

Incidence of Open Angle Glaucoma among Patients with Pseudoexfoliation Syndrome in a Tertiary Eye Care Centre in South India - A Cross Sectional Study

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ABSTRACT

BACKGROUND

Open angle glaucoma forms a major proportion of glaucomas which is a leading cause of irreversible blindness worldwide. Anatomical variations in ocular structures and consequent secondary open angle glaucoma occurs in significant number of patients afflicted with pseudoexfoliation syndrome. Hence, a detailed workup and identification of glaucoma and appropriate management is essential to prevent further visual loss. We wanted to evaluate the incidence of open angle glaucoma among patients having pseudo exfoliation syndrome at Regional Institute of Ophthalmology, Trivandrum, Kerala.

METHODS

A cross sectional study comprising 142 individuals with pseudo exfoliation syndrome was conducted in Regional Institute of Ophthalmology, Trivandrum, Kerala, over a period of one year. Sociodemographic variables were collected through structured interviewer administered questionnaire followed by detailed ocular work up and visual field analysis. Data was analysed using Statistical Package for Social Sciences, SPSS 16.

RESULTS

Among 142 subjects, 70.4 % were males and 29.6 % were females. The mean age of participants was 65 years. In studied population, 83.1 % represented rural population. Incidence of open angle glaucoma among studied population with pseudoexfoliation was 10.56 % (95 % confidence interval; 5.50 % - 15.61 %). No case of normal tension glaucoma was identified during the study period. 29.57 % of subjects showed bilateral pseudoexfoliation. But among patients with pseudoexfoliation (PEX) glaucoma, 78.9 % had bilateral disease. Mean intra ocular pressure in eyes with PEX glaucoma was 27.38 ± 5.75 mm Hg and in PEX eyes without glaucoma was 23.20 ± 1.6 mmHg. Pupillary dilatation was observed to be less than the normal eyes and was 5.62 mm. 4 % of eyes with PEX had some form of zonulopathy.

CONCLUSIONS

Hospital based incidence of open angle glaucoma among patients with pseudo exfoliation is 10.56 %.

KEYWORDS

Pseudoexfoliation, Open Angle Glaucoma, Incidence, Intraocular Pressure, Gonioscopy

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BACKGROUND

Pseudoexfoliation syndrome is an age-related systemic microfibrilopathy, caused by progressive accumulation and gradual deposition of extracellular grey and white material over various tissues.¹ The material deposits in ocular structures and leads onto secondary open angle glaucoma characterized by increased intraocular pressure (IOP) and corresponding visual field defects. It is the most common identifiable cause of open angle glaucoma worldwide.² Pseudoexfoliation is typically a disease of old age. The advancements in medicine have brought tremendous changes to human society with increase in the life expectancy along with improvements in the quality of life. The pseudoexfoliation syndrome is recently gaining escalating importance as life span of the population is increasing. This is a relatively new demographic phenomenon. As the population ages, the ratio of older adults to working-age adults, also known as the old-age dependency ratio, is also expected to rise. So there is a global trend in thinking in favour of geriatric health care. Pseudo exfoliation is thus a very important topic for research in ophthalmology. Estimation of the incidence helps to understand the magnitude of the problem which shall provide a light in planning the required screening and intervention.

We wanted to evaluate the incidence of open angle glaucoma among patients having pseudo exfoliation syndrome at Regional Institute of Ophthalmology, Trivandrum, Kerala.

