International Journal of Otorhinolaryngology and Head and Neck Surgery
Chatterjee I et al. Int J Otorhinolaryngol Head Neck Surg. 2023 Aug;9(8):613-619
http://www.ijorl.com
pISSN 2454-5929 | eISSN 2454-5937

DOI: https://dx.doi.org/10.18203/issn.2454-5929.ijohns20232216

Original Research Article

Multistage standardization of Beraphone and OAE on neonates

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Received: 21 May 2023
Revised: 09 July 2023
Accepted: 10 July 2023

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ABSTRACT

Background: Universal newborn hearing screening is a strategy to identify children with all kinds and degrees of hearing impairment, to lower the age at the time of diagnosis for early hearing amplification, to maximize their linguistic competence and literacy development.
Methods: This study was conducted over the period of 9 months on 200 newborns selected from well-baby nursery and 30 infants from the SNCU unit of the hospitals to obtain field evidence of newborn hearing screening in Indian context by using TEOAE and AABR tests of MAICO easy screen beraphone instrument as well as to standardize the instrument. The process was carried out in different phases at different state government hospitals and the data was collected from the different departments of the hospitals. The obtained data were transferred to an excel spreadsheet. Then the nonparametric Mann-Whitney U test and Wilcoxon Signed rank test were done by using SPSS software version 21. The detailed analysis was done for the age, sex and ear specific values.
Results: The results showed a significant difference not only between well-baby and SNCU but also between left and right ear. It is represented both in the tabular and graphical way to explain the findings in detail.
Conclusions: It can be stated that the MAICO easy screen beraphone instrument can be used for clinical and further research purposes related to newborn hearing screening suitable for infants up to 3 months of age because of its high sensitivity and specificity value.

Keywords: Newborn hearing screening, AABR, OAE, MAICO instrument, SNCU, Well-baby

INTRODUCTION

Hearing is so critical to the normal development and acquisition of language that we review pre-lingual hearing loss, which is either present at birth or begins before the age of five years, when language has normally been acquired. Universal newborn hearing screening (UNHS, 2004) is a strategy that enables to identify congenital deafness and hearing loss. Based on the World Health Organization (WHO) hearing screening guidelines, successful screening would include the availability of accurate, reliable screening tool(s); demonstration of earlier diagnosis; consideration for adverse effects of screening; evaluation of the availability and effectiveness of earlier intervention following diagnosis; consideration of the adverse effects of earlier intervention; and

evaluation of the longer-term outcomes from earlier diagnosis and intervention.[1] Significant hearing loss if undetected will impede speech, language and cognitive development. Significant bilateral hearing loss is present in 1 to 3 per 1000 new born infants in the well-baby nursery population and in 2 to 4 per 100 infants in the intensive care unit population in India. It is an established fact that if hearing loss is present it should be detected and remediated before the baby is 6 months old. Neither universal screening nor a high risk screening exists in majority of the hospitals in our country. In such a situation, a centralized facility catering to all hospitals in the city is a practical option. It is the practicability of this program that makes it relevant for replication in other cities of the country, making it a model screening program for any developing country.[2]

The American academy of pediatrics task force on newborn and infant hearing recommends UNHS by 3 months of age with intervention by 6 months of age. The joint committee on infant hearing (JCIH) position statement provides guidelines that include Newborn Hearing Screening (NHS) soon after birth, before discharge from hospital, or before 1 month of age, diagnosis of hearing loss through audiological and medical evaluation before 3 months, and intervention through interdisciplinary programme for infants with confirmed hearing loss before 6 months of age.[3,4] A study was done on NHS Program in the State of Tamil Nadu, India to know the performance levels, strengths and weaknesses to provide suggestions for building effective future programs.[5] They had found that TEOAE was the preferred test in the screening program. NHS protocol was found to be variable at each site and for each patient. The time between second screening and diagnostic testing went up to 3-6 months. However, there was a lack of organized system for documenting the program outcome. A prospective study on the NHS program for all infants, irrespective of risk factors for better detection and timely intervention aimed to estimate the incidence of hearing loss among the high risk groups.[6]

The total number of 26,487 neonates were underwent hearing screening using four stage protocols with OAE tests and final confirmation with BERA tests. They found the incidence of hearing loss among high risk group was 0.188/1000, and among the non-risk group was 0.528/1000. The investigators further recommended implementing NHS as a mandatory program along with multi-staged protocol based screening for hearing loss which will help in initiating treatment at an early stage to prevent further damage.

