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Predicting and classifyng hearing loss in sailors working on speed vessels using neural networks: a field study

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Keywords: Noise; noise-induced hearing loss (NIHL); modelling; neural network (NN)

Abstract
Background: *Noise-induced hearing loss (NIHL) is one of the main risk factors affecting people's health and wellbeing in the workplace. Analysing NIHL and consequently controlling the causing factors can significantly affect the improvement of working environments.* **Methods:** *One hundred and twelve male sailors participated in this study. They were classified into three groups depending on occupational noise exposure: (A) none, i.e., sound pressure level (SPL) lower than 70dBA, (B) exposed to SPL in the range of 70-85dBA, and (C) exposed to SPL exceeding 80dBA. In a first phase, hearing loss shaping risk factors were identified and analysed, including hearing loss in different frequencies, age, work experience, sound pressure level (SPL), marital status, and systolic and diastolic blood pressure. Then, neural networks were trained to predict the hearing loss changes of personnel and used to determine the weight of hearing loss factors. Finally, the accuracy of predicting models was calculated relying on Bayesian statistics.* **Results and conclusion:** *In the present study using neural networks, five models were developed. Their accuracy ranged from 92% to 100%. The frequencies of 4000Hz and 2000Hz showed the strongest association with the hearing loss of the sailors. Also, including systolic and diastolic blood pressure did not have any impact on predicted hearing loss, indicating that SPL was poorly correlated with extra-auditory effects.*

Introduction

Noise exposure is one of the most common risk factors in work environments, and associated with hearing impairment, hypertension, heart diseases, irritability, and sleep disorders. The most important effect is noise-induced hearing loss (NIHL) modifying workers' hearing threshold [1, 2]. NIHL is due to sound pressure levels (SPL) higher than 85dBA at frequencies of 3000, 4000, and 6000Hz. Such impairment can be diagnosed early, before permanent hearing loss, which occurs if exposure continues [3]. Such damage to the hearing system, it makes it hard to communicate with the surrounding

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environment, and verbal comprehension of individuals, especially in noisy environments. As a result, it can also increase the risk of accidents in job environments [4-6].

More than 12% of the world population (about 600 million people) suffer from job-related adverse effects. In the US, but NIHL prevalence is about 23% [7]. Besides, according to the Norwegian Labor Inspectorate, NIHL represented about 59% of overall job-relevant diseases reported in 2006 in Norway [8]. A systematic review also showed that in industrial and developing countries, noise exposure at work is causing 7% and 21%, respectively, of hearing loss cases [9]. For example, 26.9% of workers from Malaysia suffer from hearing loss at frequencies in the range of 3000-6000Hz, and about 21.6% suffer from diagnosable hearing loss [10]. In Iran, it has been estimated that at least 1 million workers are exposed to excessive job noise and candidates for hearing loss, which represents a population of about 14% of the workforce in the industrial sector [11].

Working on the deck or in the engine room of cruise vessels, landing crafts, [11] and speed vessels leads to the exposure to the high level of noise caused by the marine engine and its deriving force, or even the noise caused by wind and moving on the sea [12]. Hearing loss can also affect the performance of personnel and can be recognised as a factor driving human mistakes in marine accidents [13]. People working on vessel engines also suffer from vibroacoustic diseases, and skeletomuscular diseases [14]. According to the International Maritime Organization (IMO) standard to protect individuals against damaging noise pressure levels in vessels, the permitted noise exposure is equal to 85dBA in work environments, about 75dBA in the engine control room, 65dBA in command and navigation space, and about 60dBA in resting rooms. According to this standard, the cumulative limit of exposure in 24hrs should not exceed 80dBA [15]. In a recent survey, the dosimetry results of most jobs and measured vessels' personnel exposure were higher than 85dBA [16]. It was also shown that the average daily SPL for engine mechanics in any type of vessel was about 91.2 to 94.3 dBA and 84.7 to 88.4 dBA for the ship operators in vessels, higher than the values presented by IMO [17]. Hearing loss is frequent among the personnel of ships and is correlated with age, work experience, BMI, and non-infectious chronic diseases [18]. Also, in a study conducted on five different vessels in Brazil, about 56.5% of the personnel were suffering from NIHL. Seamen working in the engine room showed the highest level of NIHL at 78.8% [16].

Data mining (DM) is the process of extracting insightful patterns and information from large datasets, and it has improved decision-making for organisations through valuable data analysis [19]. Data mining algorithms have been widely used to predict hearing loss changes and hearing system impairments [20-22]. One of the most applicable algorithms is the artificial neural network (ANN). The ANN is a powerful tool based on the biologic network used to solve practical problems such as discovering and classifying models obtained by data, medical imaging, speech recognition, etc. ANN consists of a group of artificial neurons capable of data processing using a calculative approach. It has the learning ability based on input data [23]. The main advantage of the ANN is the capability of this method to identify all probable interactions among predicting variables. Also, it can carefully recognise the complicated nonlinear correlation between independent and dependent variables [24]. Communication is vital among personnel of high-speed vessels and can be severely damaged by hearing loss. Since, to the best of our knowledge, no study has so far been explicitly conducted on this group of people, the present study has applied neural networks to achieve the following goals: (i) determining equivalent sound pressure levels for the personnel; (ii) determining the hearing loss status of both ears in personnel working on the studied harbour; (iii) identifying and classifying hearing loss shaping factors; (iv) classification and prediction of hearing loss using neural networks; (v) determining the error rate and accuracy of ANN algorithms.

