Original Article

The Shiraz Pediatric Eye Study; a Population Based Survey of School Age Children: Rationale, Design and Baseline Characteristics

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Abstract

Purpose: To describe the rationale, study design, methodology, and baseline characteristics of the Shiraz Pediatric Eye Study, a population-based survey of schoolchildren in Shiraz, Iran.

Methods: This population-based study included schoolchildren aged 6–12 years from all four educational districts of Shiraz who were recruited in years 2015–2016. Stratified random sampling was used to select 2400 participants from all districts. Data were recorded from a detailed interview and ocular evaluation of each eligible student. The eye examination comprised uncorrected and best corrected visual acuity measurement, refraction, external eye examination (including specific strabismus and lid evaluation tests), slit lamp biomicroscopy, intraocular pressure measurement, the Ishihara color vision test, and stereoacuity. Exophthalmometry, optical biometry, and optical coherence tomography were performed for a randomly selected subset of children. General characteristics and socioeconomic variables were also recorded to assess risk factors.

Results: From a total of 2400 selected students, 2001 (83.3%) participated in the study. The mean age of the students was 9.1 ± 1.6 years, and 59.7% were girls. Most children had at least one parent with a diploma or less than diploma (63.5%), and 2.2% had illiterate parents.

Conclusion: This study is expected to provide accurate estimates of the prevalence of visual impairments and their related determinants in Shiraz. In addition, it will identify children who should be targeted by blindness prevention programs.

Keywords: Ocular Disease; Pediatric; Population-based Survey; Shiraz; Visual Impairment

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INTRODUCTION

Visual impairment (VI) in the pediatric population is an important public health problem.[1-4] The personal,

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economic, and social consequences of VI in children are life-long and affect learning, communication, and future employment.[5-10] The main causes of VI in children are uncorrected refractive error, amblyopia, and strabismus, which are estimated to affect about 12.8 million children from 5 to 15 years old worldwide.[1-3,11-13]

The global initiative known as "VISION 2020: the Right to Sight" in collaboration with the World Health Organization (WHO) and the International Agency for the Prevention of Blindness (IAPB) was launched in 1999 with the aim of eliminating avoidable blindness.[14] In this program, the correction of refractive error is categorized as "childhood blindness" with high priority.[15,16]

Although the main causes of childhood VI are preventable and curable, this condition remains an important and growing problem, especially in developing countries.[17] The main factors that contribute to this situation are patients' lack of knowledge regarding appropriate treatments, inequitable distribution of health care services, and differences in accessibility to services.[5,17]

The wide geographic variation in the prevalence of childhood VI reflects the interactions of this condition with socioeconomic variables.[6] In addition, accurate information about the prevalence of childhood VI and its major determinants are crucial for public health policy makers to improve health care service provision and prevent blindness.[3,4,18] Although many studies have assessed the VI prevalence among children worldwide,[1,11,19-21] to the best of our knowledge, few studies have been performed in Iran,[2,6,13] of which none have addressed the demographic and household socioeconomic determinants of VI.

This study provides a population-based dataset for childhood VI and explores its major risk factors in schoolchildren in Shiraz, Iran.

The specific goals of this study were as follows:

- To determine visual acuity (VA) and refraction in schoolchildren 6–12 years old in the Shiraz population.
- To identify the major determinants of VI in schoolchildren in this population.
- To determine the prevalence of myopia, hyperopia, different types of astigmatism, and amblyopia in the same population.
- To determine the prevalence of ocular hypertension and glaucoma, and normal ranges for intraocular pressure (IOP) and central corneal thickness (CCT).
- To determine the prevalence of binocular disorders including all forms of heterophoria and strabismus.
- To determine the prevalence of lid disorders such as ptosis and lid mass.
- To determine the prevalence of color blindness and abnormal stereoacuity.
- To determine the prevalence of anterior segment disorders including cornea, lens, and pupil abnormalities.
- To determine the prevalence of posterior segment disorders including optic disc and macular abnormalities.
- To determine normal ranges for pupillary distance and near point of convergence (NPC), and their clinical implications.
- To determine normal ranges for ocular biometric parameters including axial length, corneal curvature, anterior chamber depth, and white to white distance.
- To determine normal ranges for retinal nerve fiber layer (RNFL) thickness, macular thickness, and macular volume according to optical coherence tomography (OCT) data.

