Comparison of BOA and OAE in hearing screening programmes

REGISTER NO. M2K05

An Independent project submitted in part fulfillment of the first year M.Sc. (Speech and Hearing), University of Mysore, Mysore.

ALL INDIA INSTITUTE OF SPEECH AND HEARING, MANASAGANGOTHRI, MYSORE - 570 006.

MAY, 2001

CERTIFICATE

This is to certify that this independent project entitled "Comparison of BOA and OAE in hearing screening programmes" is the bonafide work in part fulfillment for the degree of Master of Science (Speech & Hearing) of the student with (Register No. M2K05).

Mysore,

May;-2001

0-10mams

Director'

All India Institute of

Speech & Hearing,

Mysore -570 006

CERTIFICATE

This is to certify that this independent project entitled "Comparison of BOA and OAE in hearing screening programmes" has been prepared under my supervision and guidance. It is also certified that this has not been submitted earlier in any University for the award of any other Diploma or Degree.

Mysore,

May, 2001

Mr. Animesh Barman

Arrively Boz

Lecturer

Department of Audiology

AIISH, Mysore - 570 006.

DECLARATION

This independent project entitled "Comparison of BOA and OAE in hearing screening programmes" is the result of my own study under the guidance of Mr. Animesh Barman, Lecturer, Department of Audiology, All India Institute of Speech & Hearing, Mysore, and has not been submitted earlier in any University for the award of any other Diploma or Degree.

Mysore,

Register No. M2K05

May, 2001.

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INTRODUCTION

Auditory channel is the route through which speech and language development usually takes place. A child born with hearing loss will have impaired development of speech and verbal language skills. Hearing loss affecting neonates and young children is a major cause of delayed intellectual, linguistic and social development. Current evidence suggests that uncorrected hearing impairment during the first three years of life results in permanent developmental anomalies of central auditory system. Moreover, delayed identification and management of severe to profound hearing impairment may impede the child's ability to adapt to life in a hearing world or in a deaf community.

The first three years of life are most important for speech and language development. The average age for detection of severe hearing loss remains to be around 3 years while the lesser degree losses go undetected even longer. The result is that for many infants and young children, the opportunity for optimal hearing rehabilitation is lost during the period most crucial for speech and language learning.

Therefore, hearing impairment should be recognized as early as possible so that hearing habilitation can take full advantage of the plasticity of the developing sensory systems and the child can enjoy normal social development.

The above discussion makes it imperative for audiologists to take up the challenge to identify a child with hearing loss at the earliest possible time. There are two possibilities, one to test and evaluate every child born thoroughly, which is not feasible; or to screen all children or at least a selected population of children whenever and wherever they are accessible soon after birth.

Screening, as accepted by WHO is defined as "the presumptive recognition of unrecognized disease of defects by the application of tests, examinations and other

procedures which can be applied rapidly". Auditory screening is an attempt to identify persons who have significant hearing defects, from a population of predominantly people with normal/adequate hearing (Hedgecock, Miller & Rose, 1973).

Hearing screening tests are administered in either individual or group settings, the stimuli used in these tests range from pure tones and speech to noise produced by various noisemakers, squeakers and environmental sounds (Anderson, 1972).

Glorig (1965) related the period from birth to 3 years of age the most critical for hearing impairment detection. Two important aspects of testing were stressed.

- (1) that the quality of sound be known by the tester.
- (2) lack of response is not confused with lack of hearing.

Test of hearing can be classified into:

- (a) Behavioral tests
- (b) Objective tests.

(Martin, 1977; McCormick, 1986; Northern & Downs, 1991)

Although non-behavioural or objective measurements are useful and may be necessary in the evaluation of hearing in infants, it is to be remembered that no single auditory test is precise enough to be a perfect and complete assessment tool (Northern & Downs, 1991).

Behavioral tests involve careful behavioural observation and assessment of unconditioned or conditioned responses given by a subject which are active responses to the presence of a sound stimulus (Northern & Hayes, 1996).

In spite of the limitations like habituation of response, need for extensive training of audiologists regarding what response to accept at what age and the inconsistency in the intensity of the stimuli presented using noise makers (due to inability to monitor it), BOA is still popular because of its time and cost effectiveness. Moreover, it does not require extensive technical equipment.

Objective tests are non-behavioural methods to assess the hearing status. They are physiological or electrophysiological methods and do not require active participation from the subject such as auditory brainstem response, otoacoustic emissions (OAEs), immittance audiometry, etc.

Well developed DPOAEs have been observed in neonates (Samurzynski, Leonard, Kin, Lafreniere & Jung, 1990). DPOAE responses of neonates were found to be higher than the TEOAE responses. Also DPOAE has been found to correspond well with behavioural audiometric thresholds (Probst & Harris, 1993). Irrespective of controversies regarding the best parameters for obtaining DPOAE, it is well established that it promises to be an excellent clinical tool for audiologists especially for screening purpose and hence has been taken up for the study along with the behavioral test.

Jerger & Hayes (1976) strongly recommended the use of "cross check principle" in paediatric audiometry i.e. use of objective measures (ABR, OAE) as confirmation of behavioral results.

On the lines of the foundation laid by Jerger and Hayes, two procedures Behavioral Observation Audiometry' (BOA) and Otoacoustic emissions (OAE) have been planned for the study which involves screening of the age group 0-3 years.

Aims of the study:

 To compare behavioral screening results (using paediatric audiometer and noise makers) with otoacoustic emission screening results and to find out the correlation between the two.

- 2. To compare and correlate the efficiency of the three procedures i.e. Behavioural observation using Paediatric Audiometer (PA), behavioral observation using noise makers (NM) and OAE.
- 3. Attempt has also been made to correlate HRR results with other screening results as HRR is considered as a part of screening procedure.
- 4. To develop a test battery which can be used for screening based on cost effectiveness, time taken and sensitivity and specificity of the procedures for each sub-group.

REVIEW OF LITERATURE

Screening is the process of applying certain rapid and simple tests; examinations or other procedures, to generally large number of persons that will identify those persons with a high probability of disorder from those persons who probably do not have the disorder. A criterion measurement cut off point is always involved, below or above which the person are suspect. Those who are identified with positive or suspicious findings must be referred for detailed evaluation and intervention (Northern & Downs, 1978).

