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Manuscript

A) Background

Detection of hearing impairment at an early stage in individuals, who are at risk, is an 1 2 important step in its prevention and control. One of the ways in which hearing impairment is identified is through hearing screening. According to Lo and McPherson (2013), hearing 3 screening through pure tone audiometry is the most widely used method. In pure tone 4 hearing screening, (ASHA, 1997) tones are presented at frequencies of 500 Hz, 1000 Hz, 5 2000 Hz and 4000 Hz from a screening audiometer through headphones placed at the ear of 6 the person being tested. Tones are presented at 25 dB HL at each frequency to each ear and 7 the person being tested will be instructed to indicate whether he/she hears the tone. 8 25 dB HL is the pass criteria kept by ASHA (1997) for pure tone screening. The person who 9 fails to respond at 25 dB HL even at single frequency in either ear is referred for the complete 10 diagnostic evaluation (ASHA, 1997). To pass the test, the person being tested has to respond 11 to all test tones at 25 dB HL in both ears. If there is no co-operation or if the person is unable 12 13 to get adjusted to the response task, the result is recorded as 'could not screen'. Quoting Sabo, Winston & Macias (2000) and Sideris & Glattke (2006), Lo and McPherson (2013) 14 emphasized the high sensitivity and specificity of pure tone audiometry, which has earned its 15 nomenclature as the gold standard. 16 An environment with low levels of ambient noise is essential to conduct pure tone 17 audiometry. Permissible noise levels specified by American National Standards Institute 18 19 (2003), for pure tone audiometry at frequencies used for screening, are shown in Table 1. 20 Ambient noise levels in the test location should remain within these values to avoid falsepositive results (Walker, Cleveland, Davis and Seales, 2013). Walker et al., (2013) also 21

mentioned that if the ambient noise levels exceed these values, it may lead to raised thresholds at low frequencies.

Weyers and de Jager (2004) conducted a study to determine if the acoustic environment would have a significant effect on the outcome of screening audiometry in industries. Conducted with calibrated audiometers, the compared the results of tests conducted in a standard compliant and a non-compliant acoustic environment. Their findings indicate a significant difference between results from the two acoustic environments at the test frequencies of 500 and 1000 Hz, but no significant differences at 2000, 3000, 4000, 6000 and 8000 Hz.

Background noise in the low frequency range is a major bottleneck in pure tone hearing screening (Bromwich et al., 2008). The ambient noise in most of the industrial situations is prominent in frequencies of 500 Hz and below (Lo and McPherson, 2013) which will mask the test tones at these frequencies. This will change the threshold detection levels at these frequencies which will further lead to false positive diagnosis. The client will be unnecessarily referred for further diagnostic tests.

Hallett and Gibbs (1983) conducted a study on the effect of ambient noise and other variables on pure tone threshold screening in primary schools. The average ambient levels were reported to be 50 dB SPL in this study, but these noise levels did not significantly affect the screening levels. The study also confirmed that the low frequency components were more prominent in the ambient noise. However, the study was limited to ambient noise levels up to 50 dB SPL only.

Kam et al., (2014) while establishing the reliability and validity of their automated hearing screening method for preschool children, observed better specificity and sensitivity in comparison to Kam, Gao, Li, Zhao, Qui and Tong, (2013). Better control of ambient noise

- 1 level (40 to 51 dB SPL) in comparison to the previous study (45 to 65 dB SPL) was cited by
- 2 the authors as one of the possible reasons for the higher sensitivity and specificity.
- Wong, Yu, Chen, Chiu, Wong and Wong (2003) reported that testing environments
- 4 with moderate to substantial ambient noise may result in over estimation of shift in hearing
- 5 threshold. They arrived at this conclusion by comparing the hearing thresholds obtained in
- 6 industrial environments with mean noise levels of 44.8 dB SPL at 500 Hz and 41.4 dB SPL at
- 7 1000 Hz with the thresholds obtained in standard acoustic conditions.
- As per census (2011) carried out by Government of India, out of the 121 crore
- 9 Indians, 83.3 crore (69 %) live in rural areas. 47% of the persons with hearing disability, that
- 10 is, about 24.00 lakhs stay in rural areas. Hence there is a huge demand to carry out hearing
- 11 screening services in rural areas. But, the number of professionals available in rural areas is
- 12 very less. Hence, hearing screening services are not being extended to most of the Indian
- 13 rural population.
- 14 An Information and Communication Technology (ICT) based indigenous online
- 15 hearing screening system was developed to extend hearing screening services to the villager's
- doorstep, addressing the issue of lack of trained manpower in the villages of the country
- 17 (Abraham, Chandini & Yashaswini, 2015). The system was taken to the household of the
- 18 villagers or any location in the village, where the Audiologist sitting at a central station will
- 19 conduct the test online. A social worker facilitated the testing in the rural household by just
- 20 switching on the system and by placing the headphone on the ear of the person being tested.
- 21 The system was battery operated and provided accurate test results as the test stimuli were
- 22 delivered online through a calibrated stimulus delivery system. The clinical trials of the
- 23 hearing screening system were done at three villages in Mysuru district of Karnataka state,

