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Original Article

Comparing the Effect of Different Permissible Exposure Limits on Hearing Threshold Levels above 25 dBA over Six Months

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OBJECTIVE: Countries such as Malaysia, India, and the US are still adopting 90 dBA as the permissible exposure limit for noise. Purpose of the article is to assess the development of hearing threshold levels above 25 dBA on adoption of an 85 dBA permissible exposure limit compared with a 90 dBA limit.

STUDY DESIGN: Intervention study done in two factories.

MATERIALS and METHODS: The minimum sample size required was 43 in both factories.Hearing protection devices were distributed to reduce noise levels between the permissible exposure limit and action level. The permissible exposure limits were 90 and 85 dBA, while action levels were 85 and 80 dBA for Factory 1 and Factory 2, respectively. Hearing threshold levels were measured at the outset (baseline) and in the sixth month using a manual audiometer. McNemar's and Chi-square tests were used in the statistical analysis.

RESULTS: There were statistically significant associations between participants of both factories at 4000 Hz (right ear), with a continuing level of 'deterioration'; χ^2 (1)=4.27, φ=-0.145, p=0.039 in Factory 1 and at 6000 Hz (right ear) with a 'preserved' hearing level, χ^2 (1)=9.84, φ=0.220, p=0.002 in Factory 2.

CONCLUSION: The findings suggest that the adoption of 85 dBA as the permissible exposure limit preserves hearing threshold level more at 4000 and 6000 Hz compared with an exposure limit of 90 dBA. This study suggests that the countries should review their permissible exposure limit policy.

KEY WORDS: Tuning forks, Rinne test, hearing impairment, hearing loss, hearing screen

INTRODUCTION

Background

Occupational noise-induced hearing loss is emerging more in developing countries compared with developed countries. It is also a known problem in developed countries such as the US. This occupational disease has resulted in approximately 3.8 million disability -adjusted life years (DALY) [1]. This escalating figure is most probably due to rapid industrialisation in these regions. Other comorbid conditions that may contribute to DALY such as stress, depression, hypertension, peptic ulcer, and chronic fatigue are the non-auditory effects of noise-induced hearing loss. The progression of this occupational disease is reliant on three factors: frequency; intensity; and duration of exposure to loud noise [2]. There are different views with regards to levels of noise that may lead to this slow and irreversible occupational malady. According to the US Occupational Safety and Health Administration (OSHA), the permissible exposure limit is 90 dBA; an employee should not be exposed beyond this level for more than 8 hours [3]. The US National Institute of Occupational Safety and Health (NIOSH), a research body, recommends an exposure limit of 85 dBA, with an exchange rate of 3 dB [3]. Countries such as Malaysia [4], India, and the US [5] are adopting 90 dBA as the permissible exposure limit, with an exchange rate of 5 dB. A total of 663 cases of occupational diseases were investigated in Malaysia in 2010. Of this total, around 70% of cases were diagnosed to have noise-induced hearing loss, making it as the most common occupational disease [6]. However, there is limited available literature on the comparative effectiveness of these permissible noise exposure limits. Moreover, there is insufficient scientific evidence to support the setting of 85 or 90 dBA as the permissible exposure limit.

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Objective

The purpose of this study was to assess the development of hearing threshold levels above 25 dBA upon adoption of 85 dBA as the permissible exposure limit compared with a limit of 90 dBA. It is of utmost importance to scientifically determine the legal permissible exposure limit, since it will impose issues of cost and enforcement, besides affecting hearing protection of workers. The hearing threshold level is considered normal if it is at or below 25 dBA [7]. Beyond this level, hearing sensitivity for speech may be affected [7]. The affected speech may comprise both mid and high frequencies. Continuous exposure to high noise levels may lead to noise-induced hearing loss and potentially other health-related quality -of-life issues.

MATERIALS and METHODS

Design

We conducted an intervention study comparing two factories adopting different permissible exposure limits. This intervention consisted of usage of hearing protection devices among participants from both factories; participants of one factory (Factory 1) were exposed to a permissible exposure limit of 90 dBA while the other participants (Factory 2) were exposed to a level of 85 dBA. Upon enrolment into the study, hearing threshold levels of the participants were measured to establish a baseline and then followed up at the sixth month. The participants were not exposed to any noise levels beyond 80 dBA for a period of 14 hours [4] prior to audiometry assessment at the outset and the sixth month. The participants were communicated to do their normal activities, without any limit on their non-working noise exposure during the study period. This study was conducted from February to August 2012.

Recruitment of Participants

Recruitment of the study area was initiated through online requests to the safety and health officers of the factories. The details of the study were explained to the safety and health officer, human resource manager, and chief executive officer, i.e., the objectives, sample size, target population, data collection method, intervention by hearing protection device, outcomes, and duration of the study. Upon approval to conduct this study in the factories, relevant information about this study was provided to the participants. The participation of employees was voluntary and was upon obtaining their written informed consent.