Since hearing impairment is relatively invisible, hearing screening tests have been in use for at least 60 years to identify children for further auditory evaluation. Hearing screening programs have been established in an effort to identify early the presence of severe to profound hearing loss so that habilitative measures can be instituted as soon as possible (Northern & Downs, 1978).

Screening programs became popular henceforth but soon it was learned that the programs were not identifying deaf infants very successfully, and that the large number of false positives were causing unnecessary parental anxiety and costing a lot of time and money. Subsequently in 1970, a Joint Committee of American Speech and Hearing Association, AAOO and American Academy of Paediatrics recommended that routine screening programs be discontinued. They urged that controlled experimental programs continue to investigate useful stimuli, response patterns, environmental factors, status of neonate during behaviour testing. In a supplementary statement in 1969 the Joint Committee recommended the use of high risk register to identify neonates in whom the probability of hearing less could be expected to be higher than normal. A five-point identification high risk register, represented by simple mnemonic, "the ABCDs of deafness" (Downs & Silver, 1972) came into application.

Mencher (1974) has reviewed the prospective studies which have placed the register as an acceptable tool for identifying deaf child, showing that on the average, 64% of the deaf children will be identified by the register.

Downs & Sterritt (1964) screened 17000 newborns making use of high risk register and identified 17 infants with profound hearing loss.

Further number of studies were carried out by investigators (Richards & Robert, 1967; Rossi & Guidotti, 1976). The effectiveness of high risk registers used by different investigators also varied depending upon stringency of the HRR (Feinmeser & Tell, 1976, Downs, 1976).

In order to improve the hit rate of HRR, JCIH have proposed position statements in 1982, 1990, 1994 and recent one is that proposed in 2000.

At the same time there has been a tremendous development of auditory screening tests from the primitive methods making use of different sounds' for behavioural responses to the today's sophisticated objective ABR and OAE screening procedures

Screening over the years has been done using either subjective or objective or a combination of the two procedures. Either a single procedure has been made use of or two and more procedures for comparisons in terms of different aspects.

Subjective Procedures:

The first studies of neonatal auditory behaviour, including screening programs, had to rely on observational assessment of neonatal responses to sounds since suitable instruments for reliably recording the responses were not available.

The traditional tests for hearing of the infant after birth have been described by Ewing & Ewing (1994), Sheridan (1957), Hardy, Dougherty & Hardy (1959) and Northern & Downs (1978). All involve observations of the infant's responses to selected noisemakers.

Downs & Sterritt (1967) in their classical paper on screening in infants describe in detail the procedure for recording the relevant responses. They provided a form which required trained, volunteer observers to record, using a 5 point scale, responses occurring not more than 2 sec. after the sound stimulus. However, it was found that the number of false positive and false negative results was unacceptably high.

Feinmesser & Tell (1976) presented the results of one of the first extensive screening studies using behavioral methods. They screened 17,731 newborns. Almost all were tested again at 6 months and at 3 years of age. Only 6 of 23 children ultimately diagnosed as having profound hearing loss were detected by screening test at birth. A high false positive rate was reported

Using behavioural arousal technique, Northern & Downs (1978) reported a false negative rate of 38% from screening carried out on 10,726 infants.

Taken as a whole, the evaluation of behvioural screening methods was variable but generally a little disappointing. The sensitivity and specificity of behavioral screening methods was benefited from the introduction of automated devices which have reduced errors due to observer bias. More peripheral measures of hearing function such as auditory brainstem evoked response (ABR) (Hyde, Riko, Corbin, Moroso & Albert, 1984; Jacobson & Morehouse, 1984) and Otoacoustic Emissions (OAE) (Johnson, Bagi & Elberling,1983) were evaluated as alternatives be behavioral methods. Though advent of these methods threw some doubt on the usefulness of behaviour screening, but still they constitute an important aspect of

battery of tests as they have useful preliminary and supplementary information where more complex procedures fail.

Objective procedures:

Investigators have made use of different objective procedures for auditory screening. In the earlier years the main focus was an auditory brainstem response audiometry which was researched upon extensively by numerous people for neonatal as well as infant screening (Mason, Davis, Wood & Farnsworth, 1998; Galambos, 1977; Alberti, Hyde, Corbin, Riko & Abramovich, 1983).

The advent of OAE and its widespread, applications, revolutionized the area of auditory screening also. TEOAEs especially were researched upon extensively by a number of investigators. EOAEs was made use of for the purpose of early identification of hearing impairment in neonates, not only high risk but also healthy neonates. Those referred, were tested again before discharge from the hospital. TEOAE was highly recommended (Aidan & Paludetti, 1999). TEOAEs were successfully recorded in full-term neonates on third or fourth of postnatal day and reported to be suitable for screening peripheral auditory function in infants (Engdahl, Arnesen & Mair, 1993). Striking features of TEOAEs which made it gain popularity were faster procedure, good accuracy, lesser cost and higher sensitivity (Brass, & Kemp, 1994; Aidan, Avan & Bonfils, 1999). Hence, TEOAE was almost accepted as a potential newborn screening tool when used in a carefully designed hospital based early identification programme (Maxon, White, Vohr & Behrens, 1993).

Though majority of the investigator agreed upon for TEOAE being one of the best screening procedures available, yet at the same time there were some others who differed in their view point. The sensitivity and reliability of TEOAE was put to question when it was compared across ABR, behavioral thresholds and also when follow ups were done (Wood, et al. 1997). Most of researches agreed upon the fact that though ABR was expensive, it ensured better sensitivity than OAE. But no robust

conclusions were made (Dort, Tobolski & Brown, 2000). Though ABR was agreed upon to be the Gold standard, TEOAE was accepted as choice for universal screening. At the same time improvement for standardization of test has been recommended. (Wood, Mason, Farnsworth, Davis, Curnock & Lutman, 1998, Paludetti, Ottaviani, Fetoni, Zuppa & Tortorrolo, 1999).

