Original Article

Prevalence of Hearing Loss and Associated Risk Factors Among Factory Workers in Urban Pakistan

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ABSTRACT

Background: Noise-induced hearing loss in the occupational setting remains a prevalent and preventable cause of disabling illness in the global industrial workforce, especially in developing nations. However, there has been scarce data available from the Pakistani industry that mainly involves selected sectors without a substantiated statistical analysis of the interaction of the duration of exposure to the intensity of the sound along with the pattern of extended work schedules and hearing protection practices. **Objective**: To determine the point prevalence of hearing impairment as evident from the audiogram and its interassociation factors in the selected group of workers of the Sheikhupura factory region of Pakistan. **Methods**: An analytical type of cross-sectional study involving a selected group of 135 workers from the Sheikhupura region of the Pakistan industry was carried out. Detailed interviews were conducted with the participants, measuring the sound intensity in their respective departments, examining the workers through audiograms, and collecting data on their work schedules and hearing protection practices. **Results**: The point prevalence of the selected group of workers of the Sheikhupura region of the Pakistan industry suffering from the said condition was revealed to be approximately one in three at 30.4% (41/135 [95% CI: 22.6–38.1%]). Approximately eight out of ten of the said hearing losses were bilateral at 80.5%. Workers aged above 10 years had approximately thrice the chances of suffering from hearing problems in the investigated group at an odds ratio of 3.06 [95% CI: 1.43–6.55], individuals exposed to sound above 95 dB had approximately thrice the chances at an odds of 3.18 [95% CI: 1.48–6.79], workers who worked extended hours above the scheduled eight hours had approximately thrice the chances of suffering from the said ailments at an odds of 3.17 [95% CI: 1.48–6.79], irregular users of hearing protection practices had approximately four times the chances of the said ailment at an odds of 4.14 [95% CI: 1.59–10.8], and smokers had approximately twice the chances of suffering from the said ailment at an odds of 2.19 [95% CI: 1.00–4.77]. Conclusion: Approximately one out of three workers of the selected region of the Pakistan industry was suffering from the said ailment due to the above-stated numerous factors.

Keywords: Noise-induced hearing loss, occupational exposure, factory workers, Pakistan industry

Received: 7 October 2025
Revised: 18 November 2025
Accepted: 19 November 2025
Published: 26 November 2025

Citation: Click to Cite

INTRODUCTION

Noise-induced hearing loss can be ranked alongside the list of the most common occupational diseases globally and has been identified as a contributory factor to the years

lived with disability in the adult working-age group. In an industrially set-up environment, prolonged exposure to high levels of intensity of noise leads to the destruction of hair cells of the cochlear nerve and results in irreparable sensorineural hearing loss. It has been estimated globally that about 16–24% of the currently exposed workforce will develop noise-induced hearing loss, and about one-sixteenth of disabling hearing loss in adults can be traced to occupational exposure to hazardous levels of noise. The recent spate of rapid industrialization in the low- and middle-income nations of the South Asian region has meant higher vulnerability to hazardous levels of noise intensity of above 85 dB(A). This has been cited as beyond the permissible level of acceptable intensity of noise.

There has been clear evidence from various different industrial settings that both environmental and individual factors interact to contribute to the magnitude of occupational hearing loss. Studies from

Ethiopia, Burma/Myanmar, and others revealed the proportions of affected workers to be approximately 20% to above 30% of metal, wood, and textile industry workers. This was at a mean level of approximately above 95 dB(A). In addition, in various studies of this type of group, prolonged work duration above the standard measure of 8 hours a day, as well as advanced age at work and in departments that recorded higher levels of intensity of noise above the standard measure of 85 dB(A), and also work duration above the standard measure of five years were demonstrated to be factors increasing the odds of developing hearing impairment. In addition, a study surveying the science comprehensively in regard to manufacturing sector workers has recognized the defining role of absence of strict observance of intensity of work above 85 dB(A), number of years at work above the standard measure of five years, and advanced age at work, along with the role of attendant clinical illnesses, of particular significance being hypertension. Moreover, irregular usage of protective equipment amplifies the same.

