A Comparative Study of the MB11 BERAphone and ABAER Automated Auditory Brainstem Response Newborn Hearing Screening Equipment

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OBJECTIVE

Twenty years ago, most infants and young children with permanent hearing loss were not identified until they were 2-3 years old.[1] According to the U.S. Department of Health and Human Services,[2] such late identification means that:

> . . . it is difficult, if not impossible, for many [children with congenital hearing loss] to acquire the fundamental language, social, and cognitive skills that provide the foundation for later schooling and success in society. When early identification and intervention occur, hearing impaired children make dramatic progress, are more successful in school, and become more productive members of society. The earlier intervention and habilitation begin, the more dramatic the benefits (p. 460).

The importance of identifying permanent hearing loss has been recognized for decades[3], but until recently the knowledge and technology for efficiently identifying infants and young children with permanent hearing loss were not available. These circumstances began to change in the mid-1980s with the development of new technology for hearing screening and diagnosis -- particularly the measurement in infants and young children of otoacoustic emissions (OAE) and automated auditory brainstem response (A-ABR),[4-6] and the implementation in the United States of population-based universal newborn hearing screening programs.[7] Based on the evidence about the feasibility and benefits of newborn hearing screening programs, the National Institutes of Health Consensus Development Conference[8] recommended In March 1993, the "screening of all newborns . . . for hearing impairment prior to discharge." Growing support for this recommendation was evidenced a few years later when the European Consensus Development Conference[9] concluded that the "Identification by screening at or shortly after birth has the potential to improve quality of life and opportunities for those affected . . . Implementation of neonatal screening programs should not be delayed."

The United States is now screening more than 95% of all newborns[10] and national universal newborn hearing screening programs have also been implemented in the United Kingdom, Poland, Austria and Singapore, among others.[11-14] Even developing countries such as South Africa, Nigeria, Brazil and India are seriously pursuing initiatives to screen infants and young children for hearing loss.[15-19]

It is widely acknowledged that improvements in hearing screening technology were the prime contributor to dramatically reducing the age at which hearing loss is being identified, but most people agree that this early hearing screening equipment was really not very good. In the first large scale clinical trial of universal newborn hearing screening that led to the recommendation of the NIH Consensus Development Conference that all newborns be screened for hearing loss, 26% of the newborns failed the screening test by the time they were discharged from the hospital and more than 6% were eventually referred for a diagnostic evaluation.[7] Screening done with A-ABR

during that time period also had extremely high referral rates viewed from today's perspective (for example, Mehl and Thomson[20] reported that 7% of infants were referred for diagnostic evaluations from the statewide newborn hearing screening program in Colorado).

Not surprisingly, attention continues to be focused on improving the equipment and techniques used to screen infants and young children for hearing loss.[21-25] Much of the current concern about screening equipment focuses on ways to make the process more efficient and less costly with respect to both the cost of the equipment and the cost of consumable supplies, without giving up any accuracy.

A recommendation from several previous studies for improving efficiency and reducing cost of newborn hearing screening is the use of an automated device for measuring ABR known as the BERAphone or MB11[24,26-28] According to the user manual available at www.beraphone.com:

> Traditionally, the EEG for brainstem audiometry was obtained by sticking electrodes to the head of the (neonatal) patient. The patented BERAphone® has spring-mounted, stainless-steel electrodes, headphone, and preamplifier integrated in one unit which only has to be held against the (neonatal) patient's head after the contact points on the head have been rendered more conductive by the application of electrode gel. The time consuming procedure of sticking electrodes to the head with all the preparation is not necessary anymore. Because of the use of permanent electrodes, no disposable electrodes are required; the costs of use are minimal (only some electrode gel).

Previous studies evaluating the MB11 for use in newborn hearing screening programs have been uniformly positive. For example, Stürzebecher, Cebulla, and Neumann[26] evaluated 114 infants with the BERAphone to determine the best click rate for use of this device in newborn hearing screening programs. They concluded that the BERAphone was an accurate and efficient device for hearing screening and that it was much faster than other ABR equipment.

Melagrana and his colleagues[27] compared results of the MB11 BERAphone with conventional diagnostic ABR for 201 "newborns." They concluded that, "The results obtained confirm the absolute validity of MB11 screening test in subjects at audiologic risk." Shehata and colleagues[28] tested 1349 newborns with an early version of the MB11 BERAphone and found 5 infants with permanent hearing loss. They concluded that it was "a quick and easy method with high specificity that can be recommended for newborn hearing screening." Meier and colleagues[24] evaluated the efficiency and costs of 3 different ABR hearing screening devices (the Fisher-Zoth Echoscreen –TDA, the Algo 3, and the MB11 BERAphone) by using each of the instruments with 50 different newborns. They concluded that all of the devices were appropriate to "be used for newborn hearing screen."

Although each of these articles concluded that the MB-11 BERAphone is a good choice for operating a newborn hearing screening program, none of them compared the results on the MB11 with the results of a typically used newborn hearing screening device. The closest was a study which compared MB11 results with the results of a conventional diagnostic ABR test,[27] but, in addition to not comparing the MB11 with screening equipment, this study was done with children who averaged 6 months of age, some of the children were sedated with chloral hydrate and all of the data were collected in a soundproofed room --- thus, it was not at all typical of what happens in newborn hearing screening programs.