Methods

Subjects

The present study is a cross-sectional descriptive-analytical work conducted in one harbour in

Southern Iran in 2020. According to the equivalent sound pressure level induced on the personnel, similar studies [25], and the algorithm used for modelling hearing loss data, the subjects were classified into three groups with different exposures: a control group with SPL lower than 70dBA and two exposed groups with SPL ranging 70-85dBA and exceeding 85dBA, respectively. One hundred and twelve male sailors were recruited. At the studied harbour, the vessels had a lifespan equal to or less than five years (the useful life of the vessels was five years). These vessels' overall structure and shape have been constant for over 20 years. Also, there was no culture of using personal protective equipment (PPE) in this harbour and no PPE was provided by the employer. Age and work experience of the subjects in the three study groups are presented in Table 1. Group C was older than the two other groups and had longer work experience.

Study design

The present study was performed in 7 steps: (i) selecting predicting factors to model hearing loss, (ii) performing audiometry on both ears of personnel in the selected groups, (iii) estimating permanent hearing loss in both ears and estimating overall hearing loss in personnel, (iv) classification of degree of hearing loss based on ISO and WHO guideline [26, 27], (v) using ANN algorithm to classify the hearing loss in personnel, (vi) prediction of error rate and evaluation of accuracy and sensitivity of the proposed model, and (vii) prediction of hearing loss level using ANN [20].

Selecting hearing loss shaping factors (HLSFs)

According to the previous investigations, five factors, including age, work experience, 8-hrs inducement SPL in the "A" network, frequency, and blood pressure, were selected to develop the predicting model [20, 25, 28]. The subjects in this study were adults and were classified into three age groups: (i) 20-35 years, (ii) 35-50 years, (iii) over 50 years [20]. The members of each group were placed in 3 groups based on employment years (work experience): (i) less than ten years; (ii) 10-20 years; (iii) more than 20 years [20]. The equivalent SPL was measured using calibrated level gauge (using CEL 110/2 calibrator made in the UK) model TES 1351B according to ISO-9612-2009 standard [29]. According to SPL of noise exposure, the subjects were classified into three groups: (i) control group A, including individuals working in administrative jobs posed to SPL lower than 70dBA; (ii) group B, including individuals working in the vessel repair unit posed to SPL of 70-85dBA, and group C, including sailors working on speed vessels posed to SPL higher than 85dBA. This study also analysed the frequency as an HLSF in hearing loss at frequencies of 500, 1000, 2000, and 4000Hz [20].

Audiometry

The pure tone audiometry (PTA) of both ears was measured and recorded at frequencies of 500, 1000, 2000, 4000, and 8000Hz using the AMPLIVOX-270 audiometer made in UK.

Table 1. Mean and SD of age and work experience of subjects of three study groups.

Groups	Factors	Mean	SD
Group A (SPL<70 dBA)	Age	34.03	5.78
	Work experience duration	11.54	5.73
Group B (70 dBA<SPL<85 dBA)	Age	34.12	5.07
	Work experience duration	12.15	5.10
Group C (SPL>85 dBA)	Age	37.41	6.77
	Work experience duration	16.26	6.11

Measurement of permanent hearing loss

After measuring hearing loss for the mentioned frequencies, the below equation was used to classify the permanent hearing loss of each ear based on the hearing loss at four frequencies of 500, 1000, 2000, and 4000Hz [30].

$$NIHL = (TL_{500} + TL_{1000} + TL_{2000} + TL_{4000}) \div 4 \qquad (1)$$

Where $NIHL$ refers to permanent hearing loss of each ear, and TL refers to hearing loss.

Overall hearing loss in both ears can be calculated as [30]:

$$NIHL_t = (NIHL_b \times 5 + NIHL_p) \div 6 \qquad (2)$$

Where $NIHL_t$ refers to permanent hearing loss in both ears, $NIHL_b$ refers to permanent hearing loss in the stronger ear, $NIHL_p$ refers to permanent hearing loss in the weaker ear.

Classification of the hearing loss degree of personnel based on WHO guideline

The WHO Guideline was used to classify the degree of hearing loss, classified into six groups: (i) normal hearing (hearing loss below 25dBA), (ii) mild hearing loss (26-40dBA), (iii) moderate hearing loss (41-55dBA), (iv) relatively severe hearing loss (56-70dBA), (v) severe hearing loss (71-90dBA), and (vi) profound hearing loss (above 91dBA) [27].

Blood pressure

Blood pressure was measured by the sfigmomanometer Erkameter3000, made in Germany.

Using ANN algorithm to model hearing loss of personnel

Weka V.3-8-5 was used to process and model the relevant data on personnel hearing loss, developing five models. Model 1 includes data collected from group A (SPL below 70dBA); model 2 for data from group B (SPL of 70-85dBA); model 3 for data from group C (SPL above 85dBA); model 4 for data collected from both groups B and C as input, and finally, model 5 for data from all groups.

Neural networks

Neural networks are used in data mining and modelling [31]. These networks are nonlinear prediction models fitted by training for the task of classification and prediction. Neural networks are inspired by the human brain and consist of three types of nodes: input, output, and middle nodes (hidden nodes). The interconnected nodes in the neural network are called neurons. The neurons apply functions to the inputs and map them to the outputs. The output of neurons can be the input of subsequent layer neurons [32]. Figure 1 illustrates the layers in a neural network.

An initial structure is created to model and classify data in these networks, and weights are initialised with random values. Then, a gradient descent algorithm is used during the training process to set the weights [32]. Once the model is trained appropriately, it can map the inputs to the desired outputs. The WEKA V.3-5-8 was used to make a classifier model. According to the nested cross-fold validation, learning rate, batch size, momentum, number of iterations, and number of hidden layers are selected by the software as the gradient's parameters, also descent algorithm to set the network weight.