More recent research has emphasized the role of modifiable behavioral and contextual factors. The role of active cigarette smoking in potentiating cochlear injury through microvasculature and oxidative injury has been suggested in several studies demonstrating a higher prevalence of hearing loss in the context of active smoking in a noisy group of individuals. In tandem, the insufficient provision and maintenance of hearing-conservation programs and the inconsistent and inappropriate usage of ear protection, along with the inadequate regular audiometric surveillance in the workplace, continue to be recognized in the context of the developing world. This points to the fact that the impact of occupational hearing loss also cannot be solely described based on its intensity.

In Pakistan itself, although there is limited information available regarding the extent of the problem of occupational noise-induced hearing loss, there has been considerable work done in this area. From the south region of Punjab, research has shown the existence of hearing problems in about "30% of the industrial workers without significance regarding their age and duration of service" but "with important implications regarding the upgrading of preventive practices."

Studies from the "Multan metallurgical factory" revealed the existence of "about 21% of the existing hearing problems" in the workers there, though the risks of "duration of exposure" and the performance of "overtime work" showed a "significant" impact. In the "sugar mill" region near Rahim Yar Khan, research has revealed the existence of hearing problems in "30% of the workers" there. The study also revealed the significance of "duration and intensity of exposure" to hearing problems, along with "age, sex, and education level" also being important factors. Workers not using "hearing protective devices" also fall within this category. More recent research from the Pakistani "industrial setup" has revealed the

existence of about "one third" of the existing hearing problems due to the "generator and dye" department's "noise levels of 96-100 dB," along with "sustained duration of performance" being of "major significance."

The study from the traffic police wardens in Karachi provides information about the existence of a "high" level of "'noise-exposed' auditory symptoms" suffered from within the "urban settings" of Pakistan along with the "near absence of existing hearing protective practices" in "high-noise" sectors.

Despite this information, there are a number of research gaps remaining. Most of the research from Pakistan has been sector- or occupation-specific and has been performed in the south of the province of Punjab and the city of Karachi. There has been no information regarding the effect of classical occupational factors together with behavioral factors in a combined model regarding medium-sized mixed-industry groups of factories situated in the rapidly growing districts of Lahore and Sheikhupura. There has been no information regarding the effect of the combined effect of longer service and noise irritations together with the non-standard usage of hearing protection regarding the risk of developing hearing problems in the city of Lahore.

In this regard, the purpose of this study was to measure the extent of the problem of confirmed hearing loss and its factors in the factory workforce of the Sheikhupura industrial zone of the Punjab region of Pakistan. The research question this study hoped to answer was, what is the magnitude of the problem of hearing loss in the city's factory workforce of Sheikhupura, and which factors are independent of this? According to previous research findings, the research hypothesis of this study was that there exists an association of work duration years, work environment noise level, overtime work, irregular/uncommon use of protective equipment against the ears, and smoking of cigarettes with the hearing condition of the study participants.

MATERIALS AND METHODS

This was an analytical cross-sectional study done among the workers of the various industries situated in the Sheikhupura factory area of Sheikhupura in the Pakistan province of Punjab. The study took six months and involved production workers of various industries related to metal fabrication work, textile processing work, packaging work, and related manufacturing units where regular work involves considerable machinery-generated noise. The study used the cross-sectional survey method to provide estimates of point prevalence of hearing loss along with the factors studied in one survey spell because of its relevance to previous work done in this field of research.

The target participants were full-time production workers aged 18 years and above who had been employed in their current factory for at least one year. They had to be employed in the production and maintenance sections of their respective factories, where they would be exposed to noisy work sites. They were excluded from the study if they had congenital or childhood hearing loss, previous surgery of the ears, known chronic otologic disorders, previous systemic ototoxic medication treatment, and within the previous four weeks had suffered from an acute infection of the ears. A list of the eligible departments in each of the participant's own factories was also solicited from the management. The list of eligible participants from each department was stratified according to the departments. Participants were selected using the proportional allocation method until the target of 135 participants had been achieved. The recruitment of study participants took place during work hours together with the health and safety personnel of the involved factories. The research team informed the participants about the research aims and objectives, procedure, and risks