Till late DPOAE, though found to be promising technique (Salata, Jacobson & Strasnick, 1998) was not investigated as much as TEOAE. Though both TEOAE and DPOAE are similar certain aspects of their application to paediatric population, yet DPOAEs scored over TEOAEs in certain aspects. Franklin, McCoy, Martin & Lonsbury-Martin (1992). Studied the test-retest-reliability of DPOAE in normal human ears. They concluded that the consistency of repeated measures of DPOAEs was generally excellent, particularly within the mid to high frequency range (2000 to 8000 Hz). On comparison with ABR, for its efficiency as a tool for identification of hearing loss, DPOAEs were found to have similar test performance. Though perfect test performance as never achieved, sensitivity for each measure increased with the magnitude of hearing loss (Norton, et al, 2000). DPOAEs was also found to correspond well with behavioural audiometric thresholds (Harris, 1990), Probst & Harris, 1993). Most of the researchers agreed upon that DPOAEs are strong and can be detected in almost all normal hearing subjects (Probst, Lonsbury, Marin, & Martin, 1991)

Smurzynski, Jung, Lareniere, Kim, Kamath, Rowe, Holman & Leonard (1993) reported presence of well developed DPOAEs in new borns based on screening results using DPOAEs.

Bowes (1999) screened high risk infants using DPOAEs and also compared the results with ABR. They reported sensitivity and specificity of DPOAE to be 100 and 90% respectively. They commented on DPOAE being better than TEOAE as it

gives frequency specific information. The authors recommended DPOAE as an excellent screening tool for all its salient features.

As seen by the studies reported above, OAE has been recommend as the primary screening tool by most of the researches owing to feasibility in terms of time, cost and sensitivity. DPOAE promises to be an efficient screening tool having an edge over TEOAE

But most of the recent overseas studies that have been carried out make use of only objective methods. The same trend cannot be followed in Indian set ups due to economic constraints. So, there is need for development of screening kit which would take into consideration factors like cost, time, population (to be screened) without compromising much on sensitivity.

METHODOLOGY

The aims of the study were to compare BOA and OAE results to find out the correlation between them and to develop a screening test battery suitable for Indian population.

The methodology used was as follows:

Subjects:

A total of 165 subjects in the age range 0-3 years were screened at immunization centers in the hospitals. They were divided into 5 subgroups based on development of auditory behaviour as reported by Northern & Downs (1978).

Age (in months)	Number of subjects screened
0-4	53
4-7	32
7-9	16
9-13	26
13-36	38

Instru mentation:

Following equipment were used for screening:

(a) **OAE**:

For measuring emissions AuDX (Biologic) Screening OAE equipment was made use of.

Stimulus parameters:

The default parameters shipped on the AuDX which were used are as follows:

 F_2 frequencies across which subjects were screened were 5000 Hz, 4000 Hz, 3000 Hz and 2000 Hz. The ratio of primaries (F_2/F_1) was constant at 1.22. L_1 intensity was 65 dB SPL while L_2 was 55 dB SPL.

Response parameters:

DP Frequency: 2F₁-F₂

Noise Calculation:

Average amplitude of 100 Hz above and 100 Hz below the DP frequencies.

b) For Behavioral screening:

Pediatric audiometer and noisemakers were made use of, for behavioural screening.

Paediatric Audiometer:

The frequencies across which the subjects were screened were (in Hertz) 500, 1000, 2000 and 4000. Screening was done at a constant intensity of 80 dB SPL for all age groups as reported by Wharrad (1988).

Noise makers:

Noise makers which were made use of, are given below along with their frequency composition as measured previously

Noisemaker	Frequency range and frequency at which maximum output (SPL) is obtained.					
Metal khanjeera	1140-7360 (2500 Hz)					
Mouth organ	740-5860 Hz (2200 Hz)					
Drum	800 - 1700 Hz (800 Hz)					
Jingles	800-1700 Hz (6080 Hz)					
Squeaker	Maximum energy centered	around 4-				
	8 kHz.					

Environment:

Testing was carried out when the noise levels were minimum at a particular set up.

c) High risk register:

The high risk register for deafness should be the basis of any infant screening program (Northern & Downs, 1978). Joint Committee on Infant Hearing (JCIH) specifies purpose of risk indicators that are often associated with infant and childhood hearing loss, that is normal hearing at birth does not preclude delayed onset or acquired hearing loss, in that case risk indicators help identify infants who should receive ongoing audiologic and medical monitoring and surveillance

Selected HRR questions based on study carried out at AIISH, which was adapted from HRR protocols given by JCIH (1984), were also used

c) Procedure:

Prior to behavioral testing or OAE screening, HRR was administered. Those who were found to be at risk were considered as having failed in the test and viceversa.

Hearing Screening by Behaviour Observation:

Following the administration of HRR, behavioural screening was done on the subjects in a quiet room with low ambient noise levels using either paediatric audiometer or noise makers.

The duration of presentation was approximately ½ -2 seconds with an interstimulus duration of 15 seconds (Hodgson, 1978). Stimuli were presented from side or back. Use of paediatric audiometer and noisemakers was in random order to avoid order effect.

OAE:

Otoacoustic emission screening was done following behavioral screening most of the time. However, this was not so when the subject was asleep

Preparation of the subject:

First the subject's ear canal was examined for the presence of wax or debris. An appropriate tip was selected and installed on the probe. The subject's pinna was pulled backwards and downwards to straighten the ear canal, following which the probe was inserted. Care was taken to minimize child's body movements during OAE measurement. Measurement of emission was initiated at 5 kHz and proceeded in the descending order automatically till 2 kHz. Following this results were noted.

RESPONSE CRITERIAS:

1. Hearing screening by behaviour observation:

With the development of auditory behaviour, there occurs change in the responses of the children. Responses obtained after the stimuli presentation for a specific group as per the following table were considered as pass

Age (in months)	Responses
0-4	Eye widening/blink, startle, arousal from sleep, quietening, general body movements, crying.
4-7	Rudimentary head turn, eye ball movements, general body movements
7-9	Direct localization of sound source (head turn towards side and below), eye ball movement.
9-13	Direct localization of sound source.
13-36	Localization of sound in any plane

Subjects were retested if there was no response observed after initial presentation, before considering them as having failed.

If subjects responded for 2 out of 4 frequencies, for paediatric audiometer and 3 out of 5 noisemakers, they were considered as pass.

2. **OAE**

The instrument considers 6 dB (DP-NF) criterion for pass/refer. Keeping in mind the noisy conditions of testing environment instead of 6 dB, 5 dB (DP-NF) criteria for pass/fail was made use of which has also been reported by Wilson (1980).

