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Performance of two hearing screening protocols in the NICU

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Abstract. *Performance of two hearing screening protocols in the NICU.* We recently started a hearing screening program for the newborns of the neonatal intensive care unit (NICU) of Shanghai Children's Medical Center. The program consisted of a two-step screening stage using DPOAE and automated ABR (AABR) at the age of a few days, and a diagnostic stage including otoscopy, measuring middle ear impedance and click evoked ABR at the age of two months. Babies who were referred on either the basis of DPOAE or DPOAE-AABR screening were referred for diagnostic work-up. Of the 200 NICU infants, twenty-nine (14.5%) were referred by a single session DPOAE screening. Of these, nine (4.5%) were identified by the DPOAE-AABR screening. At the age of two months, six NICU babies (3%) had a significant hearing loss based on click-evoked ABR. None of the infants who were referred by DPOAE but had passed the AABR screening were found to have actual hearing loss. Our study reports the successful implementation of a two-step screening protocol for 'at risk' babies in Shanghai. We hope that our efforts represent a first step towards the implementation of universal hearing screening throughout the People's Republic of China.

Introduction

Approximately one out of 1000 healthy newborns has a hearing loss that, if untreated, will interfere with normal development.[1] The incidence of such a hearing loss in babies admitted to the neonatal intensive care unit (NICU) is 20 to 40 times higher.[2] This is most probably because of their unfavorable health condition and the extreme fragility of the cochlea and the auditory pathways.[3] From a technical point of view, the high incidence of hearing loss in NICU babies allows for the evaluation of the performance of hearing screening methods based on relatively small samples.

Currently, two acceptable methodologies for newborn hearing screening coexist: measuring auditory brainstem responses (ABR) and measuring evoked otoacoustic emissions (EOAE).[2] These methods probe different physiological phenomena of the auditory system; ABR records the electrical response of the cochlea and the auditory pathways, whereas EOAE measures sound that is generated by the cochlea and that travels retrogradely through the middle ear so as to be available in the external ear canal. Both methodologies have their variants: in automated ABR (AABR), an algorithm compares the obtained responses with a template representing the electrical response of normal babies and yields a pass or a fail result; in "classic" click evoked ABR, an examinator decreases the click intensity up to a level at which wave V of the ABR-tracé is no longer discernable. The EOAE techniques for hearing screening are available in two forms: transient EOAE (TEOAE) which uses clicks, and distortion-product EOAE (DPOAE) which simultaneously delivers two tones with appropriately balanced frequencies and intensities. Each of the techniques has its potential pros and cons; e.g. AABR can be operated by laymen, but does not give information on the depth or frequency dependence of the hearing loss in case of a fail result, DPOAE might provide the frequency dependence of a moderate hearing loss, and TEOAE is a very fast screening method. In spite of its limitations – need for subjective interpretation, limited frequency information, relative long test duration and need for sedation – classic ABR remains the gold standard for the objective estimation of the hearing of very young children. Many studies have reported the performance of screening methods in both healthy and NICU babies. The referral rates in NICU babies range from 11% to 25% and are higher than the proposed upper limit[4] of 4% especially for the TEOAE technique. For example, with TEOAEs, Kok *et al.*[5] reported a 14% referral rate in very-low-birth-weight babies and

Vohr *et al.*[6] reported a referral rate of 6.5% in healthy babies. With AABR, Jacobson *et al.*[7] reported a referral rate of 11.2% in NICU babies and Iley and Addis[8] reported a referral rate of 4.5% in healthy babies. Nevertheless, hearing screening with these methodologies is feasible, and if followed by specialized investigations, successfully identifies the deaf or hard-of-hearing babies who ultimately benefit from early intervention.[4,9]

Since 1999, newborn hearing screening is required by law in most American states and is recommended in some European countries. The Republic of China has not yet adopted universal hearing screening, but the department of otolaryngology of Shanghai Children's Medical Center recently started hearing screening of NICU babies with a two-step screening protocol based on DPOAE and AABR. The results of this initiative, which also involved a comparison of two screening protocols, are in line with published data from all over the world and also reveal the strikingly similar attack rate of hearing loss in human race.

Subjects and methods

Subjects in this study were patients in the NICU at Shanghai Children's Medical Center. In total, 400 ears of 200 subjects (110 males and 90 females) were tested. Their ages ranged between 3 and 24 days (on average 16 days).

