OUTCOMES WITH OAE AND AABR SCREENING IN THE FIRST 48 HOURS – IMPLICATIONS FOR NEWBORN HEARING SCREENING IN DEVELOPING COUNTRIES

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ABSTRACT

***Objective*:** Early discharge of newborns (<24 hours after birth) from birthing centres is an important barrier to successful newborn hearing screening (NHS) in developing countries. This study evaluated the outcome of NHS within the first 48 hours using an automated auditory brainstem response (AABR) device without the need for costly disposables typically required, and transient evoked otoacoustic emissions (TEOAE).

Methods: NHS was performed on one hundred and fifty healthy newborns (300 ears) with TEOAE and AABR techniques before discharge at a hospital. A three-stage screening protocol was implemented consisting of an initial screen with TEOAE (GSI AUDIOscreener+) and AABR (Beraphone MB 11). Infants were screened at several time points as early as possible after birth. Infants were only re-screened if either screening technique (TEOAE or AABR) initially yielded a refer outcome. The same audiologist performed all TEOAE and AABR screenings.

Results: Over the three-stage screen AABR had a significantly lower refer rate of 16.7% (24/144 subjects) compared to TEOAE (37.9%; 55/145 subjects). Screening refer rate showed a progressive decrease with increasing age. For both TEOAE and AABR, refer rate per ear screened 24 hours post birth was significantly lower than for those screened before 24 hours. For infants screened before 12 hours post birth, the AABR refer rate per ear (51.1%) was significantly lower than the TEOAE refer rate (68.9%). Overall AABR refer rate per ear was similar for infants screened between 24 to 36 hours (20.2%) and 36 to 48 hours (18.9%) but significantly lower than for TEOAE (40.7% and 41.9%, respectively). Lowest initial refer rates per ear (TEOAE 25.8%, AABR 3.2%) were obtained after 48 hours post birth.

Conclusion: In light of the early post birth discharge typical in developing countries like South Africa, in-hospital screening with AABR technology is significantly more effective than TEOAEs. AABR screening with a device like the MB 11 is particularly appropriate because disposable costs are negligible.

KEYWORDS:
Age at screen; Developing countries; Early intervention; Newborn hearing screening; Otoacoustic emissions; Automated Auditory Brainstem Response

1. Introduction

Prevalence of congenital and early-onset hearing impairment ranges from 0.5 to 5 per 1000 infants based on studies from various countries [1-6]. At least 90% of infants with hearing loss live in developing countries [7]. Undetected hearing loss can lead to delayed or impaired speech and language development, social and emotional problems, academic failure and restricted vocational outcomes [8-11]. The earlier a hearing loss is detected, the earlier intervention can begin, which increases the likelihood of optimizing a child's potential across developmental areas [2,10].

It is recommended that universal newborn hearing screening (UNHS) be performed within the first month of life, and that a screen result be obtained before hospital discharge whenever possible to reduce the subsequent need for outpatient follow-up [11]. All infants should have access to hearing screening during which a physiologic measure such as otoacoustic emissions (OAE) or automated auditory brainstem responses (AABR) [11] is used. Although both AABR and OAE are accepted as reliable measures for newborn hearing screening (NHS) they may present with false-positive results due to patient and environment related factors [12]. AABR is less affected 24 to 48 hours post birth than OAE by transient conditions in the external auditory canal (e.g. collapse of the ear canal and the presence of debris) and middle ear (e.g. presence of amniotic fluid and mesenchyme), making it more likely that newborns will refer with OAE screening than AABR screening [13,14]. Environmental factors such as excessive ambient noise in the test environment or test skills and experience of the screening staff may also negatively affect screening outcomes for both OAE and AABR [15]. False-positive results may lead to parental anxiety and worry as well as monetary costs resulting from parents' lost time from work, transportation to health care facilitates,

unnecessary tests, and probably more consequential costs and follow-up defaults which is a matter of special concern in developing countries like South Africa [16,17].