METHODS

Overview

In this cross-sectional population-based study conducted from September 2015 to March 2016, 2001 eligible children aged 6–12 years were examined at our clinic. Examinations were performed weekly on Thursdays from 8 a.m. to 4 p.m. and nearly 150 participants were examined weekly.

Ethical Considerations

The protocol for this study complies with the tenets of the Declaration of Helsinki, and was approved by the ethics committee of our university. Written informed consent was obtained from all parents of the participating students before examinations were performed. Parents were informed about the aims of the study and told that their participation was entirely voluntary, and that they had the right to withdraw from the study at any time. The confidentiality of all personal data was preserved. The results of the study are available to the participants. Children were referred to an appropriate specialist if they were deemed to require further diagnostic evaluation or therapeutic interventions.

Study Population and Sample Size Estimation

Population

The study included 2400 children aged 6 to 12 years from all four educational districts in Shiraz affiliated with the Ministry of Education. The sample consisted of 1.8% of all 132,512 elementary schoolchildren in the survey area.

Inclusion criteria

All elementary schoolchildren between 6 and 12 years old who could cooperate well during all ocular examinations were included.

Exclusion criteria

Students whose parents did not give their consent to participate and those from special schools for handicapped children were excluded from the study.

Sample size

We found no previous studies designed to accurately determine the prevalence of VI in the Shiraz population. Refractive error is the most prevalent cause of VI throughout Iran. Thus, the mean prevalence of refractive error in Iran[2,22-27] was used to estimate sample size for the Shiraz Pediatric Eye Study with the formula[28]

$$n = \frac{N(Z_{1-\alpha/2})^2 \, p(1-p)}{d^2(N-1) + Z^2 p(1-p)}$$

Where $N = 132{,}512$. For values of $Z = 1.96$ with a desired confidence level of 95%, $d = 0.01$ and $P = 5.87$, a minimum sample of 2000 participants was required. Assuming a participation rate of 80%, the final sample size was calculated as 2400 schoolchildren.

Sampling plan

The entire population was defined as all elementary schoolchildren within the study area. Population density in different educational districts was obtained from the most recent academic year census (2013). Sample selection was performed in two stages.

First stage: stratification

Sample stratification was performed according to the four educational districts. The appropriate number of participants from each elementary school was calculated in proportion to the number of students and schools in each district [Table 1].

Second stage: random sampling

The first-order random sampling units were schools, which were selected using Microsoft Excel 2007 software (approximately an equal number of boy and girl schools). The second-order sampling units were classes, if there was more than one class in each grade (classes sampled by randomized selection). The third-order random sampling units were students in selected classes that participated in the survey.

Recruitment process

The recruitment process started with educational department coordination to obtain official permission to visit the schools and to access student census data. In the second step, a list of selected schools and the number of students in each school was prepared based on the census data. The heads of health education from all four educational districts received training about student selection and how to invite parents to visit the eye clinic. Finally, selected students received an invitation card in which the date and time of the appointment were indicated.

In the first clinical phase, parents read and signed an informed consent form that included the main objectives of the study and details about the examination process. Then they completed the first questionnaire about basic demographics and household socioeconomic status, as well as past medical history, drug history, and eye health history of each eligible child. Detailed information was collected on the following: age, sex, family members, birth order, history of consanguineous marriage, parental education, parental occupation, history of systemic diseases, history of drug use, neonatal history, and history of ocular diseases in children and their first-degree relatives. Next, optometric and ophthalmologic examinations were performed at five locations. Optical biometry and OCT imaging studies were performed for approximately one-fifth of randomly selected students (one out of every five participants) in each session. This selection was based on the standard sample size formula, budget restrictions, and limitations on the use of technical devices to obtain a normative database from these measurements. Finally, students with suspected ocular abnormalities were referred to an appropriate ophthalmic subspecialty service for further evaluation. The study process is summarized in Figure 1.

