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THE PREVALENCE AND RISK FACTORS FOR AGE-RELATED MACULAR DEGENERATION IN RURAL(TRIBAL)(TRIBAL)-URBAN INDIA

Ophthalomology

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ABSTRACT

A population-based cross-sectional study was carried out. Of the 6617 subjects ≥ 60 years enumerated ones, 5495 (83.04%) participated in the eye examination. A detailed history including data on demographic, socio- economic, and ocular history was obtained. Participants underwent detailed ophthalmic evaluation including 30° 3-field photograph as per Age-Related Eye Disease Study protocol. The ARM was graded according to the International ARM Epidemiological Study Group. Age- and gender-adjusted prevalence of early ARM was 20.91% (20.86–20.94) in the rural(Tribal) population and 16.37% (16.32–16.42) in the Tribal population. Similarly, the prevalence of late ARM was 2.26% (2.24–2.29) and 2.32% (2.29–2.34) in the rural(Tribal) and urban population, respectively. In both rural(Tribal) and urban populations, risk factors that were related to both early and late ARM were age, per year increase (OR, range 1.00–1.08); middle socioeconomic status(OR, range 1.05–1.83); and smokeless tobacco (OR, range 1.11–2.21). Protective factor in both was the presence of diabetes mellitus in all ARM (OR, range 0.34–0.83). Risk factors, only in the rural(Tribal) arm, were female gender (OR, range 1.06–1.64), past smoker (OR, 1.14), and serum low-density lipoprotein cholesterol level (OR, 1.03).

KEYWORDS

Macular Degeneration, Rural(tribal)(tribal)-urban.

INTRODUCTION

As the longevity increases, so does the aging population, which is true for both developed and developing countries. It has been estimated that by 2025, the geriatric population would rise to more than 1.2 billion, of which ~ 840 million would be living in the developing countries. With such a projected increase in the geriatric population, it is expected to have proportionate increase in the prevalence of age-related macular degeneration.In India, the prevalence of age-related maculopathy (ARM) has been reported by three population-based studies: the Andhra Pradesh Eye Disease Study (APEDS); the INDEYE study; and the Central India Eye and Medical study (CIEMS). In the APEDS and CIEMS, the sample size was calculated not to estimate the prevalence of ARM, but to estimate the prevalence of all eye diseases across subjects of all age groups (in APEDS) and among those older than 30 years (in CIEMS). In the INDEYE study, although the sample size was calculated to estimate the prevalence of ARM, the population was hybrid of rural(Tribal) and urban; separate prevalence rates of ARM in rural(Tribal) versus urban populations were not reported. Therefore, the present study—Rural(Tribal)–urban Age-related Macular degeneration study—was conducted, having a proportionate sample of both the rural(Tribal) and urban population; the objectives were to report the age and gender-adjusted prevalence rates of early and late ARM and associated risk factors. The early ARM included the presence of drusen and/or retinal pigment epithelium (RPE) abnormalities; and late ARM, in addition, included geographic atrophy of RPE or choroidal neovascular complex.

MATERIAL AND METHODS

A population-based cross-sectional study, was conducted. The institutional review board approved this study and a written consent was obtained from the subjects as per the Declaration of Helsinki.The sample size was calculated based on the INDEYE feasibility study. This study reported the prevalence of late ARM in the North Indian population to be 1.4%; however, the prevalence rate among subjects older than 60 years was 2.2%, and in those older than 70 years, it was 4.6%. Considering an increase in the prevalence rate of ARM in the population with time, we assumed that the prevalence of late ARM could be ~ 3.5% in those older than 60 years; therefore, keeping a design effect of 2 with precision of 80% and compliance of 80%, the estimated sample size was 6617. The sample (N = 6617) was divided into rural(Tribal) and urban proportion., the population was divided as 59% (rural(Tribal)) and 41% (urban). The proportional sample was calculated based on rural(Tribal)–urban divide: 3904 (60%) rural(Tribal) and 2713 (40%) urban.In both rural(Tribal) and urban areas, the sampling method was multistage random cluster sampling; a cluster was defined as having a population of 1200–2000, and if it exceeded this number, the population was divided into two or more clusters. A proper mapping and listing of the households was carried out in a systematic manner to avoid omissions or duplications. A geographic map showing all major structure of the study area was prepared, and all houses were numbered serially. Family members living on the same premises and sharing a common kitchen were defined as one household. A door-to-door survey of all the households on both the sides of the street was conducted in the selected division (rural(Tribal) and urban) till we enumerated the calculated sample size.The people aged 60 years or older or those turning 60 in the present calendar year and resident at the target address for a minimum period of 6 months were included in the study. People who resided at the target households for a period of o6 months, temporary residents (people who have permanent residence elsewhere), a resident who died after the enumeration but before examination, and an eligible resident who could not be contacted after five visits by the social worker at the residence were excluded from the study. Individuals who could not be transported to the examination center because of health reason were also excluded from the study.In urban areas, the eligible subjects were given an appointment date for a comprehensive eye examination at the hospital. All the patients were brought to the base hospital. Once the comprehensive evaluation was completed, the subjects were transported back to their residence. In rural(Tribal) areas, the eligible subjects were given an appointment date for an eye examination at a convenient place chosen in a village where a customized mobile van, fitted with similar kinds of equipment that were used in the base hospital, was stationed .

