Hoveyzeh ear cohort study in southwest Iran: Objectives and design

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Abstract

Background: Hearing loss is the fourth leading cause of disability in the world. The growing trend of this disease has made it a serious public health issue that requires well-designed and coordinated measures at the global, regional, and local levels. The current cohort study aimed to estimate the prevalence and incidence of different types of hearing loss and identify the risk and protective factors in the study population.

Methods: Hoveyzeh ear cohort (HEC) is a population-based cohort study that focuses on the audiological profile of 10,009 participants 35-70 years old who will recruit between May 2017 to January 2023. This study is conducted in the enrolment phase consisting of three steps registration, audiological assessments, and follow-up phase.

Results: A total of 1845 participants, aged 35-70 years old, that have been registered in the Hoveyzeh Cohort Study (HCS) are included in this pilot study. Our findings revealed that 947 participants (51.3%) had some degree of hearing loss in the pilot study. The prevalence of hearing loss was significantly correlated with demographical and socioeconomic variables including age, sex, educational level, marital status, wealth status, skilled levels, Townsend index, and smoking (p-value<0.05). We also found a significant correlation between the prevalence of hearing loss with clinical variables including tinnitus sensation, dizziness sensation, and history of diabetes, hypertension, cardiovascular disease, ear surgery, head trauma, and noise exposure (p-value<0.05). However, no significant correlation was found between the prevalence of hearing loss and the type of residence, wealth index, and alcohol consumption.

Conclusion: Our results demonstrated that hearing loss is an important contributor to the burden of chronic disability in Iran. There is a wide range of demographic, socio-economic, and medical parameters that affect the consequences of hearing loss. This study can provide the context of many studies in the field of hearing.

Background

According to the Global Burden of Disease report, hearing loss is the fourth leading cause of disability globally [1]. It has been shown that the prevalence of hearing loss doubles with every 10-year increase in age. Approximately half of the persons in their 7th decade (60 to 69 years of age) [2] and about 80% who are 85 years of age or older [3] experience hearing loss that is severe enough to influence daily communication. In the most recently published report, WHO estimated that about 466 million people, 6.1% of the world's population, has been subjected to disabling hearing impairment in 2018 [4]. This report predicted that this estimate would rise to 630 million by 2030 and over 900 million by 2050. This increasing trend has emerged as a serious public health issue that necessitates appropriate, well-designed, and well-coordinated actions at global, regional, and local levels [4–6].

Importantly, the burden of hearing impairments over the life span is significant both individually and socially. It has been demonstrated that hearing loss in adults can adversely influence their health,

economic and psychosocial conditions and leads to social isolation and a diminished quality of life [7–10]. As compared with age-matched adults with normal hearing levels, older individuals with hearing loss reveal several negative health outcomes including higher rates of hospitalization [9], falls and frailty [11], death [12] as well as higher rates of depression and dementia [15]. On a societal aspect, hearing-impaired usually indicate lower levels of education compared to those with normal hearing sensitivity. Furthermore, hearing-impaired adults usually show higher levels of underemployment or unemployment and lower income levels compared to their normal-hearing peers [7, 16].

Generally, the hearing acuity reduces with age - physiologically beginning by the third decade of life. The age-relating loss (ARHL) usually shows a symmetrical sensorineural hearing loss (SNHL) in the high frequencies, which influences speech understanding in noisy situations [18, 19]. SNHL, predominately induced by damage to the sensory hair cells in the inner ear, has been reported as the main cause of permanent hearing impairment. In addition to ARHL, the main factors contributing to the rising trend in hearing impairments are the increased rate of non-communicable diseases (NCDs), the use of ototoxic medications, and noise exposure [17, 19]. However, estimations of hearing loss prevalence across various cohort studies differ due to various tonal frequencies used to calculate a pure tone average, hearing threshold cut-offs to define hearing loss and binaural or monoaural definition of hearing loss. Furthermore, differences in cohort characteristics (recruitment of population sample or volunteer cohort) and the age of the participants in the cohort study also constrict comparison across studies [2, 20].