Evaluation of accuracy and error rate of developed models

Accuracy (ACC) and F-measure have been used to assess model accuracy, based on the confusion matrix where the dimensions are equal to the number of classes of each model. The primary diameter shows the percentage of samples predicted correctly in a confusion matrix. An example of a 2*2 confusion matrix has been illustrated in Table 2.

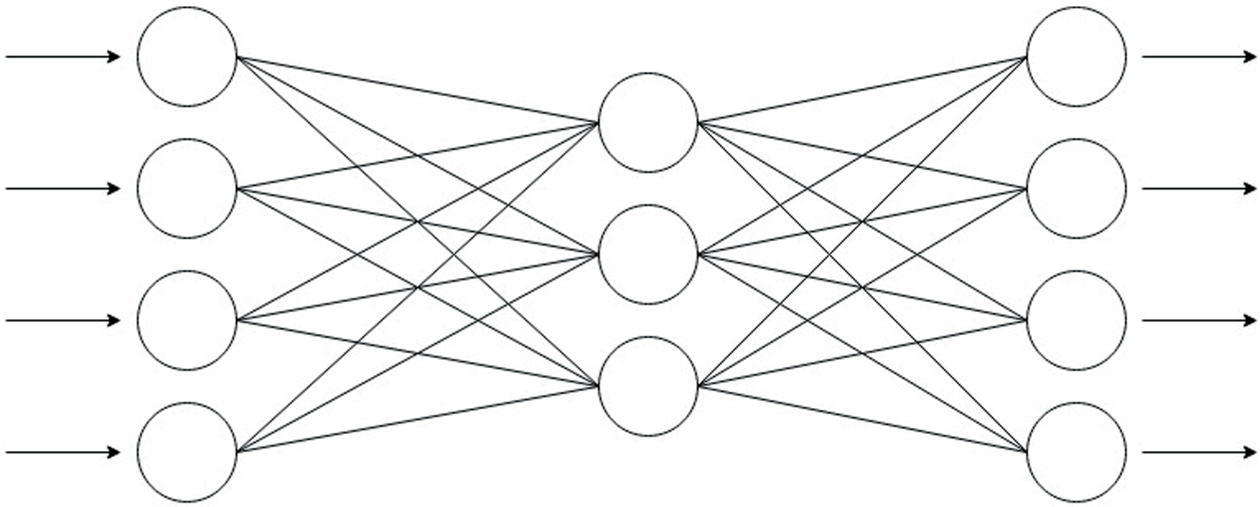

Figure 1. Schematic of layers in a simple neural network [33].

Table 2. A 2*2 confusion matrix.

	Positive (1)	**Negative (0)**
Positive (1)	True Positive	False Positive
Negative (0)	False Negative	True Negative

The equation (3) was used to estimate the ACC index [34]:

$$\text{Accuracy} = \frac{\text{True positives} + \text{True negatives}}{\text{All cases}} \quad (3)$$

The F-measure index is an alternative measure the accuracy relying on formula (4) [34]:

$$F1 = 2\frac{\text{precision} \times \text{recall}}{(\text{precision} + \text{recall})} = \frac{\text{True positive}}{\text{True positive} + \frac{1}{2}(\text{False Positive} + \text{False Negative})} \quad (4)$$

Statistical analysis

In the present study, data were analysed using IBM SPSS software version 20 made by SPSS Inc. in the USA. Descriptive statistic indices (frequency, percentage, mean and standard deviation) were used to summarize data. Pearson's correlation coefficient and Student's t-test were used to assess associations and differences, respectively.

Results

Noise exposure and hearing loss

Four categories of Hearing loss status (HLS) were identified: No (0-25dB), Mild (26-40dB), Moderate (41-60dB), and Severe hearing loss (61-80dB). Exposure levels were used to distinguish three groups of workers (respectively A, B, and C), whose levels of noise exposure were reported as mean values (minimum – maximum) in the first column of table 3.

Eighty-five out of 112 subjects showed normal audiograms, 21 (i.e., 10, 20, and 25% of the groups respectively A, B, and C) showed a mild HLS, one of group B (3%) and four of group C a Moderate HLS, and just one worker belonging to group C showed a severe HLS. Thus, there was a correlation between the exposure level and hearing loss.

Table 3. The overall hearing loss status (HLS) in the three study groups identified according to exposure levels, respectively <70 dB(A), 61-85 dB(A), and >85 dB(A) as mean (range).

Exposure group	No 0–25 dB N (%)	Mild N (%)	Moderate N (%)	Severe N (%)	Total	chi-square p-value
A 60 dB(A) (45-68)	35 (89.74%)	4 (10.26%)	0	0	39 (100%)	0.0001
B 76 dB(A) (71-83)	26 (76.47%)	7 (20.59%)	1 (2.94%)	0	34 (100%)	
C 96.5 dB(A) (86-104)	24 (61.54%)	10 (25.64%)	4 (10.26%)	1 (2.56%)	39 (100%)	

Table 4. Correlation between hearing loss and predictors other than noise.

Factor	Group	Pearson correlation coefficient (r)	P value
Age	Group A	0.299	0.064
	Group B	0.349	0.043
	Group C	0.408**	0.01
	All subjects	0.414**	0.0001
Work experience	Group A	0.298	0.065
	Group B	0.430	0.011
	Group C	0.206	0.207
	All subjects	0.360**	0.0001
Diastolic blood pressure	Group A	-0.541	0.03
	Group B	0.061	0.803
	Group C	-0.097	0.653
	All subjects	-0.092	0.490
Systolic blood pressure	Group A	0.085	0.754
	Group B	-0.013	0.955
	Group C	-0.002	0.911
	All subjects	-0.033	0.805

Hearing loss according to age, work experience, marital status, and hypertension

Pearson's correlation coefficients between hearing loss and age, work experience, and blood pressure are presented in Table 4. Neither systolic nor diastolic blood pressure was associated with hearing loss, whereas a correlation was found between HLS and both age and duration of exposure (work experience).

