

Ethics of a Clinical Study on the Incidence of Primary Open-angle Glaucoma in a Tertiary Care Hospital

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ABSTRACT

Aim: To study the incidence of primary open-angle glaucoma (POAG) in a tertiary care hospital.

Material and methods: The present study was conducted on the patients diagnosed with POAG in the outpatient department for one year. A total of 60 patients were diagnosed with POAG during this study period. Detailed history and thorough ocular and systemic examinations were made.

Result: It is evident from this study that POAG is more common in the elderly population, particularly in the fifth decade, with the mean age among all patients being 51.02 ± 13.63 . Males were affected more than females (the ratio is 3.3:1). The incidence of POAG during the study period was 0.152 among all OPD attendance.

Conclusion: To improve the incidence of POAG, population-based screening of POAG is not feasible, but opportunistic screening of POAG can be done in outpatients in elderly, diabetic, hypertensive, and myopic populations when presenting with complaints of reduced vision.

Keywords: Fundoscopy, POAG, Tonometry, Visual field.

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INTRODUCTION

Glaucoma is a diverse disease group of eye diseases with multifactorial aetiology, characterized by an acquired loss of retinal ganglion cells, progressive optic neuropathy with morphological abnormalities in optic nerve head (ONH) and, visual field defects, in which raised intraocularly (IOP) is a significant and only modifiable risk factor.¹ The estimated prevalence of glaucoma in the world was 60.5 million in 2010 and is expected to increase to 79.6 million in 2020.² Studies have shown that 12 million Indians have already been affected by the disease by 2010 and has been estimated to increase to a 16million by 2020.² The diagnosis of POAG may be delayed due to the lack of early symptoms. Glaucoma is irreversible, slowly progressive and usually remains asymptomatic until late. If not treated or inadequately treated, glaucoma often results in visual impairment and blindness.³

Glaucoma is a lifelong disease and is a leading cause of irreversible but preventable blindness (5.80%) in India, next to cataracts (62.50%).⁴⁻⁶

The complainant verdicts are the same in glaucoma and eyes as a whole, but the scale of plaintiff compensation is higher in glaucoma than in other illnesses of ophthalmology. Some of the litigation causes included failure to diagnose glaucomatous disease, adverse drug reactions, and intervention complications.⁷ Therefore, sound knowledge about open-angle glaucoma is essential to avoid unnecessary harassment. So, we aimed to examine the incidence of primary open-angle glaucoma (POAG) in a tertiary care hospital to keep data to deal with a further course of action.

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MATERIALS AND METHODS

The present study was conducted for one year on patients diagnosed with primary open-angle glaucoma (POAG) in the outpatient department. A total of 60 patients were diagnosed with POAG during this study period. Written and informed consent was taken from all the patients.

All cases diagnosed and treated as POAG irrespective of age and sex were included in the current study. We have excluded the primary angle-closure glaucoma, secondary glaucoma, congenital glaucoma and the cases with lenticular opacity, corneal scarring or opacity.

Detailed ocular history regarding the diminution of vision, redness, photophobia, seeing of blind spots or coloured halos, and associated symptoms such as nausea and headache were enquired. History of frequent changes of presbyopic glasses, intermittent pain and redness were asked. General medical history of diabetes, hypertension and cardiac diseases, and a family history of similar were inquired about.

A thorough ocular examination was done, including visual acuity, refraction, tonometry, slit-lamp biomicroscopy, gonioscopy, perimetry, and optical coherence tomography (OCT).

Intraocular pressure (IOP) was measured using a Goldman applanation tonometer (GAT). IOP was measured three times in each eye, and the pressure was taken as the median of these three readings. The same observer performed IOP measurements. The analysis of retinal nerve fibre was done with OCT (Stratus OCT™ model 3000, Carl Zeiss Meditec Inc). Visual field analysis was done with Automated Humphrey Visual Field Analyser, and the strategy used is SITA (Swedish Interactive Threshold Algorithm). Before the conduction of the study, ethical approval was obtained from the ethics committee of the institute.

RESULTS

The incidences of the cases are narrated in Table 1.

The incidence of POAG during the study period is 0.152. The gender-wise distribution of the cases is mentioned in Table 2.

Our study reveals a higher incidence of primary open-angle glaucoma in males (76.67%) than in females (23.33%). ($p=0.0052$).

The cases of the primary open-angle glaucoma in the present study are mentioned in Table 3.

We get that 49 patients (81.66%) were above 40 years of age in this study population. Maximum numbers of patients were in the 5th decade.