The eligible participants in each factory were those exposed to a noise level above the action level. The action level was defined as a sound level of 85 dBA in Factory 1 and 80 dBA in Factory 2; the daily noise doses were equal to 0.5 in both factories [4]. The amount of exposure was half of the permissible exposure limits. The exclusion criteria were: subjects who refused to participate; contract workers, since they were not continuously employed and exposed to the noise; lorry drivers, since they were not stationed in the factory; those having diseases of the ear such as chronic suppurative otitis media or malignancy; employees who had experienced physical trauma to the ear due to penetrating injury or fall; and those who had undergone ear surgery. This information was obtained via a questionnaire. The participants from both factories were adopting 90 dBA as the permissible exposure limit before the study and hence, they were wearing hearing protection devices to reduce noise exposure to levels between the permissible exposure limit and action level. Appropriate hearing protection devices were distributed by the safety and health officers to participants of both factories at the outset, after noise measurement and initial audiometry assessment. They were taught the proper insertion techniques by these officers. The hearing protection devices were made up of synthetic and corded types of ear plugs, which are reusable. To ensure continuous usage of these devices, the participants were supervised at all times by the officers during work.

Sample

The research population consisted of workers of two factories in the automobile industry who were exposed to noise levels beyond the action level. The participants from the factories were exposed to a range of noise levels, from 80 to 98 dBA, determined by conducting an initial noise area survey. All the participants worked in 8-hour shifts. The total population exposed to noise levels above the action level was 260. Of the eligible participants, 203 of them participated in this study. Fifty-seven eligible workers did not participate, mostly due to busy work procedures and the predilection of those employees against participation in the study. Based on information from the literature [8], the sample size required was 43 respondents for each factory based on a two-sided significance level of 0.05 and power of 80%. The calculation of sample size was performed using Power and Vanderbilt, Nashville, United States [9, 10]. Taking into account an estimated 20% lost to follow-up, the minimum sample size required was 52 in each factory. The sample size limitation was addressed by calling the employees by phone and providing them incentives (food) to participate.

Noise Area and Personal Exposure Noise Measurement

Noise area measurement was performed using sound level meters [4], calibrated and approved by the Department of Occupational Safety and Health (DOSH; Larson Davis, Model Spark 706 RC and Spark 703+). In Factory 1, the zones were categorised into areas of more than 90 dBA, between 85 and 90 dBA, and below 85 dBA, whereas in Factory 2 areas were categorised as more than 85 dBA, between 80 and 85 dBA, and below 80 dBA. Sound level meters were calibrated just before noise measurement and checked again afterwards. The noise level of an area was measured at one point in time and the assessment was not repeated.

Noise exposure among employees was measured using a personal noise exposure dosimeter [4], calibrated and approved by the DOSH (Larson Davis, Model Spark 706 RC and Spark 703+). The measurement was done in each job area, whose action levels exceeded those in the factories. One employee was chosen from each job area for measurement of noise exposure [4]. The noise dosimeters were worn by the participants for the entire shift while at work and were switched off during breaks. The average noise exposure was recorded. An exchange rate of 5 dB was applied during the measurement of noise. The dosimeters were calibrated just before and checked again after noise measurement. We categorised workers by the area and not the individual. This was practised since for individuals, sound levels fluctuate more from day to day than area levels [11]. The instrument that showed a higher measured level of noise, thus causing more damage to hearing, was used for calculating the noise reduction rate (NRR).

Hearing Threshold Level

A manual audiometer was used to collect data on hearing threshold levels of the participants in Factory 1 and Factory 2. It was calibrated and approved by the DOSH (Model asi 17, equipped with TDH-39 headphones). This audiometer was placed in a soundproof booth and calibrated according to the Factories and Machinery (Noise Exposure) Regulations 1989 [4]. Audiometry assessment was conducted in the soundproof booth of a specially designed vehicle of NIOSH, Malaysia for this purpose. The noise level within the vehicle was 25 dBA. Initial audiometry assessments were taken as baseline audiograms and subsequent audiometry tests were given to all participants of both factories at the sixth month. The test frequencies measured were 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz for both ears of the participants. The participants underwent audiometry assessment pre-work. To increase the reliability of the measurements, two consistent readings were taken before entering them in the audiogram. The workers were advised not to be exposed to noise levels above 80 dBA 14 hours before the audiometry assessment. Hence, they were instructed not to participate in activities such as listening to loud music or shooting.

Intervention

Hearing protective device

Hearing protection devices, i.e., ear plugs [4], as shown in Figure 1, were used to reduce noise exposure levels among participants to levels between the permissible exposure limit and action level. These devices were distributed by safety and health officers to participants of both factories after the initial audiometry assessments. Noise levels were obtained after conducting noise area and personal noise exposure monitoring. Noise levels that showed higher values on these measurements among participants were used in the calculation of noise exposure reduction. The hearing protection devices were made up of synthetic and corded types of ear plugs, which are reusable. To ensure continuous usage of these devices, the participants were supervised at all times during work.