As per the American speech and hearing association, screening programs target permanent childhood hearing loss irrespective of type.[7] Passing a screening does not mean that a child has normal hearing across the frequency range. Because minimal and frequency-specific hearing losses are not targeted by NHS programs, newborns with these losses may pass a hearing screening leading to interference with the speech, language, and psycho-educational development of children. Monitoring of hearing, speech, and language milestones throughout childhood is essential.

Unfortunately, hearing loss is often not detected until a child is more than 2 years old, especially in rural areas due to poor awareness about deafness and its relation with speech and language development as well as lack of infrastructure such as the non-availability of ENT surgeon, audiologist, audiological equipment, and speech therapist. Parents can assess hearing of their child at home if there is adequate awareness to check it.[8] Study showed the awareness was poor among the mothers; and the sources of information on NHS were antenatal clinic, mass media and friends. The awareness of factors affecting hearing loss, were very low.[9] For instrumental analysis there are two screening methods that may be used are AABR & OAE. AABR is a dedicated hearing screening device.[10] It has an agreement with conventional ABR up to 98%. It uses a 35 dB near hearing level click.

The time necessary for screening varies with the setting, but ranges from 4 to 15 min. As part of the audiological diagnostic test battery, OAEs can contribute to differential audiological diagnosis, to monitor the effects of treatment and can be helpful in the selection of hearing aids and of surgical options.[11] A study in the support of the NHS was done on 370 infants, from both low and high risk groups before postnatal discharge using three tests: standard ABR, automated analysis of ABR, and automated analysis of evoked OAE which showed Automated OAE was the most sensitive test for subsequently confirmed hearing impairment.[12]

A study was carried out in a tertiary care teaching hospital over a period of 12 months on 1000 babies including 693 normal and 307 high-risk babies who underwent OAE test within the first 3 days of birth. Those who failed in this test underwent repeated OAE after 6 weeks, followed by BERA. It was concluded that a proper protocol and methodology is required for the early detection of hearing loss so that rehabilitation can be started at the earliest.[13] Many developed countries have well established UNHS programs. In India, the viability of such a program, in an already overburdened health system is indeed a challenge.

The importance of the introduction of screening for congenital deafness in specialized centres in India, despite its challenges, has been reflected in a pilot study which was undertaken to evaluate the possible burden of hearing loss among neonates born at a tertiary care hospital in Southern India. 500 neonates were screened with automated distortion product OAE (A-DPOAE) for hearing loss, 9.2% of whom had one or more high risk factors. Although 6.4% had hearing loss at initial assessment, only 1.6% had hearing loss on retesting with A-DPOAE. Retesting with OAE before an AABR helped to exclude patients without hearing loss. The frequency of moderate to moderately severe hearing loss in this study was 0.6%.[14]

Need of the study

Though, India as a country has been successful in lowering mortality rates, the burden of disability has not come down, in fact, it has risen down the years. The neonatal screening significantly helps in earlier diagnosis and leads to better intervention. Therefore, there is a high need to establish a standardized norm and protocol to carry out hearing screening in the neonates throughout the country, which will significantly help in the socio- cultural development of the child as per the normal timeline.

The latest and unique innovation in the field of NHS which offers a fast automated ABR test for newborns without the use of adhesive disposables, to grant babies the comfort is the BERAPHONE instrument that comes with integrated electrodes and a speaker with ear cushion in a single unit with a unique CE-Chirp which stimulates all regions of the cochlea at the same time to generate much higher responses and faster results than a standard click. This leads to highly accurate results for ABR Tests under normal nursing conditions.[15] The instrument is time and cost effective as it contains both the OAE and AABR in single set up, that is specially designed for the NHS program purposes. Therefore, the specificity and the sensitivity of the instrument need to be measured in order to future implication as a standard tool of investigation for the NHS program in this sub-continent.

METHODS

Comparative survey (Cohort group) research design was used in this present study. This study was done to obtain field evidence of newborn hearing screening in babies staying in well baby nursery and SNCU in Indian context by using TEOAE and AABR tests of MAICO easyScreen BERAPHONE instrument. This was conducted over the period of 9 months (from August, 2021 till April, 2022) on 200 newborns selected from well-baby nursery and 30 infants from the SNCU unit of the hospitals to standardize the instrument.

