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COHORT PROFILE

Cohort Profile: Shahroud Eye Cohort Study

Akbar Fotouhi,[1]* Hassan Hashemi,[2,3] Mohammad Shariati,[4,5] Mohammad Hassan Emamian,[4] Kamran Yazdani,[1] Ebrahim Jafarzadehpur,[6] Hassan Koohian,[2] Mohammad Reza Khademi,[7] Kamran Hodjatjalali,[2] Ahmad Kheirkhah,[3] Reza Chaman,[4] Sarvenaz Malihi,[4] Mehdi Mirzaii[4] and Mehdi Khabazkhoob[2]

[1]Department of Epidemiology and Biostatistics, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran, [2]Noor Ophthalmology Research Center, Noor Eye Hospital, Tehran, Iran, [3]Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran, [4]Department of Public Health, Shahroud University of Medical Sciences, Shahroud, Iran, [5]Education Development Center, Tehran University of Medical Sciences, Tehran, Iran, [6]Department of Optometry, Tehran University of Medical Sciences, Tehran, Iran and [7]Faculty of Medical Sciences, Open University of Shahroud, Shahroud, Iran

*Corresponding author. Department of Epidemiology and Biostatistics, School of Public Health, Tehran University of Medical Sciences, 14155-6446 Tehran, Iran. E-mail: afotouhi@tums.ac.ir

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The Shahroud Eye Cohort Study was set up to determine the prevalence and incidence of visual impairment and major eye conditions in the 40–64-year-old population of Shahroud as a Middle Eastern population. The first phase of the study was conducted in 2009–10. Using random cluster sampling, 6311 Shahroud inhabitants were invited for ophthalmologic examinations; of these, 5190 participants completed phase 1 (participation rate of 82.2%). All participants were interviewed to collect data on participants' demographics, occupation status, socioeconomic status, history of smoking, and medical and ophthalmic history, as well as history of medication, and the quality and duration of their insurance. DNA and plasma samples, as well as four dots of whole blood were collected from participants. Extensive optometric and ophthalmologic examinations were performed for each participant, including lensometry of current glasses, testing near and far visual acuity; determining objective and subjective refraction; eye motility; cycloplegic refraction; colour vision test; slit-lamp biomicroscopy and intraocular pressure measurement; direct and indirect fundoscopy; perimetry test; ocular biometry; corneal topography; lens and fundus photography; and the Schirmer's (1008 participants) and tear breakup time tests (1013 participants). The study data are available for collaborative research at Noor Ophthalmology Research Center, Tehran, Iran.

Why was the cohort set up?

In their review article, Wong and Hyman[1] have demonstrated the key role of population-based eye studies of the past 30 years in providing essential information concerning the burden of major eye disease and their risk factors. The authors also present a list of unanswered questions in ocular epidemiology. Similarly, latest advances were discussed at the Fourth U.S. Symposium on Ocular Epidemiology of the National Institute of Health, and interesting articles have been published in a special issue of the *Ophthalmic Epidemiology Journal*.[2–6]

Population-based eye studies, despite their outstanding role in epidemiologic research, have had a number of limitations, which we will point out briefly. First, these population-based studies are limited to certain regions; considering the geographic variation in

prevalence of many eye diseases and the role of proposed risk factors in different populations, lack of information from all populated areas of the world means that the bigger epidemiologic picture is incomplete. As far as we know, although population-based studies have been carried out in the Middle Eastern region,[7–21] none has had follow-up phases.

Second, a small proportion of studies have followed up patients, and the importance of prospective cohort studies in clarifying the epidemiology of disease goes without saying.

Third, not all studies are sufficiently comprehensive because of high costs and/or recent advances in technology and our ability to document eye-related variables concerning corneal topography, ocular biometry and biomarkers. This is especially true in the case of older population-based studies. Fourth, issues concerning values and ethics, such as equity and equality, as well as quality of life and quality of vision as the final outcome, have received more attention from health authorities in the past two decades. Many population-based studies, particularly older studies, have failed to address these aspects, and more information is needed.