Noise levels of each job area were obtained by determining the appropriate NRR. There was an addition of 7 dB to the calculated NRR in order to convert dBA to dBC. This calculation was done since the hearing protective devices were in dBC units. The figures obtained were then multiplied by 50% (50% derating) [12]. The formula used to calculate the NRR was as follows:

Exposure of noise level in the specific job area={measured noise level - [(NRR - 7) × 50%]} [13] (Factory 1 or Factory 2). In Factory 1, the perceived noise levels were reduced to levels between 85 and 90 dBA. In Factory 2, the perceived noise levels were reduced to levels between 80 and 85 dBA. The workers were instructed regarding appropriate insertion of noise protectors.

Compliance

The continuous usage of ear plugs among participants was ensured by providing a checklist for the supervisors of both factories, to be used for monitoring. We also monitored by conducting regular spot checks at these factories on the usage of the hearing protection devices.

Blinding

The participants and safety and health officers were blinded to the adoption of levels of permissible exposure limits. There were two trained audiometric technicians (a single observer for each worker) at a time carrying out the measurement of hearing thresholds of the participants of both factories randomly. They were blinded to the allocation arm, as they did not know which factory was adopting 85 or 90 dBA as the permissible exposure limit during the measurement of hearing thresholds. The same technicians carried out the assessment at the outset and also at the sixth month. The statistician who analysed the data was blinded to which factories had embraced 85 dBA or 90 dBA as permissible exposure limits. We were not blinded as the NRR needed to be considered in each job area for both factories.

Figure 1. Hearing protection device (Ear plug)

Statistical Analysis

The data analyses were performed using SPSS version 20 for Windows. Data from the participants were imputed using the intention-to-treat principle. In this principle, all the participants who had signed the written consent forms were included regardless of their participation in the intervention, and for those who were lost to follow-up at the sixth month, the baseline values were imputed. The independent t-test was used to analyse the average age difference among participants of the 85 and 90 dBA groups. The Chi-square test was used to detect differences between subjects of the two factories in the frequencies of categorical characteristics, such as cigarette smoking, exposure to hand-arm vibration, and also exposure to hobbies that may lead to hearing loss. Fisher's exact test was used to detect differences in the frequencies of alcohol consumption among the two groups. The Gamma test was used to detect differences in the frequencies of duration of employment between the two groups. McNemar's test was conducted to detect any change in hearing threshold levels beyond 25 dBA among the participants over six months. If there were changes, the Chi-square test for association was conducted among participants of both factories to determine preservation of hearing threshold level among these participants. Hearing threshold levels were said to be 'preserved' among participants if the levels were at or below 25 dBA after intervention. Before intervention, these subjects had hearing threshold levels above 25 dBA. If hearing threshold levels among subjects before and after intervention were at or below 25 dBA, the intervention was said to have 'maintained preservation' of hearing threshold levels. On the other hand, hearing threshold levels were said to have 'deteriorated' if hearing threshold levels among subjects were above 25 dBA after intervention. Before intervention, these subjects had hearing threshold levels at or below 25 dBA. If hearing threshold levels among subjects before and after intervention remained unchanged, above 25 dBA, then adoption of the permissible exposure limit had resulted in 'continued deterioration' of hearing threshold levels. A p-value of less than 0.05 was considered statistically significant.

Ethics Approval

Written authorisation was obtained from the relevant personnel to conduct this study in the automobile industry. Ethical approval was then obtained from the Research and Ethics Committee, University of Malaya (MEC Ref. No: 848.37). The participants' information sheets were distributed to the participants, specifying the objectives, maintenance of confidentiality, and that the participants were free to opt out at any time during the study. Contact details were given in the event the participants needed to clarify any doubts pertaining to the study. The written informed consent forms were collected before participants were allowed to take part in this study.

RESULTS

The mean age of the participants was 27.1±6.6 years. The majority (more than 90%) of the participants were Malay males. Most of these workers were single and more than 60% of them had once smoked. About 3% of these subjects had once consumed alcohol. More than one-third of these employees had only primary or secondary school education and hence most of them earned less than RM 3000 per month. Almost 90% of them had worked for less than 5 years in these factories. More than a third had hobbies that might contribute to hearing loss such as listening to loud music, scuba diving, or shooting. More than a third were exposed to hand-arm vibration. There were 106 participants from Factory 1 who were exposed to noise levels of 90 dBA as the permissible exposure limit. The remaining 97 of participants were from Factory 2 and exposed to 85 dBA. In Factory 1, employees were working in Production Control (PC) Press, Quality Control (QC) Press, Welding, and Maintenance departments while in Factory 2, the workers were in PC Resin, QC Resin, Kaizen, and Painting departments. More than a fifth of the subjects were in each department. The basic socio-demographic characteristics and risk factors for hearing loss were compared between the two factories, as shown in Table 1. Differences of independent variables between the factories were not statistically significant.