The study was accomplished in following steps: Ethical and technical clearance from the collaborators such as the Auditivo hearing services Private Limited, New Delhi, the MAICO Diagnostics GmbH, Germany, Ali Yavar Jung National institute of speech and hearing disabilities, Regional Center, Kolkata were taken. The permission for data collection in the particular institutions were taken from the higher authorities and the concerned persons of the State Government hospitals. Written consent was taken from the institutions and parents/care-givers. The data collection which took more than 3months of duration was carried out by using Behavioral Observation Audiometry (BOA), TEOAE and AABR. For BOA, 1000Hz tone was played from Tone Generator Mobile Application at the highest loudness level of the mobile phone, approximately 60-80dBSPL. The responses were measured by a 3 point rating scale, where 0 represents absence of response, 1 represents non-differentiable response and 2 represents presence of response.

Table 1: Inclusion criteria.

Group-1	Group-2
No significant prenatal medical history	Significant medical history (both prenatal & perinatal)
No significant history of risk factors	Presence of risk factors
No significant perinatal medical history	NICU stay > 48 hrs
Full term delivery	Currently not in ventilation
Age more than 1 day	Age more than 1 day

Table 2: Exclusion criteria.

Group-1	Group-2
Birth weight <2250gms	Age below 1 day
Gestational age < 35 weeks	Infants on ventilators
Age below 1 day	Presence of middle ear infection
Presence of middle ear infection	

After the perceptual analysis, the TEOAE was administered using MAICO Easyscreen Beraphone & OAE instrument and the responses were stored in the device. The TEOAE had tested 4 testing frequencies, such as 1.4 KHz, 2 KHz, 2.8 KHz and 4 KHz, which were previously set in the instrument by the manufacturer. The responses were recorded in term of stimulability rate (%), artifact rate (%) and time (sec) of the response. The positive responses were indicated by PASS (√) and negative responses were indicated by REFER (X). Both the ears were tested independently. The time window for TEOAE was maximum 60 seconds for each ear. The test got stopped automatically if three of the four test frequencies' responses were obtained. Next to TEOAE, AABR was done by using the Beraphone instrument. The instrument comes with built-in wireless electrodes that are placed within the handset of Beraphone. While starting the AABR test, first the impedance of the instrument was measured by placing the handset on the baby's head. Before placing the electrodes of the Beraphone the conduction gel was applied to both the skin of the baby and the surface of the electrodes. This gel was used to get better impedance value and less artifact of the test. The AABR was been administered at 35dBnHL using unique CE-Chirp tone and the responses were recorded in term of artifact rate (%) and time (sec) of the response. Like TEOAE, AABR responses were also shown by using PASS (√) for positive responses and REFER (X) for negative responses. The total time window for AABR was 180 Seconds but thee test got stopped automatically if the response was achieved before the cut off time. Both the ears were tested individually just like TEOAE.

After the collection of data, those who were found to be referred were counseled for diagnostic evaluation of OAE and ABR to measure the concurrent validity. For this purpose, the patients were reassessed at the principle place of research with the help of Path medical senteiro Diagnostic OAE instrument and IHS DUET Diagnostic ABR instrument. Subjects from each group were re-evaluated and the sensitivity of the MAICO easyScreen Beraphone instrument was measured along with the concurrent validity measurement.

The accumulated data were compiled in a excel spreadsheet for statistical analysis. The data from the Beraphone instrument were first transferred to the Hearsim OtoAccess software of MAICO and then manually fed in an excel spreadsheet. The statistical analysis was done by using SPSS software version 21. The descriptive frequency, mean, standard deviation and graphical techniques were obtained. The data was subjected to Shapiro Wilks tests for normality. The data was significantly deviation from normal distribution (i.e., $p<0.05$). Therefore, the nonparametric Mann-Whitney U test was carried out to see the significant difference between both groups for parameters. The nonparametric Wilcoxon Signed rank test was carried out to see the significant difference between left and right ear. The statistical significance values were compared with 0.05 or 0.01 level of significance.

RESULTS

In India, there is no standardize norm for NHS. This current study was aimed to obtain field evidence of NHS in babies using MAICO easyScreen BERAPHONE & OAE instrument to screen 230 babies from different state government hospitals that were collaborated for the project, from both well baby nursery and SNCU units. The detailed analysis was done where the age, sex, ear specific values, and the results of the tests were analyzed individually. Both the tabular and graphical representations were made to explain the findings in detail.