Given the fact that previous studies have not compared the results of the MB11 BERAphone with currently used screening equipment for the same babies in a typical newborn hearing screening settings, the objective of this study was to compare the results of the MB11 with the results of the Biologic ABAER -- a widely used newborn hearing screening device marketed by Natus Medical Inc. (www.natus.com). All data were collected as a part of a well-established newborn hearing screening program in the same setting and using the same screening personnel who were working in the program so that the results would be as comparable as possible with what happens in "real-life."

METHODS

Data for the study were collected from August of 2006 through July 2007 for 290 newborns in a hospital in the western United States that had operated a successful universal newborn hearing screening program for more than 10 years. The hospital has approximately 4,000 births per year and has a well-baby nursery and a level III neonatal intensive care unit (NICU). Prior to the commencement of the study, hearing screening for approximately 99% of the newborns in this hospital was completed using otoacoustic emissions (OAE) equipment (Otodynamics Ltd) as a first stage screening and an automated auditory brainstem response (A-ABR) testing using the ABAER equipment for all babies in the well-baby nursery who failed the OAE test. Prior to the study, babies in the NICU were tested with both the OAE and the ABAER equipment.

The goal of the study was to compare the screening results of the MB11 and the ABAER with a sample of newborns in which each baby was screened with both devices. The MB11 equipment in the study used an automated detection algorithm and a novel, more efficient, broad-band stimulus (CEChirp™) with a calibrated stimulus level of 35 dBnHL[29-31] that was different from the algorithm used in previous studies with the MB11.[24, 26-28]

All babies who failed either the MB11 or the ABAER were to be followed up with diagnostic audiologic testing to determine his or her hearing status. Babies were selected and an invitation to participate in the study given to parents so that about 50% of the sample would include babies who had failed the initial OAE screening test and about half would be babies who had passed the initial OAE. Over representation of

babies who failed the initial OAE screening test was done to increase the number of newborns in the sample who had congenital hearing loss.

The hospital's Institutional Review Board (Ethics Committee) reviewed and approved the study but did not require parents to provide written consent since the study was considered a part of the hospital's ongoing quality improvement process. The order of testing was randomly alternated between the MB11 and the ABAER. Results for each baby on each test along with information about the order of testing, time to do testing, and brief demographic information about the baby was recorded on a form designed specifically for this study.

Data was collected by six different screeners who had been screening babies in this hospital using the OAE and ABAER equipment for at least three years. Screeners were trained by their supervisor who had been trained in using the MB11 equipment by a representative of MAICO. Following this training, each of the screeners did screening on at least 25 infants with the MB11 equipment. These infants were not enrolled in the study. A second training session was then conducted by a representative from MAICO who observed each of the screeners doing the MB11 testing, gave feedback, and confirmed that all the screeners were using the equipment correctly and competently.

Babies enrolled in the study had each ear tested with both the ABAER and the MB-11. The equipment used first for each baby was alternated (49.3% of the ears were tested first with the ABAER, and 50.7% were tested first with the MB11). If an ear did not pass the ABAER or MB-11 on the first attempt, a second attempt was made to rule out poor placement of earphone or probe. If the ear still did not pass for that piece of equipment, that ear was considered to have failed the screen.

Each screener was provided with a stop watch to time how long it took to do a screen for each ear with each piece of equipment. Screening time did not include transporting the baby to the location where testing was to be done, but did include the time the screen took for each ear including quieting the baby, documenting results, second attempts at screening when necessary, and other related activities. Times were recorded on the data sheet for each ear for piece of equipment.

The screener also recorded the baby's "state" at the time of testing for each ear on each piece of equipment using the following rating scale:

- Sleeping peacefully during test
- Awake, but relatively quiet during test
- Somewhat fussy during test
- Very fussy during test

The final sample consisted of 290 newborns who had been tested on both ears with OAE and were then screened with both the ABAER and the MB11 in random order. In almost all cases (>95%), the screener completed both tests during the same session. In a few cases where the session had to be interrupted, a different screener completed the

second test, but this was rare. Of the 290 babies, 45.6% were female and 54.4% were male. The mean birth weight was 6 pounds 9 ounces (range 3 lbs 10 oz to 9 lbs 6 oz), gestational age ranged from 36 to 41 weeks with a mean of 38.8 weeks, and 87 of the 290 babies (30%) had spent some time in the NICU. A disproportional number of NICU babies were included in the sample to increase the probability of having some babies with permanent hearing loss in the sample.

RESULTS

Table 1 shows the number of babies included in the sample who failed or passed the initial OAE screening, were tested first by each piece of equipment, and the "state" of the baby during the ABAER or MB11 test. As can be seen, pass rates were very similar for each piece of equipment across the levels of initial OAE Screening Result and Order of Testing, but quite different (as would be expected) for the State of the Baby During ABR Testing. There was also a statistically significant interaction for the percentage of babies passing between screening device and State of Baby During ABR Testing ($p<.05$) indicating that higher pass rates can be achieved with the MB11 when babies are "fussy." These findings should be interpreted with caution however, since relatively few "fussy" babies were included in the study.