The patients who required treatment were transported to the base hospital on a given appointment date.Data on demographic, socioeconomic, and ocular history were obtained from all the patients at the base hospital and in the van. The socioeconomic status was assessed using a multiple index questionnaire and the scoring was characterized as: low (score, 0–14), middle (score, 15–28), and high (score, 29–42). The questionnaire included the following variables: family possession such as refrigerator, television, washing machine, and so on, own or rented house, type of house (thatched or brick), possession of vehicle (car, scooter, etc), and other financial liability or commitment. The same questionnaire and scoring were used in another population-based study. A detailed questionnaire was administered regarding the medical history, a general physical examination, tobacco and alcohol consumption history, and educational and occupational history. The data in the medical history included duration and treatment of diabetes mellitus or hypertension, a family history of diabetes mellitus, and coronary artery disease. The ocular history included details of the first and the last eye examination,

present or past ocular complaints, and revious treatment or ocular surgery. The tobacco and alcohol consumption history included duration, type, amount, and age at start, and present and past status. Tobacco types were classified either as a smoked tobacco or smokeless tobacco. Smoked tobacco included cigarettes, cigars, cigarillos, pipes, waterpipes, kreteks (clove cigarettes), bidis (tobacco in a tendu or temburni leaf tied with a cotton thread, and papirosy (cardboard tube tipped cigarettes), whereas smokeless tobacco included chewed-tobacco (loose leaves) and snuff (finely chopped tobacco). The blood pressure was recorded, in the sitting position, in the right arm to the nearest 2 mm Hg using the mercury sphygmomanometer (Diamond Deluxe BP apparatus, Pune, India). Two readings were taken, 5 min apart, and their mean was taken as the blood pressure.All the subjects underwent a detailed ophthalmic evaluation that included assessment of visual acuity and refraction using modified ETDRS chart (Light House Low Vision Products, New York, NY, USA), anterior segment examination using a slit-lamp Zeiss SL 130 (Carl Zeiss, Jena, Germany), measurement of intraocular pressure using Goldmann applanation tonometer (Zeiss AT 030 Applanation Tonometer; Carl Zeiss), and fundus examination using binocular indirect ophthalmoscope (Keeler Instruments Inc., Broomall, PA, USA). Grading of len opacities was performed using the Lens Opacities Classification System (LOCS chart III; Leo T Chylack, Harvard Medical School, Boston, MA, USA) by experienced ophthalmologists (SSP and SG). Cataract grading was carried out with dilated pupil on slit lamp while comparing it with LOCS III standard photographs. Retinal photographs were obtained after pupillary dilatation (Carl Zeiss fundus camera; FF-450, Zeiss, Jena, Germany). The ARM was graded according to the International ARM Epidemiological Study Group and stratified into stages based on the grading in the worst eye .The grading agreement, which was carried out by two independent observers (Retina specialists) in a masked manner, was 0.62 for early ARM and 0.87 for late ARM. All subjects underwent estimation of fasting blood glucose by enzymatic assay (Merck Micro Lab 120 semiautomated analyzer, Darmstadt, Germany), total serum cholesterol (CHOD-POD method), high-density lipoproteins (CHOD-POD method after protein precipitation), serum triglycerides (CHOD-POD), hemoglobin (calorimetric hemoglobinometer), and packed cell volume (capillary method).

There were two groups: subjects with known diabetes and newly diagnosed subjects, during enrollment. The definition of subjects with known diabetes was to consider if they were using antidiabetic drugs, either oral or insulin or both, along with dietary recommendations. For newly diagnosed subjects, oral glucose tolerance test (OGTT) was used. First step was screening at the household: capillary blood glucose by finger prick using Accutrend Alpha (Roche Diagnostics, Rotkreuz, Switzerland) was carried out with a minimum of 8 h of overnight fasting. Second step was confirmatory in the mobile van in rural(Tribal) and base hospital in the urban arm, all underwent OGTT, a reading of $\geq$ 200 mg% was the cutoff point. To enhance the compliance and minimize the dropouts, fasting blood glucose was estimated even on Sundays or a day of their choice.The crude age- and gender-specific prevalence rates of early and late ARM were assessed. Direct age standardization of our study population to the Censes of India population was conducted. The association of the variables with ARM was assessed using Student's t-test for the continuous variables and the Pearson's $\chi 2$ test for the categorical variables. Logistic regression analysis was performed to determine the risk factors using odds ratio estimates with 95% confidence intervals (CIs). Furthermore, a stepwise multivariate regression analysis was performed with Po0.05 being required for entering the model and remaining there. SPSS software (version 13.0; SPSS Inc., Chicago, IL, USA) was used for statistical analysis.

