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Outcomes with OAE and AABR screening in the first 48 h—Implications for newborn hearing screening in developing countries

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ABSTRACT

Objective: Early discharge of newborns (<24 h 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 h 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 150 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 h post birth was significantly lower than for those screened before 24 h. For infants screened before 12 h 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 h (20.2%) and 36 to 48 h (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 h 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.

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

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to patient and environment related factors [12]. AABR is less affected 24 to 48 h 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 h 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 h 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 h 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 h after birth [22]. In comparison healthy infants in South Africa are discharged from a state hospital or clinics between 6 and 24 h 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 h 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 h 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 h 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 h 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 g (SD 396 g). 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 (Fig. 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.

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