat hearing screening. Within a resource-striken context, where availability of all screening measures options may not be feasible, current study findings suggest the use of a two-stage AABR protocol or TEOAE/AABR protocol.

Key Words: AABR, DPOAE, hearing, measures, newborn, objective, risk-based, screening, South Africa, TEOAE

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INTRODUCTION

The use of sensitive and specific hearing screening measures is key to a successful and efficacious newborn hearing screening (NHS) program. Evidence suggests that a variety of objective screening measures, such as otoacoustic emissions (OAEs) or automated auditory brainstem response (AABR) may be employed within such a program (Berninger and Westling, 2011). Their use is stated to be possible either in isolation or in combination with each other.

Careful selection of these screening measures for inclusion in NHS programs may be influenced by factors such as sensitivity, efficiency, invasiveness, as well as cost-effectiveness. Although OAEs are reportedly simpler, faster, cheaper, and noninvasive measures, they have a documented weakness of providing limited assessment of the auditory system (Choo and Meinzen-Derr, 2010); although they do play an integral role in the diagnosis of auditory neuropathy by providing information that guides the differential diagnosis of this condition. This limitation is an additional strength of the AABR which is known to provide more information regarding the auditory pathway and allows for better detection of auditory neuropathy in infants; particularly when used in combination with OAEs. Despite the strengths that the AABR has over OAEs, it requires more knowledge and expertise to conduct when compared with OAE testing; it is typically more expensive, and it requires a longer test time (Choo and Meinzen-Derr, 2010). All these factors may influence the implementation of an NHS program in different contexts.

Various hearing detection and intervention position statements suggest that different screening measures should be used for diverse screening contexts. Internationally, for example, the Joint Committee on Infant Hearing proposes OAEs or AABR for infants admitted to well-infant nurseries, with AABR being the endorsed preference for infants in a neonatal intensive care unit (NICU) (American Academy of Pediatrics, Joint Committee on Infant Hearing, 2007; Benito-Orejas et al, 2008; Berg et al, 2011). “TEOAE is perhaps the commonest screening test in NHS program worldwide because it is easier and quicker to perform with less expensive consumables” (Olusanya and Bamigboye, 2010). TEOAEs have been more commonly explored within screening protocols, either as a single screening measure or in combination with AABR.

The use of TEOAEs was investigated within an NHS protocol in Western Sicily where the aim was to develop a low-cost protocol with a good “screen sensitivity.” Newborns who “passed” the initial screening with no risk factors were discharged, whereas those who either “passed” with a risk factor or “referred” with or without a risk factor underwent a second screening followed by an audiological assessment (where indicated). A 99.6% final specificity was indicated by this protocol. The authors of this study concluded that false-positive (FP) results were observed in the group of neonates who “referred” without the presence of a risk factor and that repeated TEOAE screening (at least four times) in this group reduces the number of more expensive, secondary level evaluations (Martines et al, 2007). These findings are further supported by studies that have employed a two-stage TEOAE screening protocol or a multiple (at least three) stage TEOAE screening protocol followed by clinical auditory brainstem response (ABR) if indicated (Hergils, 2007; Berninger and Westling, 2011). A number of authors (Olusanya et al, 2008; McGurgan and Patil, 2014) argue for the use of OAE and AABR as the use of OAEs in isolation may miss the proportion of babies with auditory neuropathy or auditory dysfunction. Multiple use of the same screening measure such as TEOAEs may not be feasible to adopt within the South African context as it may result in further delays.

Abbreviations: AABR = automated auditory brainstem response; ABR = auditory brainstem response; DPOAE = distortion product otoacoustic emission; FN = false negative; FP = false positive; NHS = newborn hearing screening; NICU = neonatal intensive care unit; OAE = otoacoustic emission; TEOAE = transient evoked otoacoustic emission; TN = true negative; TP = true positive
in diagnosis as well as an increase in loss to follow-up because of multiple appointments for OAE screening only. A test-battery approach or cross-check principle to screening may therefore be more appropriate to ensure a higher percentage of true-positive (TP) and true-negative (TN) results.