The recommended time for NHS screening after birth is later than 24 hours to avoid the increased incidence of transient outer and middle-ear conditions affecting screening outcomes in the first hours post birth [9,15]. Screening with an OAE technique within the first 24 hours post birth reportedly results in referral rates as high as 20% [9,18,19]. Referral rates drop to as low as 3% when screening is performed between 24 and 48 hours after birth [9,18,19]. Referral rates of less than 4% are generally achievable when an infant is screened with OAE combined with AABR in a two-step screening system or with AABR alone before discharge [15,20].

The reported distribution of typical discharge times for newborns in the United Kingdom are 16% on the day of birth, 35% the following day; 21% after 2 days and 28% for 3 days after delivery [21]. In the US, healthy infants are typically discharged from the hospital between 24 and 48 hours after birth [22]. In comparison healthy infants in South Africa are discharged from a state hospital or clinics between 6 and 24 hours after birth [23,24]. Postnatal care is provided by family members or at primary health care clinics [25], even though the World Health Organization [26] recommends that newborns born in health facilities should not be sent home in the crucial first 24 hours of life.

Early discharge of newborns in South Africa is an important challenge to successful implementation of hospital-based NHS. An additional challenge is the cost associated with screening, particularly costs related to disposables involved in testing each infant. Typically AABR screening has been more expensive than OAE screening due to the higher costs of disposables [27]. In South Africa the vast majority (81%) of private hospitals conducting screening reportedly use OAE screening in the healthy newborn ward compared to only 1% employing AABR, due to the additional costs associated with this type of screening [28]. The AABR's higher specificity reduces the costs of further diagnostic testing, however, as well as the time parents have to invest in order to reach

a diagnosis [27]. In South Africa, only 53% of private hospitals reported some form of NHS, due to lack of appropriate equipment and time constraints [28].

AABR screening is rare in the public health sector of South Africa due to the significantly increased costs compared to OAE screening. AABR equipment is typically more costly than OAE screening [29]. However, it is the increased disposable-related expense of AABR (e.g., disposable ear tips or muffs and electrodes) that raise the costs significantly. A newer generation AABR device, the *Beraphone MB 11 (Maico),* has provided an alternative AABR tool without the requirement for disposables. Its design eliminates the need for disposable ear tips and electrodes, allowing for AABR screening at significantly reduced costs per screen [30]. This type of technology may allow screening of infants at early ages in a health care context where babies are typically discharged before 24 hours after birth, without the costs associated with traditional AABR equipment. Screening technology with limited disposable costs, and that is less susceptible to transient middle ear influences within the first 48 hours after birth, may more readily be utilized for hospital-based screening in typical developing world contexts like the South African public health care system. The aim of this study was therefore to evaluate the outcome of NHS within the first 48 hours using the MB 11 AABR device compared to transient evoked otoacoustic emissions (TEOAE) screening.

2. Methods

Newborn hearing screening was conducted in a hospital in South Africa. Institutional research and ethics committee approval was obtained from the University of Pretoria and the hospital involved before data collection commenced.

2.1 *Subjects*

Hearing screening with TEOAE and AABR was performed before hospital discharge for one hundred and fifty healthy newborns (300 ears). Infants were screened at several

points in time as early as possible after birth. Delays in obtaining informed consent due to hospital protocol, time of delivery, and other logistical factors resulted in some delays to screening. All newborns participating in the study had no documented medical difficulties and were in a well-baby nursery. There were 75 male (50%) and 75 female (50%) infants. The median gestational age was 39 weeks and the mean birth weight was 3208 grams (SD 396 grams). The majority of newborns were born via caesarean section (74.2%), which is representative of births in the private health care sector in South Africa.

A pilot study with TEOAE and AABR screening techniques was conducted on sixty healthy newborns before the formal data collection phase commenced. This allowed the audiologist to refine screening techniques, test procedures, and data collection before commencing the study.

2.2 Screening Protocol

All parents of infants to be screened were provided with an information brochure prior to screening. Screening was conducted either in a room within the maternity ward or in the nursery, depending on the space available. After informed consent was obtained from a parent, each newborn underwent screening with the TEOAE and AABR. Infants were screened at several points in time as early as possible after birth. Infants were only re-screened if either of the screening techniques (OAE or AABR) initially yielded a refer outcome. All TEOAE and AABR screening was performed by the same audiologist. The audiologist was experienced in NHS.