Definitions

Refractive error

Myopia was defined as a spherical equivalent (SE, sphere + ½ cylinders) ≤ −0.50 diopters (D); hyperopia was defined

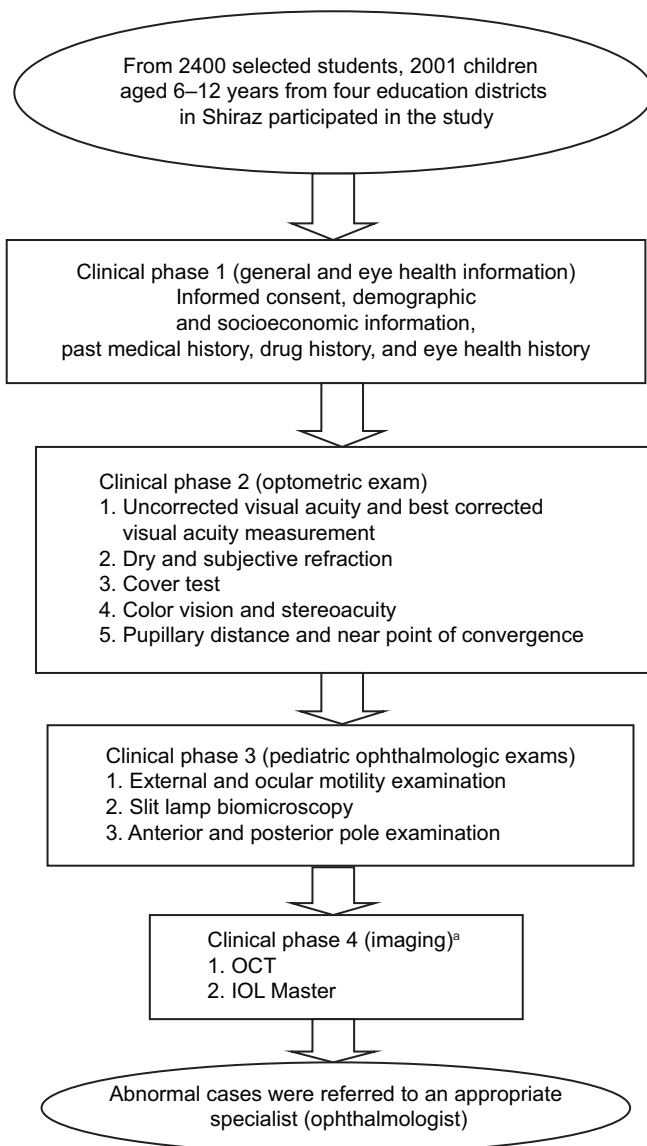| Education districts	Elementary schools			Students			Sample of students per school	Participants	
	No.	%	Sample	No.	%	Sample		No.	%
1	152	29.6	45	38,783	29.3	703	16	622	88.4
2	113	22.1	25	32,267	24.3	584	23	575	98.4
3	115	22.4	26	32,618	24.6	590	23	462	78.3
4	133	25.9	34	28,844	21.8	523	15	342	65.3
Total	513	100	130	132,512	1.00	2400	-	2001	83.3

Table 1. Distribution of the study population and participation rate in each of the four education districts

From 2400 selected students, 2001 children aged 6–12 years from four education districts in Shiraz participated in the study

Clinical phase 1 (general and eye health information)
Informed consent, demographic
and socioeconomic information,
past medical history, drug history, and eye health history

Clinical phase 2 (optometric exam)
1. Uncorrected visual acuity and best corrected
   visual acuity measurement
2. Dry and subjective refraction
3. Cover test
4. Color vision and stereoacuity
5. Pupillary distance and near point of convergence

Clinical phase 3 (pediatric ophthalmologic exams)
1. External and ocular motility examination
2. Slit lamp biomicroscopy
3. Anterior and posterior pole examination

Clinical phase 4 (imaging)[a]
1. OCT
2. IOL Master

Abnormal cases were referred to an appropriate specialist (ophthalmologist)

Figure 1. Shiraz Pediatric Eye Study examination process. [a]The IOL master and optical coherence tomography (OCT) were performed randomly for approximately one-fifth of the participants in each session.

as SE $\geq$ +2.0 D; astigmatism was defined as cylinder power $\geq$ 0.75 D.[29]