Among the various populations and contexts, the planning and implementation of risk-based NHS programs also requires careful consideration with regard to the choice of screening measures. Differences in screening measures in various contexts and populations being screened have been documented. In the United Kingdom, for example, well babies are reported to receive TEOAEs followed by AABR if indicated by poor TEOAE results, whereas newborns requiring NICU care routinely receive both TEOAE and AABR screening (Sim et al., 2009). This screening practice differs from some birthing facilities in the United States of America, where AABR is the common screening measure of choice followed by DPOAE and TEOAE. The HPCSA (2007) position statement recommends the use of AABR for screening in the NICU and OAE for follow-up immunization visits. Although recommendations exist, these are primarily based on research conducted in developed contexts, with no research having been performed regarding the use of various screening measures in high-risk neonates within the South African context. Hence, there is still an evident lack of focus on screening methods and their effectiveness in published literature from South Africa (Moodley and Storbeck, 2015). South Africa appears to be in the infancy stages of implementation of NHS programs, with very few public sector hospitals providing some form of NHS (Theunissen and Swanepoel, 2008). This evidence highlights the need for a more structured, manageable interim approach to NHS such as risk-based NHS. Published literature from South Africa has also indicated the lack of standardized screening methods and measures adopted. It was hoped that the current study would assist in guiding evidence-based best practice, as it aimed to explore the best combination of screening measures that can be used to effectively conduct risk-based NHS. This exercise would assist in determining the best screening measure combination for the purpose of reducing FP and false-negative (FN) results. This would consequently provide information regarding the most cost-effective and accurate combination while reducing the number of follow-up visits required for accurate diagnosis.

METHODS

Objective of the Study

The current study aimed to establish which combinations of audiological screening measures provide both true-positive (TP) and true-negative (TN) results for risk-based screening, at and across time.

Research Design

A longitudinal, repeated measures design was employed over a 29-mo period. This involved a systematic and well-designed investigation involving repeated hearing screening and diagnostic measures in participants who were identified and diagnosed as being high-risk neonates.

Participants

A nonprobability, purposive sampling method was used as the sample was characteristic and representative of high-risk neonates. The sample consisted of 325 high-risk neonates who were discharged from the NICU and high care wards to “step down” wards at two public sector hospitals within an academic hospital complex. One hundred and seventy eight (54.8%) of the participants were female, and 147 (45.2%) were male (the male to female ratio was 0.83). The majority of the participants were Black African (85.5%), followed by Colored (10.2%), White (2.5%), and Indian (1.9%). Two hundred and twenty four participants (69%) were delivered by caesarean section and 101 (31.1%) by natural vaginal delivery. Of the participants delivered by caesarean section, 159 (48.9%) were delivered by emergency caesarean section, whereas 65 (20%) were delivered by planned or elective caesarean section. The median birth weight of participants was 1,390 g (interquartile range IQR 1,190–1,555 g; range 690–4,020 g). Birth weight was further categorized into normal birth weight (>2,500 g), low birth weight (1,500–2,499 g), very low birth weight (1,000–1,499 g), and extremely low birth weight (<999 g) (WHO, 2004). The majority of participants (59%) had very low birth weight followed by those with low birth weight (29%), with only 13 (4%) of the participants in the study group being of normal birth weight. The mean gestational age of participants was 31.3 weeks (standard deviation 2.8 weeks; range 25–41 weeks).

Procedures

All of the procedures (screening and diagnostic) were conducted by an audiologist with experience in NHS and pediatric audiology. The average age at which the initial hearing screening was conducted was 21 days.

TEOAE, DPOAE, and AABR screening were conducted using the AccuScreen at two different intervals or time periods, with the first being prior to discharge and the second, six weeks after discharge (Figure 1). All participants who underwent an initial hearing
screening were scheduled to undergo a repeat hearing screening on the same day as their first neonatal follow-up clinic visit (six weeks after discharge). Specifications for each measure as well as the pass/refer criteria that were implemented are detailed in Table 1.

Participants who passed the repeat hearing screening were booked for diagnostic behavioral audiometry at six months corrected age to ensure the inclusion of risk-based surveillance for late or delayed-onset hearing impairment. Although some well-established programs in developed contexts involve audiological monitoring every six months until two years of age (Beswick et al, 2013), the protocol in the current study adopted the recommendations made in the clarification to the American Academy of Pediatrics, Joint Committee on Infant Hearing (2007) position statement (JCIH, 2008). Owing to the burden placed on audiologists for six monthly audiological follow-up assessments, the responsibility for surveillance of all infants was shifted to the primary care provider who is expected to refer to the audiologist if a concern regarding hearing loss arises (JCIH, 2008). This recommendation appeared to be in line with the context of the current study as follow-up screening at the research sites was conducted at neonatal follow-up clinics. These clinics include pediatricians who conduct regular follow-up of these high-risk babies until two years of age. Hence, if any hearing loss was to be suspected following the six-month audiological assessment, these babies would be referred by pediatricians. Visual reinforcement audiometry was used as it has been the recommended gold standard for determining NHS test performance from six months corrected age (JCIH, 2000). Soundfield testing was conducted using the Interacoustics AC40 diagnostic audiometer. Testing was conducted using warble tones at 500 Hz, 1, 2, and 4 kHz. The use of insert earphones or headphones did not prove feasible when assessing participants from the pilot study as they were restless and often did not permit the placement of insert earphones or headphones. In addition to behavioral audiometry, high-frequency tympanometry and diagnostic OAE testing (where possible) were included within