A three-stage screening protocol (figure 1) with the TEOAE and AABR was implemented. A refer outcome in the first stage indicated that further screening was required before discharge, to rule out any uncertainty regarding the hearing status of the infant. Refer criterion for subjects was a unilateral or bilateral refer for either screening device.

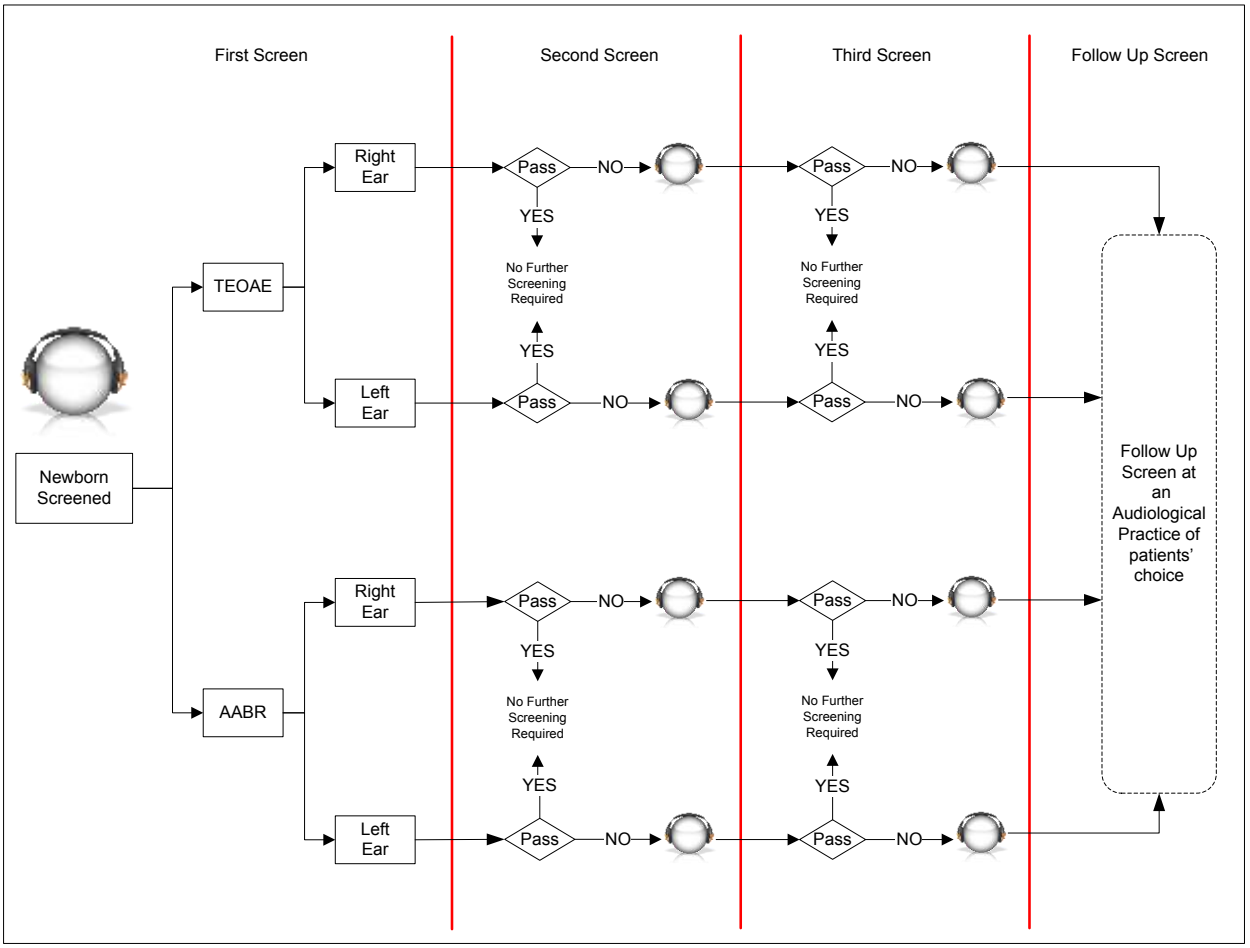

Figure 1. Three-Stage screening protocol employed during data collection

A second-stage screen with the equipment (TEOAE or AABR) was only conducted on ears that yielded a refer result during the initial screen. The third-stage screen was also conducted in the same manner. If a newborn did not pass the third-stage screen, an opportunity was provided for an appointment for a re-screen at the hospital between 2 days and 6 weeks after birth. A screen was not repeated within a stage unless the environment was too noisy or incorrect placement/insertion was evident. "Too noisy" was defined by the noise parameters set on either the TEOAE or AABR, and a placement/insert problem was identified when the calibration of either screening technique was unsuccessful. The first ear to be screened was randomly selected, depending on which ear was most accessible (i.e., facing upwards away from the cot) before the infant was turned over to screen the opposite ear. TEOAE screening was

conducted first 83.1% of time, while AABR was conducted first 16.9% of the time. This was due to equipment-related factors established during the pilot study. The cold gel tended to wake babies if AABR screening was conducted first, and the gel was difficult to remove before conducting the TEOAE. The TEOAE was less invasive with regard to preparation of the newborn and, thus, had less effect on the newborn's state for the next screening method. Test time was recorded for each screening test, excluding the time required to set up, start up and shut down each screening device and to prepare the infant. The ear specific time segments were measured with a stopwatch for the TEOAE and read from the MB 11 software for the AABR screening.

2.3 Instrumentation

The screening techniques provided a *pass* or *refer* result without the need for a subjective data analysis. The Beraphone MB 11 AABR device (figure 2) consists of a

Figure 2. Beraphone MB 11 screening an infant