- 1 India. Validation of the system was done by comparing the results with that of a portable
- 2 diagnostic Audiometer.
- 3 As most of the rural areas in India didn't have the required infrastructure such as
- 4 sound treated rooms or quiet rooms, the trials of the online hearing screening system had to
- 5 be conducted in available places such as buildings of community worship, households or
- 6 offices such as village panchayats. During the field trials of the online hearing screening
- 7 system, the ambient noise levels at the locations of field trials were observed to be above 50
- 8 dB SPL. Most of the previous studies have investigated the effect of noise levels up to 50 dB
- 9 SPL on the result of screening test or on the thresholds. Environment in which these previous
- studies were conducted were usually in schools or in industries and not in villages, where the
- 11 acoustic conditions were different. To chalk out an action plan to extend hearing screening
- 12 services to Indian rural areas, there is a need to find out the effect of the acoustic environment
- in Indian villages on the outcome of hearing screening audiometry. None of the previous
- 14 studies have investigated this.
- Aim of the present study was to investigate the effect of ambient noise levels on the
- outcome of screening audiometry in Indian rural set up. Thus the objectives of the study
- 17 were:-
- a. To conduct pure tone hearing screening tests on a group of individuals at three
- 19 selected locations in typical Indian rural setup.
- b. To measure the ambient noise levels in these three rural locations, when the pure tone
- 21 hearing screening test is conducted.
- 22 c. To conduct pure tone hearing screening tests on the same set of individuals in a
- 23 standard test room with ambient noise levels complying to ANSI standard.

d. To determine the effect of ambient noise levels on the outcome of screening audiometry by comparing the results of the test conducted in a standard compliant test room with the results of the test conducted in rural locations.

B) Materials and Methods

i. Participants

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- 4 a. Measurement of ambient noise levels: Three locations were chosen for the study, one
- 5 each from the nearby villages (Village I, II & III) of Mysuru district in Karnataka, India.
- 6 Location A was a room in a meditation centre in village I. Location B was a house hold
- 7 located in a residential area comprising about 100 houses in village II. Location C was a
- 8 room in the office of the village Panchayat in village III. A standard audiometric test room
- 9 complying with maximum permissible ambient noise limits specified by ANSI (2003) was
- 10 also chosen for the study.

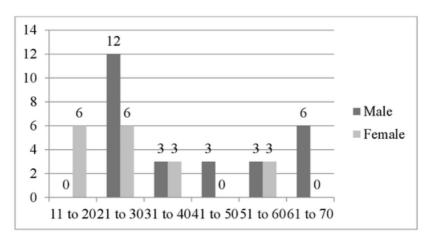


Figure 1: Age and gender wise distribution of participants

- 11 b. Pure tone hearing screening: A total of forty five participants aged 18 years and above as
- 12 per the distribution shown in Figure 1 participated in the study. Fifteen each of them were
- 13 from one of the three villages chosen for the study (maximum distance of 25 km from the test
- 14 location). All the participants voluntarily participated in the study and were not paid for it.

ii. Material

- a. Measurement of ambient noise levels: Ambient noise levels were measured at all three
- 2 locations and the standard compliant test room chosen for the study using a Larson & Davis
- 3 (Type 824) sound level meter fitted with 1/2" free field measuring microphone (Type 2540)
- 4 and 1/2" preamplifier (Type PRM 902). All the noise samples were recorded through B&K
- 5 BZ 7226 sound recording system.
- b. Pure tone hearing screening: The pure tone hearing screening test was carried out using a
- 7 portable audiometer (Proton Dx) with Telephonics TDH-39 supra-aural headphones on all the
- 8 participants. The equipment was calibrated according to ANSI S3.6-2010.