**Table 1. Specifications for Screening Measures**

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<th>Screening Measure</th>
<th>Specifications</th>
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| TEOAE | Stimulus level: 70–84 dB sound pressure level (dBSPL) (45–60 dBHL)  
Frequency range: 1.5–4.5 kHz  
This screening measure required 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 in order or a “pass” result to be obtained |
| DPOAE | Stimulus levels: L1/L2 60/50 dBSPL  
Frequencies: 1, 2, 3, 4, 5, 6 kHz  
“Pass/Refer” criterion: “Pass” result at 4/6 frequencies |
| AABR | Stimulus level: 35 dBnHL  
Stimulus type: broadband, 2–4 kHz  
Electrode placement: nape of the neck, high forehead, cheek  
Impedance test indicators: Good (<4 kΩ)  
Fair (4–12 kΩ)  
Poor (>12 kΩ)  
Impedance balance indicators (difference between high forehead and nape of the neck):  
Good (0–2 kΩ)  
Fair (2–4 kΩ)  
Poor (>4 kΩ) |
the test battery. Responses to visual reinforcement audiometry testing were considered normal if thresholds were obtained at 25–30 dBHL (approximately +10 dB relative to adult thresholds) (BSA, 2014).

Diagnostic ABR (conducted under natural sleep) was conducted if a “refer” result was obtained from both screening intervals or the repeat hearing screening rescreening for both OAEs and AABR or AABR only. Diagnostic ABR was conducted using the GSI Audera. Testing consisted of a two-channel, bilateral neurological click ABR using a stimulus rate of 11.1/sec at 80 dBnHL. If waves I, III, and V were visible at normal latencies and had normal amplitudes, a one-channel, bilateral auditory click ABR using a stimulus rate of 33.1/sec and a one-channel, bilateral tone burst ABR at 500 Hz and/or 1000 Hz using a stimulus rate of 39.09/sec were conducted. Using click stimuli along with but before tone burst stimuli provides multiple diagnostic results without increasing test time (Hall and Swanepoel, 2010). If there were delayed absolute wave latencies and the amplitudes were reduced, a tone burst ABR was conducted at 500, 1000, 2000, and 4000 Hz. (Hall, 2007; Hall and Swanepoel, 2010). Stimulus intensity levels were decreased in 20-dB steps and increased in 5- to 10-dB steps. This was conducted as a means of minimizing test time without sacrificing the quality of the data obtained (Hall and Swanepoel, 2010). The criterion for estimated hearing within normal limits was the presence of wave V at a stimulus intensity of 20 dBnHL (Can et al, 2015). If a clear neurological ABR was not obtained at an increased intensity level (90 dBnHL), an auditory steady-state response was conducted to establish estimated hearing thresholds (Hall, 2007; Hall and Swanepoel, 2010).

During both screening and diagnostic measures, careful consideration was paid to patient-related factors and the test environment that may influence the reliability of the results obtained. Requirements such as a tightly fitting probe and a quiet test environment were met during the data collection. The researcher avoided holding the probe during testing to prevent it from touching the ear canal wall and causing interference with the signal (Olusanya, 2010). The researcher also conducted screening with the baby swaddled or in the Kangaroo Mother Care position to facilitate a calm state, with minimal movement and restlessness which could result in the probe slipping out during screening (Olusanya, 2010). With regard to TEOAE screening, the researcher ensured that the artifact value did not exceed 20% and that the stimulus stability was 80% or greater as stipulated in the AccuScreen manual. Accurate OAE screening results have been demonstrated when background or ambient noise levels do not exceed 65–68 dBA (Olusanya, 2010; Salina et al, 2010). Sound levels were measured during screening to ensure that ambient noise did not exceed 65 dBA.

Data Analysis

Owing to the absence of participants with hearing loss in the current study sample, analysis could only be conducted in relation to specificity (% TN findings) and not sensitivity. To establish which combinations of tests had the best specificity (% TN), screening outcomes were compared with diagnostic audiological outcome. The participant was classified as presenting with an overall “refer” if the outcome for any one test was “refer.” Proportions were compared by the z-test for proportions, with critical p-values adjusted (to 0.013) for multiple comparisons. The overall screening outcomes (at the initial hearing screening and repeat hearing screening) for different test combinations were compared using McNemar’s test for paired data. Proportions across different test combinations were compared by the z-test for proportions (Agresti and Kateri, 2011).