Recent evidence has shown that a significant percentage of hearing loss prevalence in adults could be prevented by taking appropriate measures and interventions such as community-oriented health education [19, 21, 22]. However, many world countries, particularly low, and middle-income countries, lack strategies and programs to reduce exposure to risk factors such as occupational noise exposure, use of ototoxic drugs, and having NCDs [21, 23]. Iran has the second rank of the population in the Middle East with an aging population. There is no published population-based cohort study on ear diseases in southwest Iran and on Arab ethnicity. Moreover, ear disorders' risk factors, etiologies, and development mechanisms vary based on geographical, cultural, and social conditions. The main objective of the HECS are as follow:

1. To estimate the prevalence and incidence of NCDs to identify the risk and protective factors of the NCDs in the study population
2. To build a biobank for assessing the possible roles of physiological, genetic, and epigenetic markers in the prognosis and diagnosis of the NCDs
3. To determine the relationship between the NCDs and hearing impairment

Methods

The aim, design, and setting of the study

The PERSIAN Cohort Study is a continuous program of studies designed to evaluate the health, nutritional and functional status of the civilian non-institutionalized Iranian population. Each sequential cross-sectional study utilizes a complex sampling method to assess a sample of the population, with selective oversampling of racial minorities, low-income individuals, and older adults [24]. The Hoveyzeh cohort study is a subcategory of the PERSIAN Cohort Study focused

on NCD assessments and NCD risk factors of the Arab ethnicity in the southwest region of Iran [25] (Fig. 1). The Hoveyzeh Ear Cohort (HEC) is designed in the context of the Hoveyzeh cohort study and focuses on the audiological profile of 10,009 adults who participate in both the interview and medical examination between May 2017 to January 2023. The main objectives of the HEC study are 1) to estimate the prevalence and incidence of hearing loss in the study population; 2) to identify the risk and protective factors in the study population; 3) to assess the possible roles of physiological, genetic, and epigenetic markers in prognosis and diagnosis of hearing loss; 4) to determine the relationship between the NCDs and hearing loss.

Hoveyzeh ear cohort phases

A) Enrolment phase

STEP 1: Registration

On the first day of the visit, participants will be referred to the Hoveyzeh cohort study center and will be informed of their written consent. Then, their personal information will be registered and a specific 11-digit code will be assigned to each participant.

STEP 2: Audiological questionnaire

A detailed case history will be obtained from the participants before the hearing assessments. The questionnaire (35-item) included the history of auditory-vestibular symptoms (vertigo/dizziness, tinnitus, ear fullness), noise exposure, head trauma, ototoxic drugs consumption, ear surgery, ear infections, systemic disorders (e.g., hypertension), and NCDs.

STEP 3: Audiological assessments

Audiologic testing is conducted to evaluate hearing thresholds across the frequencies necessary for human communication. Auditory thresholds are typically measured to differentiate various types of hearing loss and to characterize the pattern of hearing loss across different frequencies. The audiological test battery is composed of pure tone audiometry (PTA), speech audiometry, immittance audiometry, and otoacoustic emissions (OAE) measurements. All audiological tests are conducted in a double-walled sound-attenuating booth according to ISO 8253 – 1.50 standards.

1. Pure tone audiometry: A clinical two-channel audiometer (AC40, Intracoustics, Denmark) coupled with a standard (Telephonic TDH 39, Supra-aural) and extra high-frequency (Sennheiser HDA-200, Circum-aural) headphones are utilized to determine the hearing thresholds. Conventional pure-tone air conduction (AC) and bone-conduction (BC) thresholds are established in octave intervals from 250 Hz to 8000 Hz and from 250 Hz to 4000 Hz, respectively using the modified Hughson-Westlake procedure. For both AC and BC measurements, the hearing threshold at 1000 Hz in each participant's ear will be assessed twice to determine test-retest reliability. The hearing threshold is defined as the lowest intensity at which presented stimuli are detected at least 50 percent of a series of ascending trials. Normal hearing was defined as the perception of a sound stimulus at an intensity less than or equal to 20 dB HL in all frequencies. For the extended-high frequency measurement, four test frequencies of 10000, 12000, 14000, and 16000 Hz will be evaluated. However, when the subjects failed to respond to the audiometer's maximum intensity, the instrument's highest output level was taken as their hearing threshold. Both conventional and extended-high frequency audiometry are carried out by an experienced audiologist blinded to the study.
2. Speech audiometry: Word-recognition score (WRS) test is carried out to measure the individual’s ability to identify and repeat single-syllable words presented at supra-threshold hearing levels. The words used for WRS assessments include a list of 50 words that were phonetically balanced for the relative frequency of phonemes in the Arabic language.

