

A Prospective Study of Patients with Pseudoexfoliation Glaucoma and Its Management in a Tertiary Care Centre in South India

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ABSTRACT

BACKGROUND

Pseudoexfoliation syndrome is the most common identifiable cause of open angle glaucoma worldwide. Pseudoexfoliation glaucoma develops in 50 % of patients with pseudoexfoliation syndrome. The purpose of this study was to assess the clinical profile, intraocular pressure (IOP), gonioscopic findings, disc changes and need for medical or surgical line of management for the control of pseudoexfoliation glaucoma.

METHODS

It was a prospective hospital based interventional study of 68 consecutive patients diagnosed with pseudoexfoliation glaucoma, who presented to the glaucoma clinic at a tertiary care centre from Nov 2017 to Mar 2019.

RESULTS

68 patients diagnosed with pseudoexfoliation glaucoma were evaluated during the study period from November 2017 to March 2019. Male predominance of 43 (63 %) was noticed. Mean age group of study population was 68 years with 44 (65 %) of patients in age group of 61 – 75 years. 55 cases had bilateral pseudoexfoliation. 85 (69 %) eyes had a pressure of > 21 mm of Hg. 97 (79 %) eyes had open angles, 4 (3 %) occludable angles, 22 (18 %) had closed angles. 4 (3 %) of eyes had cup disc ratio < 0.5, 49 (40 %) eyes had cup disc ratio of 0.5 - 0.7, 64 (52 %) had > 0.7 cupping. 38 (31 %) eyes were controlled on medical therapy with topical antiglaucoma medications. In 14 (11 %), eyes were treated with Nd: YAG PI (neodymium-doped yttrium aluminium garnet peripheral laser iridotomy) with medical treatment, 59 (48 %) eyes were taken up for triple procedure. 10 (8 %) eyes could not be controlled using medical therapy and had to be taken for surgical treatment.

CONCLUSIONS

Pseudoexfoliation glaucoma leads to irreversible visual loss if high IOP is not treated leading to glaucomatous optic nerve damage and visual field loss. The response to medical therapy is poor and needs surgical intervention.

KEYWORDS

Pseudoexfoliation Glaucoma, Intraocular Pressure, Optic Nerve Damage, Dandruff Like Material

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BACKGROUND

Pseudoexfoliation Glaucoma is an age-related disorder with most cases occurring in late 60s and early 70s.¹ It is characterised by presence of white dandruff like pseudoexfoliation material at the pupil border on undilated examination, or anterior lens capsule on dilated examination, or on the trabecular meshwork on gonioscopy, with or without Sampaolesi's line and pigment deposition in the angle in patients, with intraocular pressure of 21 mmHg or greater in presence of characteristic glaucomatous optic nerve changes with or without glaucomatous visual field defects.² About 40 % of exfoliation syndrome patients develop glaucoma and it is the most common identifiable cause of open angle glaucoma worldwide.¹ A less common mechanism of glaucoma in patients with pseudoexfoliation is acute or chronic angle closure glaucoma.³

It is an age related microfibrilopathy with varied prevalence worldwide.^{2,4} It is associated with mutations in *LOX1* gene (15q24) which codes for elastic fibre components of extracellular matrix.⁵ Most cases of exfoliation syndrome were diagnosed in Scandinavia.³ The prevalence in the rural population of south India was 3.8 % and glaucoma was present in 13 % of them.⁴ It occurs equally in both genders.³ It can occur unilaterally or bilaterally.¹ Renewed interest in this long-known entity is due to poor prognosis, higher fluctuations in IOP levels and more severe optic nerve and visual field damage when compared to primary open angle glaucoma⁶. It often does not respond to medical therapy and requires early surgical intervention.

METHODS

It was a hospital based interventional, prospective study carried out from November 2017 to May 2019, where 68 patients diagnosed with pseudoexfoliation glaucoma attending glaucoma department in a tertiary care centre were evaluated by the same surgeon. Patients were diagnosed with pseudoexfoliation glaucoma on the basis of presence of pseudoexfoliation on slit lamp examination before and after pupillary dilatation and presence of typical glaucomatous optic nerve head damage or/and glaucomatous visual field damage, where increased intraocular pressure (> 21 mm of Hg) is considered a risk factor. Those patients willing to give written informed consent were included in our study.