Amblyopia

Amblyopia is an optically uncorrectable loss of VA in the absence of an organic defect. Unilateral amblyopia was defined as a 2-line difference in best-corrected VA between the two eyes or acuity in the amblyopic eye less than 20/30, plus at least one of the following conditions: (a) constant or intermittent strabismus, (b) history of strabismus surgery, (c) anisometropia consistent with the worse eye (i.e., >1.00 D SE anisohyperopia, >3.00 D SE anisomyopia, or >1.25 D anisoastigmatism), or (d) evidence of past or present visual axis obstruction for at least 1 week (e.g., cataract, pseudophakia,

aphakia, significant corneal opacity, ptosis, or eyelid hemangioma). Bilateral amblyopia was defined as bilateral loss of best-corrected VA with a history of bilateral visual axis obstruction or bilateral significant ametropia (i.e., >4.00 D SE hyperopia, >6.00 D SE myopia, or >2.50 D astigmatism).[12] Children with coexisting fundus or anterior segment abnormalities precluding normal vision were not considered amblyopic. Those with a history of amblyopia or amblyopia treatment (patch, spectacles, etc.) were included as having amblyopia.

Glaucoma

Glaucoma was defined in this study as the presence of a combination of optic neuropathy such as optic disc cupping more than 0.3, disc asymmetry 0.2 or progressive cupping, visual field change, IOP more than 21 mmHg, or anterior segment changes such as enlarged corneas or Descemet's membrane splits.[30]

Strabismus

Strabismus means ocular misalignment. This is a condition that interferes with binocular vision. To test for strabismus, a cover test was performed using prism bar at near (40 cm) and distance fixations (6 m) by an expert optometrist for all children.[12] Strabismus was classified as heterotropia (constant versus intermittent), and micro-strabismus (defined as deviations $\leq$ 10 prism diopters).

Color vision

Color vision was defined as the inability to distinguish objects based on the wavelengths (or frequencies) of the light they reflect, emit, or transmit. The perception of colors is a subjective process whereby the brain responds to the stimuli that are produced when incoming light reacts with the several types of photopsins in the eye. In the present study, abnormal color vision was categorized based on Ishihara color vision test results.

Stereopsis

Stereopsis was defined as a perception of depth and 3-dimensional structures obtained based on visual information deriving from both eyes by individuals with normally developed binocular vision. It is measured at 40 cm distance using Polaroid glasses. Persons with corrective glasses should wear theirs for near correction. The stereoacuity worse than 40 s of arc was considered abnormal.

Near point of convergence

The NPC was determined by placing a fixation object 40 cm in front of the participant's head. The object was moved toward the child until one eye lost fixation. The

NPC was recorded as the point at which the eye lost fixation and the object moving toward the eyes was first perceived as two separate images. The eye that was able to maintain fixation was considered the dominant eye. For children, normal NPC values are 7 to 8 cm; any NPC value greater than 8 cm was considered potentially abnormal.

Clinical examination

The clinical examination was performed by study-certified personnel including six ophthalmic technicians, three optometrists, and a pediatric ophthalmologist. Ocular examination included the following procedures performed in the order listed below:

Visual acuity

Uncorrected (UCVA) and best spectacle-corrected visual acuities (BSCVA) were measured by optometrists from a distance of 6 m (20 feet) with a Snellen E chart (LED visual chart projector, LC-13, MEDIZ Inc., City, Korea).

Refractive error

Refractive errors were measured with a Topcon autorefractometer (Rm-8900, Tokyo, Japan). The results were refined by trained optometrists using a manual retinoscope. Then, subjective and cycloplegic refraction were examined and recorded for each eye separately. For cycloplegic refraction, we used cyclopentolate 1% eye drops every 10 min, applied twice. Cycloplegic refraction was examined 20 min after the last application of cyclopentolate eye drops. In addition, the glasses used by children with ametropia were evaluated using a Nidek automated lensometer (LM–1000 P, Tokyo, Japan).

Slit lamp biomicroscopy results

The anterior segment of the eye was examined by a pediatric ophthalmologist using a slit lamp biomicroscope (BM 900, Haag-Streit, Bern, Switzerland). The optic disc and macula were also evaluated using a Volk 90 D condensing lens.