3. Immittance audiometry: Acoustic immittance measurement is conducted to determine the middle ear function using a commercially middle ear analyzer (Model GSI-33, Intracoustics, Denmark). Tympanometric parameters are recorded using a 226 Hz probe tone over an ear canal with a pressure range of + 200 to − 400 daPa. Ipsilateral and contralateral acoustic middle ear acoustic reflex thresholds are also recorded for the stimulus frequencies 500, 1000, 2000, and 4000 Hz. The acoustic reflex thresholds will be obtained using an ascending procedure with a 5-dB step size beginning at 85 dB HL (reflex thresholds are recorded at levels lower than the initial start level) and not exceeding a stimulus presentation level of 105 dB HL. An absent reflex is tabulated as the level 5 dB greater than the maximum stimulation level at any one frequency; that is, an absent reflex was indicated as 110 dB HL.
4. OAE Assessment: OAEs are sounds measured in the external ear canal and reflect active processes in the cochlea. Distortion-product OAE (DPOAE) test is conducted using a Madsen Capella system (GN Optometric, Denmark). DPOAE levels were measured for f2 frequencies of 1000 to 6000 Hz with a frequency ratio (f2/f1) of approximately 1.22, and with fixed levels of 65 and 55 dB SPL for L1 and L2, respectively. The acceptance criterion for DOPAE response is set at a signal-to-noise ratio (SNR) of at least 6 dB and a DPOAE level of at least 0 dB SPL.

B) Follow-up phase

The follow-up of the HEC study will be performed at least 15 years after the initial enrollment time. Every 5 years, the subjects will be re-assessment for risk factors and hearing evaluation. All diagnostic and therapeutic documents will be evaluated and archived. To reduce attrition rates, the following precautions are taken: 1) during the baseline interview, telephone numbers, and addresses of two members of the

participant's families have been recorded; 2) for participants that do not answer the call, a trained local invitee will come to the door.

Quality assurance and control

A pilot study has been designed before starting the main study to identify and correct potential problems in the data collection instruments and procedures. All interviewers and examiners are trained according to the study protocol by experienced audiologists and epidemiologists. The teams responsible for quality control (QC) of the HEC project are established at three different "national", "regional", and "local" levels. The national team is located at the PERSIAN Cohort site, the regional level at the University, and the local level is located at the site of the HEC. The QC teams are responsible for ensuring the assessments' high quality, data collection, and analyses. All issues including stages of the project including invitation, enrollment, interviewing, audiological assessments, and data recording are monitored under the supervision of one otolaryngologist, one audiologist, and two epidemiologists. Moreover, the accuracy of the recorded data in the online system is monitored by an independent external observer.

Statistical analysis

Descriptive statistics were performed using mean and standard deviation (SD) for quantitative variables, and frequency and percentage for categorical variables. The chi-square test was used to assess associations in univariate analysis. A p-value less than 0.05 was considered a statistically significant level. A Stata version 16 was used for the statistical analysis.

Results

Participant characteristics

A total of 1845 participants, registered in the Hoveyzeh Cohort Study [25], were included in this pilot study. The age of the study participants was between 35 and 70 years old (Table1).

Table 1

Demographic characteristics and Audiometry in participants in a pilot study in Hoveyzeh Ear Cohort (HEC) study

Variables		Hoveyzeh Ear Cohort Study (Pilot study) n=1845	Hoveyzeh Cohort Study n=10,009
Age group	35-39 years	290 (15.7)	1912 (19.1)
	40-44 years	346 (18.8)	2025 (20.2)
	45-49 years	320 (17.3)	1797 (18)
	50-54 years	294 (15.9)	1482 (14.8)
	55-59 years	301 (16.4)	1281 (12.8)
	60≥ years	294 (15.9)	1512 (15.1)
Gender	Male	727 (39.4)	4026 (40.2)
	Female	1118 (60.6)	5983 (59.8)
Marital status	Single	52 (2.8)	343 (3.4)
	Married	1608 (87.2)	8760 (87.5)
	Widow	150 (8.1)	737 (7.4)
	Divorced	35 (1.9)	169 (1.7)
Education levels	Illiterate	1182 (64.1)	6209 (62)
	Primary school	299 (12.6)	1665 (16.7)
	Secondary school	128 (6.9)	673 (6.7)
	High school	131 (7.1)	741 (7.4)
	University	105 (5.7)	721 (7.2)
Skilled levels	Skilled level 1	59 (11.1)	346 (3.5)
	Skilled level 2	419 (78.9)	2377 (72.8)
	Skilled level 3	11 (2.1)	126 (1.3)
	Skilled level 4	42 (7.9)	417 (4.2)
Wealth index	Poorest	349 (18.9)	2000 (20)
	Poor	384 (20.8)	2033 (22.3)
	Moderate	396 (21.5)	1982 (19.8)
	Rich	382 (20.7)	2023 (20.2)
	Richest	334 (18.1)	1971 (19.7)