In Iran, the epidemiology of eye disease has received more serious attention in the past decade, and a number of population-based studies have been executed[7–14]; the most extensive one was the Tehran Eye Study, which provided a great amount of information concerning ocular epidemiology in the population of Tehran.[8,22–30] Our initial plan was to follow up participants of the Tehran Eye Study, but Tehran is a huge city, and its large population is constantly moving; a pilot study showed a low re-entry rate of previous participants as well as a low participation rate. Therefore, we designed a prospective cohort study to be conducted in Shahroud, with three main justifications: (i) Limited information around the world about the trend of certain eye diseases; prospective cohorts in some fields, such as retinal disease, are limited to one or two cohorts. (ii) No prospective cohort study has been conducted in the Middle Eastern region, and many eye diseases show different prognosis in different areas of the world. (iii) Instrumental information collected from this study is unprecedented even in cross-sectional studies; as a cohort, this study should provide valuable information in the next phases. The city of Shahroud is located 400 km east of Tehran, and has a stable population as far as migration is concerned. The objectives of Shahroud Eye Cohort Study include the following: (i) Determining the prevalence (phase 1) of visual impairment and major eye conditions and their incidence in later phases and follow-ups. (ii) Collecting valuable information concerning ocular biometrics, including data from topographers and aberrometers, their normal range in the population and their association with major eye disease. Follow-up measurements of these variables in the next phases of the project enable us to study the secular changes. (iii) Assessment of the prognosis and natural course of eye diseases, as well as their determinants. (iv) In the genomic era, the interaction of genetics and the environment with many disease and ocular indices still requires extensive study. Collection of biologic samples from the participants (including DNA extraction of the participants) provides the grounds for genetic epidemiology studies, such as the genome-wide association study. (v) Examining data on the socioeconomic status of the participants and their eye-care-seeking behaviour to study ocular disorders and diseases from this point of view. (vi) Data collection methods varied, and some indices/variables have been measured by two or more methods. Therefore, we are able to compare the accuracy of measurements for many of these indices or determine the agreement between different measurement methods.

Who is in the cohort?

Geographically, Shahroud is located in the north east of Iran (Figure 1). According to the 2006 census, the population of Shahroud was 133 835. The target population in this study was Shahroud inhabitants aged between 40 and 64 years. Samples were selected from among Shahroud inhabitants through a cluster random sampling method, and for this purpose, 300 clusters, with 20 people in each cluster, were considered. As far as the Iranian primary health care system is concerned, Shahroud is covered by nine health care centres. We used each health care centre as a stratum and calculated the number of clusters proportionate to the population served by the centre. Electronic databases of these centres provided the sampling frame (complete listing of all households) for each stratum. A systematic sampling procedure was used to select the index households for each cluster. Skilled interviewers approached 40- to 64-year-old members of the targeted households, completed the preliminary data forms and handed them written invites to have a complete eye examination at the study eye clinic. Interviewers of the present project were selected from health care volunteers. The advantage is that they are originally selected from among the people, are well respected by people and employing them improved people's participation in the study.

Between January 2009 and January 2010, of the 6311 eligible individuals in the sample, 5190 participants completed phase 1 (participation rate of 82.2%). Table 1 compares respondents and non-respondents in terms of basic variables; the age distribution was similar, but men and employed people were slightly underrepresented among participants. Overall, the similarity between the two groups appeared to be acceptable, and *P* values could be attributed to the large sample size.

Twenty percent of the original study sample was randomly selected as the subsample, so they would

Figure 1 Geographic location of Shahroud in Iran

have more thorough tests and examinations. This is because performing complete examinations are very time-consuming, and in some tests/examinations, the required sample size was considerably smaller than the study sample. The other reason was to select control samples for future case-cohort studies. Random selection of the subsamples allowed their group to be similar to the total sample in terms of age, sex, occupation status, marital status and eye-related variables.