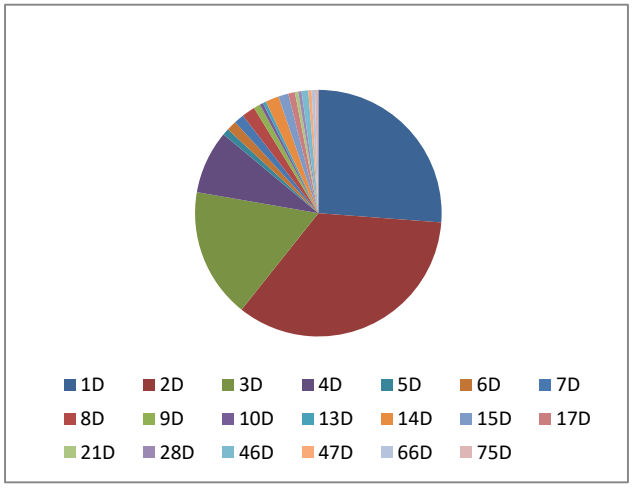

Figure 1: Age wise distribution.

Table 3: Frequency table of all accumulated data.

Variables	Response	N
Data type	Well baby	199
	SNCU	30
	Total	229
Age	1D	60
	2D	79
	3D	39
	4D	19
	5D	2
	6D	3
	7D	3
	8D	4
	9D	2
	10D	1
	13D	1
	14D	4
	15D	3
	17D	2
	21D	1
	28D	1
	46D	2
	47D	1
	66D	1
	75D	1
	Total	229
Sex	Male	135
	Female	94
	Total	229
Perceptual analysis	Absent	35
	Non differentiable	74
	Present	120
	Total	229
Remarks	Counselled	29
	Discharge	198
	Suspected case of ANSD	1
	Test due	1
	Total	229

The (Table 3) showed the accumulated data in respect to age of the babies when NHS was done, gender, perceptual analysis (BOA) and the overall remarks given to the babies after the testing were done. The percentage of these factors showed 86.9% were taken from well-baby nursery and 13.1% were taken from the SNCU. (Figure 1) showed the percentage of occurrence as per age of the babies while hearing screening was done. This data is combined of both the groups. The (Table 4) replicated the detailed statistical analysis for the well-baby group that showed there was significant difference between two ears in terms of stimulus stability % and artifact % for TEOAE data and artifact % for AABR data but as the p value is greater than 0.05, it indicated that there was no significant difference between two ears in terms of test timing for both TEOAE and AABR data in well-baby group. The (Table 5) depicted the elaborated statistics of the accumulated SNCU data.

Table 4: Detailed evaluation for well-baby group (n=197).

Findings	Variables	Response	Mean	Median	SD	Wilcoxon Signed Ranks Test	
						|Z| value	P value
TEOAE Findings	Stimulus Stability %	Left	94.35	98.00	7.33	2.810	0.005**
		Right	92.14	96.00	8.22		
	Artifact%	Left	9.88	2.00	15.48	2.094	0.036*
		Right	13.02	5.00	17.48		
	Time(sec)	Left	22.36	18.00	16.03	1.067	0.286
		Right	23.58	20.00	16.43		
AABR Findings	Artifact%	Left	15.56	15.00	10.93	1.998	0.046*
		Right	13.78	14.00	10.13		
	Time(sec)	Left	28.45	19.00	27.97	1.147	0.251
		Right	30.70	19.00	30.14		

* Indicates significant at p<0.05, ** Indicates significant at p<0.01

Table 5: Detailed evaluation for SNCU group.

Findings	Variables	Response	Mean	Median	SD	Wilcoxon Signed Ranks Test	
						|Z|	P value
TEOAE Findings (n=30)	Stimulus Stability %	Left	88.47	90.50	9.90	0.589	0.556
		Right	87.83	89.50	7.84		
	Artifact%	Left	25.40	20.00	18.98	0.746	0.456
		Right	27.50	22.00	22.77		
	Time (sec)	Left	50.77	60.00	16.48	0.267	0.790
		Right	50.57	60.00	17.42		
AABR Findings (n=26)	Artifact%	Left	16.58	13.50	12.74	1.186	0.236
		Right	12.58	9.50	11.91		
	Time (sec)	Left	95.50	80.00	67.74	1.065	0.287
		Right	113.15	144.50	69.16		

As it was indicated that the p value for all the parameters of TEOAE and AABR data were higher than 0.05, there was no significant differences between two ears for the group. The results of left ear was same as the right ear. The (Table 6) showed the combined TEOAE results of left ear for both the groups, where it was remarkably differentiable that between the groups, the passing rate was higher in well-baby while the referral rate was higher in the SNCU group.