Type of residency	Urban	1175 (63.4)	6176 (61.7)
	Rural	675 (36.6)	3833 (38.3)
Hypertension history	Yes	547 (29.6)	2643 (26.4)
	No	1298 (70.4)	7336 (73.6)
Diabetes history	Yes	442 (24.0)	2226 (22.2)
	No	1403 (76.0)	7783 (78.8)
Cardiovascular history	Yes	302 (16.4)	1483 (14.8)
	No	1543 (83.6)	8527 (85.2)
Tinnitus	Yes	504 (27.3)	1053 (10.5)
	No	1341 (72.7)	8956 (89.5)
Head trauma history	Yes	273 (14.8)	594 (5.9)
	No	1572 (85.2)	9415 (94.1)
Dizziness	Yes	628 (34.0)	3210 (32.1)
	No	1217 (66.0)	6799 (67.9)
Smoking	Yes	374 (20.3)	2098 (20.9)
	No	1471 (79.7)	7911 (79.1)
Alcohol consumption	Yes	30 (1.6)	197 (2)
	No	1815 (98.4)	9812 (98)

Our findings revealed that the prevalence of hearing loss was associated with demographic and socioeconomic factors such as age, gender, educational level, marital status, wealth status, skill levels, Townsend index, and smoking habit ($P<0.05$). Furthermore, the prevalence of hearing loss was significantly higher in patients with a history of dizziness/vertigo, head trauma, noise exposure of noise, tinnitus, ear infection, ear surgery, hearing loss in the family, cardiovascular disorders, diabetes, and hypertension compared to those who had not these symptoms or disorders ($P<0.05$). However, the prevalence of hearing loss did not significantly correlate with the type of residence, wealth index, and alcohol consumption factors.

The result of trend analyses indicated that with increasing participants' age, the prevalence of hearing loss has increased significantly ($P<0.001$). We also found that the highest prevalence of hearing loss has occurred in poor, skilled level 2, and illiterate patients (Table 2).

Table 2

Comparing participant’s characteristics based on the hearing loss status in the pilot of the Hovyzeh Ear Cohort Study

Variable		Hearing loss		P-value*
		No n (%)	Yes n (%)	
Age group	35-39 years	222 (24.7)	68 (7.2)	<0.0001
	40-44 years	234 (26.1)	112 (11.8)	
	45-49 years	178 (19.8)	142 (15.0)	
	50-54 years	120 (13.4)	174 (18.4)	
	55-59 years	90 (10.0)	211 (22.3)	
	60≥ years	54 (6.0)	240 (25.3)	
Gender	Male	267 (29.7)	460 (48.6)	<0.0001
	Female	631 (70.3)	487 (51.4)	
Marital status	Single	39 (4.3)	13 (1.4)	<0.0001
	Married	781 (87.0)	827 (87.3)	
	Widow	59 (6.6)	91 (9.6)	
	Divorced	19 (2.1)	16 (1.7)	
Education levels	Illiterate	533 (59.4)	649 (68.5)	<0.0001
	Primary school	157 (17.4)	142 (15.1)	
	Secondary school	68 (7.6)	60 (6.3)	
	high school	75 (8.4)	56 (5.9)	
	Universities	65 (7.2)	40 (4.2)	
Skilled levels	Skilled level 1	28 (11.2)	31 (11.0)	0.014
	Skilled level 2	186 (74.4)	233 (82.9)	
	Skilled level 3	7 (2.8)	(1.4) 4	
	Skilled level 4	29 (11.6)	13 (4.6)	
Wealth index	Poorest	152 (16.9)	197 (20.8)	0.199
	Poor	183 (20.4)	201 (21.2)	
	Moderate	206 (22.9)	190 (20.1)	
	Rich	191 (21.3)	191 (20.2)	
	Richest	166 (18.5)	168 (17.7)	