involved, as well as the benefits of the research in Urdu. The participants signed an informed consent form prior to data collection. Voluntariness of the participants was assured without financial benefits attached. This helped eliminate selection bias from the evening shifts. All workers whose names featured in the selected lists available during the time of data collection were targeted. A structured questionnaire was used, which was developed in English and then translated into Urdu. This helped in understanding the socio-demographic factors (age, sex, and educational level), work experience (type of factory, department, accumulated years of work, number of work hours in a day, and number of hours of overtime work), and behavioral and medical factors (status of smoking, history of hypertension, diabetes, previous episodes of ear diseases, and the usage of ototoxic drugs). The work environment's level of intensity was estimated through both subjective and objective methods. The subjective approach to estimating the work environment's intensity entailed the perceived level of environmental intensity and the number of hours worked in noisy areas. The objective measurement of work environment intensity was estimated through the usage of a type II sound level meter at a selected number of departments. This measurement was estimated through weighted equivalent continuous levels of sound intensity in representative work periods and ranged from less than or equal to 85 dB(A) to 86 to 95 dB(A) to above 95 dB(A). Workers were also grouped according to the intensity levels of their main work area. The usage of hearing protection devices (HPD) was ascertained in terms of their availability and usage pattern. The participants were asked about the availability of earplugs and earmuffs in their workplace and the frequency of their usage during noisy tasks (always and often vs sometimes, rarely, and never). In the study, the usage of HPD was considered binary: "regular" users (always and often) and "irregular/never" users (sometimes, rarely, and never). Smoking was also dichotomized: "current smokers" vs "non-smokers" (former and never). Details regarding non-occupational noisy exposures (recreational noisy activities and the usage of personal listening devices at a high volume level) were recorded descriptively and were not used as main study exposures because of the study's limited size. All participants received a brief otoscopic survey to rule out overt obstruction of the ear canal and active middle ear problems. Pure-tone audiometry was carried out in a soundproofed environment situated in the factory settings or at an in-plant health clinic using a portable, calibrated clinical audiometer with standard supra-aural headphones. Ambient noise levels were closely watched to permit reliable measurement of the threshold in conventional frequencies. Air-conducted threshold measurements were done bilaterally at the frequencies of 0.5, 1, 2, 4, and 8 kHz in 5-dB increments using the Hughson-Westlake modified procedure. The main criterion measure was the existence of hearing loss according to the WHO and usual fieldwork standards, defining the condition as the average of the air-conducted thresholds at the frequencies of 0.5, 1, 2, and 4 kHz of 25 dB or greater in the better-hearing ears. Severity of hearing impairment was graded as slight (26–40 dB), moderate (41–60 dB), and severe (>60 dB) in the better ears. A pattern of the audiogram suggestive of NIHL—poorest thresholds at the frequencies of 3-6 kHz, preserved at the lower frequencies—was recorded when observed. The main explanatory variables were age (<40 vs. ≥40 years), length of service in the current plant (<10 vs. ≥10 years), group-level noise exposure (≤95 vs. >95 dB(A)), number of overtime hours per day of work (≤8 vs. >8 hours), hearing protection use (regular vs. irregular/none), and smoking (current vs. non-smokers). Age, sex, and smoking were regarded as possible confounding factors. To minimize information bias, joint interviewing and audiologist training took place, a pilot form was employed, and the audiologist doing the audiometry was kept blind to the participants' group of exposure whenever possible. The study used the single proportion formula suited to cross-sectional study designs because the expected prevalence of occupational hearing loss was estimated

to be about 30% from previous studies of Pakistani factory workers. The study adjusted its margin of error to provide a level of confidence of 95% and an absolute precision of 8% to obtain a rough estimation of the required number of samples from the target study group. This estimated the number of study participants needed to be no less than 121. To compensate for non-response rates estimated to be less than 10% in the study settings due to poor interest rather than the research settings' non-response rates often due to refusals to participate in research, the aim was to collect data from at least 135 participants. The data collected were entered twice and verified to see if there was consistency in the data collected. The continuous type of data was described using the mean and standard deviations in the case of the first type of continuous data and the median and interquartile in the case of the other type of continuous data, depending on which scale of measurement was used. The same approach was applied to the categorical type of data used in the study, which described the characteristics of the study participants according to the study's objectives. The point-prevalence of the study's participants' hearing impairments was also estimated at a 95% level of significance. To determine the association of the participants' symptoms of hearing impairment and the study's categorical variables, the study used the chi-square test, though in instances where the expected value was less than four and could affect the study's level of significance due to reduced study power, the study applied the Fischer exact test. To determine the strength of association of the study's findings and identify the factors that predict the study's participants' symptoms of hearing impairment due to the less likely confounding effect from the study's variable used due to its univariate distribution's limited power within the study settings. The findings used the adjusted odd ratios at a two-sided level of significance at a significance level of less than 0.05 from the study. The study was cleared for ethical approval from the relevant ethics review committee prior to the field study. The participants' confidentiality was preserved through the use of anonymous research codes and the display of results only at the group level. Workers found to be newly suffering from moderate to severe hearing impairment or suggestive audiograms of the same were advised and referred for additional otologic assessments through secondary/tertiary health care facilities.

