A COMPARISON OF AUTOMATED AUDITORY BRAINSTEM RESPONSE (AABR) WITH INTEGRATED ELECTRODES AND OTOACOUSTIC EMISSIONS (OAEs) IN HIGH RISK NEWBORN HEARING SCREENING

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"Anything is possible to a willing heart."

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ABBREVIATIONS

ABR	Auditory Brainstem Response
AABR	Automated Auditory Brainstem Response
AD	Auditory Dyssynchrony
APGAR	Appearance, Pulse, Grimace, Activity, Respiration
AN	Auditory Neuropathy
DB	Decibel
DP	Distortion Product
DPOAEs	Distortion Product Otoacoustic Emissions
ORL	Otorhinolaryngology
G	Gram
HREC	Human Research Ethics Committee
HUSM	Hospital Universiti Sains Malaysia
IQR	Inter Quartile Range
JCIH	Joint Committee on Infant Hearing
NHS	Neonatal Hearing Screening
NICU	Neonatal Intensive Care Units
OAEs	Otoacoustic Emissions

PASW	Predictive Analytics Software
PC	Personal Computer
UNHS	Universal Neonatal Hearing Screening
SPSS	Statistical Package of Social Science
SNHL	Bilateral Sensorineural Hearing Loss (SNHL)
TEOAEs	Transient Evoked Otoacoustic Emissions
TORCH	Toxoplasma, Others (syphilis), Rubella, Cytomegalovirus, Herpes

ABSTRAK

TAJUK

Perbandingan Antara "Automated Auditory Brainstem Response *(AABR)"* dan "Integrated Electrodes and Otoacoustic Emissions *(OAEs)*" Dalam Saringan Pendengaran Di Kalangan Bayi Yang Berisiko Tinggi di Hospital Universiti Sains Malaysia (HUSM)

OBJEKTIF

Untuk membandingkan keputusan saringan pendengaran menggunakan AABR (melalui mesin MB11 BERAphone) dan "Integrated Electrodes dan Otoacoustic Emissions (OAEs)" di kalangan bayi yang berisiko tinggi dalam HUSM

TATACARA

Saringan pendengaran ini dilakukan dalam kajian keratan rentas. Seramai 195 bayi yang berisiko tinggi memenuhi kriteria- kriteria yang telah ditetapkan terlibat di dalam kajian ini. Bayi yang berisiko tinggi dalam masalah pendengaran diuji menggunakan mesin OAEs dan diikuti dengan mesin MB11 BERAphone di wad yang sama dan dilakukan setelah pesakit yang telah dirawat di wad disahkan sihat dan boleh didiscaj dari hospital. Kedua – dua mesin ini akan menghasilkan signal "lulus" atau " rujuk" sebagai keputusan. Keputusan yang telah dikeluarkan tidak memerlukan sebarang kemahiran yang canggih untuk dianalisa.

Keputusan yang dibuat oleh kedua – dua mesin ini sebagai " rujuk" akan disaringkan sekali lagi dengan menggunakan mesin ABR untuk menentukan keputusan muktamad. Masa akan direkodkan semasa ujian saringan pendengaran oleh kedua – dua mesin tersebut bagi tujuan analisa. Bagi mengurangkan ketirisan semasa penggunaan kedua -dua mesin tersebut, kami menyediakan dua orang penganalisa yang akan membuat saringan ke atas pesakit.