RESULTS

In this study, 6617 subjects were enumerated;: rural(Tribal), 3904; urban, 2713. Of these, 6617 enumerated persons, 5495 (83.04%) participated in the eye examination; dropout rates were 16.34% and 17.84% in the rural(Tribal) and urban population, respectively. Of these 5495 subjects who participated in the eye examination, 5379 (81.29%) underwent retinal imaging; 74 (rural(Tribal), 60; urban, 14) were not willing for the dilatation; and 42 (rural(Tribal), 32; urban, 10) were not cooperative. The retinal images were noted to be ungradable in 431 subjects in the rural(Tribal) population and 157 subjects in the urban population. Therefore, in the final analysis 4791 subjects (rural(Tribal), 2743; urban, 2048) were included.The prevalence of early and late ARM in the rural(Tribal) and urban populations. Age- and gender- adjusted prevalence of early ARM was 20.91%, 95% CI (20.86–20.94) in the rural(Tribal) population and 16.37%, 95% CI (16.32–16.42) in the urban population. Similarly, age- and gender-adjusted prevalence of late ARM was 2.26%, 95% CI (2.24–2.29) and 2.32%, 95% CI (2.29–2.34) in the rural(Tribal) and urban population, respectively. No significant difference was observed gender-wise with respect to early and late ARM in both rural(Tribal) and urban populations.The age and clinical parameter-wise prevalence of early ARM. In the rural(Tribal) population, prevalence of only drusen was 11.41%, 95% CI (11.37–11.44); drusen with hyperpigmentation, 4.89%, 95% CI (4.86–4.91); and drusen with hypopigmentation, 4.61%, 95% CI (4.59–4.63). In the urban population, prevalence of only drusen was 9.42%, 95% CI (9.38–9.46); drusen with hyperpigmentation, 4.77%, 95% CI (4.74–4.79); and drusen with hypopigmentation was 2.18%, 95% CI (2.16–2.20). In the urban population, the crude prevalence of early ARM showed increasing trend with increasing age (trend P-value = 0.012); no such trend was observed in the rural(Tribal) population.In the rural(Tribal) arm, compared with those without ARM, subjects with late ARM were older (mean age, 65.13 vs 68.49 years); less prevalence of diabetes mellitus was observed in both early ARM (24.7% vs 14%) and late ARM (24.7% vs 9.4%). Similarly, in the urban arm, compared with those without ARM, subjects with early and late ARM were older (early: 66.35 vs 67.52 years; late: 66.35 vs 70.38 years). With regard to consumption of tobacco, there were two types of users: smokers and smokeless tobacco users.In the rural(Tribal) arm, smokers were 13.99% (384/2743) and smokeless tobacco users were 27.96% (767/2743); similarly, in the urban arm, smokers were 10.25% (210/2048) and smokeless tobacco users were 13.72% (281/2048).

DISCUSSION

Our study found that the prevalence of early ARM was ~ 21% in the rural(Tribal) population and ~ 16% in the urban population. Similarly, the prevalence of late ARM was ~ 2% in both rural(Tribal) and urban populations. The predominant lesion in early ARM, in both rural(Tribal) and urban populations, was only drusens with no pigment abnormalities. The prevalence of drusens with pigmentary abnormalities such as hyper- or hypopigmentation was noted in ~ 5% of the population in the rural(Tribal) subjects, and in urban subjects, the prevalence of hyperpigmentation was more compared with that of hypopigmentation (5% vs 2%). Previous epidemiological studies have shown that the presence of drusens and associated pigment abnormalities were associated with progression to late ARM. Therefore, it is imperative to follow and educate all these patients who have shown evidence of early ARM, that is, the population at risk, 2 out of 10 subjects above the age of 60 years. While smoking—as a risk factor—has been associated with ARM in other populations,30,31 we found association of smokeless tobacco use as risk factor in both urban and rural(Tribal) populations. Of the estimated 852 million tobacco users, globally, nearly 301 million were in China and 275 million in India.32 We observed that the prevalence of smokeless tobacco, in this study, was almost two times in the rural(Tribal) population when compared with urban population (27.9% vs 13.7%), and this could be the probable reason for higher prevalence of early ARM in the rural(Tribal) compared with that in the urban population (~21% vs 16%).

CONCLUSION

The study reports smokeless tobacco as a risk factor for both early and late ARM and identified a higher prevalence of early ARM in the rural(Tribal) population compared with urban population.

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