METHODS

We did a cross sectional observational study in the Regional Institute of Ophthalmology, Trivandrum, Kerala, a tertiary care teaching hospital in South India among patients having pseudoexfoliation syndrome who attended our Outpatient department for various complaints from January 2017 to January 2018. The incidence of normal tension glaucoma among these patients was also estimated. The study was done with institutional ethical clearance and after obtaining informed written consent from patients. Patients with clinical appearance of pseudo exfoliation in either eye above 40 years was included. Patients who were already on IOP lowering medications / who underwent any surgical procedure for IOP lowering, previous ocular trauma and other secondary glaucomas were excluded. Estimation of the sample size was calculated using Cochran's formula

$$\text{Sample size} = \frac{Z_{1-\alpha/2}^2 p(1-p)}{d^2}$$

Where

$Z_{1-\alpha/2}$ = Is standard normal variate (at 5 % type I error (P < 0.05) it is 1.96)

P = Expected proportion in population based on previous studies.

d = Absolute error or precision, here taken as 5 percentage.

Study conducted in Scandinavian population showed a prevalence of 8 % of open angle glaucoma among PEX patients. In India, studies showed varying results. Glaucomatous optic neuropathy was found in 13 % of PEX cases in a study conducted in South India. In the present study 13 % was taken as expected proportion P. Applying the values in the formula, sample size obtained was 174.

We had a total number of 179 subjects with stipulated features suggestive of pseudo exfoliation. Of them, 37 patients were eliminated as they were not completely fulfilling the qualifying criteria. Few of them were not available for follow up visits which were intended for important investigations like field analysis. Finally, data from a total of 142 subjects were considered for analysis.

Patients were primarily identified from the regular outpatient department on whom slit lamp examination was done and pseudoexfoliation was noted. The participants were classified as pseudoexfoliation if white, flaky, dandruff-like material at the pupillary margin, iris surface or on the anterior lens capsule was present in either eye.

Structured interviewer administered questionnaire for sociodemographic variables and medical history especially diabetes and hypertension was taken. IOP was recorded twice using Goldmann applanation tonometry between 8 a.m. and 9 a.m. and again 2 hours after dilatation and higher reading was chosen. Gonioscopy was done using indirect 2 mirror gonioscope (Goldmann) after instilling proparacaine eye drops (0.5 %) coupled with viscoelastic material. Schaeffer's system of grading was employed where grade 4 was the wide open angle corresponding to 35 - 45 degrees. Presence of wavy pigment deposition anterior to Schwalbe line [Sampaolesi line], uneven pigmentation of trabecular meshwork, presence of pseudoexfoliation material in angle noted. Pupil was maximally dilated using 0.8 % tropicamide 5 % phenylephrine combination and dilatation measured using horizontal slit of slit lamp. The anterior lens capsule was examined for deposition of materials in a 3 zone pattern with intermediate clear area. Lens was examined for the presence of cataract, subluxation and phacodonesis. A fundus examination with + 90 D lens was done for assessment of optic disc. Disc was considered to be glaucomatous or suspected glaucomatous if one or more of the following findings were observed.

Generalized / focal enlargement of the cup, vertical cup disc ratio more than 0.6, superficial splinter haemorrhage, retinal nerve fibre layer defect, translucency of neuroretinal rim, development of vessel overpass, asymmetry of cupping, peripapillary atrophy [beta zone]. 2 baseline reliable visual fields [C - 30 - 2] of both eyes were done and interpreted according to Anderson criteria³

Patients with typical morphological changes of optic disc and retinal nerve fibre layer and consistent visual field defects not explainable on other grounds and IOP > 21 mmHg were diagnosed to have glaucoma and was further classified into open angle glaucoma and closed angle based on gonioscopic appearance.

Patients with typical morphological changes of optic disc and retinal nerve fibre layer and consistent visual field defects not explainable on other grounds, and never having recorded an IOP value more than 21 mm of Hg when

measured by Goldmann applanation tonometer were considered as normal tension glaucoma.

Statistical Analysis

Incidence of open angle glaucoma was calculated as the proportion of the number of patients with PEX glaucoma in at least one eye to the number of screened individuals. Analysis of data was done using SPSS software 16. Comparison of sex distribution and zonulopathy between the PEX patients with glaucoma and without glaucoma was analysed by chi square test. Comparison of mean age and IOP between the two groups were analysed by independent sample t test. Comparison of median age between the two groups was analysed by Mann-Whitney U test.