Patients not willing to give written informed consent, known cases of primary open angle glaucoma (POAG), primary angle-closure glaucoma (PACG), pigment dispersion syndrome, secondary glaucoma due to systemic or ocular pathology, history of ocular trauma, uveitis, capsular delamination, patients with co-morbidities of the retina, patients who were non complaint to treatment and/or who did not follow up regularly for 12 months were excluded from the study. Relevant ocular and medical history, best corrected visual acuity on Snellen's, pupillary reaction and slit lamp was done. Intraocular pressure was recorded by Goldmann applanation tonometry. Gonioscopy was performed on all subjects using a Sussman Type 4 mirror

handheld gonioscope. An occludable angle was diagnosed if the pigmented trabecular meshwork was not visible in more than 180° of the angles in dim illumination. Subjects with open angles had their pupils dilated with 5 % phenylephrine and 1 % tropicamide eye drops. Slit lamp evaluation was done to look for deposits on pupil border on undilated examination, anterior lens capsule on dilated examination on lens zonules through patent peripheral iridotomy (PI) and on the trabecular meshwork on gonioscopy, with or without Sampaolesi's line. Cataract grading by LOCS II system was done in those patients where the pupil dilated to 6 mm or more. Stereoscopic evaluation of the fundus and the optic disc with + 90 D /+ 78 D lens was performed. Glaucomatous optic nerve damage was diagnosed based on a combination of one or more of the following features: (i) vertical cup - disc ratio of 0.7 or more (physiological cups were excluded); (ii) vertical cup - disc asymmetry of 0.2 or more between the two eyes; (iii) characteristic glaucomatous excavation of the cup. Visual field changes were looked for when a reliable visual field was obtained.

Aim was to reduce the intraocular pressure to the "Target" pressure range which prevented further glaucomatous damage based upon their disc changes and visual field changes. Diagnosed cases of pseudoexfoliation glaucoma with occludable angles were taken up for laser peripheral iridotomy. Pseudoexfoliation glaucoma with open angles undergoing medical therapy with aqueous suppressants or/and prostaglandin analog or/and miotic agents was followed up at the end of one month and every three months for one year. Patients in whom the intraocular pressure remained too high despite maximally tolerated medical therapy, progressive glaucomatous damage on maximum medical therapy, patient unable to tolerate or adhere to medical regimen were taken up for trabeculectomy alone or with combined small incision cataract extraction. Patient were followed up as followed up on post-operative day 1, after one month following surgery and every three months for one year. At each visit, patient's complaints, slit lamp examination, vision by Snellen's and intraocular pressure by Goldman's Applanation tonometer was carried out. Visual fields and gonioscopy were done at 6-month intervals.

Inclusion Criteria

Patients were diagnosed with pseudoexfoliation glaucoma on the basis of presence of pseudoexfoliation on slit lamp examination before and after pupillary dilatation and presence of typical glaucomatous optic nerve head damage or/and glaucomatous visual field damage, where increased intraocular pressure (> 21 mm of Hg) is considered a risk factor. Those patients willing to give written informed consent were included in our study.

Exclusion Criteria

The following patients were excluded from our study:

1. Patients not willing to give written informed consent.
2. Known cases of primary open angle glaucoma (POAG).

- Known cases of primary angle closure glaucoma (PACG).
- Known cases of all secondary glaucoma due to systemic or ocular pathology.
- Patients with history of ocular trauma.
- History of uveitis
- Known cases of capsular delamination.
- Known cases of pigment dispersion syndrome.
- Patients with co-morbidities of the retina.
- Patients who were non complaint to treatment and/or who did not follow up regularly for 12 months.

Statistical Analysis

Based on the previous study by Rao V, Doctor M, Rao G. after rendering treatment, intraocular pressure was 16.50 ± 1.32 mm of Hg, the sample size calculation is:

$$n = (Z\alpha^2\sigma^2) / d^2$$

Where z_α = standard table value for 95 % CI= 1.96,
 σ = standard deviation= 1.32 and d = 0.5 (expected precision)
 $n = 26.7 = 27$
 Lost to follow up 10 %, hence n = 30.