This study reveals that POAG is more prevalent in the elderly, particularly in the fifth decade. Among the 60 cases, the majority (56.67%) of the cases were 41-60 years. The youngest patient in the study population was 19 years, while

the oldest was 82 years old, and the mean age of presentation was 51.02 years.

DISCUSSION

This cross-sectional study was done year to study the incidence of the POAG. Statistically, Chi-Square (χ^2) and Probability values (p) were used, and a $p < 0.05$ was considered statistically significant. The study population was the patients attending the hospital's outpatient department during this period and being diagnosed as POAG.

Primary angle-closure glaucoma is a significant cause of gradual painless loss of vision. This study revealed that direct open-angle glaucoma incidence during the study period was 0.152% Table 1 of the total patients attending the outpatient department. The different authors found the incidences similar to our study mentioned in Table 5.

Our one-year incidence rate is comparable with a few of the handful of available one-year incidence studies, like Visual Impairment studies, Mukesh *et al.*⁸ Incidence was further increased in the Barbados Eye Study Group by Leske *et al.*⁹, and it was conducted in the black population of age 55 years and above.

The low incidence in our present study is attributed to the lack of awareness and ignorance among the general population regarding glaucoma and the nearly symptomless and insidious nature of POAG.

In our study, males were three times more affected than females. (M:F ratio= 3.3:1). It has been observed that most of the cases occurred among males (76.67%) than females (23.3%). In this study p -value = 0.0052, which is statistically significant.

A study known as Aravind Comprehensive Eye Survey done in 2003-2009 also found that males have an increased risk of developing POAG compared to females (M: F=2.2:1). The

Table 1: Incidence of the cases

Total number of cases attending the outpatient department	39498
Total number of primary open-angle glaucoma	60
Incidence	0.152

Table 2: Sex distribution

Sex	Number of cases	Percentage
Male	46	76.67
Female	14	23.33
Total	60	100%

$\chi^2=7.82$, $p=0.0052$

Table 3: Age distribution

Age in years	19-40	41-60	>60
Males	6	28	12
Females	5	6	3
Total	11	34	15
Percentage	18.33%	56.67%	25%

$\chi^2=11.715$, $p=0.006$

Table 4: Statistics of age distribution

Mean age	51.02
Standard deviation	13.63
Standard error of mean (SEM)	1.76
95% Confidence Interval	54.47 47.57
Minimum	19
Maximum	82
Median (50 th percentile)	52

Table 5: Incidence of POAG recorded by different authors

Authors	Incidence (%) in the 2-year study
Mukesh <i>et al.</i> (2002) ⁵	0.1
Leske (2001) ⁶	0.2
Our study (2018)	0.152

Table 6: Sex distribution in different studies done by other authors

Authors	Male POAG (%)	Female POAG (%)
Sun <i>et al.</i> ¹¹	45.6	54.4
Narayan <i>et al.</i> ¹²	58	42
Ramakrishnan <i>et al.</i> ¹³	68.75	31.25
Our study	76.67	23.3



Rotterdam Study¹⁰ also found that males were three times more affected than females. Sex distribution in different studies done by other authors like our topic is shown in Table 6.

Few population-based studies like the Blue Mountain eye disease study¹³ found a higher incidence of females than males.

Our study found male preponderance in all age groups. Most of the mentioned studies were population-based studies. Ours being the hospital-based one, socio-economic and cultural constraints play an essential role, leading to neglect and under-reporting of females with POAG. Most young females came for their refractive error correction and were later diagnosed as POAG.

Our study revealed that POAG is more common in the elderly, particularly in the fifth decade and above. The mean age at presentation was 51 years. The highest numbers of cases were in the age group 40-60 years range (58.33%), and among these patients, 57% cases were in the 5th decade.

The mean age in our study was comparable with other Indian studies, and Narayan *et al.*¹⁴ and TakeP *et al.*¹⁵ had fixed the lower age of the patient as 40-45 years, respectively. Similarly, the average study population in the Blue Mountain Eye Study 14 was 66.

CONCLUSION

POAG has been rightly labelled as a silent thief of sight due to the initial symptomless manner in which it permanently affects eyesight.

Unawareness and ignorance of the general population must be alleviated regarding the nature of POAG. Its familial nature must be understood. To improve POAG incidence, population-based screening of POAG is not feasible. Still, opportunistic screening of POAG can be done in outpatient departments, especially in elderly, diabetic, hypertensive, and myopic populations, when presenting with complaints of reduced vision.

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