handheld headphone unit that integrates the preamplifier and a set of three fixed touch-electrodes connected to a laptop computer [30]. Electrode gel was applied at the three electrode sites (vertex, ground and mastoid) on the baby's head. Electrode placement was as follows: non-inverting electrode was placed on the vertex; inverting electrode on the mastoid ipsilateral to the stimulus; and ground electrode was positioned just above

the ear ipsilateral to the stimulus. The vertex electrode could be adjusted to the individual size of the baby's head. Electrode gel was placed on the integrated electrodes before the earphone was placed surrounding the baby's ear with the resting electrodes on the prepared sites. The CE-Chirp stimulus™ was presented at 93 CE-chirps® per second at 35 dB nHL. Results were reported as either a *pass* or *refer*. The result was a *pass* if the presence of a non-random signal was detected with a confidence level >99.9% within 120 seconds. The result was a *refer* if pass criterion was not reached [30,31]. The cut-off frequencies of the band pass filter were 163 Hz and 1930 Hz [32].

TEOAE screening was conducted using the GSI AUDIOscreener+™. The probe of this handheld device was placed in the external ear canal of the newborn with a rubber tip. The device used in-ear calibration before screening commenced. The click stimulus intensity was set at 84 dB peak equivalent SPL at a rate of 64 Hz for a maximum time of 240 seconds (band pass filter of 1000 to 4000 Hz). An automated pass criterion of two bands was utilized based on TEOAE signal to noise ratio (max. noise 60 dB and max. signal 70 dB) and TEOAE reproducibility within 128 to 2048 frames. The TEOAE frequency band low cut-offs were 3500, 2500, and 1500. The high cut-offs were 4500, 3500 and 2500. A reproducibility value of 60 to 80% was required for the band response to be considered a *pass*.

2.4 Data management and analysis

All data were recorded and subsequently captured on an MS Excel database. SPSS version 21 was used for the statistical analysis. Descriptive statistics provided the frequency distribution and measures of central tendency. Chi-square test was used to investigate correspondence between test outcomes. Analysis of differences in outcomes across ages was performed by grouping three age categories and conducting the Wilcoxon signed rank test and Mann-Whitney test. The significance level for all statistical tests was set at the 5% level.