RESULTS

The mean age of participants was 65.20 ± 7 . The minimum age was 42 and the maximum was 90 years. 75 % of subjects belonged to the age group between 60 and 69 years. 32 % belonged to 70 - 79 years and 30 % to 50 - 59 years' age group, 3 % to people above 80 years and only 2 % belonged to people less than 50 years [Figure 1].

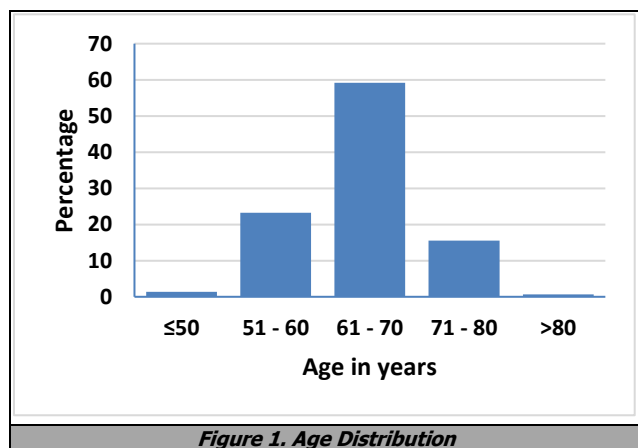


Figure 1. Age Distribution

Out of 142 subjects 100 were males and 42 were females. Males constituted 70.4 % and females contributed 29.6 %. [Figure 2]

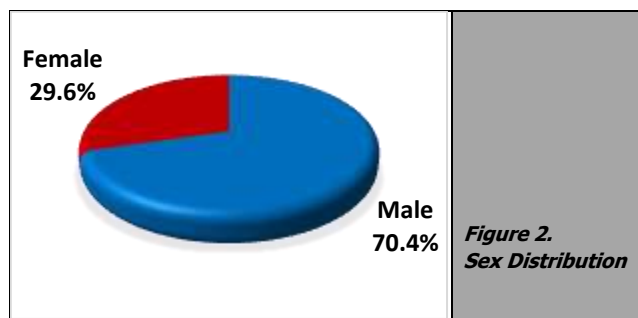


Figure 2. Sex Distribution

In studied population 83.1 % of patients represented rural population. Urban population was only 16.9 % [Figure 3].

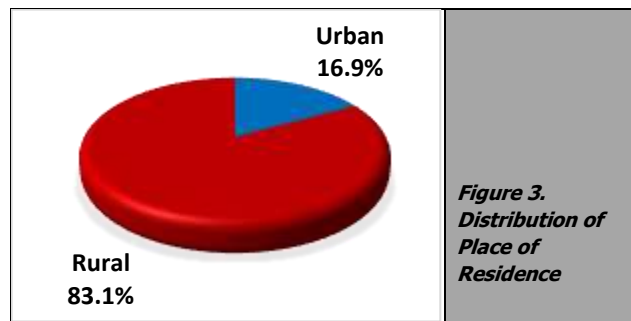


Figure 3. Distribution of Place of Residence

Glaucoma

Glaucoma was detected in 31 eyes of 19 patients. 14 patients had bilateral disease. [figure 4]

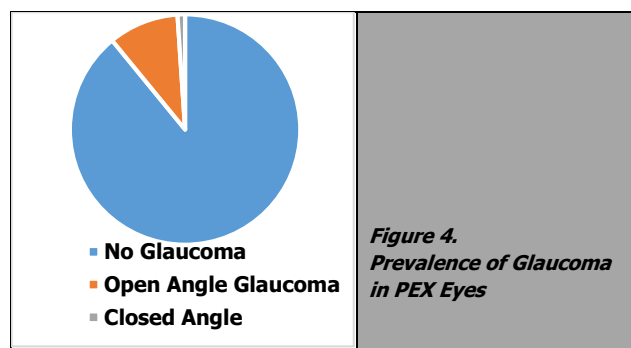


Figure 4. Prevalence of Glaucoma in PEX Eyes

Open angle Glaucoma	Frequency	Percent	95 % CI for Prevalence
No	127	89.44	
Yes	15	10.56	5.50 % - 15.61 %
Total	142	100	