KEPUTUSAN

Seramai 195 bayi (87, 44.6% adalah lelaki dan 108, 55.4% adalah perempuan) terlibat dalam kajian ini. Risiko kesan sampingan ubat adalah yang paling ramai (51.8%) diiringi dengan kesan penyakit kuning (51.3%) dan berat lahir < 1500g (27.2%). MB11 BERAphone mempunyai markah tertinggi bagi lulus ujian saringan pendengaran (89.8%) berbanding dengan OAEs sebanyak (85.2%). MB11 BERAphone mempunyai peratus yang sedikit bagi ujian saringan yang "rujuk" iaitu 10.2% berbanding OAEs adalah 14.8%. Ini menunjukkan perbezaan saringan pendengaran diantara kedua - dua ini adalah tercapai. Bagi "true negative" untuk MB11 BERAphone adalah (29.4%) lebih tinggi berbanding OAEs iaitu (11.8%). "False negative" MB11 BERAphone adalah (5.9%) dan OAEs adalah (0.0%). Daripada 195 bayi, seramai 182 (93.4%) bayi menunjukkan kesepakatan di antara kedua - dua mesin saringan pendengaran ini dan seramai 13 (6.6%) bayi tiada kesepakatan. Dari situ, sasaran kesepakatan tercapai (kappa = 0.698, $p<0.001$). Ujian masa bagi saringan pendengaran yang telah dilakukan oleh kedua - dua mesin menunjukkan MB11 BERAphone adalah lebih kurang 5 minit (IQR: 25^{th}-75^{th}) dan OAEs adalah lebih kurang 2 minit (IQR: 25^{th}-75^{th}). Ini menunjukkan perbezaan masa di antara kedua – dua mesin tercapai ($p = <0.001$).

KESIMPULAN

Kesimpulannya, saringan pendengaran menggunakan MB11 BERAphone adalah sesuai digunakan semasa ujian saringan di kalangan bayi –bayi yang berisiko tinggi. Walaupun terdapat keputusan “false negative” menggunakan MB11 BERAphone dan kemungkinan keputusan tersebut tidak tepat disebabkan beberapa faktor yang mempengaruhi keputusan tersebut. Terdapat kesepakatan di antara dua mesin tersebut. Walau bagaimanapun, masa yang diambil oleh MB11 BERAphone untuk membuat ujian saringan pendengaran setiap bayi mengambil masa yang agak lama berbanding dengan OAEs. Kami mencadangkan OAEs dan MB11 BERAphone boleh digunakan bagi peringkat pertama ujian saringan pendengaran, kemudian bayi boleh disaringkan sekali lagi melalui ABR sekiranya keputusan saringan pendengaran adalah “rujuk” pada peringkat pertama.

ABSTRACT

TITLE

A Comparison of Automated Auditory Brainstem Response *(AABR)* with Integrated Electrodes and Otoacoustic Emissions *(OAEs)* in High Risk Newborn Hearing Screening in Hospital Universiti Sains Malaysia.

OBJECTIVE

To compare the outcome between AABR (by using MB11 BERAphone method) and Integrated Electrodes and Otoacoustic Emissions (OAEs) in high risk newborn in Hospital Universiti Sains Malaysia.

METHODS

This is an observational study which is a cross-sectional study design involving two methods in the same subject. A total of 195 high risk newborn and who have fulfilled the inclusion and exclusion criteria will be participate in our study. These high risk babies were subjected to OAEs and followed by an MB11 BERAphone screening test at the same setting as near to discharge as possible or once the patient is stable enough to do a hearing screening. Both instruments produced a "pass" or "refer" result and did not require any special skills for the interpretation of results. The "refer" result from OAEs and MB11 BERAphone will be screened using ABR to determine the false positive. The time will be measured by total staff time spent on each instrument. To minimise the measurement bias, two testers will be used to handle both screening methods.

RESULTS

There were 195 newborns (87, 44.6% boys and 108, 55.4% girls) who participated in this study. Ototoxic medication was the most common risk factor (51.8%) followed by hyperbilirubinaemia (51.3%), and birth weight <1500g (27.2%). MB11 BERAphone had a higher passing rate (89.8%) as compared to OAEs (85.2%). MB11 BERAphone had a lower refer rate (10.2%) compared to OAEs (14.8%). These differences are statistically significant. The true negatives are MB11 BERAphone (29.4%) and OAEs (11.8%). False negative MB11 BERAphone (5.9%) and OAEs (0.0%). Out of 195 newborns examined, 182 (93.4%) showed agreement between the two techniques, whereas in 13 (6.6%) there was no agreement. Inter-observer agreement was good (kappa = 0.698, p=<0.001). The median test time that was done for each newborn using MB11 BERAphone was 5 minutes (IQR: 25^{th}-75^{th}) and OAEs was 2 minutes (IQR: 25^{th}-75^{th}). The difference were statistically significant (p = <0.001).