Modelling and classifying of HLSFs

The "Correlation Attribute Eval" tool was used in WEKA to correlate each factor with overall hearing loss. The results of each model are presented in the following paragraphs:

Model 1: Effect of HLSFs on hearing loss changes in group A (SPL below 70dBA)

The weight of HLSFs in the control group is presented in Figure 2. Hearing loss in group A at the frequency of 4000Hz in the right ear weighted at 0.844 has the most effect on hearing loss changes. Also, hearing loss at frequencies of 1000Hz and 4000Hz in the left ear, and 1000Hz in the right ear was obtained at 0.775, 0.754, and 0.747 in ranks 2-4 of hearing loss shaping, respectively. Systolic blood pressure, marital status, and diastolic blood pressure showed a low weight, with values at 0.055, 0.054, and 0.029, respectively.

The accuracy of model 1 was 100%. In fact, all normal subjects (N = 35) and those with mild hearing loss (N = 4) were correctly classified, without any misclassification.

Model 2: Effect of HLSFs on hearing loss changes in group B (SPL of 70-85dBA)

In Figure 3, the results of modelling HLSFs for model 2 are illustrated. The hearing loss factor at the frequency of 4000Hz in the left ear weighted at 0.817 had the most effect on overall hearing loss. Also, the frequencies of 2000Hz on the left ear, 2000Hz and 4000Hz on the right ear have affected hearing loss at 0.812, 0.810, and 0.806, respectively (in ranks 2-4 of hearing loss shaping). In this model, three factors, of diastolic blood pressure, marital status, and systolic blood pressure weighted respectively 0.21, 0.195, and 0.16. Work experience and age in the model 2 weighted at 0.324 and 0.318 were more effective than model 1.

The accuracy and the F-measure of model 2 were 91% and 92%, respectively: all normal subjects but one (classified as having a moderate hearing loss) were classified as normal (N=26). Five subjects with predicted mild severity actually had a mild hearing loss, whereas two subjects with a moderate predicted severity also had a mild hearing loss.

Model 3: Hearing loss changes in group C (SPL above 85dBA)

The effect of HLSFs on hearing loss in model 3 is presented in Figure 4. According to the results of this model, hearing loss in the frequency of 4000Hz on the right ear at 0.611 has the most effect

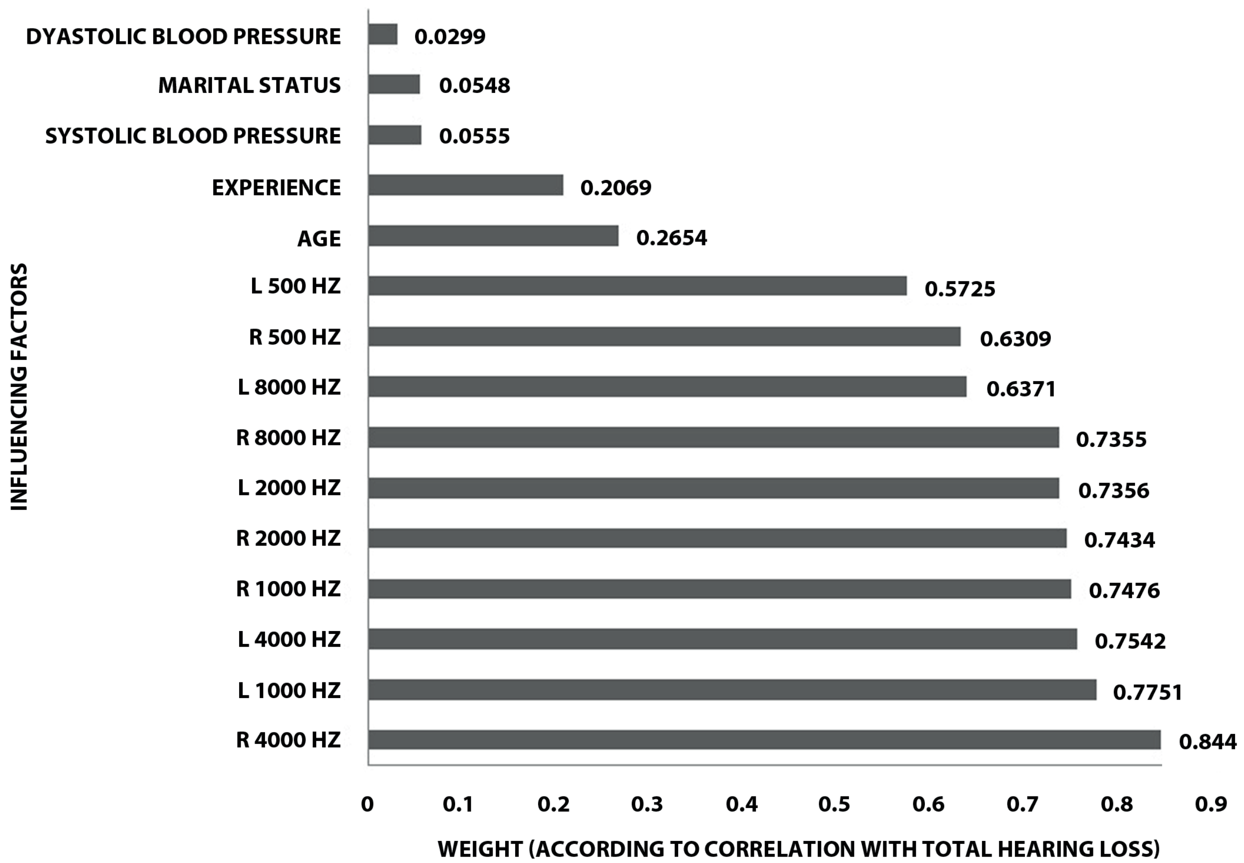

Figure 2. Weighting HLSFs in model 1 depending on correlation with hearing loss.
R: right ear, L: left ear.