Table 6: TEOAE finding results of left ear.

Data type		Result		Total
		Pass	Refer	
Well baby	Count	193	6	199
	% within Data type	97	3	100
SNCU	Count	9	21	30
	% within Data type	30	70	100
Total	Count	202	27	229
	% within Data type	88.2	11.8	100

After calculating the Chi-square tests it was derived that from the passing rate calculation, the specificity and sensitivity of the TEOAE test was very high for left ear. The (Table 7) showed the combined TEOAE results of right ear for both the groups, where it was significantly differentiable that between the groups, the passing rate was higher in well-baby while the referral rate was higher in the SNCU group.

Table 7: TEOAE finding results of right ear.

Data type		Result		Total
		Pass	Refer	
Well baby	Count	194	5	199
	% within Data type	97.5	2.5	100
SNCU	Count	11	19	30
	% within Datatype	36.7	63.3	100
Total	Count	205	24	229
	% within Datatype	89.5	10.5	100

After calculating the Chi-square tests it was derived that from the passing rate calculation, the specificity and sensitivity of the TEOAE test was very high for right ear. The (Table 8) showed the detailed AABR findings for left ear in both the groups which denoted the pass rate was

significantly high in the well-baby group. The referral rates of groups were also correlating with the pass rate. The Chi-square test also showed the high specificity of the AABR test for left ear.

Table 8: AABR finding results of left ear.

Data type		Result		Total
		Pass	Refer	
Well baby	Count	195	4	199
	% within Data type	98	2	100
SNCU	Count	17	13	30
	% within Datatype	56.7	43.3	100
Total	Count	212	17	229
	% within Datatype	92.6	7.4	100

The (Table 9) showed the detailed AABR findings for right ear in both groups which denoted the pass rate was significantly high in the well-baby group than the SNCU group. The referral rates of two groups were also correlating with the pass rate. The Chi-square test also showed the high specificity of the AABR test for right ear.

Table 9: AABR finding results of right ear.

Data type		Result		Total
		Pass	Refer	
Well baby	Count	196	3	199
	% within Data type	98.5	1.5	100
SNCU	Count	16	14	30
	% within Data type	53.3	46.7	100
Total	Count	212	17	229
	% within Data type	92.6	7.4	100

DISCUSSION

From the detailed statistical evaluation, it can be derived that there was significant difference between two groups' scores and the well-baby group had given more positive responses than the SNCU group. As the presence of ambient noise was very high for both the groups, the overall artifact level was higher in this study. It was shown that there was significant difference between the ears in terms of all the parameters of two testing except the test timing. The test timing was almost same for two ears. In well-baby group the timing was less than the SNCU group as the refer rate was higher in SNCU group and for refer data it covered the whole time window to record. The stimulus stability % was high for the groups, suggesting good and reliable data was collected from both the groups. Similar studies has been done on NHS to compare the results between test groups and the finding are more or less supportive of the current study.[13,16,17] Therefore, the discussions can be summarized on a positive note that the MAICO easyScreen Beraphone instrument is suitable for NHS program as it has the high specificity and sensitivity score and also a very useful tool that requires less time, effort and user friendly for both the clinician and the subjects. The main constraint of this instrument is the placement of the fixed electrodes because of which the newborns till the age of 3 months are suitable for the screening. After that, the enlarged diameter of the head circumference will result in impedance mismatch for the AABR screening. This point should be considered while doing further research or using it in the clinical practice. Otherwise the instrument is good for both clinical and field research overview.

Limitations

The limitation of the study was the sample size and the age of the subjects. Along with this the validation with standard ABR was not well justified.

CONCLUSION

This current study can be concluded as the instrument is highly user friendly, less time consuming, non-invasive and having high specificity and sensitivity score, therefore this instrument can be used for clinical practice in future. This instrument can be used for newborn hearing screening in hospitals and audiological clinics. As the instrument is having in-built memory storage system to store recorded data, the accuracy of the result will be high and the documentation will be fair. Therefore, there should be a standardized norm related to newborn hearing screening in this sub-continent.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Chatterjee I, Ata S, Shatapathy P, Kumar S, Sammadar P, Makkar S, et al. Multistage standardization of Beraphone and OAE on neonates. Int J Otorhinolaryngol Head Neck Surg 2023;9:613-9.