CONCLUSION

The MB11 BERAphone is still a reliable device for auditory brainstem response among high risk newborn hearing screening. In the presence of false negative in MB11 BERAphone, it might not really be significant in this study due to a few factors affecting the result. Both agreements were good. However, the duration of time for hearing screening for each newborn took a significantly longer time compared to OAEs. Therefore, we recommend that both methods can be used as a first screening, followed by a screening using ABR for those whose result was “refer” from the first screening.

1. INTRODUCTION

CHAPTER 1

1. INTRODUCTION

Hearing is the ability to perceive sound by detecting vibrations. Hearing is performed primarily by the auditory system in which mechanical waves, known as vibrations are detected by the ear and transduced into nerve impulses that are perceived by the brain (primarily in the temporal lobe). Hearing loss is a partial or total inability to hear. Hearing loss may occur in one or both ears. In children hearing, problems can affect the ability to learn spoken language later on when they grow. So it is important to detect earlier which of these babies are on the high risk of hearing impairment.[1]

Early diagnosis and intervention are necessary for social and linguistic development in children with congenital hearing loss. The Universal Newborn Hearing Screening (UNHS) has proven beneficial in detecting hearing impairment shortly after birth and with adequate habilitation, it gives the child a better chance of normal development. Many techniques are used for the evaluation of hearing sensitivity and among them we have Integrated Electrodes Otoacoustic Emissions (OAEs) and also automated auditory brainstem response (AABR).[2]

Otoacoustic emissions (OAEs) hearing screening is used widely in hospital-based newborn hearing screening programs. Otoacoustic emissions (OAEs) screening can help to detect sensorineural hearing loss occurring in the cochlea. It can also call attention to hearing disorders affecting the pathway to the inner ear. The procedure is performed with a portable handheld screening unit. A small probe is placed in the child's ear canal. This probe delivers a low-volume sound stimulus into the ear. The cochlea responds by producing an otoacoustic emission, sometimes described as an “echo,” that travels back through the middle ear to the ear canal and is analysed by the screening unit. The otoacoustic emissions (OAEs) screening

performed by White et al (1993) on 1,850 neonates showed a sensitivity of around 100% and a specificity of 73%.[1]

The automated auditory brainstem response (AABR) screener is a dedicated hearing screening device which provides information not only about the outer/middle ear and cochlea but also about the auditory pathway up to the brainstem. AABR screening is highly sensitive. The screening is based on the measurement of synchronous activity in the auditory nerve up to the colliculus inferior in the brainstem as a reaction to click stimuli delivered to the ears. It is useful in infants at risk of hearing impairment, including those admitted to a Neonatal Intensive Care Unit (NICU).

MB11 BERAphone is one of the automated auditory brainstem response (AABR). The MB11 BERAphone is a more recently developed hearing screening device. MB11 BERAPhone is the only automatic ABR screener without adhesive electrodes. The click stimulus used simultaneously reaches cochlear areas generating a more robust and faster auditory response compared to normal AABR clicks. The MB11 BERAphone test showed very good specificity 96.8% and sensitivity 100%.[3]

Auditory Brainstem Response (ABR) is the gold standard test, which is essential to a correct neonatal screening programme both in patients not passing the test with otoacoustic emissions (OAEs) and automated auditory brainstem response (AABR). The auditory brainstem response (ABR) reflects the function of the entire auditory pathway up to the brainstem. While both ABR and the alternate screening technology of otoacoustic emissions (OAEs) detect cochlear hearing loss, only ABR detects auditory neuropathy.

However, it has some drawbacks such as high cost, difficult instrument transportation, long execution time, and a need for qualified personnel to interpret the ABR. This study is conducted due to there being only a few research studies done about the comparison of MB11 BERAphone with OAEs. So far, there is no research study done in Malaysia comparing both of these instruments.