Analysis:

Statistical analysis using phi coefficient was carried out to find the correlation between the four procedures used for screening. Test of significance for the coefficient was also done.

Descriptive analysis was done for 2 subgroups i.e. 7 to 9 months and 9 to 13 months as the phi coefficient could no be calculated due to its limitation.

Cost effectiveness was calculated based on the time taken to screen each child, cost of the equipment, other expenditures etc. Details are shown in the Table 7. The formula used to calculate the cost per child using each test is given below.

Here,

S = Salary for a person per day

R = Total number of children screened per day

C = Cost of equipment

N = Number of children screened in five years (assuming that the instrument can be used for 5 years).

M = Maintenance/recurring cost

T = Transport charges

Salary for a professional per day is approximately Rs.250/-. Transport charges for 12 km from Institute is considered Rs.42. If the screening is done within the Institute then no transport charges were added. Number of working hours are eight but seven hours was taken for calculation approximately as half an hour was usually spent for break and half an hour for travel. Total number of working days considered was 245 i.e. excluding 52 Saturdays, 52 Sundays and other Government holidays.

Sensitivity and specificity of the procedures was compared against OAE results. OAE was considered as standard as Jerger & Hayes (1976) stated that any behavioural results should be cross checked with objective measures. Procedure to calculate sensitivity and specificity which was adopted by Dort, et al, (2000) used for this study.

RESULTS (STATISTICAL ANALYSIS)

For the purpose of comparison of different procedures used for screening, phi coefficient and then significance of the coefficient was calculated. Procedures were compared across subgroups and for overall data.

1. Results obtained in **0-4 month** age group.

		OAE		N	NM		PA
		F	P	F	P	F	P
HRR	F	1	2	0	3	0	3
	P	20	30	3	47	3	47
OAE	F			3	18	3	18
	P			0	32	0	32
NM	F					3	0
	P					0	50

Table 1(a) Represents the number of passes and fails between the tests

Key: Applicable for all tables.

HRR - High Risk Register

NM - Noise Makers

PA - Paediatric Audiometer

OAE - Otoacoustic Emissions

	OAE		N	M	PA	
	Value	Approx. Sig.	Value	Approx. Sig.	Value	Approx, Sig.
HRR	-031	819	-0.60	.662	-0.60	0.662
OAE			.302	.028	.302	.028
NM					1.000	.000

Table 1(b) Represents the correlation value phi and the approximate significance level for phi.

From the tables, it can be seen that results obtained using paediatric audiometer and noise makers have a significant positive correlation as 50 out of total 53 infants passed in both while 3 subjects have failed in both the procedures.

Significant low positive results were obtained when otoacoustic emission results were compared with either noisemakers or paediatric audiometry results. It can be seen from Table 1 that discrepancy occurred for 18 cases who passed in both PA and NM screening but failed in OAE screening thus resulting in a low positive correlation.

No significant correlation was seen when HRR results were compared with the other three results which is mainly due to discrepancies seen among the test results, as shown in Table 1.

2. Results obtained for 4-7 months age group

		OAE		NM		PA	
		F	P	F	P	F	P
HRR	F	2	0	1	1	1	1
	P	16	14	3	27	2	28
OAE	F			4	13	3	14
	P			0	15	0	15
NM	F					3	0
	P					1	28

Table 2(a) Shows the number of passes and fails between the tests

	OAE		N.	M	PA		
	Value	Approx. Sig.	Value	Approx. Sig.	Value	Approx. Sig.	
HRR	238	.185	.291	.106	.358	.046	
OAE			.355	.045	.302	.087	
NM					.851	.000	

Table 2(b) Shows the correlation value phi and approximate significance level for phi

From the tables 2a and 2b it can be clearly seen that 28 out of 32 children passed in both paediatric audiometry and noise makers while 3 failed in both, indicating a significant high positive correlation among the two.

Significant low positive correlation was obtained for results of OAE and noise makers where 15 subjects had passed in both the procedures and 4 failed in both, but discrepancy was seen in 13 subjects who passed when noisemakers were used, but failed in OAE screening.

It can be seen from the above tables, that no significant correlation was found for OAE and paediatric audiometry as 14 children out of the total passed in paediatric audiometry screening but failed in OAE.

No significant correlation was found between HRR and other three test results as there were more number of children with discrepant results.

3. Results obtained for **7-9 months** age group.

		O	AE	NM		PA	
		F	P	F	P	F	P
HRR	F	2	1	0	3	0	3
	P	7	6	1	12	0	13
OAE	F			1	8	0	9
	P			0	7	0	7
NM	F					0	1
	P					0	15

Table 3(a) Shows the number of passes and fails between the tests.

	OAE		N	M	PA	
	Value	Approx. Sig.	Value	Approx. Sig.	Value	Approx. Sig.
HRR	.101	.687	124	.620	0	0
OAE			.228	.362	-	-
NM					-	-

Table 3(b) Shows the correlation value phi and approximate significance level for phi.

It can be clearly seen from the above table that there is a good agreement between the results obtained using noisemakers and paediatric audiometer screening as 15 out of 16 cases passed in both the tests. Whereas, OAE results did not show a good agreement with results obtained in noise makers/paediatric audiometer screening. This is mainly due to the number of subjects who passed in behavioral screening but failed in OAE screening.

No significant correlation is seen for results obtained using HRR when it was compared with OAE and noise maker results, as the number of cases passed/failed in both the procedures is less.

Agreement was seen between the results obtained using HRR and PA but not a perfect agreement. It can also seen from table 3a that no cases failed in both the procedures and there were 3 discrepant cases who passed paediatric audiometer screening but failed in HRR.

4. Results obtained for **9-13 months** age group.

		OAE		NM]	PA	
		F	P	F	P	F	P	
HRR	F	1	1	0	2	0	2	
	P	9	15	0	24	0	24	
OAE	F			0	10	0	10	
	P			0	16	0	16	
NM	F					0	0	
	P					0	26	

Table 4(a) Represents the number of passes and fails between the tests.

	OAE		N	M	PA	
	Value	Approx. Sig.	Value	Approx. Sig.	Value	Approx. Sig.
HRR	.068	.727	-	-	-	-
OAE			-	-	-	-
NM					-	-

Table 4(b) Represents the correlation value phi and approximate significance level for phi.