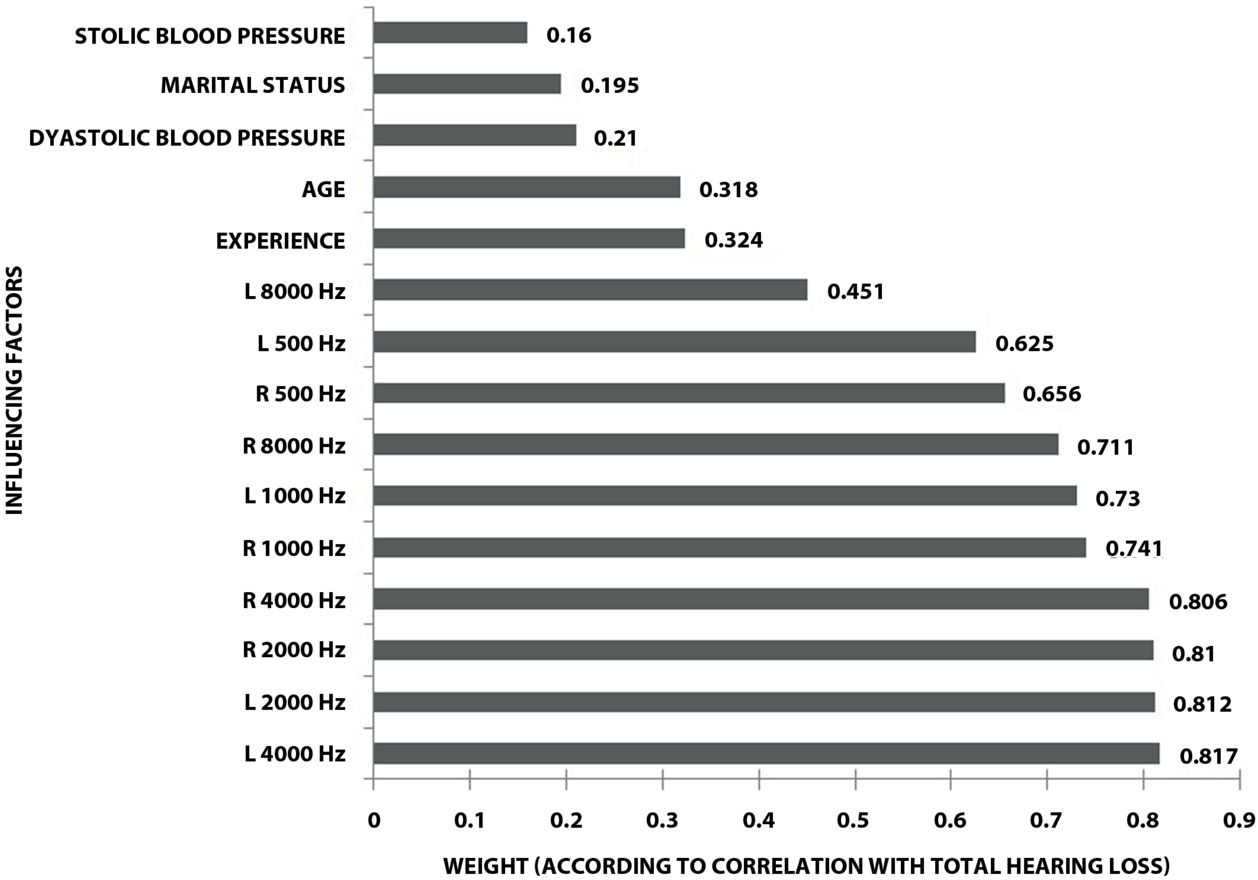

Figure 3. Weighting HLSFs in model 2 depending on correlation with hearing loss.
R: right ear, L: left ear.

on overall hearing loss. Also, the results of the said model showed that hearing loss factors could affect overall loss in frequencies of 4000Hz in the right ear, 2000Hz in the left ear, and 2000Hz in the right ear at 0.610, 0.592, and 0.588 in ranks 2-4, respectively. Therefore, it could be mentioned that the noise with frequencies of 4000 and 2000Hz has been the main factor for hearing loss in this job group. Also, model 3 showed that age with an effectiveness of 0.4755 had been the most influential factor in overall hearing loss compared to two other models. Besides, the weight of work experience in this model was 0.3087. It was at a higher level than model 1, and its value was close to model 2. Hence, it could be mentioned that controlling the two factors can leave a significant effect on reducing hearing loss in this job. Also, factors including marital status, diastolic blood pressure, and systolic blood pressure weighted at 0.1571, 0.0754, and 0.0711.

Hearing loss in group C was correctly classified in 92.3 % of subjects. One predicted as normal actually had a mild HLS, one predicted as having a moderate HLS actually had a severe HLS, and one classified as having a severe HLS actually had a moderate HLS.