3. Results

Initial TEOAE and AABR screening was completed on 150 healthy newborns (300 ears) at various ages post birth.

3.1 Screening outcomes

As summarized in Table 1, most ears were successfully screened. A small number of ears were not screened due to the infants' state, noise levels, and/or probe fit issues. Only one ear (1/300; 0.3%) could not be screened with either the TEOAE or AABR throughout the three-stage screen, and 92.7% of ears (278/300) were screened with both TEOAE and AABR techniques initially. 41.3% of subjects passed bilaterally with both TEOAE and AABR at the initial screen. Over the three-stage screen TEOAE had a significantly higher refer rate of 37.9% (55/145 subjects) than AABR (16.7%; 24/144 subjects). Overall AABR had a significantly ($p<0.001$; Chi-Square) lower initial refer rate per ear compared to the TEOAE. Right ears had a significantly ($p<0.05$; Chi-Square) lower refer rate for both screening techniques compared to left ears. Rescreen refer rates were also higher per ear for TEOAE (49.5%) compared to AABR (36.1%) screening (Table 2). The TEOAE presented with a higher false-positive (i.e. an ear referred initially but passed on the second or third screen) rate (39/103; 37.9%) than the AABR (3/61; 4.9%).

Mean screen duration for a pass result was 31 seconds (SD 26) for TEOAE and 53 seconds (SD 40) for the AABR. The mean duration for a refer result was 109 seconds (SD 18) with TEOAE and always 180 seconds for AABR due to the test protocol. If the pass criterion was not reached after 180 seconds of test time, the result "refer" was displayed in the lower right corner. There was no significant difference ($p>0.05$; Wilcoxon) in time between the left and right ears when both passed or both referred with a TEOAE. Half the TEOAE pass results (48.5%) were obtained within the first 20 seconds of screening and half the AABR pass results (50.0%) were obtained between 11 and 40 seconds.

Table 1. Outcomes of three-stage newborn hearing screening with TEOAE and AABR

	TEOAE		AABR	
	N (ears)	%	N (ears)	%
FIRST SCREEN				
Refer rate right	56/146	38.4	27/145	18.6
Refer rate left	66/143	46.2	39/145	26.9
Refer rate combined	122/289	42.2	66/290	22.8
Unable to screen	11/300	3.7	10/300	3.3
SECOND SCREEN				
Refer rate right	21/43	48.8	14/25	56.0
Refer rate left	24/46	52.2	10/29	34.5
Refer rate combined	45/89	50.6	24/54	44.4
Unable to screen	3/92	3.3		
THIRD SCREEN				
Refer rate right	3/7	42.9	1/5	20.0
Refer rate left	3/7	42.9		
Refer rate combined	6/14	42.9	1/7	14.3
Unable to screen			1/8	12.5
OVERALL SCREEN				
Refer rate right	31/146	21.2	12/145	8.3
Refer rate left	39/143	27.3	18/145	12.4
Refer rate combined	70/289	24.2	30/290	10.3
Unable to screen	11/300	3.7	10/300	3.3