iii. Procedure

- 9 a. Measurement of ambient noise levels: 480 noise samples were taken for one minute
- 10 duration, one sample in every 125 msec. Measurements were taken while conducting the
- 11 hearing screening test and the equivalent noise level 'Leq' was noted during the test for each
- 12 subject, at each test location. Levels from all the noise samples were averaged to obtain the
- 13 noise level during the testing. All the measurements were taken by selecting dB A live fast
- 14 response mode in the Sound Level Meter. Noise samples were also recorded with 24-bit
- 15 resolution and 48 kHz sampling frequency, for further analysis.
- The measuring microphone was kept at a height of 1.2 meters from the floor at a
- 17 distance of 0.15 meters from the ear of person. Distance of the measuring microphone from
- 18 the immediate wall was kept just greater than 1 meter. If there was any window at the
- 19 measurement site, a minimum distance of 1.5 meters was kept from the window. Measuring
- 20 microphone was always oriented towards the direction which showed the highest reading.

1 b. Pure tone hearing screening: Pure tone hearing screening test was conducted through portable audiometer at each of the rural locations and also in a standard compliant test room 2 at AIISH, Mysore. The hearing screening was done at four test frequencies (500, 1000, 2000 3 & 4000 Hz) and at four different intensity levels (25, 30, 35 & 40 dB HL). 25 dB HL was 4 included as per ASHA guidelines, 30 dB HL was included as it was used in some of the 5 earlier studies (Kam et al., 2013). 35 & 40 dB HL were used as an extended range as it gives 6 supplementary information. Duration of the pure tones was 3 seconds (Kam et al., 2013) and 7 the inter stimulus interval ranged from 4-6 seconds. The hearing screening started with right 8 9 ear at 500 Hz and 25 dB HL. The participants were instructed to indicate when he/she hears the tone. If there was a positive response, test was repeated at the next higher frequency. If 10 11 the participant did not hear the tone, the tone level was increased up to 40 dB HL in 5dB steps till a positive response was obtained. The same procedure was followed for other 12 13 frequencies and for the other ear. The level where two positive responses obtained out of 14 three presentations were considered as the threshold.

iv. Analyses

Spectrum analysis of the noise recorded at the three test locations were carried out
with B & K Pulse Reflex analysis system. The absolute difference (in dB HL) in the hearing
thresholds for each frequency tested, obtained from each of the test locations and standard
compliant test room, was calculated for every subject. The means and standard deviations of
these differences were then computed for all frequencies. The comparison between the
thresholds at each test frequency, at each test location and standard compliant test room was
done with Wilcoxon signed rank test.

C) Results

i) Measurement of Background noise levels

1 The Background noise levels were measured at test locations in the three villages and also in the standard compliant test room and the values are shown in Table 2. In the standard 2 compliant test room, the noise levels were observed to be well within the permissible limits. 3 In all the three test locations in the villages, the measured values were found to be much 4 higher than the permissible noise levels at all the four test frequencies. However, it was 5 observed that the differences were much higher at 500 Hz and 1000 Hz, but less at 2000 Hz 6 and 4000 Hz. Figure 2 shows the levels at all frequencies up to 4000 Hz. The concentration 7 of the ambient noise in the frequencies up to 800 Hz at locations A, B & C is evident from 8 9 Figure 2.

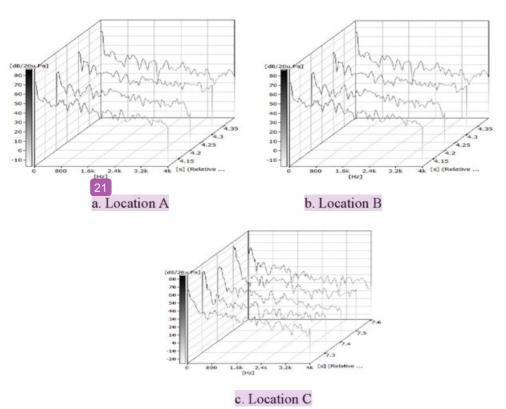


Figure 2: Spectrum of ambient noise in the test locations

ii. Pure tone hearing screening

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The thresholds obtained for each participant in the test location were compared with the thresholds obtained for the same participant in the standard compliant test room. Mean