2. LITERATURE REVIEW

2. LITERATURE REVIEW

2.1 UNIVERSAL NEONATAL HEARING SCREENING

The ear is one of the important parts of the body in which to function as hearing. Hearing is one indicator for a baby to grow as a normal child in terms of cognitive development, as well as neurodevelopment. Early neonatal hearing screening was developed all over the world to prevent late detection of hearing impairment. Thus, hearing screening was done during the neonatal period. Hearing loss may have significant adverse effects on the development of speech, language capabilities and social - emotional development, as well as leading to worsening educational and occupational performance in adulthood. Regular physical examinations cannot detect hearing loss, so neonatal hearing screening (NHS) is necessary. Hearing loss may be sensorineural or conductive, permanent or transient, unilateral or bilateral and of varying severity. Infants with moderate or worse (>40 dB) bilateral sensorineural hearing loss (SNHL) have heightened risk of poor speech and language development outcomes if hearing augmentation/intervention programs are not implemented promptly.[4]

The incidence of permanent hearing impairment in newborns ranges between 1.0% and 5.5% across regions and countries.[5] Many studies have illustrated the validity and reliability of Universal Neonatal Hearing Screening (UNHS) programs in the early detection of newborn hearing impairment. More importantly, newborns with hearing loss that is detected early can receive intervention before 6 months of age, which is critical in allowing them to develop linguistic, cognitive and logical abilities on par with normal infants. Because of their feasibility and effectiveness, Universal Neonatal Hearing Screening (UNHS) programs have been implemented in many countries all over the world; its coverage rate is one of the most important indicators to evaluate the impact of these programs.[5]

2.2 NEONATAL HEARING SCREENING AMONG HIGH RISK NEWBORN

In most countries, newborn hearing screening programmes that screen only high-risk infants have been in existence for more than 20 years. However, this group of infants with hearing loss comprises only 50% of newborn population with hearing loss. Therefore, hearing screening programs that screened only high-risk neonates missed out 50% of hearing impaired newborns, who are from among infants without any risks factors. The prevalence of hearing loss is estimated to be between 2.5% and 10% among high-risk infants.[1]

The risk factors of hearing loss in neonates were first documented in 1994 and then revised in 2000 by the Joint Committee on Infant Hearing (JCIH). The newborn high risk group included infants who had asphyxia (low APGAR score, 0–4 at 1 minutes or 0-6 at 5 minutes), meningitis, congenital or perinatal infections, anatomic defects or stigmata, hyper bilirubinemia, a family history of hearing loss, low birth weight, ototoxic medications, syndromes known to be associated with hearing loss and neonatal illnesses requiring mechanical ventilation.[6,7] Other risk factors have been tested, such as maternal drug abuse, persistent high pulmonary pressure, intra-ventricular haemorrhage, high C reactive protein levels but were not proven to be significant.[7]

High risk newborns can be divided into congenital and acquired hearing loss. Mostly, they have hearing impairment at birth and are potentially identifiable by newborn and infant hearing screening. The risk factors for congenital hearing loss such as craniofacial anomalies, syndromes related with hearing loss, a family history of hearing loss, premature baby and in utero infection. However, some congenital hearing loss may not become evident until later in childhood. Hearing impairment can also be acquired during neonatal or infancy period for various reasons. Examples of babies who are at high risk of acquired hearing loss are those

who suffer from such conditions such as meningitis, otitis media, mechanical ventilation, hyper bilirubinaemia and ototoxic medications.[8]