Study Protocol

The study protocol consisted of a "two-step" *screening stage* at the age of a few days, and a *diagnostic stage* at the age of 2 months (Figure 1). In the screening stage, all subjects were tested with DPOAE and, if the test result was a fail, also with AABR. All subjects that failed the DPOAE screen, irrespective the test result of AABR, were referred for the diagnostic stage. Such a protocol allows for the direct comparison, in retrospect, of the screening performance of DPOAE alone and DPOAE combined with AABR ("two-step"). In the diagnostic stage, subjects underwent an otologic examination, measuring of the acoustic impedance of the middle ear, and classic clik-evoked ABR. All subjects were tested under sedation (chloral hydrate, 0.5 cc/kg) in a supine position on a bed in a sound proof room.

DPOAE screening

DPOAEs were measured with a commercially available system (Grason-Stadler, Inc (GSI) 60) A special neonatal probe coupled the device to the external ear. Six stimuli consisting of pairs of pure tones ($f1$ and $f2$ with $f2/f1 = 1.2$ and $f1$: 65 dB SPL and $f2$: 55 dB SPL) were separately delivered ($f1$: 500, 1000, 1593, 2562, 3187, and 4031 Hz). The device analyzed the intermodulation product with the highest intensity ($2f1$-$f2$). The pass criteria for each intermodulation product corresponding to $f1$ are show in Table 1. When at least 4 of the 6 intermodulation products met the criteria, we considered the result of the DPOAE screen as a "pass"; in all other cases, the result was a "fail".

ABR screening

The AABR was performed with a SLE screener (SLE Company, SLE Diagnostic, UK). Clicks were delivered at a fixed intensity of 35 dB nHL.

Classic click evoked ABR was performed using a MK 22 device (Amplaid Biomedical Division of Amplifon S.P.A, MK 22 diagnostic screener, Italy).

Electroencephalic activity was recorded from the scalp; the positive electrode was placed on the forehead, the negative electrode was placed on the ipsilateral mastoid, and the ground electrode was placed on the contralateral mastoid. Electrodes were filled with a conductive gel, and the interelectrode impedance was below 5 kΩ. The surface potentials were amplified and bandpass-filtered (cutoff: 100-2500 Hz and slopes: 12 dB/octave). Clicks of 100 μs duration were delivered in alternating polarity at a repetition rate of 21 Hz. Responses were recorded for 10 ms following each click onset. The average response was obtained twice by recording responses to two series of 2000 clicks. Clicks were first delivered at 80 dB nHL, and if responses reliably yielded peak V, the stimulus level was decreased with 20 dB. If peak V could not be visualized, stimulus level was increased with 5 dB. The ABR threshold was defined as the lowest click level at which peak V could be visualized in the two response series. Based on the ABR thresholds, hearing loss was categorized into following classes: mild (36-50 dB nHL), moderate (51-70 dB nHL), severe (71-90 dB nHL) and profound (> 90 dBnHL).

Acoustic impedance measuring

The acoustic impedance of the middle ear and ipsilateral acoustic reflexes (at 0.5 and 1 kHz) were

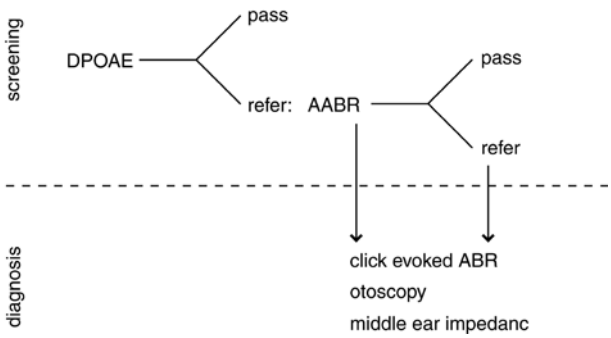

Figure 1
Schematic illustrating of the single DPOAE and the combined DPOAE/QABR study protocol.

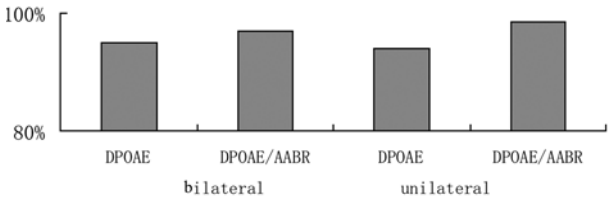

Figure 2
Bilaterally and unilaterally pass rates for the single DPOAE and the combined DPOAE/AABR technique in 200 babies.