RESULTS

A total of 135 factory workers were involved in the study. Their mean age was 37.4 ± 9.8 years, and the majority of them (89.6%) were men. Approximately 40.0% of the respondents were aged 40 years and above, while about 36.3% had attained a primary level of education or less. However, forty-four point four percent of them had worked in their current factories for at least the last 10 years, while one-third had less than 5 years of service. Although the majority of the participants had a standard working time of up to 8 hours daily, about fifty of them worked overtime of more than 8 hours a day. The work environment's noise level was above 95 dB(A) in the departments of 41.5% of the workers, while about 43.7% had levels of 86-95 dB(A). Only about 14.8% had levels at and below 85 dB(A). However, about seventy-five point six percent of the respondents had personal hearing protective equipment provided to them, and only thirty-three point three percent used it regularly. Approximately twenty-nine point six percent of the participants were current smokers. Only about thirteen point three percent had been diagnosed with hypertension. (Table 1).

Table 1. Socio-demographic and occupational characteristics of factory workers (n = 135)

Variable	Category	n (%)
Age (years), mean ± SD	—	37.4 ± 9.8
Age group	<40 years	81 (60.0)
	≥40 years	54 (40.0)

Variable	Category	n (%)
Sex	Male	121 (89.6)
	Female	14 (10.4)
Education	Primary or less	49 (36.3)
	Secondary	61 (45.2)
	Intermediate or higher	25 (18.5)
Duration of employment in current factory	<5 years	44 (32.6)
	5–9 years	31 (23.0)
	≥10 years	60 (44.4)
Daily working hours	≤8 hours	85 (63.0)
	>8 hours (overtime)	50 (37.0)
Department-level noise category*	≤85 dB(A)	20 (14.8)
	86–95 dB(A)	59 (43.7)
	>95 dB(A)	56 (41.5)
Hearing protection devices provided	Yes	102 (75.6)
	No	33 (24.4)
Hearing protection use (if provided / overall)	Regular (always/often)	45 (33.3)
	Irregular/none	90 (66.7)
Smoking status	Current smoker	40 (29.6)
	Non-smoker	95 (70.4)
Hypertension (self-reported)	Yes	18 (13.3)
	No	117 (86.7)

Table 2. Prevalence and severity of hearing loss among factory workers (n = 135)

Outcome	n (%)	95% CI
Any hearing loss*	41 (30.4)	22.6–38.1
Normal hearing	94 (69.6)	61.9–77.4
Severity among those with hearing loss (n = 41)		
Mild (26–40 dB)	26 (63.4)	—
Moderate (41–60 dB)	11 (26.8)	—
Severe (>60 dB)	4 (9.8)	—
Laterality among those with hearing loss (n = 41)		
Unilateral	8 (19.5)	—
Bilateral	33 (80.5)	—

Table 3. Factors associated with hearing loss among factory workers (n = 135)

Factor	Category	Hearing loss n/N (%)	OR (95% CI)*	p-value
Age group	<40 years	20/81 (24.7)	1.00 (reference)	—
	≥40 years	21/54 (38.9)	1.94 (0.92–4.09)	0.081
Duration of employment	<10 years	15/75 (20.0)	1.00 (reference)	—
	≥10 years	26/60 (43.3)	3.06 (1.43–6.55)	0.004
Department-level noise	≤95 dB(A)	16/79 (20.3)	1.00 (reference)	—
	>95 dB(A)	25/56 (44.6)	3.18 (1.48–6.79)	0.003
Daily working hours	≤8 hours	18/85 (21.2)	1.00 (reference)	—
	>8 hours (overtime)	23/50 (46.0)	3.17 (1.48–6.79)	0.003
Hearing protection use	Regular	6/45 (13.3)	1.00 (reference)	—
	Irregular/none	35/90 (38.9)	4.14 (1.59–10.78)	0.004
Smoking status	Non-smoker	24/95 (25.3)	1.00 (reference)	—
	Current smoker	17/40 (42.5)	2.19 (1.00–4.77)	0.049