Table 2. Screening outcomes before 24 hours and after 24 hours post birth

	FIRST SCREEN		SECOND SCREEN		THIRD SCREEN	
	N (ears)	%	N (ears)	%	N (ears)	%
<12 hours						
TEOAE refer rate right	16/23	69.6				
TEOAE refer rate left	15/22	68.2				
TEOAE refer rate combined	31/45	68.9				
AABR refer rate right	10/24	41.7				
AABR refer rate left	14/23	60.9				
AABR refer rate combined	24/47	51.1				
12-24 hours						
TEOAE refer rate right	17/39	43.6	2/5	40.0		
TEOAE refer rate left	18/36	50.0	1/4	25.0		
TEOAE refer rate combined	35/75	46.7	3/9	33.3		
AABR refer rate right	8/40	20.0	1/4	25.0		
AABR refer rate left	11/35	31.4	4/5	80.0		
AABR refer rate combined	19/75	25.3	5/9	55.6		
24-36 hours						
TEOAE refer rate right	13/42	31.0	8/12	66.7		
TEOAE refer rate left	16/42	38.1	6/11	54.5		
TEOAE refer rate combined	29/84	34.5	14/23	60.9		
AABR refer rate right	4/38	10.5	5/8	62.5		
AABR refer rate left	6/40	15.0	4/8	50.0		
AABR refer rate combined	10/78	12.8	9/16	56.3		
36-48 hours						
TEOAE refer rate right	9/28	32.1	4/8	50.0	2/5	40.0
TEOAE refer rate left	11/26	42.3	7/14	50.0	1/3	33.3
TEOAE refer rate combined	20/54	37.0	11/22	50.0	3/8	37.5
AABR refer rate right	5/30	16.7	2/5	40.0		
AABR refer rate left	7/29	24.1				
AABR refer rate combined	12/59	20.3	2/11	18.2		
<48 hours						
TEOAE refer rate right	3/15	20.0	7/18	38.9	1/2	50.0
TEOAE refer rate left	5/16	31.3	10/17	58.8	2/3	66.7
TEOAE refer rate combined	8/31	25.8	17/35	48.6	3/5	60.0
AABR refer rate right			3/8	37.5		
AABR refer rate left	1/18	5.6	2/10	20.0	1/2	50.0
AABR refer rate combined	1/31	3.2	5/18	27.8	1/3	33.3

3.2 Age effect on screening outcome

Screening refer rate per ear showed a progressive decrease with increasing age (Figure 3). The AABR refer rate per ear was significantly lower ($p<0.001$; Chi-Square) than the