Model 4: Modelling hearing loss in groups B and C exposed to SPL above 70dBA

Figure 5 illustrates the effect of HLSFs in model 4. In this model, the right ear hearing loss in the frequency of 2000Hz weighting at 0.674 has the most effect on the overall hearing loss. Besides, the frequencies of 4000Hz in the left ear, 2000Hz in the left ear, and 4000Hz in the right ear weighted 0.672, 0.670, and 0.659 in ranks 2-4 have been effective, respectively. This shows the high significance of 2000Hz and 4000Hz frequencies affecting

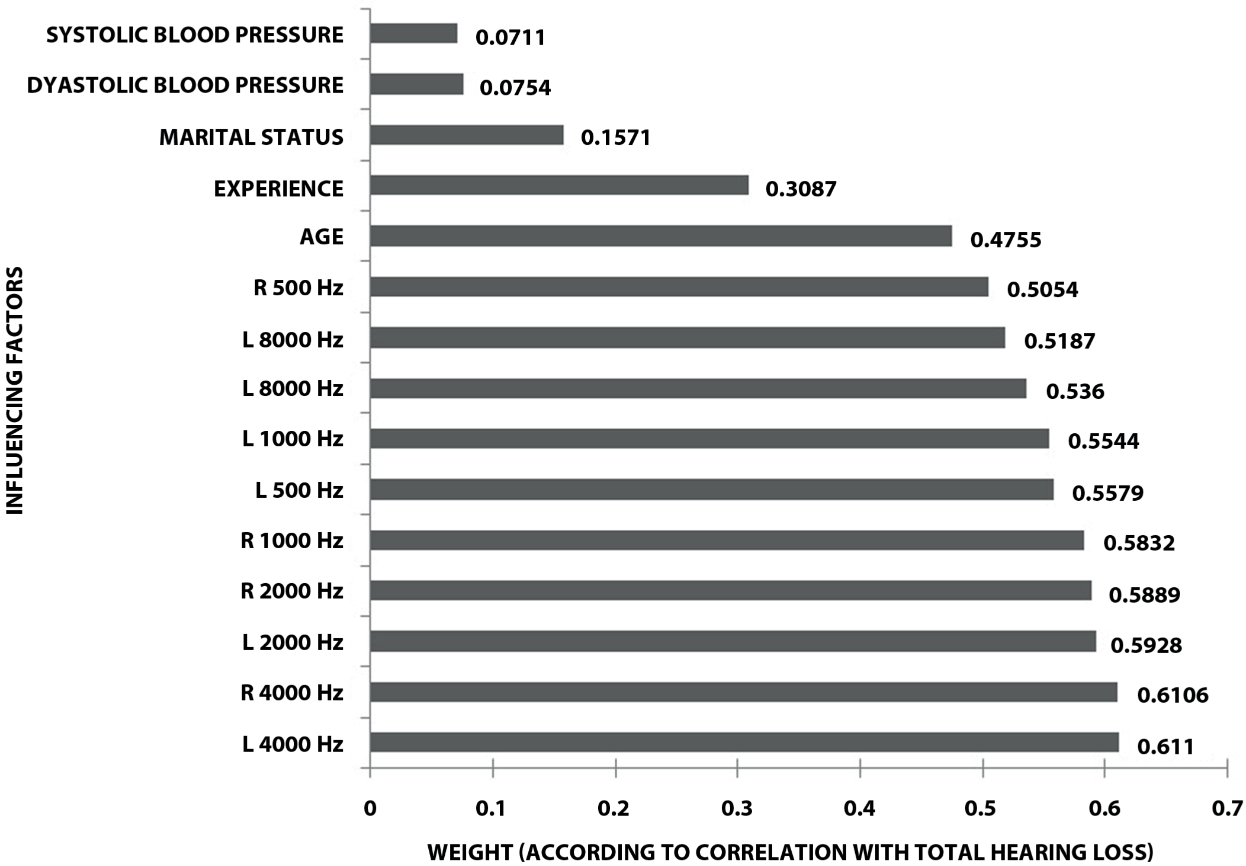

Figure 4. Weighting HLSFs in model 3 depending on correlation with hearing loss.
R: right ear, L: left ear.

hearing loss of personnel. In this model, age and work experience weighted at 0.440 and 0.336 have had a high effect on hearing loss compared to previous models. In this model, three factors including SPL, systolic and diastolic blood pressure weighted at 0.135, 0.102, and 0.083.

The model's accuracy based on ACC and F-measure is equal to 97%. In fact, all but two subjects out of 73 subjects were correctly classified: one predicted as normal actually had a moderate HLS, and one predicted as having a moderate HLS actually had a severe HLS.

Model 5: Modelling the effect of HLSFs on hearing loss changes in three study groups

Figure 6 presents the results of the model obtained from data of three study groups. According to the results in model 5, same as model 4, four HLSFs at the frequencies of 2000Hz in the right ear, 4000Hz in the left ear, 2000Hz in the left ear, and 4000Hz in right ear weighted respectively at 0.7087, 0.7086, 0.704, and 0.700 in ranks 1-4 have affected hearing loss. Compared to models 1 and 2, age and work experience weighted at 0.417 and 0.337 had the most effect on hearing loss. Also, the SPL factor weighted at 0.249 in this model was more effective on hearing loss than it was in model 4. Hence, controlling age, work experience, and decreasing SPL of the equipment in vessels can decrease the hearing loss rate. Finally, marital status, systolic and diastolic blood pressure weighted 0.136, 0.047, and 0.015 had the least effect on loss hearing, respectively.