Table 1. Incidence of Open Angle Glaucoma

Based on gonioscopic evaluation, 28 eyes of 15 patients had open angle glaucoma. Of which 13 patients had bilateral disease. Incidence of open angle glaucoma among studied population with pseudo exfoliation was 10.56 % (95 % ci 5.50 % - 15.61 %). 3 eyes of 2 patients had closed angles. One patient had bilateral disease at presentation. One patient presented with unilateral closed angles with an anteriorly subluxated lens.

Bilaterality

Only 29.57 % of subjects had bilateral pseudo exfoliation. But among patients with glaucoma 78.9 % had bilateral glaucoma.

Normal Tension Glaucoma

No case of normal tension glaucoma during the study period was identified. Mean IOP in PEX eyes with glaucoma was 27.38 ± 5.75 mmHg [range 12 - 36] and in PEX eyes without glaucoma was 23.20 ± 1.6 mmHg. Mean IOP in non PEX eyes in unilateral cases was 16.81 ± 2.30 mmHg.

Visual Acuity

Mean visual acuity of the study subjects was calculated taking the acuity of the worst eye with pseudo exfoliation. It

was found to be 0.9 (log MAR) range 0.6 - 1.3. Cataract was invariably seen in all those eyes. And cataract could be the leading contributing factor for the decrease in visual acuity.

Zonulopathy

Pseudoexfoliation is known to affect the zonules subsequently weakening them leading to conditions like zonular dialysis, subluxation or dislocation of lens. In our study out of 281 eyes studied, 11 eyes had weak zonules evident by either subluxation or phacodonesis under slit lamp examination.

Seen in 11 (7.7 %) in the study population; it was significantly higher in those with glaucoma 8 (72.7 %) value < 0.001; odds ratio 24.2 (5.7 - 102.7). Confidence interval was wide because of the small number in this category.

Pupillary dilatation was known to be impaired in pseudoexfoliation. Mean pupillary dilatation was 5.62 mm ± 1.408 in involved eyes and 7.2 mm in apparently uninvolved eyes.

On comparing data of patients with and without open angle glaucoma, the mean age was found to be higher in patients with glaucoma than without glaucoma. 82.1 % of glaucomatous patients were males. [Table 5]. Comparison of sex distribution and zonulopathy between the two groups were analysed by chi square test. Comparison of mean age and IOP between the two groups were analysed by independent sample t test. Comparison of median age between the two groups was analysed by Mann-Whitney U test.

	PEX with Glaucoma [OAG] (N = 28)	PEX no Glaucoma (N = 110)	P Value
Age in years (mean ± SD)	68.3 ± 8.9	64.7 ± 6.3	0.015
Median Age	70	65	0.013
Sex male - N (%)	23 (82.1 %)	73 (66.4 %)	0.115
Female - N (%)	5 (17.9 %)	37 (33.6 %)	
IOP (mean ± SD)	27.38 ± 5.75	23.20 ± 1.6	0.352
Zonulopathy - N (%)	8 (28.6)	3 (2.7 %)	< 0.001

Table 2. Comparison of Age, Sex Distribution and Zonulopathy in PEX

Among Patients with and without glaucoma systemic comorbidities like Diabetes mellitus was noted in 7 (25 %) patients in PEX glaucoma and 31 (28.18 %) in PEX non-glaucomatous patients. Hypertension and dyslipidaemia were noted in 5 (17.85 %) and 6 (21.42 %) patients with glaucoma and 29 (26.36 %) and 17 (15.45 %) patients of PEX without glaucoma respectively. However, these values were not statistically significant (P > 0.1).