How often have they been followed up?

The recruitment phase of the study was completed in January 2010. The second phase of the study is projected to start 5 years after the first phase. We have considered the following, to keep contact with the participants in the period between the two phases:

(i) Short questionnaires will be prepared to complete missing data. These will be sent out along with gifts to help maintain contact with the participants.
(ii) Participants will be divided into different groups depending on their health status, presence of systemic or eye disease, having certain risk factors, etc. Each group will annually receive relevant educational brochures, which are prepared in simple language.
(iii) Results and achievements of the study will be prepared in simple brief reports to help people understand the effect of the project on personal and community health. This can greatly encourage participants to stay in the project.

What has been measured?

In this project, a wide range of data was collected in the first phase as the baseline data of the cohort. Table 2 presents a list of performed measurements and the study sample in each part. Collected data are described as follows.

Interview

A questionnaire comprising eight sections and 83 questions was completed through face-to-face interviews. In the first section, general information regarding age, sex, ethnicity, marital status, education and religion was recorded. The second and third sections concerned the job status, occupation type and socioeconomic status, along with a list of assets as an indicator of a person's socioeconomic status. The next section enquired about the participant's history of medical conditions, such as history of diabetes, hypertension or eye disease such as cataracts, glaucoma, retinal problems, ocular trauma, as well as eye care visits, optometry visits and the services they had received. History of medical treatments was recorded

Table 1 Comparison of respondents and non-respondents in terms of basic variables

Variables	Respondents number (%)	Non-respondents number (%)	*P*-value (χ^2)
Sex			
Women	2990 (57.6)	449 (40.1)	<0.001
Men	2200 (42.4)	672 (59.9)	
Age (years)			
40–44	960 (18.5)	234 (21.0)	0.171
45–49	1390 (26.8)	309 (27.7)	
50–54	1285 (24.8)	253 (22.7)	
55–59	954 (18.4)	206 (18.5)	
60–64	601 (11.6)	114 (10.2)	
Marital status			
Single	68 (1.3)	22 (2.0)	0.034
Married	4794 (92.4)	1048 (93.5)	
Widow	292 (5.6)	48 (4.3)	
Divorced	36 (0.7)	3 (0.3)	
Occupation status			
Employed	1114 (21.5)	357 (31.8)	<0.001
Retired	853 (16.4)	173 (15.4)	
Unemployed	52 (1.0)	17 (1.5)	
Disabled	45 (0.9)	7 (0.6)	
Homemaker	2673 (51.5)	401 (35.8)	
Other	453 (8.7)	166 (14.8)	
Eye problem			
Yes	3495 (67.3)	637 (56.8)	<0.001
No	1695 (32.7)	484 (43.2)	
Reading glasses			
Yes	2632 (50.7)	465 (41.5)	<0.001
No	2558 (49.3)	656 (58.5)	
Spectacles			
Yes	1521 (29.3)	300 (26.8)	0.088
No	3669 (70.7)	821 (73.2)	
	Respondents mean (standard deviation)	Non-respondents mean (standard deviation)	*P*-value (*t*-test)
Education (years)	5.99 (5.17)	6.08 (5.28)	0.600
Age (years)	50.92 (6.24)	50.45 (6.34)	0.022
Household members	4.11 (1.37)	4.13 (1.36)	0.706
Household members (40–64 years old)	1.73 (0.45)	1.72 (0.47)	0.333

in the next section. The final section covered issues such as the participant's type, duration and quality of insurance.

Height and weight were measured and recorded. Blood pressure was measured and recorded twice for each participant using an Omron M3 Intellisense (HEM-7051-E, Omron Corp, Tokyo, Japan) automated electronic oscillometric blood pressure monitor, with medium/large cuffs.