Type of residency	Urban	585 (65.1)	585 (61.8)	0.073
	Rural	313 (34.9)	362 (38.2)	
History of hypertension	Yes	200 (22.3)	347 (36.6)	<0.0001
	No	698 (77.7)	600 (63.4)	
History of diabetes	Yes	156 (17.4)	286 (30.2)	<0.0001
	No	742 (82.6)	661 (69.8)	
Has cardiovascular disease	Yes	120 (13.4)	182 (19.2)	<0.0001
	No	778 (86.6)	765 (80.8)	
History of hearing loss in the family	Yes	50 (5.6)	103 (10.9)	<0.0001
	No	848 (94.4)	884 (89.1)	
History of ear surgery	Yes	3 (0.3)	11 (1.2)	0.035
	No	895 (99.7)	936 (98.8)	
History of ear infection	Yes	40 (4.5)	135 (14.3)	<0.0001
	No	858 (95.5)	812 (85.7)	
Tinnitus	Yes	103 (11.5)	401 (42.3)	<0.0001
	No	795 (88.5)	546 (57.7)	
History of noise exposure	Yes	81 (9.0)	235 (24.8)	<0.0001
	No	817 (91.0)	712 (75.2)	
History of head trauma	Yes	107 (11.9)	166 (17.5)	0.001
	No	791 (88.1)	781 (82.5)	
Dizziness	Yes	226 (25.2)	402 (42.4)	<0.0001
	No	672 (74.8)	545 (57.6)	
Smoking	Yes	115 (12.8)	259 (27.3)	<0.0001
	No	783 (87.2)	688 (72.7)	
Alcohol consumption	Yes	12 (1.3)	18 (1.9)	0.220

Discussion

HEC study is the first ear cohort in the middle east region that has been designed in the context of the Hoveyzeh adult cohort study. This study evaluates auditory system disorders and related factors in the Arab ethnic group. Conducting this study in the context of an adult cohort study provides a basis for

investigating the relationship between ear diseases and genetic factors, nutrition, socioeconomic status, and history of NCDs diseases.

The results of the current pilot study of HEC demonstrated that participants' age is an important factor in hearing loss so about 70% of registered subjects showed some degree of hearing loss. Similar to other studies, the presence of systemic comorbidities such as hypertension [27, 28] and diabetes [29–31] was significantly higher in patients with hearing loss than in those subjects without hearing loss. Participants with hearing loss were more likely to have tinnitus as compared with those without hearing loss. This finding is similar to other studies [32, 33]. In line with other studies [31, 34, 35], smoking was associated with hearing loss. Our findings on the burden of hearing loss agree with other studies in which the prevalence of hearing loss increased with exposure to occupational noise [30, 31, 36].

The main strengths of the current project are (1) high participation rate; (2) comprehensive audiological assessments covering a wide range of variables; (3) persistent population due to low immigration rates from and to the region; (4) robust quality control; (5) long follow-up period, up to 15 years; (6) the ethnicity and lifestyle of Iranian Arabs living at the cohort site are highly similar to Iraq's and Kuwait's Arab ethnicity. Therefore, the findings of the HEC project can be generalized to a wide geographical area containing millions of people; (7) Considering that the present study was performed in the context of the adult cohort, the data of the adult study can be evaluated to measure the relationship between risk factors and auditory outcomes. The current study has its limitation. This study includes only adult individuals in the age range of 35–70 years old; thus, we may not generalize our findings to other age groups.

Conclusion

According to the results of the current pilot study, it seems that the hearing loss in Hoveyzeh cohort study` participants is an important issue. A wide range of demographic, socio-economic, and medical factors affect the auditory system. This project will provide a good basis for many studies in the field of hearing in the future. Based on the results of this study, we will try to provide appropriate educational, health, and treatment interventions related to hearing.

Declarations

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Authors' contributions

NS, AB, SS, BCh, and ZR contributed to the design. BCh contributed to the statistical analyses of this investigation. ZR contributed to the data collection and preformation of this investigation. NS, AB, SS, HP, FR, BCh, and ZR contributed to the data interpretation and preparation of the manuscript contributed to data collection. All authors have read and agreed to the published version of the manuscript.

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Ethics approval and consent to participate

This project was approved by the ethics committee of Ahvaz Jundishapur University of Medical Sciences (Ethical code: IR.AJUMS.REC.1396. 353). The study was performed in accordance with

the Helsinki Declaration and its later amendments. All participants signed informed written consent forms for the interviews, auditory system examinations, and access to administrative records.

Consent for publication

Not applicable.

Availability of data and materials

The data are held by the HEC research team at the Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran. We welcome collaboration with other researchers. Data from our cohort study is available for researchers who submit a research proposal to our scientific committee. More details about questionnaire contents, clinical assessments, and contract rules can be found on our website (https://cohort.ajums.ac.ir). A research proposal editable form can be downloaded and sent to hoveizeh.cs@ajums.ac.ir.

Competing interests

The authors declare that they have no conflict of interest.

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Figures

Figure 1

The geographic location of Hoveyzeh city in Iran