DISCUSSION

Many frequency and prevalence studies regarding pseudo exfoliation have been performed worldwide. It was found to be prevalent in old age population. In our study the mean age of participants was 65.20. Oldest participant was 90 years old and the youngest was 42. The 42-year-old subject was an outlier. The majority of subjects were within 60 and 70 years. Virtually all studies unanimously found out that the disease was more common over age 50.⁴⁻²²

The patients with bilateral involvement were older in age.⁷ Studies from different parts of the world showed different gender distribution. Some studies argued females were more affected with pseudo exfoliation.²³ Many studies from India showed no general predilection, while Krishnadas et al. found the disease to be more prevalent in males.²⁴ Males are more involved in outdoor activities, and this may probably explain the male preponderance. In our study, males constituted 70 % of the subjects; 82 % of patients with glaucoma were males. Studies from India and middle east suggested more prevalence among men.^{14,24,25,26,27}

In the present study, 83.1 % of patients came from rural population. Rural population is believed to be greatly exposed to the risk factors like sunlight because of their increased outdoor activity. Most of the patients coming from rural areas were farmers or agricultural workers. Three patients were fishermen and they were significantly exposed to sunlight for a longer period. In another large population based study by Aravind H, et al. the prevalence of pseudoexfoliation syndrome in the rural population of South India was 3.8 %.²⁵

In our study, pseudoexfoliation was bilateral in 29.57 %. It was slightly less compared to other south Indian studies.^{24,25} Bilateral presentations were reported to be 50.9 % by Arvind et al.²⁵

Unilateral involvement may be an early asymmetric presentation, as a precursor to bilateral disease. Interestingly, among patients with glaucoma, 78.9 % had bilateral glaucoma. This was probably due to the delayed presentation which allowed development of disease bilaterally. Pseudo exfoliation is a systemic disorder which essentially could be bilateral. Initially, patients present with unilateral disease. Mizuno and Muroi suggested that most such cases had occult pseudoexfoliation in the seemingly unaffected or "normal" fellow eye.²⁸ Unilateral involvements is often regarded as a precursor to bilateral disease.

The prevalence of open angle glaucoma among studied population with pseudo exfoliation was 10.56 % (95 % CI 5.50 % - 15.61 %). This result was consistent with other South Indian studies.²⁵ Two major independent population-based studies from South India reported prevalence 7.5 % and 13 %.^{24,25} Patients with PXF glaucoma tend to present late with advanced visual loss if not screened early.

Patients with PEX glaucoma have higher IOP with greater fluctuations and marked spikes. It is likely to cause more severe optic neuropathy compared to patients with primary open angle glaucoma. PEX glaucoma develops in approximately 50 % of patients with PEX syndrome over time. It is recognized as the most common type of secondary open angle glaucoma. A patient with primary open angle glaucoma may also have PEX findings in eye. The latter may not be contributing to the mechanism of glaucoma. A definitive diagnosis of PEX glaucoma could be made in such patients in the future by specialized genetic testing of myocilin levels.²⁹

The most important mechanism for glaucoma is believed to be through the clogging of trabecular meshwork by exfoliation material which is a product of defective elastin metabolism. The material is a glycoconjugate surrounding a protein core. Exfoliation material can either be produced at

the trabecular meshwork itself or it can be produced somewhere else and then passively washed towards it by aqueous current. It causes disorganization and degeneration of juxtacanalicular trabecular meshwork and schlemm's canal. Focal collapse of the canal occurs causing a decrease in the aqueous outflow. This will eventually cause a rise in the intra ocular pressure. A study of aqueous humor dynamics suggest a decrease in the uveoscleral outflow also. The pathology as to why some eyes develop glaucoma while others do not require further analysis. Variability in the amount of material and metabolic activity of enzymes in various patients may contribute. The porosity of juxtacanalicular meshwork also differ in patients. Clinically the changes may be detected by gonioscopy which reveals pigment deposition on trabecular meshwork, more-dense in inferior angle and anterior to Schwalbe's line.