- 1 and SD of the differences at each test frequency are shown in Table 3. The comparison
- 2 between the thresholds obtained at each of the three locations and at the standard compliant
- 3 test room was done using Wilcoxon Signed Ranks test. The results showed that there is no
- 4 significant difference between the thresholds at 1000, 2000 & 4000 Hz (p <0.01) in all the
- 5 three locations, when compared with the thresholds obtained in the standard test room.
- 6 Significant difference was observed at 500 Hz test frequency in all the three locations.
- 7 Number of participants who were passed and referred after the screening test at each of the
- 8 test locations are shown in Table 4 with pass criteria kept at 25 and 30 dB HL.
- 9 Test specificity is the ability of a test to correctly identify those without the disease.
- 10 The specificity of the hearing screening test at the three locations was calculated by
- 11 comparing with the test results obtained at the standard compliant room for different test
- 12 frequencies (500 Hz, 1000 Hz, 2000 Hz & 4000 Hz) at two referral criterion levels
- 13 (25 and 30 dB HL). These results are tabulated in Table 5. It can be noted from the Table 5
- 14 that the specificity at 500 Hz was lesser at both the referral criterion levels compared to other
- 15 higher frequencies. When the referral criterion was set to 25 dB HL, the overall specificity of
- the screening software were found to be 43.33%, 16.67% and 16.67% respectively at
- 17 Locations A, B & C. When a higher criterion level of 30 dB HL was considered, it showed an
- increase in specificity as it was found to be 86.67%, 80% and 90% at Locations A, B & C
- 19 respectively.

D) Discussion

i) Ambient noise levels at the test locations

- The ambient noise levels observed at the test locations A, B & C (58.3, 60.1 and
- 21 64.8dB SPL respectively) were higher than the noise levels recorded by Hallett & Gibbs
- 22 (1983), Wong et al. (2003) and Kam et al. (2013). Thus the acoustic environment in a rural

- 1 location in India was found to be different from the environment in which the previous
- 2 studies were conducted.

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- 3 Spectrum of the ambient noise at all the three locations has shown that the noise is
- 4 prominent at low frequencies and would thus affect the test results at 500 Hz test tone. This
- 5 is in accordance with the previous studies conducted by Hallett and Gibbs (1983), Lo and
- 6 McPherson (2013) and Bomwich et al. (2008).

ii) Effect of ambient noise levels on the outcome of screening audiometry

Hearing screening programs are regularly conducted for industrial workers in the

industrial set up itself where the ambient noise levels will be above the permissible levels.

Similarly, screening is also done for school children in their respective schools in an

environment with higher ambient noise levels. Differences between the thresholds obtained

from these two test scenarios against the thresholds obtained from a standard compliant

12 location have been previously reported in literature. However, such a comparison with the

thresholds obtained from an Indian rural set up has not yet been reported. In the present

study, we compared the hearing thresholds of a group of participants from three rural

15 locations with the thresholds obtained at a standard test room. Consequent variations in pass

16 / referral results were also compared at two levels (25 and 30 dB HL) of screening.

Significant difference in thresholds was observed only at 500 Hz test frequency in all the three locations. This is in accordance with the results of the study conducted by Weyers and de Jager (2004). Mean difference between the thresholds was maximum (5.33dB) at locations B & C at 500 Hz test frequency. This can be explained by the higher noise levels recorded at locations B & C and also its prominence in frequencies below 500 Hz. For the same reason, the test specificity was also observed to be poor at 500 Hz in all the three

locations at 25dB HL criterion level. The poor sensitivity at 500 Hz shows that the test results

- are significantly influenced by the prominent background noise. Even though the specificity
- 2 was better at 30 dB HL criterion level, it was evident that the presence of background noise at
- 3 the lower frequencies was influencing the test results at all the village locations. At 1000 Hz
- 4 frequency the specificity was found to be better and reached 100% with 30 dB HL criteria.
- 5 At higher frequencies of 2000 and 4000 Hz, the background noise did not affect the results.
- 6 This was expected as the noise levels at these frequencies were comparatively lower to the
- 7 noise levels at 500 Hz in all the three locations.

Hallet and Gibbs (1983) reported that noise levels below 50 dB SPL did not significantly affect the screening levels for pure tone screening programs conducted in primary schools. If the noise levels in the range of 58.3 to 64.8 dB observed at the test locations can be brought down below 50 dB, the influence of noise on the screening levels can be eliminated. Simple noise reduction techniques such as keeping the waiting room and registration room of the participants little away from the test location, closing the doors and windows of the room housing the test location at the time of testing and laying sacks made of jute on the floor of the test location may help to achieve this. However, these options were not tried out during this study.