Table 2 Domains covered in the data collection of the first phase, and the number of samples in each domain

Measurement dimension	Sample size	Instruments
Total of invited people	6311	
Total participants	5190	
Subsample participants	1017	
Contact information	5190	
Interview	5184	
General information		
Job status and occupation type		
Smoking status		
Socioeconomic status		
History of medical conditions		
History of medical treatments		
Blood sample	5189	
Blood sugar	5189	
Plasma sample	5189	
Whole dot blood	5189	
DNA extraction	5189	
Weight and height	5190	
Blood pressure	5190	Omron M3 Intellisense automated electronic blood pressure monitor
Colour vision	5102	Farnsworth D-15 test
Visual acuity		Topcon KR 8800 refractometer
Far	5190	LogMAR chart
Near	5163	M-unit measure of acuity chart
Contrast sensitivity in subsamples	1000	Vector vision CVS1000
Eye motility testing	5178	
Schirmer's test in subsamples	1008	Schirmer's test
Tear breakup time (TBUT) in subsamples	1013	
Refraction		
Non-cycloplegic	5187	
Cycloplegic	4771	
Perimetry	4836	Humphrey matrix perimeter
Photography		
Lens	4697	Topcon SL-7E Photo slit lamp
Fundus	4949	Nidek AFC-230 Fundus Camera
Eye examinations		
Slit lamp examination	5185	Haag-Streit BM 900 slit lamp
Intraocular pressure	5185	Goldmann applanation tonometry
Direct ophthalmoscopy	5168	
Biograph	5184	Allegro BioGraph
Pentacam	4688	Pentacam HR
Aberrometry (Zywave) in subsamples	700	Zywave aberrometer

Biological resources

A blood sample was drawn from each participant to test the blood sugar level, to prepare DNA and plasma samples and for testing (placing 4 dots of whole blood on Whatman paper). All DNA, blood and plasma samples were coded and kept frozen at −80°C in uniform packaging. DNA was isolated from blood samples using the phenol–chloroform extraction technique.

Colour vision

The Farnsworth D-15 test was used to assess colour vision in both eyes of each participant. The Farnsworth D-15 test is the most well known and most common sorting-type colour test, which is used in primary care colour vision assessment.[31] The test has good reliability,[31] and it is acceptable for the assessment of acquired colour vision disorders.[32]

Optometric examinations

Two optometrists were in charge of optometric examinations. These included lensometry of current glasses, testing near and far visual acuity, determining objective and subjective refraction, eye motility and cycloplegic refraction.

Lensometry

Participants' spectacles, if any, were tested using the non-automatic analogue Topcon lensometer (Topcon Corporation, Tokyo, Japan).

Visual acuity

The uncorrected, corrected and presenting (or habitual) visual acuity was tested using the LogMAR chart. Near vision (presenting, uncorrected and corrected) was tested at a distance of 40 cm using the M-unit measure of acuity.

Autorefraction

This was done using a Topcon KR 8800 refractometer (Topcon Corporation, Tokyo, Japan).

Refraction

Objective and subjective refraction was determined. After the first series of eye examinations, if the ophthalmologist found no contraindication, cycloplegic drops (one drop of 1% cyclopentolate and one drop of 2.5% phenylephrine) were instilled twice, 5 minutes apart, and cycloplegic refraction was done 30 minutes after the second time.

Eye motility

The two optometrists used the cover test to check eye motility.

Visual field examination

Visual field defects were detected using a Humphrey Matrix Perimeter (Carl Zeiss Meditec, Dublin, CA, and Welch Allyn, Skaneateles Falls, NY). Investigations have demonstrated the accuracy of the method in testing visual field defects.[33–35]

Contrast sensitivity

Contrast sensitivity is the lowest contrast level detected by the participant for a given target size. It is not only important for daily activities such as reading and driving,[36] but its measurement is also important in certain eye condition where contrast sensitivity is impaired despite normal visual acuity.[37–39] Contrast sensitivity was tested using the Vector Vision CVS1000 (VectorVision, Greenville, OH) in subsample participants. The reliability and validity of the device in measuring contrast sensitivity have been documented.[40]