Data were analysed using Microsoft Excel data analysis tool. Analysis of variance (ANOVA): Two Factor without replication test was run to see the significance F value to determine if the Intraocular pressure changes after medical treatment and/or surgery were significant to reduce disease progression. Test to detect disproportion in the sex distribution of patients was used. Patients intraocular pressure ranges were detected and categorized depending upon the distribution of pseudoexfoliation (PXF) material on ocular structure in both left and right eye. Data of all patients was analysed across various parameters such as gonioscopy findings, disc cupping. Changes in intraocular pressure were tracked across various time intervals (1 month, 3 months, 6 months, and 12 months) when patients were on medical treatment or after surgical treatment. A (P < 0.001) was considered as statistically significant for all tests.

RESULTS

68 consecutive patients with pseudoexfoliation glaucoma, who presented to the glaucoma clinic at a tertiary care centre were evaluated. Out of the 68 patients studied, 43 (63 %) were males and 25 (37 %) were female. The mean age group of study population was 68 years. 44 (65 %) patients were in the age group of 61 – 75 years, 13 (19 %) between 45 – 60 years and 11 (16 %) belonged to age group of 76 - 90 years. 55 (81 %) presented with bilateral pseudoexfoliation glaucoma while only 7 (10 %) in right eye (RE) alone and 6 (9 %) in left eye (LE) alone. 85 (69 %) eyes had a baseline pressure of > 21 mm of Hg, 38 (31 %) eyes were in normal range of 10 – 21 mm of Hg.

Majority of cases that is, 38 (62 %) left eyes, 47 (76 %) in right eye had pseudoexfoliative material deposited over

the pupil margin and anterior capsule of lens followed by deposition of fibrillary material on pupil margin alone i.e. 16 (26 %) in left eye and 10 (16 %) in right eye. (TABLE 1)

		IOP (mm of Hg)			
		< 10	10 - 21	> 21	
PXF material - LE	Endothelium, Pupil	0	0	1	1 (2 %)
	Endothelium, Pupil, Lens	0	0	1	1 (2 %)
	Lens	0	1	0	1 (2 %)
	Pupil	0	6	10	16 (26 %)
	Pupil, Lens	0	13	25	38 (62 %)
	Pupil, Lens, Angle	0	0	3	3 (5 %)
	Pupil, Lens, Angle, Zonules	0	0	1	1 (2 %)
LE Total	0	20	41	61	
PXF material - RE	Endothelium, Pupil	0	0	0	0 (0 %)
	Endothelium, Pupil, Lens	0	0	1	1 (2 %)
	Lens	0	0	1	1 (2 %)
	Pupil	0	4	6	10 (16 %)
	Pupil, Lens	0	14	33	47 (76 %)
	Pupil, Lens, Angle	0	0	2	2 (3 %)
	Pupil, Lens, Angle, Zonules	0	0	1	1 (2 %)
RE Total	0	18	44	62	

Table 1. Distribution of IOP and PXF Material on Ocular Structure (LE and RE)

97 (79 %) eyes had open angles, 22 (18 %) had closed angles, 4 (3 %) eyes had occludable angles. 4 (3 %) eyes had cup disc ratio < 0.5, 49 (40 %) of eyes had cup disc ratio of 0.5 - 0.7, 64 (52 %) had > 0.7 cupping, 6 (5 %) had no view of disc due to cataract. 38 (31 %) eyes were controlled on medical therapy with topical antiglaucoma medications. 14 (11 %) eyes were controlled with Nd: YAG PI and medical treatment, 59 (48 %) eyes were taken up for triple procedure (trabeculectomy with small incision cataract surgery with intraocular lens implantation). 2 (2 %) eyes were treated with cataract surgery with rigid IOL and surgical peripheral iridotomy followed by topical antiglaucoma medication. 10 (8 %) eyes were converted from medical to surgical treatment due to failure of medical treatment. (Chart 1)