An important limitation of our study was that all the subjects participated in the study were found to have normal hearing. This was because, being a hearing screening program no selection criteria other than the age group were considered for selection of the participants. Hence, the sensitivity of the screening test at the test locations could not be computed. The effect of ambient noise levels on the thresholds of persons with hearing impairment could not be estimated, due to the same reason.

Another limitation of the study is the limited number of locations selected in the villages. However, as the noise levels across these locations were found to be differing only

- by 6 dB, it may be assumed that, these locations represent the general scenario in Indian rural
- 2 areas.

E) Conclusions

- The ambient noise levels observed at all the three test locations in villages I, II & III
- 4 were higher than 58.0 dB. This was higher than the noise levels in the test locations where
- 5 school screening and industrial screening were reported in the previous studies. Substantial
- 6 levels of low frequency background noise were influencing the test results at 500 Hz test
- 7 frequency majorly, when compared with the results of the test conducted in a standard test
- 8 room. This leads us to the following conclusions:-
- 9 a) Use of 500 Hz test frequency for hearing screening programs in rural locations in India
- may lead to variations in the estimate of the prevalence of hearing loss.
- b) If 500 Hz tone is used, all the referred cases should be screened once again in the standard
- 12 compliant test rooms, before proceeding to the diagnostic tests.
- 13 c) The criteria for the prevalence of hearing impairment should be adjusted for the effects of
- 14 background noise by comparison with hearing thresholds obtained from a standard
- 15 compliant test room.
- d) Bringing down noise levels to below 50 dB at the test locations will help to reduce false
- 17 positive and false negative results.
- 18 These findings of the study will help to precisely plan and conduct the hearing screening
- 19 programs at rural locations of India, effectively and accurately.

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G) List of tables

23

Table 1: Maximum Permissible Ambient Noise Levels for Audiometric Test Rooms (ANSI, 2003)

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Frequency (Hz)	500	1000	2000	4000
Maximum Permissible Noise Level (dBA)	19.5	26.5	28.0	34.5

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Table 2: Measured values of ambient noise levels

		Backgroun	d noise level (d I	B L _{Aeq})
Frequency (Hz)	Location A	Location B	Location C	Standard Compliant test room
500	51.9	56.8	65.6	18.0
1000	49.9	56.2	61.9	17.4
2000	43.6	50.3	49.0	17.4
4000	39.3	45.4	44.6	17.1
Overall	58.3	60.1	64.8	22.1

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Frequency	Ears	Absolute difference (dB) - Location A		differen	olute ce (dB) - tion B	Absolute difference (dB) - Location C	
		Mean	SD	Mean	SD	Mean	SD
500 Hz	Left	3.33	3.09	4.67	2.97	4.67	2.97
	Right	3.33	3.62	5.33	2.97	5.33	2.97
1000 Hz	Left	0.67	1.76	2.00	2.54	2.00	2.54
	Right	1.0	2.07	1.33	2.29	1.33	2.29
2000 Hz	Left	0.0	0.0	0.0	0.0	0.0	0.0
	Right	0.0	0.0	0.0	0.0	0.0	0.0
4000 Hz	Left	0.0	0.0	0.0	0.0	0.0	0.0
	Right	0.0	0.0	0.0	0.0	0.0	0.0

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Table 4: Number of participants referred at each location with two different criterion levels.

Pass Criteria and test location	Participants from Location A		Particij from Loc		Participants from Location C		
location	Pass	Refer	Pass	Refer	Pass	Refer	
25 dB at Standard Compliant test room	15	0	15	0	15	0	
25 dB at village locations	7	8	2	13	2	13	
30 dB at village locations	13	2	12	3	12	3	

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Table 5: Specificity at test locations with 25 and 30 dB HL criteria

25 Frequency	500) Hz	1000 Hz 2000 Hz) Hz	4000	Hz	
Criterion	12 25 dB HL	30 dB HL	25 dB HL	30 dB HL	25 dB HL	30 dB HL	25 dB HL	30 dB HL
Specificity (%) Location A	43.33	86.67	83.33	100	100	100	100	100
Specificity (%) Location B	16.67	80	70	100	100	100	100	100
Specificity (%) Location C	16.67	90	66.67	100	97	100	100	100

Paper4

ORIGINALITY REPORT

SIMILARITY INDEX

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