The accuracy of model 5 using the ACC and F-measure was 98% and 97%, respectively. Out of 112 subjects, 85 were correctly predicted as normal, whereas 21 and 4 actually had a mild or moderate HLS, respectively. One was classified as normal,

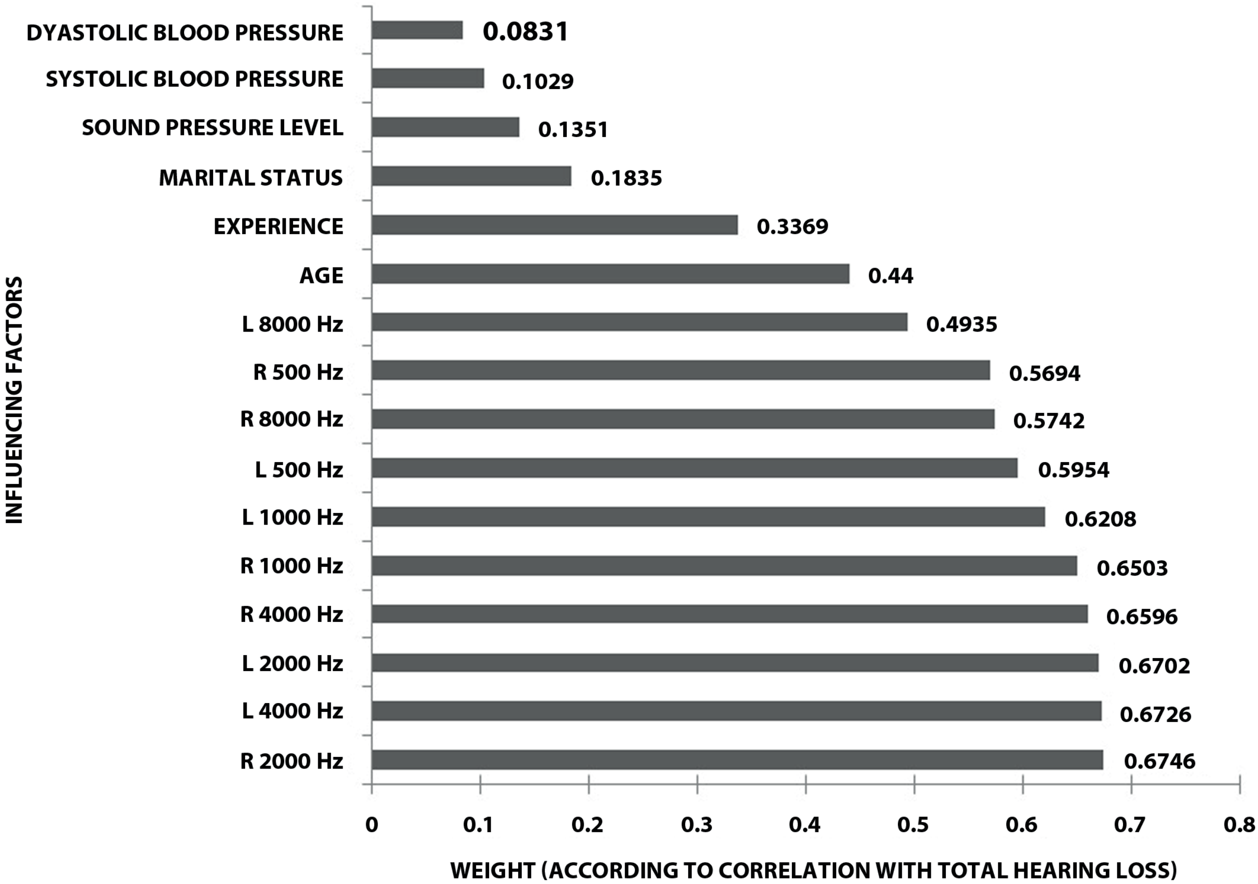

Figure 5. Weighting HLSFs in model 4 depending on correlation with hearing loss.
R: right ear, L: left ear.

whereas he had a moderate HLS, and one was predicted as having a moderate instead of a severe hearing loss.

Receiver Operating Characteristics (ROC) curves of model 5 demonstrated that the AUC value of the model is equal to 100% in normal and mild hearing loss, while the AUC of the model for prediction of moderate and severe hearing loss was obtained at 99.9% and 95.5%, respectively (not shown).

Discussion

The present study was conducted to analyse the effect of different factors on hearing loss changes among personnel working on speed vessels in a harbour in Southern Iran, employing 112 male sailors. Hearing loss shaping factors (HLSFs) were analysed along with the correlation between hearing loss and predictors. Hearing loss was correlated with age and work experience.

Then, an artificial neural network (ANN) was used to classify hearing loss and the model performance was defined by ACC and F-measure. In the study conducted by Albizu et al. on the evaluation of noise exposure and its effects on hearing loss of 466 commercial fishers in Brazil, measurements of SPL showed that the SPL in most parts of fisherman vessels was higher than 80dBA, mostly at frequencies of 4000 and 6000Hz [16]. In our study, we confirmed a significant correlation between hearing loss and age and work experience, whereas the most affected frequencies were 4000Hz and 2000Hz in the right and left ear, respectively.

Levin et al. evaluated the hearing loss and noise exposure among commercial fishers in the Coast Gulf, showing the highest hearing loss was at high frequencies (3 to 8 KHz). A significant correlation