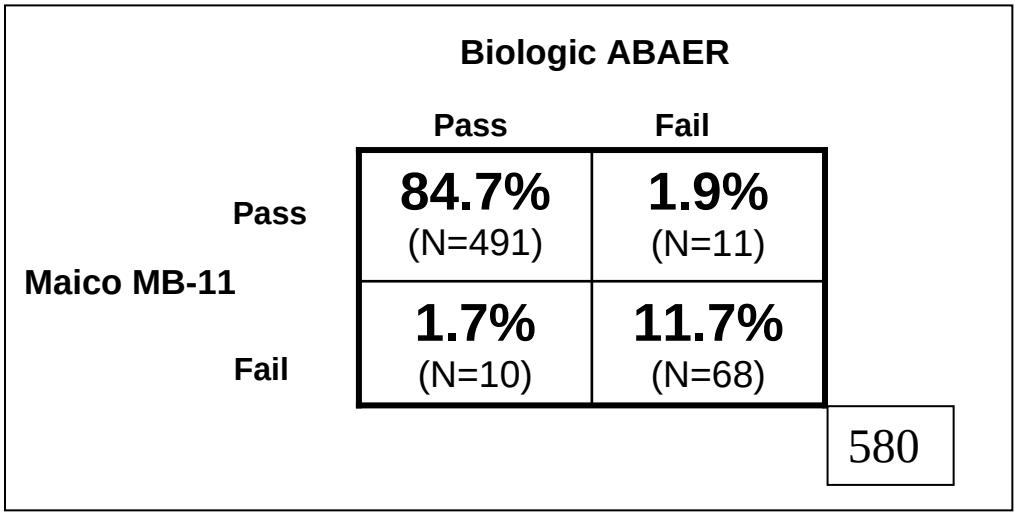
Table 1. Percent of ears passing the MB11 and ABAER for selected sample characteristics

		MB11	ABAER
All Babies		**86.6%** (n=502/580)	**86.5%** (n=501/580)
Initial OAE Screening Result	Pass	**97.0%** (n=263/271)	**98.5%** (n=267/271)
	Fail	**77.3%** (n=239/309)	**75.7%** (n=234/309)
Test given first	ABAER	**87.8%** (n=251/286)	**88.5%** (n=253/286)
	MB11	**85.4%** (n=251/294)	**84.4%** (n=248/294)
State of Baby During ABR Testing	Sleeping peacefully during test	**94.3%** (n=217/230)	**90.5%** (n=191/211)
	Awake, but relatively quiet during test	**81.1%** (n=193/238)	**86.9%** (n=252/290)
	Somewhat fussy during test	**87.0%** (n=80/92)	**80.9 %** (n=55/68)
	Very fussy during test	**60.0%** (n=12/20)	**27.3%** (n=3/11)

Figure 1 shows the agreement between the screening results for the MB11 and the ABAER for the 580 ears of the 290 newborns who were included in the study. As can be seen, 96.4% of the ears had the same result (84.7% that passed both, plus 11.7% that failed both). The results were very similar when the data were divided into those for whom the MB11 or the ABAER was administered first and those where the baby had passed or failed the initial OAE screening test.

Testing time for the ABAER and the MB11, which included prepping the baby, doing the screening test and documenting the results, was moderately correlated (r=.29). The MB11 testing time was statistically significantly shorter (t=43.8, p<.001) than the ABAER. Mean testing time per ear was 6 minutes and 52 seconds for the ABAER and 2 minutes and 17 seconds for the MB11 (median testing time was 5 minutes 55 seconds for the ABAER, and 1 minute 51 seconds for the MB11).

Figure 1. Comparison of MB11 and ABAER Screening Results



It is particularly important to know whether any newborns who failed the MB11, but passed the ABAER; or who passed the MB11 but failed the ABAER were eventually diagnosed with permanent hearing loss. Table 2 shows the results of the follow-up diagnostic testing which was available for 80 of the 87 (91.9%) ears of the babies who failed one or both of the tests and survived the neonatal period. As can be seen, all of the babies later diagnosed with hearing loss failed both the ABAER and the MB11.

Table 2. Diagnostic Testing Results of Newborns who Failed Either the ABAER or the MB11

Results of Follow-up Diagnostic Testing	Results of Screening Test: ABAER: Pass MB11: Fail	ABAER: Fail MB11: Pass	ABAER: Fail MB11: Fail
Normal hearing	9	10	53
Hearing Loss	0	0	8
Deceased prior to Dx	0	0	2
Lost to Follow-up	1	1	5
TOTAL	10	11	68

CONCLUSIONS

Screening results of the MB11 were comparable to those of the Biologic ABAER (one of the most widely used devices for newborn hearing screening in the United States) in terms of overall agreement and refer rates. Testing with the MB11 required less than one-third the time and the fact that no disposable supplies are needed for the MB11 (except for a small amount of electrode gel) means that the operational cost for doing automated ABR cost is substantially lower than with other typically used equipment.

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