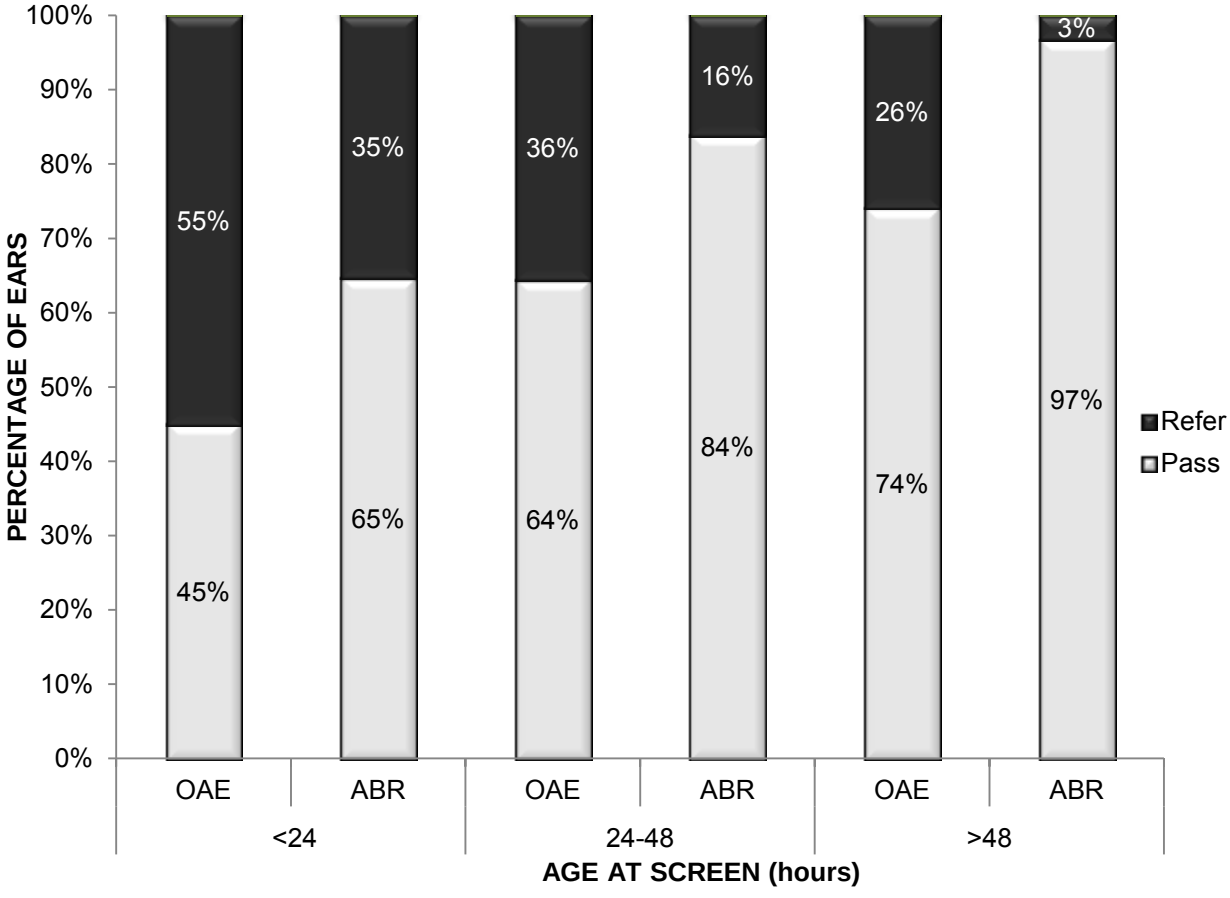

Figure 3. Initial screening outcomes according to age at screen (TEOAE n=289 ears; AABR n=290 ears)

TEOAE refer rate when an infant was screened before 12 hours after birth. Overall TEOAE refer rate per ear was similar for infants screened between 24 and 36 hours (40.7%) and between 36 and 48 hours (41.9%). Overall AABR refer rate per ear for infants screened between 24 and 36 hours (20.2%) and between 36 and 48 hours (18.9%) was also similar but significantly lower than for the TEOAE. Lowest initial refer rates per ear and per subject (TEOAE 35.3%, AABR 5.6%) were obtained after 48

hours post birth (Average age for TEOAE, 61 hours post birth; average age for AABR, 57 hours post birth). As indicated in Figure 3, the refer rate for ears screened after 24 hours was significantly ($p<0.001$; Chi-square) less than those screened before 24 hours for both AABR and TEOAE. The majority of infants were screened between 24 and 48 hours (TEOAE 47.8%, AABR 47.2%). The percentage of infants screened before 24 hours post birth was 41.5% with TEOAE and 42.1% with AABR. Few of the infants were screened 48 hours post birth for both screening techniques (TEOAE 10.7%; AABR 10.7%).

The mean age for a pass result with the TEOAE during the first screen was 32 hours (SD 15) and 25 hours (SD 14) for a refer result. The mean age for an AABR pass result was 31 hours (SD 15) and 22 hours (SD 13) for a refer result. Mean age at screen was significantly greater for those with a pass result compared to those with a refer result with either the AABR or TEOAE ($p<0.05$; Mann-Whitney test).

4. Discussion

Scheduling timing of newborn hearing screening beyond 48 hours, or even 24 hours, post birth to avoid excessive referral rates is a challenge in developing countries like South Africa where healthy newborns are typically discharged from 6 hours after birth [33]. Even though AABR is typically less affected by transient conductive pathology than OAE screening, it has not been widely adopted in existing newborn screening programs in South Africa [30,34]. This has primarily been attributed to the increased costs related to screening due to the disposables typically required for AABR screening as opposed to OAE [27]. Although the AABR technique may involve a slightly higher initial equipment cost than TEOAE technique, a newer generation AABR (the MB 11 by BERAphone) reduces screening costs and newborn preparation time because disposable electrodes and ear couplers are not required [35-37].

Consistent with the findings of previous studies [36,38], we found that referral rate decreased progressively with increasing age for TEOAE and AABR. Screening with

AABR reduced referral rates significantly compared to TEOAE regardless of age at screen. AABR also had a lower rescreen refer rate than TEOAE. Overall subject referral (after initial and rescreen) using TEOAE was more than twice that of AABR. Refer rate for ears screened with either AABR or TEOAE after 24 hours was significantly less than those screened before 24 hours. Although AABR refer rate per ear improved with increasing age, slightly more than half of the infants yielded a refer outcome within 12 hours post birth and approximately one-quarter of the infants referred when screened between 12 and 24 hours after birth.