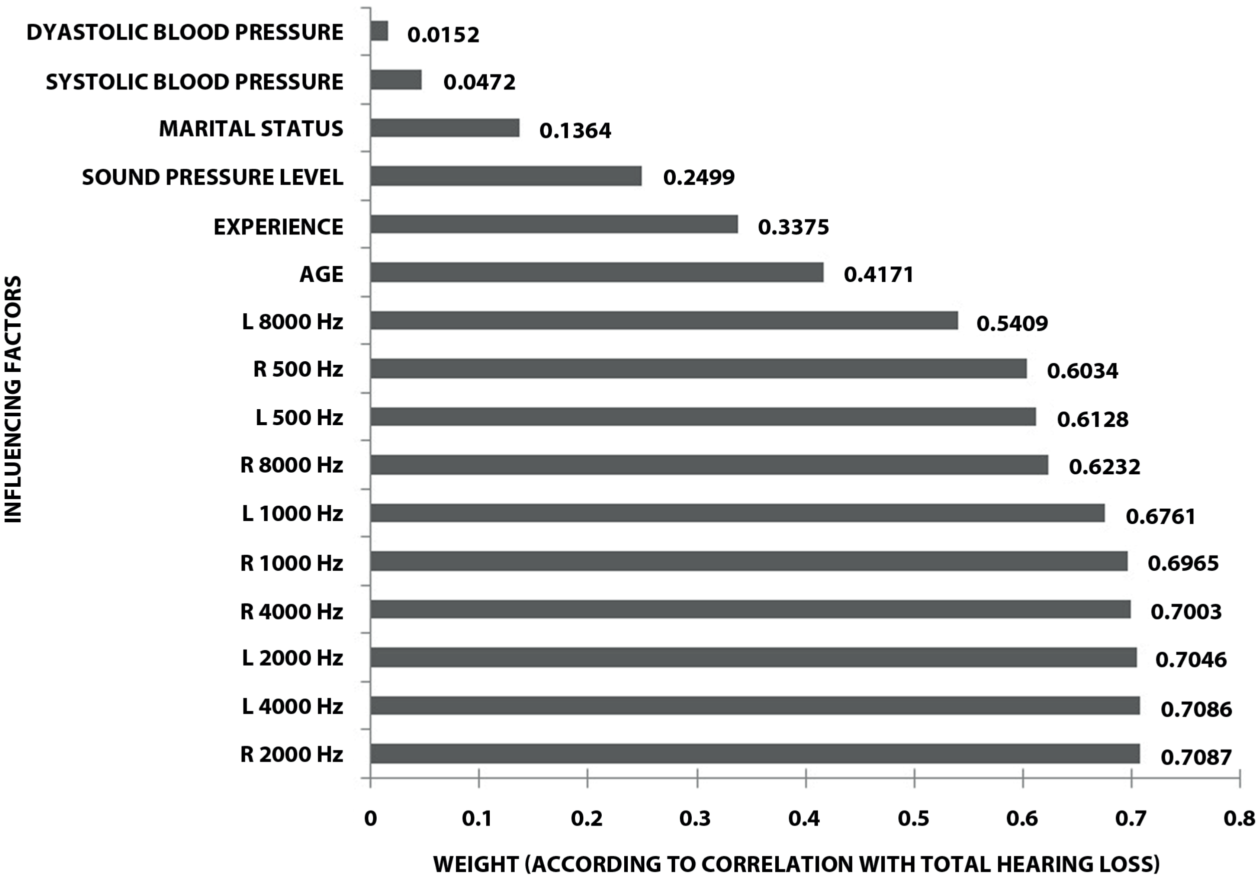

Figure 6. Weighting HLSFs in model 5 depending on correlation with hearing loss.
R: right ear, L: left ear.

was observed between work experience or age and hearing loss, with a prevalence of noise-induced hearing loss (NIHL) equal to 53.8% [35]. We also observed the highest hearing loss at high frequencies, especially 4KHz, and there was a significant correlation between age and work experience with hearing loss. The lower prevalence of hearing loss in the present study (38.46%) could be accounted for by fewer work hours. Paini et al. showed different SPLs in different parts of the vessels and engine boats in the range of 86-108dBA [36]. Our findings were consistent with such levels.

In the present study, no significant correlation was observed between hearing loss and systolic and diastolic blood pressure. Such results are consistent with the findings of Jegaden and Nguyen [37, 38]. However, in other similar studies, a significant correlation was found between noise-induced hearing loss and noise exposure with blood pressure [39, 40]. The frequency of 4000Hz weighted at 0.61-0.84 in all five models, showing the most important effect on hearing loss. In models 3-5, age and work experience weighted at 0.3-0.48 had a significant role in hearing loss. The accuracy of developed models varied from 92 to 100%.

Farhadian et al. used new neural networks and classic regression methods to investigate the role SPL, age, work experience, smoking, and using hearing protection accessories as predictors of hearing loss in 210 workers from the steel industry: 72.4% of workers had normal hearing; 23.4% mild, and 2.4% moderate hearing loss. Also, individuals were exposed to SPL of 81-95dB. Finally, the accuracy of the model obtained from the ANN and logistic regression in that study were 88.6 and 64.28%, respectively [41]. In the present study, 75.89% of personnel had normal hearing, 18.75% mild, 4.47% moderate, and 89% severe hearing loss. Thus, higher noise exposure and subsequent hearing loss seems to be associated with higher accuracy of developed models, which in the present study ranged from 92 to 100%, a level similar to that shown by Zare et al. in a mineral industry [20] and by Aliabadi et al. to predict hearing loss in personnel in a steel factory [42]. A limitation of the present study was the sample size. Further studies on larger samples possibly from multiple harbours should be investigated.

Conclusions

Age and work experience had a significant impact on the hearing loss of individuals whereas marital status and hypertension are not correlated with hearing loss. The following controlling measures are proposed to improve conditions of personnel and to reduce hearing loss:

Using sound-absorbing materials with high efficiency (high sound absorption coefficient) at the frequencies of 2000 and 4000Hz on walls of speed vessels.

Using engines with low SPL or controlling noise of engines using sound insulation and absorption materials with high efficiency at the frequencies of 2000 and 4000Hz in their chambers.

Considering hearing status and age of individuals in examinations or employment.

Retirement or early job change of personnel working on these vessels.

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Ethics Committee of BAQIYATALLAH UNIVERSITY OF MEDICAL SCIENCES (protocol code IR.BMSU.REC.1398.280).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

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Declaration of Interest: The authors declare no conflict of interest.

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