Table 1. Comparison of independent variables between participants from Factory 1 and Factory 2

Characteristics/Risk Factors	Factory 1 n=106	Factory 2 n=97	p value
Age, mean (SD)	27.94 (7.25)	26.22 (5.60)	0.060*
Smoking, n (%)			
Once-smoked	74 (69.8)	64 (66.0)	0.559**
No smoking	32 (30.2)	33 (34.0)	
Alcohol consumption, n (%)			
Once-consumed alcohol	3 (2.8)	4 (4.1)	0.712***
Not consumed alcohol	103 (97.2)	93 (95.9)	
Duration of work, n (%)			
0 -<12 months	34 (32.1)	28 (28.9)	0.909****
1 -<5years	58 (54.7)	59 (60.8)	
5 years and more	14 (13.2)	10 (10.3)	
Exposure to hand-arm vibration, n (%)			
Exposed	83 (78.3)	66 (68.0)	0.098**
Not Exposed	23 (21.7)	31 (32.0)	
Exposure to hobbies risk for hearing loss, n (%)			
Exposed	40 (37.7)	33 (34.0)	0.582**
Not exposed	66 (62.3)	64 (66.0)	

*Statistical significance is based on Independent t test; **Statistical significance is based on Chi-square test for independence; ***Statistical significance is based on Fisher's exact test; ****Statistical significance is based on Gamma test

Table 2. Comparison of noise exposure between participants from Factory 1 and Factory 2

Factory	Departments	Frequency (%) n=203	Mean (SD) dBA
Factory 1	PC and QC Press	41 (20.2)	90.8 (0.75)
	Welding and Maintenance	65 (32.0)	87.2 (1.60)
Factory 2	PC Resin and QC Resin	44 (21.7)	88.6 (1.62)
	Kaizen and Painting	53 (26.1)	90.1 (2.50)

PC: prduction control; QC: quality control

The mean noise exposure of participants from each department is shown in Table 2. There was no difference of noise exposure between participants of the two factories (0.275, 95% CI=-0.42-0.97 dBA, t (164)=0.78, p=0.436).

The Chi-square test for association was conducted between factories and hearing threshold levels above 25 dBA at 500 to 8000 Hz (both ears) at baseline. All expected cell frequencies were greater than five. There were no statistically significant associations between factories and hearing threshold levels beyond 25 dBA for all the frequencies at baseline, as shown in Table 3.

McNemar's test was conducted between participants from both factories and hearing threshold levels above 25 dBA. These associations were tested for both ears of the participants at the frequencies 500, 1000, 2000, 3000, 4000, 6000, and 8000 Hz. The hearing threshold levels of more than 25 dBA had changed significantly from pre-intervention to post-intervention among participants from both factories at all frequencies except 8000 Hz for the left ear, as depicted in Table 4 and Table 5. Hence, there was a difference in hearing threshold levels beyond 25 dBA at these frequencies (both ears) at the sixth month after adopting different permissible exposure limits.

The Chi-square test for association was done to compare association between participants from both factories and change of hearing threshold levels above 25 dBA over 6 months. The comparison was done for both ears of the participants at frequencies that showed a statistically significant difference on McNemar's test. Hence, this test was conducted at all studied frequencies except at 8000 Hz for the left ear. Most expected cell frequencies were greater than five among participants for both ears. Fisher's exact test was performed on cell frequencies equal to or below five. There was a statistically significant association between participants from both factories and change of hearing threshold levels above 25 dBA at 4000 Hz for the right ear at the 'continued deterioration' level (Table 5), χ^2 (1)=4.27, φ=-0.145, p=0.039 and 6000 Hz for the right ear at the 'preserved' level (Table

Table 3. Factories associated with hearing threshold level beyond 25 dBA at baseline