2.3 SCREENING TEST AND EQUIPMENT

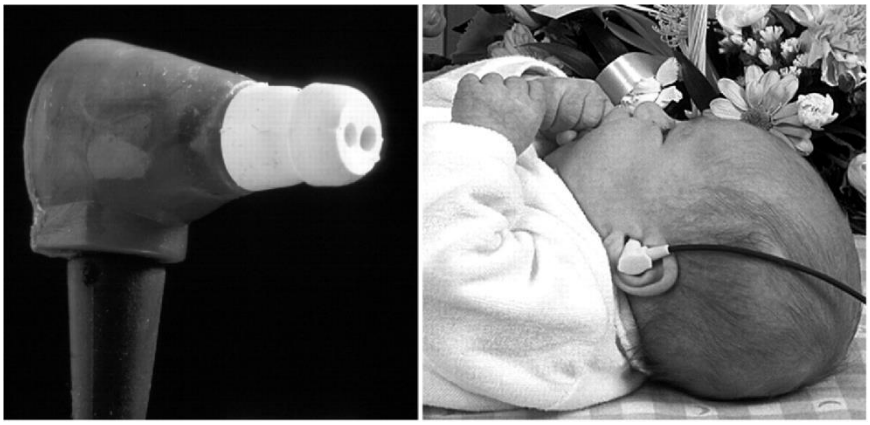
The ideal screening test would have a high sensitivity and a high specificity. A high sensitivity is particularly important to enable catching up on all infants with significant hearing loss without a delay in the diagnosis of hearing impairment. A high specificity is required, as a false positive result could lead to much workload on the diagnostic services (over referrals) and undue parental anxiety.[6] Two objective methods were used in most universal hearing-screening programs. They are automated otoacoustic emissions (OAEs) and automated ABR (AABR). They are available as handheld portable equipment with a pass or fail criterion. In this study, we are using MB11 BERAphone as an AABR and comparing it with otoacoustic emissions (OAEs). The Auditory Brainstem Response (ABR) is still the gold standard test, which is essential to correct neonatal screening programme both in patients not passing the test with otoacoustic emissions (OAEs) and automated auditory brainstem response (AABR), MB11 BERAphone.[9]

2.3.1 Integrated Electrodes and Otoacoustic Emissions (OAEs)

OAEs are used to assess cochlear integrity and are physiologic measurements of the response of the outer hair cells to acoustic stimuli. They serve as a fast objective screening test for normal preneural cochlear function through the use of probe in the ear canal.[6] The presence of normal responses in an OAEs test is a strong predictor of a full hearing function. The procedure of OAEs suppression allows for a functional investigation of the efferent

olivocochlear system, which plays an important role in auditory information processing.[10] The sensitivity and specificity of the OAEs were found to be 90% and 92.4% when compared to ABR results and 90.9% and 91.1% when compared to the children's hearing status, respectively.[11]

Currently, two types of evoked OAEs measurements are used for newborn hearing screening, transient evoked otoacoustic emissions (TEOAEs) and distortion product otoacoustic emissions (DPOAEs). DPOAEs measurements are better suited to advanced clinical investigation on adult patients, even though DPOAEs analysis is complex and interpretation is difficult. The distortion product (DP) technique is more flexible and potentially more powerful than TEOAEs analysis, having a wider useful frequency range. Waveform based TEOAEs measurements, as originally used in universal newborn hearing screening programmes, are also useful as a sensitive initial screen prior to full clinical examination. TEOAEs are also more sensitive to cochlear status changes manifested in subtle changes in the TEOAEs waveform. DPOAEs instruments can be used for screening with an appropriately low stimulus level, but DPOAEs screening instruments are generally not flexible enough for clinical applications.[12]



A B

Figure 2.1: (A) TEOAEs probe containing miniature sound source and microphone transducers. The soft disposable tip carries sound ports for the stimulus and for the microphone. DPOAEs probes have an additional stimulus port. In some probes, all ports feed a single sound tube. (B) The probe needs to be deeply inserted in the ear canal for maximum OAEs capture and noise exclusion, with the cable positioned so as to avoid noise production on movement.[13]

2.3.2 MBII BERAphone

As we know there are two methods commonly used in universal newborn hearing screening: Otoacoustic emissions (OAEs) and automated auditory brainstem response (AABR), both methods being automated. AABR is superior to OAEs, among the screening tests, because the AABR will be able to identify retrocochlear hearing impairments, such as auditory neuropathy which are missed out on OAEs screening. The AABR test uses a series of click sounds at 35 dB hearing level and detects brainstem responses to these stimuli. AABR has also been found to be time and cost effective, with a high sensitivity and a low failure rate.[14]