Ocular biometry

Ocular biometrics are important as determinants of different eye conditions, and also in cataract and refractive procedures.[41] All participants were examined with the Allegro BioGraph (WaveLight AG, Erlangen, Germany), which is capable of measuring the anterior chamber depth, axial length, corneal thickness and thickness of the lens and the retina. At the same time, the pupil diameter, white-to-white distance, radius of the corneal curvature and position of visual-optical line are determined. The accuracy of its measurements has been studied and was found to be within an acceptable range.[41-43]

Aberrometry

Subsamples were examined with the Zywave aberrometer (Bausch & Lomb, Rochester, NY), which determines both lower- and higher-order aberrations. The accuracy of the device in measuring aberrations has already been studied.[44,45]

Corneal imaging

To document the corneal topography of the participants, we used the Pentacam HR (Oculus, Inc., Lynnwood, WA). Several studies have demonstrated the accuracy and reliability of the device in making different measurements.[46–48] The Pentacam also provides objective data for the assessment of cataracts such as density, consistency and thickness.[49,50]

Ocular photography

In this project, we obtained slit-lamp photographs of the lens and fundus. Slit-lamp and lens photography was done using a Topcon SL-7E Photo slit lamp (Topcon Corporation, Tokyo, Japan). The slit-lamp photograph is a photo of the eye that includes the margins of the lids, the cornea and the iris. Lens photography was done under dilation. One photo is taken with focus on the nucleus, and the other is a retro-illumination photo of the lens.

For fundus photography, we used a Nidek AFC-230 Fundus Camera (Nidek, Chiyoda-ku, Japan)

according to the protocol of the Early Treatment Diabetic Retinopathy Study (ETDRS).[51] In non-diabetic participants, we took three standard photos from the first three ETDRS fields, and one stereoscopic image from the optic nerve in each eye. In diabetic participants, ETDRS seven-standard field photographs were taken from both eyes.

Dry eye tests

To assess dry eye, subsamples had the Schirmer's test, and the tear breakup time (TBUT) was measured. To document dry-eye-related symptoms and complaints, these participants completed a 12-item questionnaire as well.

Ophthalmic examination

Ophthalmic examinations were completed by two ophthalmologists. Slit-lamp biomicroscopy and measurement of intraocular pressure were done before pupil dilation. Once pupil dilation was achieved, clinical lens opacity grading and assessment of vitreous opacities were done using the slit lamp, and the fundus was examined using direct and indirect ophthalmoscopy. For slit-lamp biomicroscopy, we used a Haag-Streit BM 900 (Haag-Streit, Bern, Switzerland). The intraocular pressure was measured using Goldmann applanation tonometry.

In addition to lens photography, lens opacity grading was done at the slit lamp after dilation. For this purpose, the ophthalmologist made comparisons with standard photographs of the Lens Opacities Classification System III.[52] Using direct and indirect ophthalmoscopy, the ophthalmologist examined the retina and the optic disc thoroughly and systematically and recorded all observations.

What has been found?

Eight reports from the first phase of the study had been accepted and published in peer-reviewed journals by April 2012.[53–60] The prevalence of visual impairment in the city of Shahroud was determined to be lower than that reported in most studies carried out in the region. Refractive errors and cataract were shown to contribute to 85% of visual impairment in the population.[53] We found a 3.10-fold higher prevalence of visual impairment in the low economic group in comparison with high economic group.[55] Based on cycloplegic refraction, the prevalence of myopia and hyperopia was 30.2 and 35.6%, respectively.[59] The prevalence of astigmatism based on a cylinder power worse than 0.5D was 49.1%.[54] The prevalence of myopia and astigmatism was higher than that found in other parts of the Middle East.[54,59] The prevalence of hyperopia was lower than that previously reported in Iran.[59] The prevalence of a need for spectacles was found to be 13.7%; however, 41.7% of those who required spectacles were still without them. The prevalence of an unmet need for spectacles was higher in women and in the low economic group.[60] Results concerning contrast sensitivity and its determinants are reviewed in another article,[56] which can be used as a reference guide for contrast sensitivity in general populations. Contrast sensitivity declines with age, high myopia and astigmatism. The report showed wide range variability for contrast sensitivity in the normal population.[56] The prevalence of presbyopia by age and sex in the general population of Shahroud has also been reported; interestingly, presbyopia was less prevalent in this population. Only ~50% of individuals aged >45 years were presbyopic, and 17% of individuals aged >60 years were free of this condition.[58] A list of all study publications can be found at the study website: www.shecs.info.