It can be noted from table 4a that there is a perfect agreement between the results obtained using paediatric audiometer and noise makers as all the children passed in both procedures. A good agreement is seen between HRR and noise makers/paediatric audiometry results as 24 out of 26 cases passed in both the procedures. But, no significant correlation is seen between HRR and OAE results as 9 out of 26 subjects passed in HRR but failed in OAE and one failed in HRR but passed in OAE screening. Such agreement between noise makers/paediatric audiometry results and OAE results were not noticed as more number of subjects failed in OAE screening.

5. Results obtained for 13-36 months age group

		OAE		NM		PA	
		F	P	F	P	F	P
HRR	F	0	1	0	1	0	1
	P	19	18	1	36	1	36
OAE	F			1	18	1	18
	P			0	19	0	19
NM	F					0	1
	P					1	36

Table 5(a) Represents the number of passes and fails between the tests.

	OAE		N	M	PA	
	Value	Approx. Sig.	Value	Approx. Sig.	Value	Approx. Sig.
HRR	0164	0.311	0227	.0868	-0.027	0.868
OAE			0.164	0.311	0.164	0.311
NM					-0.027	0.868

Table 5(b) Represents the correlation value phi and approximate significant level for phi

From the Tables 5a and 5b it can be clearly seen that no significant correlation was obtained because no agreement can be seen between any two test results.

6. Results obtained for overall data

		OAE		N	NM		PA	
		F	P	F	P	F	P	
HRR	F	6	5	1	10	1	10	
	P	70	84	8	146	6	108	
OAE	F			9	67	7	69	
	P			0	89	0	89	
NM	F					6	3	
	P					1	155	

Table 6 (a) Represents the number of passes and fails between the tests.

	OAE		N	M	PA	
	Value	Approx. Sig.	Value	Approx. Sig.	Value	Approx. Sig.
HRR	.044	.572	.042	.587	.064	.413
OAE			.2360	.001	.228	.003
NM					.744	.000

Table 6 (b) Represents the correlation value phi and the approximate significance level for phi.

From the Tables 6a and 6b it can be clearly seen that noise makers/paediatric audiometry have significant high positive correlation, as 155 cases passed in both procedures while 6 failed in both.

Significant low positive correlation exists between OAE and noise makers/paediatric audiometry results. Out of total of 165 cases discrepant results were seen for 69 subjects in OAE vs. paediatric audiometry and for 67 subjects in OAE Vs noise makers results, hence low positive correlation.

When HRR results were compared with noise makers/paediatric audiometer/OAE results, no significant correlation is seen which is attributed to the discrepancies seen among the test results.

Sensitivity and Specificity:

Sensitivity and specificity was calculated for the three procedures noise maker, paediatric audiometry and HRR, keeping OAE as a standard (as it is an objective procedure)

		OAE			
		Fail	Pass	Total	
Paediatric audiometer	Fail	7	0	7	
	Pass	69	89	158	
	Total	76	89	165	
Noise makers	Fail	9	0	9	
	Pass	67	89	156	
	Total	76	89	165	
High risk register	Fail	6	5	11	
	Pass	70	84	154	
	Total	76	89	165	

Table 7 Represents total number of subjects pass/failed in each procedure.

PA - Sensitivity = 9.21%

Specificity = 100%

NM - Sensitivity = 11.84%

Specificity = 100%

HRR - Sensitivity = 7 89%

Specificity = 94.38%

It can be seen from the above table that the specificity of all the procedures is high while the sensitivity is low i.e. the procedures are able to identify the normals but fail to correctly identify cases with hearing impairment.

Cost effectiveness:

Each of the screening procedures were evaluated in terms of their cost effectiveness which is shown in the table given below

Cost	Procedure					
	HRR	PA	NM	OAE		
Cost/child in (Rs) including transport	2.76	1.65	1.384	4.35		
Cost/child in (Rs) excluding transport	2/38	1.46	1.194	3.97		

 Table 8
 The table gives overview of cost per child for each of the procedures

It can be seen from the above table that the cost per child was minimum when noise makers were made use of, while the costliest screening procedure was OAE, which can be explained by difference in cost of the equipment. In case of HRR the time taken for administration is more resulting in a reduction in the number of cases screened/day. So the cost per child increased.

DISCUSSION

Different researchers have made use of varied procedures and test batteries for hearing screening, yet there is no clear cut test battery for screening especially suited for Indian population.

This present study investigates the different procedures and compares them across each other.

It can be noted from the results that pediatric audiometer and noisemakers have a good correlation in all the age groups except 13-36 month group.

This can be explained by a number of reasons. First, both are subjective procedure which are relatively less affected by ambient/physiological noise. Most of the screening was carried out at immunization centres where the noise levels were high. Most of the infants/children responded for both paediatric audiometer and noise makers. As both these procedures involve higher intensity presentation (Heather & Wharrad, 1994). As the intensity is high, cases having mild/moderate hearing will also show a response Secondly, both procedures took into account the overall response which could be response of the better ear (Hodgson, 1978). Hence, it increases the pass rate for both the test procedures.

Exceptional results obtained in 13-36 month age group could be because of the fact stated by McCormick (1994) i.e. by the time child reaches mental age of approximately 18 months she/he is able to understand simple verbal instructions. This broadens the horizons for hearing test beyond confines of auditory detection in to areas of auditory discrimination of speech, because of which they might pay lesser attention to nonverbal stimuli compared to verbal. Also, they get more attracted by visual stimuli and hence use of 'distraction technique' is suggested.

Significant low positive correlation was seen, when OAE was compared against noise makers/paediatric audiometry results, in the overall data and 0-4 month

OAEs are affected by the body movements and hence it will be more affected in fully awake alert infants. But since in the present study, most of the children in the 0-4 month age group were screened while they were asleep the body movements were negligible. In spite of the physiological noise, OAEs could be obtained in this age group children Amplitude of OAE in infants has also reported to be higher (Smurzynski (1992). Also as per Mencher (1972) chance of erroneously recording a behavioral response from sleeping baby is only 1%. So better results were also obtained for noise makers/paediatric audiometry,. This explains the agreement between the results obtained using noise makers/paediatric audiometry and OAE results for this age group.