2 patients had occludable angles (1.4 %) and 2 patients had closed angles (1.4 %). One of the patients with closed angles had anteriorly subluxated lens with weak zonules. Zonular weakness may cause the forward movement of the lens, particularly when the patient assumes a prone position. This may produce a pupillary block in predisposed eyes. In advanced cases frank anterior subluxation could occur sufficiently enough to cause a pupillary block even in non-pre-disposed eyes. Additionally, breakdown of blood aqueous barrier, formation of posterior synechiae, and rigidity of the iris also contributes to the event.

No case of pseudoexfoliation with normal IOP had glaucomatous optic neuropathy during the study period, hence no case of normal tension glaucoma was identified.

The visual acuity was decreased in the PEX affected eyes. The mean acuity was 0.9 (logMAR). Cataract was observed in these eyes contributing to decreased visual acuity. Cataract showed greater prevalence in pseudo exfoliation syndrome possibly due to the ocular ischemia and oxidative stress.

Maximum pupillary dilatation after mydriatics was measured. The mean pupillary dilatation in the study eyes (5.62 mm) was less than the dilatation in the apparently uninvolved eyes (7.2 mm) from the same study population. Fibrotic and degenerative changes in the dilator pupillae muscles eventually leads to poor mydriasis. Ultrastructural changes noted in iris were deposits of typical PEX fibrils on iris and in dilator muscle, increased accumulation of extracellular matrix, including microfibrils and reduplicated basement membrane material in the periphery of iris vessels, in the dilator muscle and degenerative changes of iris pigment epithelium and dilator muscle cells.³⁰

Pseudoexfoliation affects zonular integrity. Of the 281 eyes studied, 11 eyes had some evidence of weak zonules (4 %). This emphasises the fact that weak zonules are to be anticipated when taking up a patient for cataract surgery. Schlötzer-schrehardt and naumann found that pseudoexfoliation caused weakness of the zonules at three levels.³¹ (1) at their origin and anchorage in the ciliary body. Here the zonular bundles are separated from the disrupted basement membrane of the nonpigmented epithelium. (2) in the pars plicata of the ciliary body. The zonular bundles passing alongside the ciliary processes are disrupted leading

to zonular rupture. (3) at their attachment to the anterior lens capsule.

In most cases, three zones can be noted on lens capsule. the inner central disk shaped zone can be absent in 20 - 60 % of cases.³² The intermediate clear zone due to the iris movement on the anterior lens surface and a more peripheral area with radial striations is almost always demonstrated. However, the most common type of cataract that occur is nuclear sclerosis.³³

Poor mydriasis and zonular integrity associated with nuclear sclerosis may increase the risk of intraoperative complications like vitreous loss and lens dislocation during cataract surgery. The associated glaucomatous optic neuropathy adds on to guarded visual prognosis in PEX patients undergoing surgery demanding long term follow up and appropriate management.

CONCLUSIONS

In our study a considerable number of patients were detected to have glaucoma in PEX eyes, more in elderly rural male population. Hence, a comprehensive ocular examination including slit lamp biomicroscopy and gonioscopy in aging population is essential to diagnose the most important cause of secondary glaucoma – pseudoexfoliation. Since it can run a rapidly progressive course, an early diagnosis helps to prevent adverse visual sequelae. A frequent screening for glaucoma should be considered in patients with features of pseudoexfoliation.

Limitation

The study was a hospital-based cross sectional study working on the data collected from a single tertiary care centre for a brief period of one year. So, the incidence calculated could not be projected to the general population as such. Large population based studies are required to validate our findings.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.

Financial or other competing interests: None.

Disclosure forms provided by the authors are available with the full text of this article at jebmh.com.

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