What are the main strengths and weaknesses?

Strengths

(i) The population structure is stable, and migration rate is minimal. By approaching each household only once, we were able to achieve a participation rate of >82%. Employing health care workers has been important, as they are part of the same community. Also, the primary health care system in Shahroud is organized and successfully covers almost 100% of the population, and this has facilitated execution of the project. (ii) As far as the investigators are aware, this is the only population-based prospective cohort eye study of the Middle Eastern Region. (iii) Another advantage of the project is the great amount of collected data that will help understand the ocular epidemiology and the great opportunity of studying many different associations. (iv) Several methods have been used to ensure the quality of the collected data in the first phase. We attempted to improve the quality of the project by educating the investigators about the protocol.

Reliability study

To assess the accuracy of measurements, 137 participants were selected randomly and invited to have repeated examinations with their consent. After admission, to observe ethics in research, we repeated tests that could be done without use of mydriatic and cycloplegic drops. The repeated procedures included intraocular pressure measurement, and tests for visual acuity, refraction and eye motility, which were done by a second examiner. For these data, a wide range of reliability coefficients were calculated, and all were indicative of acceptable repeatability except eye motility measurements. Coefficients were between 0.75 and 0.89 for components of visual acuity and between 0.89 and 0.98 for refraction data.

Weaknesses

(i) The study sample is limited to the 40–64-year age group, and thus conditions in younger ages cannot be studied. (ii) Compared with other cohort eye studies, the sample size seems acceptable, but the limited number of cases with less prevalent disease, or particular subgroups, may bring limitations to our study. (iii)Although a wide range of data was collected from participants, still some important information is missing, and this issue calls for attention. Participants' perception of their own vision has not been assessed. Our information regarding participants' systemic disease is limited. Other important information that needs to be collected in follow-ups includes participants' nutrition status and their exposure to sunlight.

Can I get hold of the data? Where can I find out more?

The investigators welcome sharing the data to prepare reports using data from the first phase of the project. Considering the importance of data pooling in population-based studies of the epidemiology of eye disease, we are open to collaboration in this regard. All comments and suggestions concerning the variables of the follow-up phases are also welcome. Offers and applications for collaboration and data pooling, as well as research proposals, should be sent to A.F. (afotouhi@tums.ac.ir) and H.H. (hhashemi@noorvision.com).

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Conflict of Interest: None declared.

KEY MESSAGES

- The prevalence of visual impairment in the city of Shahroud was lower than that reported in most studies in the region. Refractive errors and cataract were shown to contribute to 85% of visual impairment in this population.
- Based on cycloplegic refraction, the prevalence of myopia, hyperopia and astigmatism was 30.2%, 35.6% and 49.1%, respectively. The prevalence of myopia and astigmatism was higher than that found in other parts of the Middle East. The prevalence of hyperopia was lower than that previously reported in Iran.
- We found a 3.10-fold higher prevalence of visual impairment in the low economic group in comparison with the high economic group.
- Presbyopia was less prevalent in this population. Only ~50% of the >45-year-old individuals were presbyopic, and 17% of the >60 individuals were free of this condition.
- The prevalence of the need for spectacles was found to be 13.7%, whereas 41.7% of responders did not have spectacles. The prevalence of the unmet need for spectacles was higher in women and the low economic group.

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