Table 1
DPOAE pass criteria for each frequency

Frequencies (Hz)	Maximum allowable noise floor (dB SPL)	Minimum allowable DP magnitude (dB SPL)	Signal/noise ratio (dB)
500	-1	4	≥ 5
1000	-2	3	≥ 5
1593	-3	2	≥ 5
2562	-3	2	≥ 5
3187	-1	4	≥ 5
4031	0	5	≥ 5

measured with a commercially available device (Madsen ZO 901, Madson Company, Denmark).

Results

DPOAEs were measured in 400 ears of 200 NICU babies. Twenty-nine babies (14.5% of the NICU babies) failed the DPOAE screening. Twenty of them had a unilateral refer and nine had a bilateral refer; thirty-eight ears (9.5% of the screened NICU ears), thus, were referred on the basis of the DPAOE screening.

The 29 babies who were referred on the basis of the DPOAE screening, were subjected to the AABR test. Nine of them (4.5% of the NICU babies, 31% of the babies who failed the DPOAE test) had a fail result. Six of them had a bilateral refer and three of them a unilateral refer (Figure 2); fifteen ears (3.75% of the screened NICU ears), thus, were referred on the basis of the two-step (DPOAE-AABR) screening.

The 29 babies who were referred on the basis of the DPOAE screening, irrespective of their AABR test result, underwent a diagnostic work-up (see METHODS) at the age of two months. Six babies (3% of the NICU babies) had abnormal hearing (Table 2). Five of them had bilateral hearing loss and only one had a unilateral hearing loss. When considering subjects (as opposed to ears), the false-positive rate of the two-step screening (DPOAE-AABR) was 1.5% and that of the DPOAE screening was 11.5%. Interestingly, none of the babies who failed the DPOAE screening but passed the AABR screening had a hearing loss based on classic ABR. These data suggest that two-step screening increases test specificity without affecting its sensitivity for hearing loss. Of the three babies who were wrongly referred for diagnostic work-up, two had neonatal jaundice and one was preterm; these conditions might temporarily have affected their auditory system.

We examined whether some DPOAE frequencies were more useful than others. Of the 38 ears that failed the overall DPOAE screening, pass and fail rates of their individual DPOAE frequencies (Table 1) were compared with their AABR test result. When an ear failed the overall DPOAE screening but passed the AABR, it mostly had a pass for the intermodulation products corresponding to $f1$ of 1593 Hz (84%),

Table 2
NICU babies with abnormal ABR thresholds

			Acoustic Impedance		
Patients	Side of ears	Diagnostic ABR Thresholds(dB)	Tympanogram	Ipsilateral acoustic reflexes	
				500 Hz	1000 Hz
Case 1	Left	80 dB nHL(severe)	A type	95 dB spl	100 dB spl
	Right	70 dB nHL(moderate)	A type	100 dB spl	100 dB spl
Case 2	Left	100 dB nHL(profound)	A type	++	++
	Right	60 dB nHL(moderate)	A type	95dB spl	++
Case 3	Left	100 dB nHL (profound)	A type	++	++
	Right	70 dB nHL(moderate)	A type	95 dB spl	100 dB spl
Case 4	Left	>100 dB nHL (profound)	A type	++	++
	Right	>100 dB nHL (profound)	A type	++	++
Case 5	Left	80 dB nHL(severe)	A type	100 dB spl	++
	Right	80 dB nHL(severe)	A type	100 dB spl	++
Case 6	Left	50 dB nHL(mild)	A type	85 dB spl	90 dB spl
	Right	30 dB nHL(normal)	A type	80 dB spl	80 dB spl

* ++ = absent.

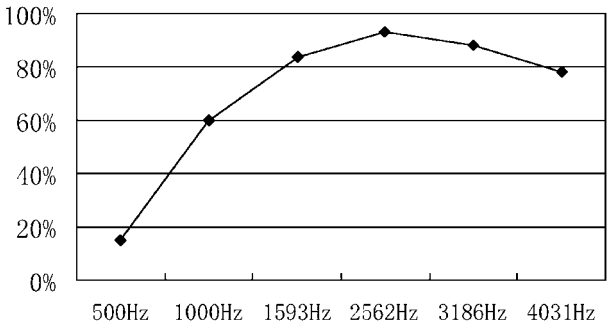

Figure 3
DPOAE frequency spectral analysis in the group of 23 ears passed AABR screening.