Overall data showed a significant agreement for noise makers/paediatric audiometry results and OAE results in spite of lack of correlation in many subgroups. This shows that there exists a definite agreement for behavioral screening and OAE screening but the strength of this relation is weakened probably due to the factors like presence of ambient noise, movements made by the child, child's own physiological noise etc. Hence, if the screening is carried out in a more favourable test environment, an improvement in degree of correlation between the two can be expected.

Poor correlation was seen for HRR results against the results obtained using other three procedures for all the subgroups. This could be explained by a number of factors.

Presence of a risk factor just identifies a child to be at risk for developing hearing loss but not necessarily indicate the presence of hearing loss. Mauk et al. (1991) reported that risk factor screening identifies only 50% of hearing loss children

Mahoney and Eichwald (1979) reported that the sensitivity and specificity for HRR were 65% and 75% respectively

Thirdly, there is lack of awareness and literacy in the general population. The family members when questioned might not be aware of the problems or they might not understand the technical terms used.

Moreover, HRR is just a questionnaire and not a procedure for evaluating hearing status. So, when it is compared against screening procedures, discrepant results can be expected.

Sensitivity and Specificity:

The validity of a screening test that is dependant on diagnostic confirmation for every person under consideration is determined by:

- 1. Sensitivity, i.e., the ability of a test to correctly identify patients with disease (hearing loss)
- 2. Specificity, i.e., the ability of the test to correctly identify those without disease (i.e. normal hearing).

All the three procedures HRR, paediatric audiometry and noisemakers showed high specificity and low sensitivity when compared across the assumed standard, OAE results. These findings can be attributed to the following reasons:

For HRR:

Sensitivity and specificity of HRR in literature has reported to be poor. Sensitivity and specificity of HRR is not very good. Mahoney (1985) reported sensitivity and specificity to be 65% and 75% only.

The criteria in HRR may show the child at risk but not necessarily indicate presence of hearing loss (Mauk, White, Mortensen, & Behrens, 1991)

The HRR may not be covering all the relevant risk factors pertaining particularly to Indian population. To prevent over referral and to improve sensitivity and specificity HRR needs to be modified.

Owing to low awareness and literacy, patient may either be unaware of the presence of problem or may not be able to understand the medical terms used

For noise makers and paediatric audiometer:

Both are subjective procedures which do not involve ear specific response i.e. ultimately the response obtained could be the better ear response (Hodgson, 1976).

The criteria that have been taken for the response to be considered as pass are relatively less strict.

The presentation level of the stimulus is high especially for the older age group where lesser intensity is sufficient to bring about response (McConnell & Ward, 1967). Even mild to moderate hearing loss cases would respond to the higher presentation levels. Hence the number of subjects who pass in the test will be more thus reducing the sensitivity of the test.

OAE:

It has been taken as the standard for comparison as it is the only objective procedure used. But it has its own disadvantages such as OAEs get affected by internal physiological noise (McPherson, Smyth, Latham, Loscher, Kei, Shi & Murdoch, 2000) or ambient noise OAEs cannot be done while the child is crying or while there are excessive movements of the body. OAE might be affected by the presence of mild impairment or any middle ear pathology.

Thus, all these factors together might have contributed to high specificity and low sensitivity, which is the reverse of what has been reported by Bowes, Smith, Tan, & Varette, 1999; Norton, et al, 2000.

Cost Effectiveness:

Development of a screening protocol is impossible without attention to its cost. Especially in Indian set up, where funds are limited and population is high, cost is an important aspect to be considered.

As described earlier, the cost of the equipment will include initial and recurring cost, but cost effectiveness considers other aspects also such as time taken/child, number of children screened/day, staff salary, transport etc. All these factors can also be considered while deciding upon the protocol

a) Time taken:

The total time taken has been further categorized into 3 aspects:

- -> Preparation time
- -> Administration time
- -> Recording time

HRR:

Not much of preparation is involved, but the administration takes longer because it is a set of questions and explaining the relevant question and obtaining the answer from the informants is a long procedure Recording time is comparatively lesser as recording was done simultaneously while administering the questionnaire.

Noise makers/paediatric audiometer:

These do not involve much of preparation. The administration takes a longer duration. There should be inter-stimulus gap of 15 seconds and presentation duration of each stimuli should be between ½-2 seconds (Hodgson, 1978) So when 5 noise

makers or 4 frequencies in paediatric audiometer were used, the administration time come upto about 1 minute 25 seconds/child.

Observed response have to be recorded for each frequency for each noise maker as pass or fail, which required an additional time. Hence total time taken to screen per child is approximately $2\frac{1}{2}$ minutes.

OAE:

Here the preparation time is slightly longer because appropriate tip for the probe has to be selected which will suit a given subject.

Administration in ideal conditions would not take more than 15-20 seconds as it is an automatic test which sweeps across the test frequencies. But in Indian set ups where noise levels are high, the time to record OAEs increases (owing to high artifacts) and needs to be repeated again to get an appropriate response.

Recording takes longer because values of DP amplitude and noise floor taken as the criteria for pass/fail was different from the instrument default criteria. In addition to the time taken to administer the test, one minute was added to the total time to take into account time lost between the 2 subjects while testing for each procedure. So overall the time taken for OAE was nearly same as that taken by HRR which is approximately 4½ minutes

b) Maximum number of children screened per day:

This was calculated keeping in mind the number of working hour per day, number of working days per year (245) and time taken to test each subject.

HRR and OAE:

The maximum number of subjects who can be screened using either of the two procedures was approximately 105 per day as the time taken per subject is more for both these procedures. On the other hand approximately 210 subjects can be screened using either paediatric audiometer or noisemakers, per day. The number is nearly double that can be screened using HRR or OAE.

The number of subjects screened per day using OAE instrument can be improved substantially if the testing environment is made more appropriate in terms of reduction of noise levels etc. OAE is reported to be the fastest screening tool available but it is not feasible in our set ups owing to high noise levels.

Overall, the time taken by noisemakers or paediatric audiometer is lesser compared to HRR and OAE measurements.

c) Cost of each procedure per child:

Screening was done either at the institute or at the hospitals/immunization centers So, costs have been calculated including transport charges or excluding it.

In both ways, the cost per child for different procedures follow this trend:

NM<PA<HRR<OAE

i.e. cost per child is minimum when noise makers were used and maximum when OAE is used for screening.