Intraocular pressure

Intraocular pressure was measured with an air-puff tonometer (CT-80, Topcon Inc., Tokyo, Japan). We measured IOP three times in each eye, and the mean of the three measurements was recorded. For IOPs greater than 21 mm Hg, Goldmann applanation tonometry was also performed.

Color vision and stereoacuity

In all participants, color vision and stereoacuity were tested with the Ishihara color vision test and Butterfly test, respectively.

Strabismus and motility

Motility and cover tests were performed to detect binocular disorders. To assess extraocular muscle performance, motility tests were performed in nine gaze positions. The degree of heterophoria and heterotropia was measured with cover–uncover tests. The magnitude of deviation was measured for both far and near distances with simultaneous prism and cover tests or prism and alternative cover test methods, and recorded separately.

Pupillary distance and near point of convergence

The pupillary distance for far and near vision and the NPC were measured with a ruler and recorded.

Scissor reflex

The presence or absence of the scissor reflex was evaluated in dilated pupils with a hand-held retinoscope.

External eye examination

The presence of ptosis or lid mass was evaluated via direct observation. Ocular protrusion, palpebral height, and lid function were measured with an exophthalmometer and ruler, respectively.

Paraclinical assessments

Optical biometry

Axial length, corneal curvature, anterior chamber depth, and white to white distance were measured with an IOL-Master 500 optical biometer (Carl Zeiss Meditec, Jena, Germany). Accuracy of the measurements was evaluated by trained staff according to the manufacturer's guidelines.

Optical coherence tomography

RNFL thickness and macular thickness and volume were measured with an OCT imaging platform (SD-OCT, Spectralis, Heidelberg Engineering, Heidelberg, Germany). All qualified images were assessed by a trained ophthalmologist.

Quality assurance

Before starting the project, several training courses were carried out for the study staff about the participant selection method, interview procedure, and clinical and paraclinical examinations. During the clinical phase (approximately 6 months), the accuracy of interviews, eye examinations, and paraclinical tests was checked and verified by project directors every week. All instruments were calibrated at the outset of the study and weekly thereafter by trained operators using the manufacturer's guidelines. Accuracy of the recorded data was assured at various levels. A trained supervisor randomly assessed

about 25% of the data sheets in each district to verify accuracy of the collected information, and any systematic errors were addressed.

Statistical Analysis

The data were entered into Statistical Package for the Social Sciences software version 15.0 (SPSS Inc. Chicago, IL, USA) by a trained operator and double-checked by an investigator. The accuracy of the final data was assessed by a qualified statistician. Demographic and socioeconomic characteristics of the children, and participation rates in different districts of the survey area, are reported with descriptive statistics. A *P* value <0.05 was considered statistically significant.

RESULTS

From a total of 2400 selected students from the four educational districts, 2001 (83.3%) participated in the study – a proportion slightly higher than our assumption (80%) in the sample size calculation. The distribution of the population, sampling procedure, and participation rate in each of the four educational districts are presented in Table 1. Participation rate ranged from 65.3% in district 4 to 98.4% in district 2.

The demographic characteristics of participants in each of the four districts are summarized in Table 2. The mean age of the students was 9.1 ± 1.6 years, 40.2% (*n* = 805) were male and 59.7% (*n* = 1195) were female. Overall, 31.1% of the students had at least one parent with a high educational

level (bachelor's degree or higher). However, most children had parents with low educational status (63.5%), and 2.2% had completely illiterate parents. Students from district 1 had the largest (43.1%), and those from district 4 had the smallest (14.3%) proportion of highly educated parents. Across districts, parental educational level was directly associated with student participation rate (65.3% in district 4, and 88.4% in district 1).

DISCUSSION

The protocol presented here for the Shiraz Pediatric Eye Study describes the design, methods, eye examination techniques, and baseline characteristics of the participants enrolled in this cross-sectional, population-based survey of schoolchildren from Shiraz, Iran. We aim to provide a valid source of data via a standard protocol based on random selection of the study sample from school clusters, precise eye examination procedures, adequate training, and effective quality assurance strategies. The data collected from this study is intended to be used to determine the prevalence of VI and their related determinants in the study population.