Factory 1 (n=106) Factory 2 (n=97)	Frequency Hz (Ear)	Above 25 dBA n (%)	Not above 25 dBA n (%)	χ^2 statistic (df)	p value*
Factory 1	500 (Right)	18 (17.0)	88 (83.0)	0.09 (1)	0.769
Factory 2		18 (18.6)	79 (81.4)		
Factory 1	1000 (Right)	10 (9.4)	96 (90.6)	0.33 (1)	0.569
Factory 2		7 (7.2)	90 (92.8)		
Factory 1	2000 (Right)	6 (5.7)	100 (94.3)	0.53 (1)	0.467
Factory 2		8 (8.2)	89 (91.8)		
Factory 1	3000 (Right)	7 (6.6)	99 (93.4)	0.91 (1)	0.341
Factory 2		10 (10.3)	87 (89.7)		
Factory 1	4000 (Right)	25 (23.6)	81 (76.4)	2.73 (1)	0.098
Factory 2		14 (14.4)	83 (85.6)		
Factory 1	6000 (Right)	43 (40.6)	63 (59.4)	0.12 (1)	0.724
Factory 2		37 (38.1)	60 (61.9)		
Factory 1	8000 (Right)	17 (16.0)	89 (84.0)	0.56 (1)	0.456
Factory 2		12 (12.4)	85 (87.6)		
Factory 1	500 (Left)	6 (5.7)	100 (94.3)	0.03 (1)	0.874
Factory 2		5 (5.2)	92 (94.8)		
Factory 1	1000 (Left)	7 (6.6)	99 (93.4)	0.02 (1)	0.903
Factory 2		6 (6.2)	91 (93.8)		
Factory 1	2000 (Left)	7 (6.6)	99 (93.4)	0.19 (1)	0.662
Factory 2		5 (5.2)	92 (94.8)		
Factory 1	3000 (Left)	11 (10.4)	95 (89.6)	<0.001 (1)	0.987
Factory 2		10 (10.3)	87 (89.7)		
Factory 1	4000 (Left)	13 (12.3)	93 (87.7)	0.44 (1)	0.509
Factory 2		15 (15.5)	82 (84.5)		
Factory 1	6000 (Left)	36 (34.0)	70 (66.0)	1.22 (1)	0.269
Factory 2		26 (26.8)	71 (73.2)		
Factory 1	8000 (Left)	14 (13.2)	92 (86.8)	0.41 (1)	0.523
Factory 2		10 (10.3)	87 (89.7)		

* Statistical significance is based on Chi-square test for independence

5), χ^2 (1)=9.84, φ=0.220, p=0.002. There were more participants who showed 'continued deterioration' of hearing threshold level above 25 dBA despite the use of hearing protection devices in Factory 1 (adopted a 90 dBA level) compared with Factory 2 (adopted a 85 dBA level) at 4000 Hz. Adoption of 85 dBA as the permissible exposure limit 'preserved' hearing thresholds among participants from Factory 2 at 6000 Hz compared with those from Factory 1. At other frequencies, there were no statistically significant associations between participants from the two factories and change of hearing threshold levels above 25 dBA, as shown in Table 6.

DISCUSSION

Noise-induced hearing loss is an irreversible and permanent occupational malady [14-16]. The participants from Factory 1 and Factory 2 had shown changes of hearing threshold levels above 25 dBA over a period of 6 months after intervention, at all tested frequencies except at 8000 Hz. In this population, around 24% of those exposed to 90 dBA as the permissible noise limit showed continued deterioration of hearing threshold level above 25 dBA, compared with half of the participants exposed to noise of up to 85 dBA. This indicates that despite the usage of appropriate hearing protection devices, exposure to noise levels between 85 and 90 dBA did not lead to improvement of hearing threshold levels. This was also found in a smaller percentage of those exposed to permitted levels between 80 and 85 dBA. These findings are consistent with a study conducted in Iran [7], where there was no significant hearing loss when exposed to noise levels below 80 dBA but hearing loss was seen when exposed to levels at and above 90 dBA. Most of the workers from both factories were smoking and exposed to hand-arm vibration, as shown in Table 1, and a third of them were exposed to hobbies such as listening to loud music; these activities increased the risk of hearing loss. This could be the reason for a hearing threshold level of more than 25 dBA in the participants exposed to 85 dBA, although the percentage was lower compared with those exposed to 90 dBA.

At the same time, around 11% of the subjects from Factory 2 were shown to have preserved hearing threshold levels at or below 25 dBA. This is in contrast to participants from Factory 1 where only less than 1% of them had shown preservation of their hearing threshold levels after usage of the appropriate hearing protection devices.

Table 4. Comparison on change of hearing threshold levels above 25 dBA among participants from Factory 1

			Post-intervention n=106		
Frequency	Ear	Pre-intervention	≤25dBA n (%)	>25dBA n (%)	p value*
500	Right	≤25dBA	65 (73.9)	23 (26.1)	<0.001
		>25dBA	4 (22.2)	14 (77.8)	
1000	Right	≤25dBA	63 (65.6)	33 (34.4)	<0.001
		>25dBA	2 (20.0)	8 (80.0)	
2000	Right	≤25dBA	74 (74.0)	26 (26.0)	<0.001
		>25dBA	0 (0.0)	6 (100.0)	
3000	Right	≤25dBA	73 (73.7)	26 (26.3)	<0.001
		>25dBA	1 (14.3)	6 (85.7)	
4000	Right	≤25dBA	57 (70.4)	24 (29.6)	<0.001
		>25dBA	0 (0.0)	25 (100.0)	
6000	Right	≤25dBA	42 (66.7)	21 (33.3)	<0.001
		>25dBA	1 (2.3)	42 (97.7)	
8000	Right	≤25dBA	79 (88.8)	10 (11.2)	0.012
		>25dBA	1 (5.9)	16 (94.1)	
1000	Left	≤25dBA	76 (76.8)	23 (23.2)	<0.001
		>25dBA	0 (0.0)	7 (100.0)	
2000	Left	≤25dBA	77 (77.8)	22 (22.2)	<0.001
		>25dBA	2 (28.6)	5 (71.4)	
3000	Left	≤25dBA	70 (73.7)	25 (26.3)	<0.001
		>25dBA	3 (27.3)	8 (72.7)	
4000	Left	≤25dBA	65 (69.9)	28 (30.1)	<0.001
		>25dBA	0 (0.0)	13 (100.0)	
6000	Left	≤25dBA	47 (67.1)	23 (32.9)	0.001
		>25dBA	5 (13.9)	31(86.1)	
8000	Left	≤25dBA	84 (91.3)	8 (8.7)	0.109
		>25dBA	2 (14.3)	12 (85.7)	