Ethical Considerations

The ethical practices undertaken in this study were guided by the World Medical Association (WMA, 2013) Declaration of Helsinki’s statement of ethical principles for medical research involving human subjects. Ethical clearance was obtained from the University Medical Ethics Committee, and permission was also obtained from the sites of relevant authorities where the study was conducted. Participant codes were used instead of participant names. Caregivers of participants were allowed to withdraw from the study at any time without any negative consequences. Participants underwent specific diagnostic evaluation, depending on the outcome of the hearing screening. Hence, diagnostic ABR was not conducted on participants who passed the hearing screening.

RESULTS

To determine sensitivity and specificity, controlled clinical trials must be conducted, whereby screening results are compared with 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). Hence, to calculate the percentage of TP (sensitivity) and TN (specificity) findings in the current study, only participants who had been followed up with diagnostic testing and had conclusive diagnostic findings (n = 91) could be included in the calculation. A total of 93 participants attended diagnostic follow-up, 6 for diagnostic ABR testing and 87 for the six-month behavioral assessment. Of these six participants who underwent diagnostic
ABR testing, five presented with estimated hearing within normal limits, and results for one participant were inconclusive because of incomplete testing due to restlessness. This participant was subsequently booked for another appointment but did not arrive.

Of the 87 participants that attended the six-month behavioral assessment, 86 (98.8%) presented with hearing within normal limits and one had inconclusive findings as reliable thresholds were not obtained for two of the four frequencies, and the participant was restless for the remainder of the assessment session, even when high-frequency tympanometry was attempted. This participant was booked for a follow-up diagnostic audiological assessment but did not arrive.

Results from combinations of audiological screening measures at the initial and repeat hearing screening were analyzed in relation to the final diagnostic outcome (n = 91) which was considered the gold standard. Analysis was conducted using the overall screening outcome per measure, per participant. The screening result was further classified as “refer” if the outcome for any one screening measure within the specified combination was “refer.” The percentage of TN findings for each of the combinations of screening measures is tabulated below (Table 2).

The percentage of TN findings was significantly higher at the repeat hearing screening (six weeks after discharge) using any test or combination of tests (p < 0.0001; p = 0.008), when compared with findings for any test or combination of tests from the initial hearing screening except for TEOAE (p = 0.028). There was no significant difference between the specificity of any test combinations within the initial hearing screening except for TEOAE which had a significantly higher specificity in comparison to the DPOAE/TEOAE/AABR test combination (p = 0.002); the DPOAE/AABR test combination (p = 0.003); and the TEOAE/AABR test combination (p = 0.008). There was no statistically significant difference between the specificity of any test or test combinations within the repeat hearing screening. Although differences were not statistically significant between any test or test combination within the repeat hearing screening, AABR yielded the highest percentage specificity (96.7%) at the repeat screening followed by TEOAE and then the TEOAE/AABR combination.

DISCUSSION

Three screening measures (TEOAE, DPOAE, and AABR) were employed in the current study within a repeated measures design. Hence, unlike other studies that have explored different combinations of screening measures on different groups of participants (Benito-Orejas et al, 2008; Berg et al, 2011), the current study involved the same group of participants at and across time. Because of the absence of hearing loss in participants who returned for diagnostic audiological assessment, only the TN rate (specificity) could be established. The current authors believe that true hearing status cannot be assumed from screening results because of possible FP and FN findings and therefore support the argument by Widen et al (2000) who stated that screening measures should be compared against a behavioral measure.

Current study findings indicated a significantly higher percentage of TN findings at the repeat hearing screening when compared with the initial hearing screening for all measures or combinations of screening measures. Moreover, the use of TEOAE yielded the highest %TN findings at the initial hearing screening (81.3%), whereas the AABR yielded the highest %TN for the repeat hearing screening (96.7%), which may suggest that both these measures may be employed within a two-stage NHS protocol. These results are supported by findings from the literature which highlight the benefits of using TEOAEs as the initial screening measure followed by AABR at the second screening.