The prevalence of childhood blindness ranges from 0.3 in developed regions to 1.5 per 1000 children in developing regions of the world. Although most causes of childhood blindness (about 80%) are avoidable, approximately 500,000 children become blind each year.[9,31] Visual impairment screening programs are a potentially important advocacy tool for policy makers.

Table 2. Comparison of demographic characteristics of participants from each of the four education districts					
Variables	Education district				Total
	1	2	3	4	
Age (mean±SD), years	8.9±1.3	9.3±1.5	8.8±1.8	9.1±1.8	9.1±1.6
Sex, n (%)					
Male	259 (41.6)	314 (54.6)	139 (30.1)	93 (27.2)	805 (40.2)
Female	362 (58.2)	261 (45.4)	323 (69.9)	249 (72.8)	1195 (59.7)
Paternal educational level, n (%)					
Illiterate	10 (1.6)	13 (2.3)	21 (4.5)	36 (10.5)	80 (4.0)
Diploma or less	330 (53.1)	340 (59.1)	355 (76.8)	245 (71.6)	1270 (63.5)
Associate degree	48 (7.7)	35 (6.1)	23 (5.0)	11 (3.2)	117 (5.8)
Bachelor or higher	209 (33.6)	179 (31.1)	50 (10.8)	40 (11.7)	478 (23.9)
Maternal educational level, n (%)					
Illiterate	7 (1.1)	6 (1.0)	21 (4.5)	36 (10.5)	70 (3.5)
Diploma or less	374 (60.1)	375 (65.2)	365 (79.0)	266 (77.8)	1380 (69.0)
Associate degree	53 (8.5)	39 (6.8)	22 (4.8)	12 (3.5)	126 (6.3)
Bachelor or higher	172 (27.7)	146 (25.4)	46 (10.0)	26 (7.6)	390 (19.5)
Parental educational level[a], n (%)					
Illiterate	5 (0.8)	5 (0.9)	10 (2.2)	25 (7.3)	44 (2.2)
Low	324 (52.1)	328 (57.0)	361 (78.1)	258 (75.4)	1271 (63.5)
High	268 (43.1)	230 (40.0)	75 (16.2)	49 (14.3)	622 (31.1)

SD: standard deviation; n: number [a]Parental education (maternal and paternal education combined) was divided into three categories: illiterate, both parents were illiterate; low, at least one parent with diploma or less than diploma educational level; and high, at least one parent with an associated degree or higher educational level

They can be used to develop targeted approaches for the prevention of childhood blindness, and as a result lead to considerable cost savings in health care systems.[32]

Screening for VIs in school-aged children requires careful consideration of elements such as coordination to obtain official permissions, skilled staff familiar with pediatric examination procedures, and specialized equipment. Improving pediatric eye care requires the active, continuing participation of all interested parties including health care providers, public health professionals, educational institutions and family members. Previous population-based eye studies in our region did not evaluate all diseases or disorders that can lead to VI in children.

The greatest challenge in the present study was non-participation by some of the selected students. To increase the participation rate and deal with challenges at the referral center, we implemented certain approaches. The clinic was open during weekends, and time was reserved at the clinic specifically for the study, the participating children, and their parents. All examination and imaging costs were waived, and ophthalmic examinations were performed in well-organized consecutive stations to enhance the participants' cooperation and satisfaction. These measures contributed to our response rate of more than 80%.

In this study, parental level of education was considered a proxy for household socioeconomic status. Accordingly, the participation rate was highest (88.4%) in district 1, where the mean level of parental education was highest, whereas the participation rate was lowest (65.3%) in district 4, with the lowest overall level of parental education. This result is consistent with previous studies that examined the direct and indirect positive impacts of parental education on the utilization of health services and child health.[33-35]

CONCLUSION

We anticipate that future reports from the Shiraz Pediatric Eye Study will provide estimates of the prevalence of VIs and their related determinants in the community. This study is also expected to provide basic information about children who should be targeted by VI and blindness prevention programs.

Financial Support and Sponsorship

Conflicts of Interest

There are no conflicts of interest.

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