NOISE-MAKERS:

Low cost for noisemakers is because of low equipment cost and little or no maintenance charges. Also, the number of subjects that can be screened per day is more compared to HRR and OAE.

PAEDIATRIC AUDIOMETER:

The cost is higher compared to noisemakers, though the number of cases screened per day is same for both. This is because of high cost of equipment and the recurring cost which is approximately Rs.52 per day.

HRR:

Inspite of almost nil initial cost and little maintenance charges the cost per child in HRR is higher compared to Paediatric audiometer and noisemakers. This can be attributed to the fact that since time taken for the procedure is more, the number of subjects screened per day reduces resulting in the hike in cost per child.

However modifications are needed in the HRR so that it is simpler, faster, more precise and relevant for the Indian population.

OAE:

The costliest procedure amongst all. High cost is due to two reasons. Firstly, the instrument price itself is very high and it needs maintenance. Secondly, number of cases screened/day is less, so the cost per child increases.

There cannot be made any changes in the initial cost or the recurring cost; but definitely the number of children screened can be increased by controlling the variables affecting OAEs like experience of the person, noise level in the test environment and state of the child etc.

GENERAL OBSERVATIONS

Difficulties/problems encountered during screening:

0-4 months:

Almost all the children responded for paediatric audiometer and noisemakers. So the possibility of false negative responses are quite high. A number of children were in deep sleep which was advantageous for recording of OAE but BOA results obtained are questionable.

Compared to BOA, OAE was more sensitive, but results were largely infiltrated due to ambient noise.

4 to 7 months:

Lot of physical activity was generally seen in the children of this age group Restlessness of the child and hence enhanced body movements made difficult to measure OAE. Most of the children in this age group also responded to paediatric audiometer and noisemakers.

7 to 9 months and 9 to 13 months:

Since most of the screening was done at immunization centres, and there are fewer vaccinations done in this age range, so the number of subjects in these age groups were lesser compared to other subgroups.

The general trend seen in the behavior was restlessness and crying/aggressive behaviour when the probe was put in the ear canal for OAE measurements. Due to lack of cooperation from the child, OAE could not be performed on a number of cases.

Most of the cases passed in screening using noisemakers and paediatric audiometer, thus increasing the chances of false positive responses.

13 to 36 months:

OAE measurement was most difficult due to active state of the children.

MAXIMUM RESPONSES OBTAINED

0 to 4 months:

A variety of responses were obtained including startle, eyeblink, eyeball movement, cessation of activity, crying, smiling etc. Out of all these the most frequent responses were eye blink and eyeball movement observed from those subjects who were awake and startle/crying/general body movements from those who were asleep. Most commonly subjects responded for drum (amongst the noisemakers used).

4 to 7 months:

Responses obtained were eyeball movements, rudimentary head turn and general body movements. Most frequently seen responses were eyeball movements

7 to 9months:

Most frequently encountered response was head turn Other responses seen were eyeball movements and eyeblinks.

9 to 13 and 13 to 36 months:

Definite head turn responses were obtained from a majority of children in this age group. It was observed that if a subject responded for a particular sound stimuli or pure tone then responses were obtained for other noise makers or pure tones also.

RECOMMENDATIONS FOR TEST BATTERY:

To decide about the test battery to be used for screening advantages and disadvantages of each procedure needs to be considered which has been reported by different investigators and also have been observed in our study are discussed below:

A. Screening through behavioural observation (using paediatric audiometer and noise makers.

Advantages common to both procedures:

- Both Paediatric audiometer and noisemakers can be made use of at all the centers irrespective of availability of electricity.
- Both procedures are less time consuming compared to HRR and OAE hence more number of children can be screened/day.
- Cost effective and easy to carryout.
- · Less affected by ambient noise
- High specificity for both NM/PA so either of them can be made use of.

Advantages of using Paediatric Audiometer:

- Frequency specific stimulus can be obtained
- Stimulus level can be maintained at constant level of intensity
- · More face validity compared to HRR or NM
- Intensity can be altered depending upon the age group which has to be screened.

Advantages of using Noisemakers:

- Easily available and do not require any maintenance
- Cost of NM is much less compared to PA.

Disadvantages (common):

- > There is rapid habituation to stimuli. Responses of infants and young children are quick to extinction without reinforcement (Northern & Downs, 1978).
- > Unilateral hearing loss cases may go unnoticed as the response obtained could be the response of the better ear (Hodgson, 1978)
- > High intensity stimuli used in behavioral screening ensure response but this is an intrinsic weakness of these methods. Infants/children with mild

- and moderate and some with severe hearing losses may pass a behavioral screening (Wharrad, 1994).
- > There can be a wide variance in the responses obtained, from a mere eye blink to head turn in the direction of source (Northern and Downs, 1984).
- > It is difficult to remove tester bias. The interpretation of the response obtained would be based upon clinician's experience, maturity, knowledge and competence.
- > More chances of obtaining false positive and false negative responses (Wharrad, 1994; Feinmesser& Tell, 1976).
- > These procedures are not useful when the child is in deep sleep.
- > Calibration is difficult here.

Disadvantages of using Paediatric Audiometer:

> Maintenance cost is higher as it's a battery operated device and needs change of batteries regularly.

Disadvantages of using Noisemakers

- > Noise makers cannot be calibrated with the precision of electronic generators so they might be helpful in obtaining reflexive, arousal and orientation responses which need to be verified.
- > Stimulus intensity cannot be maintained at constant levels.
- > Frequency specificity cannot be there unlike PA because the sound produced here is a complex sound with a wide frequency range.
- > Less face validity compared to paediatric audiometer.

B. Otoacoustic emissions

Advantages

- Can be made use of in all the age groups.
- Objective, automatic procedure
- Fastest screening instrument in centers where there is low ambient noise

- OAE can help in the identification of unilateral hearing loss as it assesses the status of each ear separately.
- If OAEs are present then mild/moderate hearing loss can be ruled out because in case of presence of hearing loss, the OAEs will be absent.
- OAEs can be done even while the child is sleeping.
- It is automatic so requires minimum skill on the part of the tester. There can be no tester bias in the interpretation of the results.
- There is better retest reliability compared to behavioral screening procedures because there wont be any habituation of response seen as in BOA
- No variation in stimulus level as can be there in the case of noisemakers.
- Hearing loss can be identified at a lesser age i.e. it reduces the age at which congenital or neonatal acquired hearing impairment is identified (Cope & Lutman, 1994).