<table>
<thead>
<tr>
<th>Test/Test Combination</th>
<th>%TN</th>
<th>95% CI for %TN</th>
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<tbody>
<tr>
<td>DPOAE + TEOAE + AABR at initial screen</td>
<td>60.4</td>
<td>50.2–69.9</td>
</tr>
<tr>
<td>DPOAE + AABR at initial screen</td>
<td>61.5</td>
<td>51.3–70.9</td>
</tr>
<tr>
<td>TEOAE + AABR at initial screen</td>
<td>63.7</td>
<td>53.5–72.9</td>
</tr>
<tr>
<td>AABR at initial screen</td>
<td>69.2</td>
<td>59.1–77.7</td>
</tr>
<tr>
<td>DPOAE at initial screen</td>
<td>73.6</td>
<td>63.8–81.6</td>
</tr>
<tr>
<td>TEOAE at initial screen</td>
<td>81.3</td>
<td>72.1–88.0</td>
</tr>
<tr>
<td>DPOAE + AABR at repeat screen</td>
<td>89.0</td>
<td>80.9–93.9</td>
</tr>
<tr>
<td>DPOAE + TEOAE + AABR at repeat screen</td>
<td>89.0</td>
<td>80.9–93.9</td>
</tr>
<tr>
<td>DPOAE at repeat screen</td>
<td>89.0</td>
<td>80.9–93.9</td>
</tr>
<tr>
<td>TEOAE + AABR at repeat screen</td>
<td>91.2</td>
<td>83.6–95.5</td>
</tr>
<tr>
<td>TEOAE at repeat screen</td>
<td>92.3</td>
<td>85.0–96.2</td>
</tr>
<tr>
<td>AABR at repeat screen</td>
<td>96.7</td>
<td>90.8–98.9</td>
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Note: CI = confidence interval.
for those who “refer” on TEOAEs (Papacharalampous et al, 2011). Other findings suggest that the use of AABR is significantly more effective than the use of TEOAEs (van Dyk et al, 2015).

With regard to the use of a combination of screening measures within a single screening session, current study findings indicated that the TEOAE/AABR combination yielded the highest percentage of TN findings (91.2%) followed by the DPOAE/AABR (89%) and DPOAE/TEOAE/AABR combination (88%). The TEOAE/AABR combination therefore had the best specificity and has been employed for the screening of NICU infants in developed contexts (WHO, 2010). FP rates have been reported to be high when hearing screening is conducted with TEOAEs instead of AABR (Papacharalampous et al, 2011). However, these FP rates reported by van Dyk et al (2015) were compared with successive screening results and not diagnostic assessment results.

Similarly, in terms of FP rates, a study conducted on high-risk newborns by Xu et al (2011) revealed that DPOAE screening alone resulted in a higher FP rate of 4.96% in comparison with the combined protocol which yielded a 2% FP rate, thus resulting in an increased TN rate. FN rates have also been reported to be higher for the single DPOAE screening when compared with the DPOAE/AABR protocol (Xu et al, 2011). Although the pass/refer criteria and screening protocol differ from the current study, these findings imply that a combination of screening measures within a protocol increases test specificity, accuracy, and validity, without affecting sensitivity for hearing loss. The use of both OAEs and AABR within an NHS protocol further assists in the prediction of the auditory neuropathy profile, particularly in high-risk newborns (Xu et al, 2011). A combination of two screening measures may also be less time-consuming and more cost-effective when compared with the use of all three screening measures employed in the current study. This is particularly important in the South African context where the choice of screening protocol employed within an NHS program is influenced by a variety of factors such as costs, logistics, infrastructural considerations, targeted referral rates, and follow-up default rates. The use of AABR alone or a combination of TEOAE/AABR within a two-stage screening protocol is believed to be a feasible model within the South African context not only with the high-risk population but also with the general neonatal population as well. The evidence-based screening protocol and criteria adopted in the current study could be used with careful attention to environmental impacts such as noise and ethical considerations with regard to informed consent for screening because hearing screening is not yet mandated by the Health Department in South Africa.

Findings from the current study have significant clinical implications as they suggest the review of existing guidelines and policies related to early hearing detection and intervention in South Africa. Furthermore, findings from the current study provide evidence-based practice for NHS in a context that demands careful use of limited resources.

CONCLUSIONS

Results from the current study have the potential to contribute toward the screening measures and protocols used within NHS programs. The use of a two-stage AABR screening protocol assists in ensuring good specificity and reducing FP and FN rates. However, the use of both OAE and AABR may also act as a cross-check principle within the screening program, with the TEOAE/AABR combination being better than the DPOAE/AABR combination in terms of specificity. These screening protocols may further assist in ensuring good sensitivity which requires further investigation as the current study did not present with any participants with hearing impairment. Current findings are particularly valuable in resource constrained contexts where the choice of screening measure or measures has implications for budgetary planning where a number of health priorities are competing for capital allocation attention.

REFERENCES