*Statistical significance is based on McNemar's test

Table 5. Comparison on change of hearing threshold levels above 25 dBA among participants from Factory 2

			Post-intervention n=106		
Frequency	Ear	Pre-intervention	≤25dBA n (%)	>25dBA n (%)	p value*
500	Right	≤25dBA	57 (72.2)	22 (27.8)	0.016
		>25dBA	8 (44.4)	10 (55.6)	
1000	Right	≤25dBA	61 (67.8)	29 (32.2)	<0.001
		>25dBA	3 (42.9)	4 (57.1)	
2000	Right	≤25dBA	67 (75.3)	22 (24.7)	<0.001
		>25dBA	2 (25.0)	6 (75.0)	
3000	Right	≤25dBA	69 (79.3)	18 (20.7)	<0.001
		>25dBA	0 (0.0)	10 (100.0)	
4000	Right	≤25dBA	62 (74.7)	21 (25.3)	<0.001
		>25dBA	2 (14.3)	12 (85.7)	
6000	Right	≤25dBA	41 (68.3)	19 (31.7)	0.200
		>25dBA	11 (29.7)	26 (70.3)	
8000	Right	≤25dBA	74 (87.1)	11 (12.9)	0.022
		>25dBA	2 (16.7)	10 (83.3)	
500	Left	≤25dBA	73 (79.3)	19 (20.7)	0.001
		>25dBA	3 (60.0)	2 (40.0)	
1000	Left	≤25dBA	72 (79.1)	19 (20.9)	<0.001
		>25dBA	1 (16.7)	5 (83.3)	
2000	Left	≤25dBA	72 (78.3)	20 (21.7)	<0.001
		>25dBA	0 (0.0)	5 (100.0)	
3000	Left	≤25dBA	67 (77.0)	20 (23.0)	<0.001
		>25dBA	1 (10.0)	9 (90.0)	
4000	Left	≤25dBA	63 (76.8)	19 (23.2)	<0.001
		>25dBA	1 (6.7)	14 (93.3)	
6000	Left	≤25dBA	52 (73.2)	19 (26.8)	0.001
		>25dBA	3 (11.5)	23 (88.5)	
8000	Left	≤25dBA	77 (88.5)	10 (11.5)	0.180
		>25dBA	4 (40.0)	6 (60.0)	

*Statistical significance is based on McNemar's test

Hence, hearing loss above 25 dBA occurs more when one is exposed to noise levels where the permissible exposure limit is fixed at 90 dBA compared with 85 dBA. The hearing loss was more significant at 4000 and 6000 Hz. These findings are consistent with a study conducted in England and Wales [17], where there were significant associations of exposure to noise and presence of notch at 4000 Hz but the findings were variable at 6000 Hz. According to Lawton [18], noise levels above 80 dBA produced temporary threshold shifts that recovered quickly when the noise insult ceased. Noise levels at or below 80 dBA may not produce hearing loss at 4000 Hz, the frequency most susceptible to noise. Lawton also mentioned that employees exposed to noise levels above 85 dBA over a period of 8 hours would acquire some degree of hearing loss. Hence, it would be more appropriate to institute a hearing conservation programme [15] at 80 dBA where action can be taken to reduce noise exposure among employees, also known as the action level, and to adopt 85 dBA as the permissible exposure limit. The Japan Society for Occupational Health [19], like the US NIOSH, recommends the permissible exposure limit of 85 dBA for a period of 8 hours.

The outcome assessor (audiometric technicians) was blinded to the allocation, as they did not know which factory was adopting 85 or 90 dBA as the permissible exposure limit during the measurement of hearing thresholds. Hence, the risk of bias was low. There was a possibility of a crossover effect because employees from the two factories might have been placed in the other factory during the study. This was avoided by informing the company that the duration of this study was 6 months and that the participants should remain in the same department and factory during this study period. The measurement of personal noise exposure level was done only on one subject in each work area. The measurement was done in this way because all workers in a job area were exposed to similar levels of noise intensities. This is also in accordance with the regulations for noise in Malaysia [4], where not all workers in a job area are required to undergo personal noise exposure measurement.