Disdvantages:

- > Equipment's initial cost is very high (approximately Rs.2 lakh for AuDx).
- > Maintenance is a problem The probe might get blocked if there is wax, debris etc. seen in the ear canal.
- > Calibration of equipment is difficult
- > OAEs cannot be measured when there is high ambient noise, when the child is crying or in case of excessive body movement.
- > Though, OAE has been reported to be highly sensitive (Stevans, et al., 1987, Kemp et al., 1997; Probst, 1987), in this study sensitivity was found to be quite low when compared across other procedures.

Choice of equipment or procedure should be made keeping in mind a number of factors such as age group to be screened, accuracy of the test procedure, test environment (eg. In a noisy set up, OAE wont be the procedure of choice), number of subjects to be screened and the funds available.

For each subgroup, recommendations of the test batteries are being made, based on our observations and findings, which can be classified as essential and ideal. Essential refers to the minimum set of required equipments while ideal is the desirable one which should be included to get better results, if resource permit.

0-4 months:

Based on the discussion, it may be suggested that noisemakers should be used as essential tool for screening. Noisemakers give useful preliminary and supplementary information about hearing status. They are cheap, easy to use and relatively unaffected by ambient noise.

Paediatric audiometer is one step ahead as it gives frequency specific information and also intensity levels can be maintained constant here. So use of paediatric audiometer depends upon availability of funds.

If battery of tests are being made use off or screening, HRR need not be administered as person with hearing impairment can easily be identified. It is time consuming and moreover identifies subjects at risk who may not necessarily have hearing loss. Joint Committee on Infant Hearing (JCIH) clearly states that purpose of HRR is to help in identifying infants who should receive audiologic evaluation and who live in geographic locations (eg. developing nations) where universal screening is not yet available

Since there was good correlation obtained for OAE and PA/NM results for this age group, OAE can be made use of, for all its advantages mentioned earlier and toad more objectivity to the protocol. Hence the choice of essential screening equipment is NM/PA which along with OAE is desirable.

4-7 *months:*

Recommendations mentioned for the previous age group remains same here as the justifications discussed hold good even for this age group.

7 to 9 and 9 to 13 months:

Noise makers/paediatric audiometer is recommended for this age group as majority of the cases responded for both.

Use of OAE or ABR may not be recommended in this age group as children are more restless and distracted and hence more body movement which would affect the OAE, ABR results.

Amongst objective tests immittance can be make use of because it is relatively less affected by activity state of the child. It would make the test battery for screening more objective. Hence, essential equipment is NM/PA and immittance added to it will make the desirable combination

13 to 36 months:

There was no significant correlation obtained for any of the procedures for this age group. A mentioned earlier, during this age there is shift of child's attention to verbal and visual stimuli, so use of only auditory stimuli would not give appropriate results.

Hence need for different test battery to be established for this age group which can include immittance as objective tool

LIMITATIONS OF THE STUDY:

- 1. The number of subjects taken up for the study was less, in each subgroup especially 7-0 and 9-13 month age to arrive at a significant statistical inference.
- 2. Test environment was not appropriate for testing at most of the places where screening was done due to high noise levels which affected the test results.
- 3. Screening was carried out at different places. So, difference in the testing atmosphere could have affected the results.
- 4. OAEs are usually affected by both physiological noise (McPherson et al., 2000) and external ambient noise So, only those children where OAE could be obtained were taken
- 5. Screening was done at constant intensity level (80 dB SPL). It has been reported in the literature (McConnell & Ward, 1967) that progressively lesser intensities are required to elicit responses as a child matures.
- 6. The child can understand simple verbal instructions at the age of 18 months. This broadens the horizon for the hearing test beyond confines of auditory detection into the area of auditory discrimination of speech, so BOA becomes unsuitable for this age.
- 7. Less strict criteria has been taken for considering a case pass and this probably could result in high specificity which might not be the case actually.
- 8. Detailed diagnostic test should have been administered especially using ABR to confirm the cases who failed in the screening.

SUMMARY AND CONCLUSION

Hearing screening has been attempted during the past 60 years with a variety of test methods, objective, subjective or in combination.

Though different procedures have been suggested there has been no test battery (making use of both subjective and objective methods) which suitable for Indian set ups.

The present study was taken up with the aim of comparison of hearing screening by behaviour observation and OAE results in terms of (a) accuracy ie. relationship between 2 results (b) time taken to screen per child (c) sensitivity and specificity of the test results and (d) cost effectiveness of each procedure

A total of 165 subjects in the age range of 0-3 years were screened at different set ups using paediatric audiometer (Arphi), noise makers and otoacoustic emissions (AuDx) HRR was also administered as a routine procedure Responses were taken in terms of pass or fail.

Subjects were divided into 5 subgroups as per the classification given by Northern and Downs (1978) based on development of auditory behaviour.

From the results obtained it has been noticed that a positive correlation exists between results obtained using paediatric audiometer and noise makers in almost all age groups suggesting the use of Paediatric Audiometer/Noisemakers for screening.

Significant but low positive correlation was found between OAE and Paediatric audiometry results & OAE and Noisemakers results No significant correlation was found for HRR when compared against all three procedures. Sensitivity was found to be low for all the procedures while specificity was very high.

Time taken/child was found to be more for HRR and OAE compared to Paediatric Audiometer and Noisemakers

Specific pattern can be seen for cost effectiveness in all the age groups which is shown below

After at length discussion regarding advantages/disadvantages, cost, time taken, sensitivity and specificity, problems encountered in each age group and the feasibility of each test, the following test battery has been suggested for screening

Age group	Essential	Desirable
0-4 months and 4-7 months	NM	NM/PA, OAE
7-9months and 9-13 months	NM/PA	NM/PA, Immittance
13-36 months	Different protocols need to be established.	

Table 9 Represents test battery recommended for each age group.

Suggestions for further research

Study on the similar lines can be taken up for a younger age group with more number of subjects, more appropriate test environment, varying intensity levels for screening different age groups followed by detailed evaluation of the referred (or failed) cases to confirm presence or absence of hearing impairment.

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