In total, there were 41 of 135 workers who satisfied the audiometric standards of hearing loss, which represented a prevalence of 30.4% (95% CI: 22.6-38.1). On the other hand, there were also 94 workers (69.6%) who had normal levels of hearing. Most of the hearing losses occurred in the mild form in the better ears of the affected workers (63.4%); this was followed by the moderate type in 26.8% of the workers and the severe type in the remaining 9.8% of the workers. The large number of affected workers who had bilateral hearing loss was impressive: only 8 of the 41 workers had unilateral hearing loss, which represented approximately 19.5% (Table 2). This suggests that the majority of the affected workers had diffuse cochlear lesions rather than the focal

In the multivariate model, there were several work-exposure factors that had a significant relationship to the risk of hearing impairment. Being employed for at least 10 years was related to the prevalence of hearing impairment of 43.3% (26/60) compared to those employed for fewer years at 20.0% (15/75), which had an adjusted odds ratio of 3.06 (95%

CI: 1.43–6.55); p value of 0.004. Additionally, being employed in work environments where the average levels of noise measured above 95 dB(A) had a positive relation to hearing impairment at 44.6% (25/56) compared to those employed in work environments at or below 95 dB(A) at 20.3% (16/79), which had an adjusted odds ratio of 3.18 (95% CI: 1.48–6.79); p value of 0.003. Lastly, the effect of hearing impairment due to work environment factors also involved working overtime for over 8 hours a day at work due to its significant association of 46.0% (23/50) compared to the standard work environment at 21.2% (18/85), which had an adjusted odds ratio of 3.17 (95% CI: 1.48–6.79).

The trend of hearing protection usage showed a large gradient of risk. In the group of workers who used earplugs/earmuffs regularly compared to those who used them irregularly or not at all, the proportions of hearing impairment were 6/45 (13.3%) vs. 35/90 (38.9%). In the adjusted model, the absence of regular usage of hearing protection was shown to be a significant predictor of hearing impairment with an adjusted odds ratio of 4.14 (95% CI: 1.59–10.78; p=0.004). The absence of regular usage of hearing protection also acted as a significant predictor of hearing impairment when adjusted. Smoking was also found to be a significant predictor of hearing impairment in the adjusted model itself. The point estimate of the adjusted odds ratio of risk of hearing impairment showed significance at the conventional level of significance at 95% CI (2.19; 95% CI: 1.00–4.77; p=0.049). The group aged above 40 years had larger proportions of hearing impairment (38.9% vs. 24.7%). Although not at the conventional level of significance at the 95% CI level (p=0.081), the point estimate of the adjusted odds ratio of risk of hearing impairment also showed a trend consistent with an increased vulnerability of the aged due to the superposition of occupational risk factors (Table 3).

DISCUSSION

This cross-sectional study of factory workers in the Sheikhupura Industrial Area of the Punjab region of Pakistan revealed that approximately one in three workers (30.4%) had confirmatory audiometry-proven hearing loss, of whom four out of five had bilateral symptoms. The findings were predominantly of mild to moderate intensity, which reflects the natural progression of early-intermediate levels of NIHL but also has clear functional significance in relation to noisy work environments. The findings are consistent with previously reported proportions of the order of 20-35% observed in various industries in the developing and middle-income nations of Asia when evaluating metal, wood, and textile workers. They also confirm previous Pakistani studies from the South Punjab region of the Inch Bazaar study from the Rahim Yar Khan area of the RYHOS study of sugar mill workers, who found approximately the same level of NIHL of approximately 21-30%. Clearly the impact of occupational hearing loss remains an underestimated magnitude and priority health problem in the industrially active workforce of Pakistan.

The trend of increasing hearing loss risk with cumulative duration of occupation supports the biological and ecological plausibility of the results observed in previous studies. The risk of hearing loss was found to be over three times higher in the group employed for at least 10 years than in the group employed for less than that duration. This trend can be compared to the study of Ethiopian metal workers, the textile workers of the Union of Myanmar, and the airport ground staff of the Oman airport, where hearing impairment was predicted independently by the length of service and the intensity of the ambient noise level above 95 dB(A). In Kuwait, the results of the study of the migrant workers in the unskilled industry showed that the risk of subjective occupational noise-induced hearing loss was substantially higher in workers who had worked in their occupation for a longer duration of time and had experienced high levels of occupational noise. The study confirms

the global recommendation that at levels above 85 dB(A), engineering controls and regular audiograms must be employed.