Transient conductive auditory dysfunction negatively influences screening results in newborns, leading to a significantly increased probability of a refer result [19]. In public hospitals in South Africa infants may be discharged within 24 hours post birth when TEOAE refer rate is highest [36,39]. The constraint of birthing facility discharge typically from 6 hours after birth for healthy babies and their mothers may necessitate the introduction of an initial or second-stage screening with AABR to minimize the referral rates prior to diagnostic evaluation [15,38]. In this study newborns initially screened with AABR at 48 hours or later had the optimal subject refer rate of 5.6% when compared to the recommended benchmark of less than 4% [11]. Excessive referral rates place an additional burden on NHS program resources (i.e., screening costs) and negatively influence successful tracking and follow-up of referred infants [40].

The risk of high TEOAE referral rates before 48 hours post birth, as demonstrated in this study, make it difficult to overlook initial AABR screening even in a resource-constrained environment like South Africa [15]. However, OAE screening techniques are typically the most widely used for initial or two-stage NHS programs worldwide, including in South Africa. The apparent explanation is a perception that OAE screening is easier and quicker to perform with less expense related to consumables than the AABR [14,15,28,41,42]. Reported overall TEOAE referral rates for subjects from NHS programs in developing countries vary considerably from those for our study (37.9%) with referral rates of 33.2% reported for Nigeria, 30% in Brazil, and 10.5% in Turkey [7,19,37]. The overall AABR screen referral rate per subject in this study (16.7%) was

higher than AABR MB 11 screening programs reported from other countries such as India (9.1%), Germany (3.8%) and Turkey (2%) [35,37,43]. A number of factors contribute to the higher refer rate in our study apart from the fact that this study was not an evaluation of an existing NHS program. The test environment in this study was neither a separate dedicated room nor a sound treated room, and screening was often conducted in the nursery [19,37]. Another contributing factor could be the high caesarean delivery rate compared to subjects in previously reported studies where the caesarean delivery rate was less than 15% [42,44]. Most importantly however the higher average refer rate for both TEOAE and AABR is largely due to the large number of ears screened within 24 hours post birth. Other studies typically screened primarily before hospital discharge but at least 48 hours post birth [7,35,37,43].

Initial screening with AABR significantly reduces the number of infants that require follow-up retesting outside of hospital discharge even for those younger than 48 hours post birth. In developing countries like South Africa where most newborns are discharged before 24 hours after birth, OAE screening is not ideal [36,45,46]. AABR is therefore recommended for NHS screening for these younger children. An added advantage of AABR is the possibility of detection of auditory neuropathy spectrum disorder typically missed by OAE screening [11]. Birthing facilities typically plagued with resource constraints related to disposable-related costs could benefit from an AABR device like the MB11 that does not require disposables. Ideally, however, newborns should be screened as late post birth as possible with best results evident after 48 hours post birth. If a hospital is unable to screen a newborn from 24 hours after birth before discharge alternative screening contexts in developing countries like South Africa may need to be considered such as immunization clinics and Midwife Obstetric Units (MOUs) in order to reduce high referral rates and the risk of excessive follow-up defaults [47,48].

5. Conclusion

Initial screening with an AABR technology (MB 11 BERAphone®) is significantly more effective than TEOAE for newborns younger than 48 hours. Screening infants within 24 hours post birth with AABR results in reduced costs associated with high referral and false-positive rates. In view of the early discharge typical in South Africa and other developing countries, AABR screening using technology without disposable-related costs may be the most appropriate choice for sustainable and cost-effective programs. However, even AABR may not be an entirely efficient option for birthing centres where infants are discharged within 24 hours after birth, due to high referral rates which influence factors such as costs, logistics, infrastructural considerations, case definition, targeted referral rates and follow-up default [15]. UNHS protocols for contexts like the South African public health care sector may require AABR technology (without the burden of disposable-related costs) in hospital-based settings with OAE reserved for screening older infants at health care visits, such as community-based immunization clinics or midwife obstetric units [14,46,47]. Utilizing different cost-effective technologies in various health contexts relating to infant age may be essential to ensure that such screening programs in developing countries like South Africa are successful.

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