Sound waves from external sources are heard through air conduction and bone conduction [20]. In air conduction, these sound

Table 6. Comparison of hearing threshold levels above 25 dBA among participants over six months

			Factory 1 (n=106)		Factory 2 (n=97)			
Frequency	Ear	Hearing Threshold Level	Yes n (%)	No n (%)	Yes n (%)	No n (%)	χ^2 statistic* (df)	p value*
500	Right	Preserved	4 (3.8)	102 (96.2)	8 (8.2)	89 (91.8)	1.82 (1)	0.177
		Preservation maintained	65 (61.3)	41 (38.7)	57 (58.8)	40 (41.2)	0.14 (1)	0.710
		Deteriorated	23 (21.7)	83 (78.3)	22 (22.7)	75 (77.3)	0.03 (1)	0.866
		Continued deterioration	14 (13.2)	92 (86.8)	10 (10.3)	87 (89.7)	0.41 (1)	0.523
1000	Right	Preserved	2 (1.9)	104 (98.1)	3 (3.1)	94 (96.9)	-	0.671**
		Preservation maintained	63 (59.4)	43 (40.6)	61 (62.9)	36 (37.1)	0.25 (1)	0.614
		Deteriorated	33 (31.1)	73 (68.9)	29 (29.9)	68 (70.1)	0.04 (1)	0.849
		Continued deterioration	8 (7.5)	98 (92.5)	4 (4.1)	93 (95.9)	1.07 (1)	0.302
2000	Right	Preserved	0 (0.0)	106 (100.0)	2 (2.1)	95 (97.9)	-	0.227**
		Preservation maintained	74 (69.8)	32 (30.2)	67 (69.1)	30 (30.9)	0.01(1)	0.909
		Deteriorated	26 (24.5)	80 (75.5)	22 (22.7)	75 (77.3)	0.10 (1)	0.757
		Continued deterioration	6 (5.7)	100 (94.3)	6 (6.2)	91 (93.8)	0.03 (1)	0.874
3000	Right	Preserved	1 (0.9)	105 (99.1)	0 (0.0)	97 (100.0)	-	1.000**
		Preservation maintained	73 (68.9)	33 (31.1)	69 (71.1)	28 (28.9)	0.12 (1)	0.725
		Deteriorated	26 (24.5)	80 (75.5)	18 (18.6)	79 (81.4)	1.06 (1)	0.302
		Continued deterioration	6 (5.7)	100 (94.3)	10 (10.3)	87 (89.7)	1.51 (1)	0.219
4000	Right	Preserved	0 (0.0)	106 (100.0)	2 (2.1)	95 (97.9)	-	0.227**
		Preservation maintained	57 (53.8)	49 (46.2)	62 (63.9)	35 (36.1)	2.15 (1)	0.143
		Deteriorated	24 (22.6)	82 (77.4)	21 (21.6)	76 (78.4)	0.03 (1)	0.865
		Continued deterioration	25 (23.6)	81 (76.4)	12 (12.4)	85 (87.6)	4.27 (1)	0.039
6000	Right	Preserved	1 (0.9)	105 (99.1)	11 (11.3)	86 (88.7)	9.84 (1)	0.002
		Preservation maintained	42 (39.6)	64 (60.4)	41 (42.3)	56 (57.7)	0.15 (1)	0.702
		Deteriorated	21 (19.8)	85 (80.2)	19 (19.6)	78 (80.4)	0.00 (1)	0.968
		Continued deterioration	42 (39.6)	64 (60.4)	26 (26.8)	71 (73.2)	3.74 (1)	0.053
8000	Right	Preserved	1 (0.9)	105 (99.1)	2 (2.1)	95 (97.9)	-	0.607**
		Preservation maintained	79 (74.5)	27 (25.5)	74 (76.3)	23 (23.7)	0.09 (1)	0.771
		Deteriorated	10 (9.4)	96 (90.6)	11 (11.3)	86 (88.7)	0.20 (1)	0.656
		Continued deterioration	16 (15.1)	90 (84.9)	10 (10.3)	87 (89.7)	1.04 (1)	0.308
500	Left	Preserved	1 (0.9)	105 (99.1)	3 (3.1)	94 (96.9)	-	-
		Preservation maintained	78 (73.6)	28 (26.4)	73 (75.3)	24 (24.7)	0.07 (1)	0.785
		Deteriorated	22 (20.8)	84 (79.2)	19 (19.6)	78 (80.4)	0.04 (1)	0.836
		Continued deterioration	5 (4.7)	101 (95.3)	2 (2.1)	95 (97.9)	-	0.448**
1000	Left	Preserved	0 (0.0)	106 (100.0)	1 (1.0)	96 (99.0)	-	0.478**
		Preservation maintained	76 (71.7)	30 (28.3)	72 (74.2)	25 (25.8)	0.16 (1)	0.686
		Deteriorated	23 (21.7)	83 (78.3)	19 (19.6)	78 (80.4)	0.14 (1)	0.711
		Continued deterioration	7 (6.6)	99 (93.4)	5 (5.2)	92 (94.8)	0.19 (1)	0.662
2000	Left	Preserved	0 (0.0)	106 (100.0)	0 (0.0)	97 (100.0)	-	-
		Preservation maintained	0 (0.0)	106 (100.0)	0 (0.0)	97 (100.0)	-	-
		Deteriorated	0 (0.0)	106 (100.0)	0 (0.0)	97 (100.0)	-	-
		Continued deterioration	0 (0.0)	106 (100.0)	0 (0.0)	97 (100.0)	-	-
3000	Left	Preserved	0 (0.0)	106 (100.0)	0 (0.0)	97 (100.0)	-	-
		Preservation maintained	0 (0.0)	106 (100.0)	0 (0.0)	97 (100.0)	-	-
		Deteriorated	0 (0.0)	106 (100.0)	0 (0.0)	97 (100.0)	-	-
		Continued deterioration	0 (0.0)	106 (100.0)	0 (0.0)	97 (100.0)	-	-
4000	Left	Preserved	0 (0.0)	106 (100.0)	1 (1.0)	96 (99.0)	-	0.478**
		Preservation maintained	65 (61.3)	41 (38.7)	63 (64.9)	34 (35.1)	0.29 (1)	0.593
		Deteriorated	28 (26.4)	78 (73.6)	19 (19.6)	78 (80.4)	1.33 (1)	0.249
		Continued deterioration	13 (12.3)	93 (87.7)	14 (14.4)	83 (85.6)	0.21 (1)	0.649
6000	Left	Preserved	5 (4.7)	101 (95.3)	3 (3.1)	94 (96.9)	-	0.723**
		Preservation maintained	47 (44.3)	59 (55.7)	52 (53.6)	45 (46.4)	1.74 (1)	0.187
		Deteriorated	23 (21.7)	83 (78.3)	19 (19.6)	78 (80.4)	0.14 (1)	0.711
		Continued deterioration	31 (29.2)	75 (70.8)	23 (23.7)	74 (76.3)	0.79 (1)	0.373