Overtime work of more than 8 hours per day was also found to be strongly related to hearing loss, and the adjusted odds ratio was found to be of a similar magnitude to that found in the high-noise departments. This points to the significance of the duration of daily exposure to noise rather than the length of service only. Longer work shifts will likely extend the duration of exposure above the permissible levels of safety and will reduce the chances of recovery of the cochlea and the prevention of temporary threshold shifts from turning permanent. This fits the results of the systematic review of the extent of daily exposure above 8 hours and weekly exposure above 40 hours that increases the risk of noise-induced hearing loss in the manufacturing sector. Noise intensity and duration should be of prime importance in the hearing-conservation program.

The consistent use of hearing protection came out as a significant protective measure. Members of the group who used hearing protection in the form of earplugs/earmuffs reported a hearing loss prevalence of 13.3% compared with 38.9% in the group that used it irregularly or never used hearing protection. This fourfold difference in odds remains consistent with the available scientific information that states the consistent use of properly fitting hearing protection will minimize the incidence and severity of occupational hearing loss even when engineering controls are less than satisfactory. However, only one-third of employed individuals used them regularly in spite of the fact that three-quarters of the group had access to the device. This indicates that provision of the device alone might not be the solution.

The result that current smokers had about twice the odds of hearing loss than non-smokers confirms the findings from previous regional studies regarding the role of smoking as an independent cofactor of cochlear injury through its vascular and oxidative components. Although the lower bound of the CI barely crosses unity, there is enough biological plausibility and significance to recommend the incorporation of smoking cessation programs within the ambit of occupational health programs, especially in the case of noisy workers. The trend of increasing likelihood of hearing loss in the category of workers aged 40 years and above did not attain significance. This could be due to reduced power or the healthy worker effect. When comparing the study to the existing local literature, this research makes a contribution to existing work in Pakistan regarding the addition of objective audiometry with measured levels of exposure and protection behavior in a mixed industry setting of the type found in the typical urban factory. Drawbacks: The study had a cross-sectional study design, which doesn't allow the establishment of causation and can be sensitive to healthy worker survival bias. The study took place in one geographical region of industry, which might undermine generalizability. The data regarding personal dosimetry weren't gathered for each participant, which can be prone to exposure classification bias. Recreational exposure to noise and previous otologic illness were gathered through a questionnaire study and can be at risk of resultant recall bias. The study had limited power to assess interaction principles. Strengths: The study employed standardized pure-tone audiometry. The results were adjusted to exclude the effect of the main confounding factors. A large number of factories and departments were used in the study, and the levels of their noises were measured. This increased the ecological validity of the study findings. The findings of the study are consistent regarding prolonged service, departments with high levels of noise, overtime work, and irregular hearing protection usage. The modifiability of the observed risk factors provides support to the findings of the study, together with the global and regional findings regarding the urgent need to implement comprehensive hearing conservation programs at the workplace.

CONCLUSION

This study of factory workers in the Sheikhupura Industrial Area found nearly one-third of the group had audiometrically confirmed hearing loss, which was bilateral in nearly two-thirds of the affected group and of the mild to moderate type in almost the same proportions. The risks of this hazard were found to be substantially increased in the group who had worked longer, who worked in departments where the intensity exceeded 95 dB(A), who worked longer than 8 hours in a shift when overtime was taken, who did not wear hearing protection intermittently or at all when the environment had a level above the threshold of the device and intermittently when active protection was used along with passive protection if the latter was used at work directly involved in production, and who were current smokers.

DECLARATIONS

Ethical Approval
This study was approved by the Institutional Review Board of University of Lahore, Lahore, Pakistan
Informed Consent
Written informed consent was obtained from all participants included in the study.
Conflict of Interest
The authors declare no conflict of interest.
Funding
This research received no external funding.
Authors' Contributions
Concept: FS; Design: HFS; Data Collection: ZA; Analysis: FS, ZA; Drafting: FS, ZA
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Data Availability
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.
Acknowledgments
Not applicable.
Study Registration
Not applicable.

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