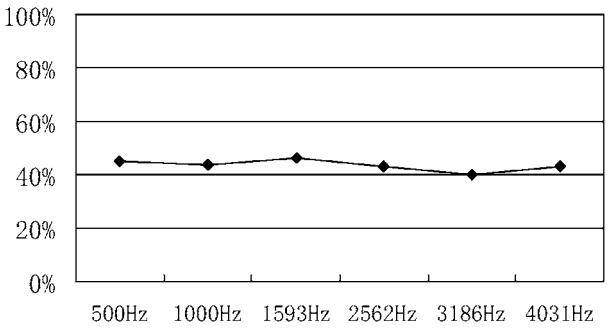

Figure 4
DPOAE frequency spectral analysis in the group of 15 ears referral AABR screening.

2562 Hz (93%), and 3187 Hz (88%) (Figure 3). When an ear failed both the overall DPOAE and AABR screening, it had slightly higher pass rates for the intermodulation products corresponding to low (500, 1000, and 1593 Hz) $f1$s than those corresponding to high (2562 Hz, 3187 Hz, and 4031 Hz) $f1$s (Figure 4). This suggests that the intermodulation products corresponding to 2565 Hz and 3187 Hz might be most useful for the purpose of hearing screening.

Discussion

Our two-step (DPOAE-AABR) screening protocol with NICU babies shows a refer rate of 4.5% and a false-positive rate of 1.5%. The false-positive rate is well below the suggested 3% of the American Academy of Pediatrics.[2] With the single session DPOA E screening, the refer rate (14.5%) and the false-positive rate (11.5%) were much higher.

In general, hearing screening based on a single screening session, irrespective of the used methodology (OAE versus ABR), yields high refer rates (5-20%). This is especially the case for NICU babies.[7] Introducing a second step in the screening protocol highly improves the specificity, probably without reducing sensitivity.[2] We are not aware of a study which reports the performance of a two-step, mixed methodology (DPOAE-AABR) screening protocol in the NICU. Performance of such a protocol, however, has been reported for normal babies; Vohr

et al.[6] reported a refer rate of 6.49%, which is slightly higher than our 4.5%. The wide range of reported refer rates suggests that factors suchs as training and motivation of the technicians, age of the screened infants, database management of the referred subjects, and ambient sound level are as important for the protocol performance as the type of screening methodology.[8,10]

This study demonstrates the effective implementation of a newborn hearing screening program. Two-step screening with DPOAE and AABR ensures high sensitivity and acceptable specificity. Our efforts identified six NICU babies who hopefully will benefit from early remediation of their hearing deficit.

References

1. Davis A, Wood S. The epidemiology of childhood hearing impairment: factor relevant to planning of services. *Br J Audiol*. 1992;26:77-90.
2. Erenberg A, Lemons J, Sia C, Trunkel D, Ziring P. Newborn and infant hearing loss:detection and intervention. American Academy of Pediatrics. Task Force on Newborn and Infant Hearing, 1998-1999. *Pediatrics*. 1999;103:527-530.
3. Yoshikawa S, Ikeda K, Kudo T, Kobayashi T. The effects of hypoxia, premature birth, infection, ototoxic drugs, circulatory system and congenital disease on neonatal hearing loss. *Auris Nasus Larynx*. 2004;31:361-368.
4. Yoshinaga-Itano C, Sedey AL, Coulter DK, Mehl AL. Language of early- and later-identified children with hearing loss. *Pediatrics*. 1998; 102:1161-1171.
5. Kok MR, van Zanten GA, Brocaar MP, Jongejan HT. Click-evoked otoacoustic emissions in very-low-birthweight infants: a cross-sectional data analysis. *Audiology.* 1994;33:152-164.
6. Vohr BR, Oh W, Stewart EJ, Bentkover JD, Gabbard S, Lemons J, Papile LA, Pye R. Comparison of costs and referral rates of 3 universal newborn hearing screening protocols. *J Pediatr*. 2001;139:238-244.
7. Jacobson JT, Jacobson CA, Spahr RC. Automated and conventional ABR screening techniques in high-risk infants. *J Am Acad Aud.* 1997;1:187-195.
8. Iley KL, Addis RJ. Impact of technology choice on service provision for universal newborn hearing screening within a busy district hospital. *J Perinatol*. 2000;20:S122-127.
9. Robinshaw HM. Early intervention for hearing impairment:differences in the timing of communicative and linguistic development. *Br J Audiol*. 1995;29:315-334.
10. Doyle KJ, Burggraaff B, Fujikawa S, Kim J, MacArthur CJ. Neonatal hearing screening with otoscopy, auditory brain stem response, and otoacoustic emissions. *Otolaryngol Head Neck Surg*. 1997;116:597-603.

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