*Statistical significance is based on Chi-square test for independence; ** Statistical significance is based on Fisher's exact test waves travel via the external auditory canal. Air conduction is affected once there is damage in either the outer or middle ear. In bone conduction, the sound waves are transmitted directly to the cochlea through the skull bones. Therefore, if there is any damage to the inner ear or auditory nerve, hearing by bone conduction is affected. Bone conduction testing is used to distinguish sensorineural from conductive hearing loss [21]. Only an air conduction procedure was used to measure hearing threshold levels in this study. To ensure that there was no damage to the outer or middle ear, an ear assessment was performed on all participants, including otoscopy examination at baseline and at the sixth month. Only participants that had no damage to the ear were allowed to undergo the audiometry assessment. There were no differences in hearing threshold levels above 25 dBA among participants from the two factories at baseline. Hence, any changes in the hearing threshold levels of subjects at post-intervention time were likely due to the effect of noise.

There were no differences in possible confounding factors among participants of the two factories such as smoking [22], consumption of alcohol [23], and exposure to hand-arm vibration [24]. There were also no significant differences among participants from the two factories in hobbies with an increased risk of hearing loss such as listening to loud music [25], shooting [26], and scuba diving [27]. Age and employment duration among the employees in both factories were also not significantly different.

A total of 43.3% participants were followed up till the sixth month. However, the total number of subjects who participated from both factories throughout the study was more than the minimum sample size required and hence, the power of the study was not affected. There were also no differences between the participants who were followed up till the end of the study and those who were lost to follow-up in age, gender, ethnicity, education level, and smoking and alcohol consumption variables.

The last option to prevent hearing loss due to noise is by wearing hearing protection devices [28]. Though it is the last option, it is the cheapest and the basis for reducing noise exposure in most industries, and so it was adopted in this study. The noise level was measured using a sound level meter and noise dosimeter. The former measures noise at a point in time whereas the latter measures the average exposure of an employee to noise over the job area [25]. The instrument that showed the higher level of noise was taken for calculation of the NRR.

In conlusion, the findings of this study suggest that adoption of 85 dBA as the permissible exposure limit preserves hearing thresholds more at 4000 and 6000 Hz compared with the limit of 90 dBA. The results of this study suggest that steps should be taken by countries to review their policy with regard to the permissible exposure limit, in order to reduce the prevalence of noise-induced hearing loss.

Ethics Committe Approval: Ethics committee approval was received for this study from the ethics committee of Malaya University (MEC Ref. Doc: 848.37).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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