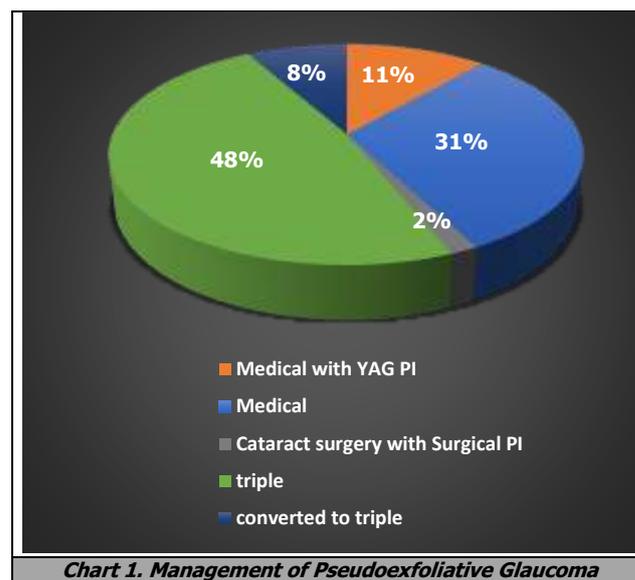


Chart 1. Management of Pseudoexfoliative Glaucoma

Medical Treatment

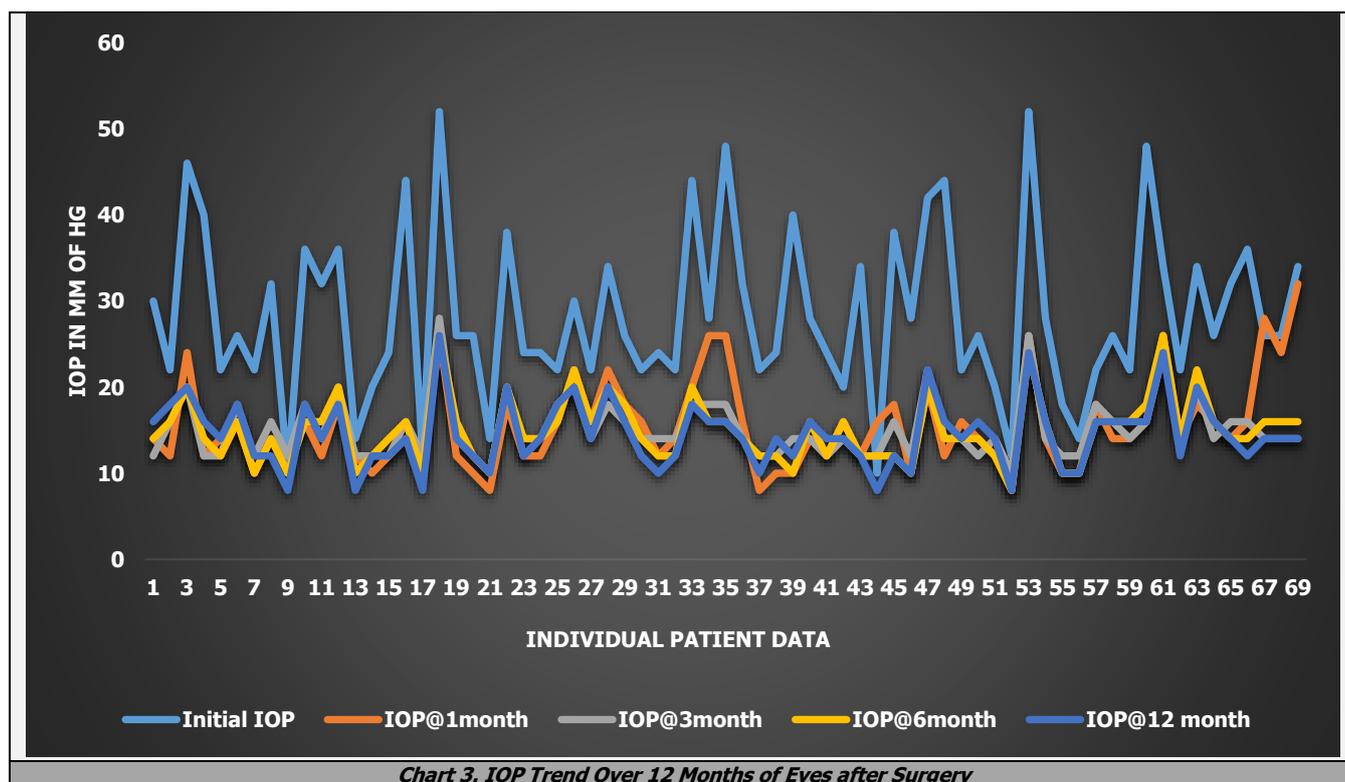
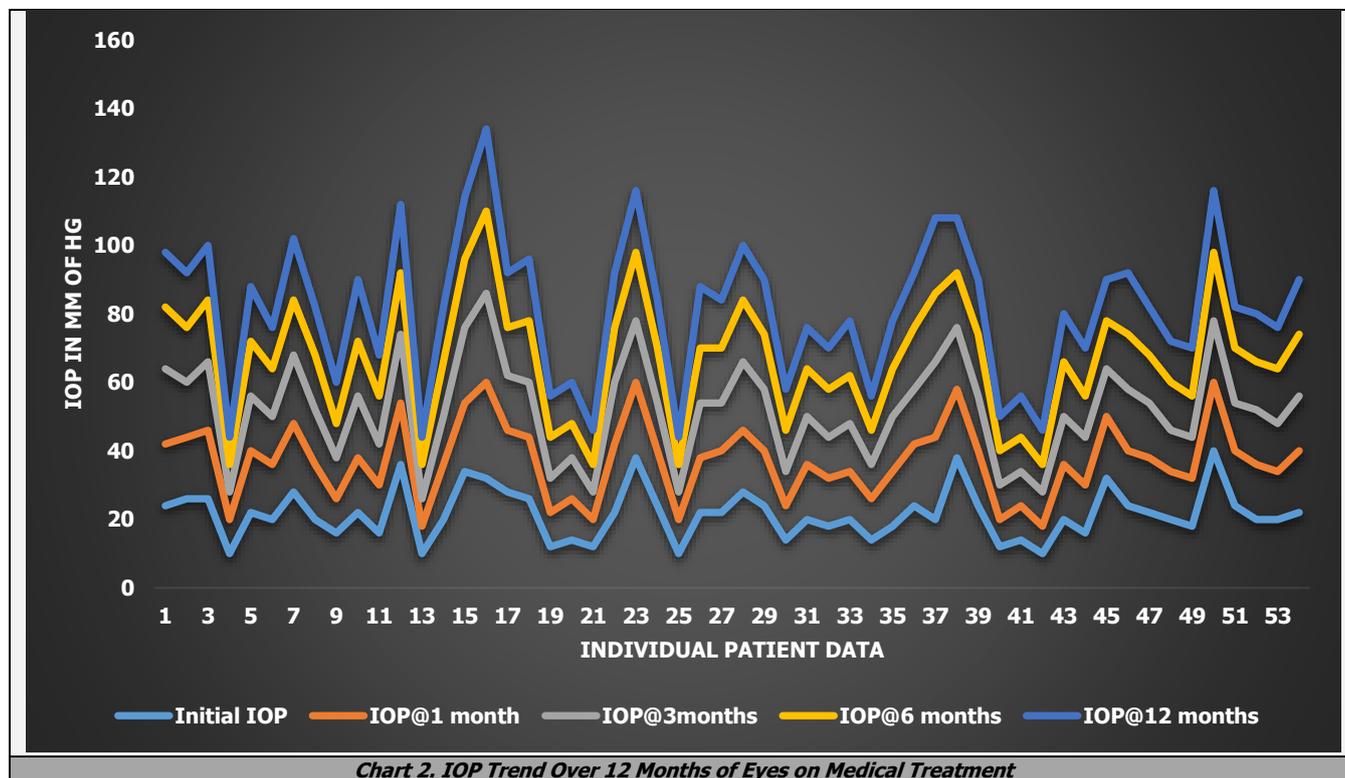
38 eyes responded well to topical antiglaucoma medication. 14 eyes had occludable / closed angles and were taken up for Nd YAG laser peripheral iridotomy on the same day as presentation, on subsequent gonioscopy angles were found to be open and pressure were controlled with topical

antiglaucoma medication. 2 eyes underwent cataract surgery with surgical peripheral iridotomy and were further managed with topical antiglaucoma medication.

In total, 54 (44 %) eyes were treated medically with topical antiglaucoma treatment. The mean intraocular pressure of the right eye and left eye was 22.1 mm of Hg and 21.1 mm of Hg respectively at presentation. The mean intraocular pressure at the end of 12 months for eyes on

medical therapy was 14.7 mm of Hg in right eye and 14.1 mm of Hg in left eye. The mean change in IOP was 7.4 mm of Hg and 7 mm of Hg in right eye and left eye respectively ($P < 0.001$, ANOVA: Two factor without replication test) which was statistically significant.

The trend of IOP at 1 month, 3-month, 6 month and 12 months is (CHART 2) as follows:



Surgical Treatment

59 (48 %) eyes presented with initial high IOP with advanced disc cupping. They were planned for triple procedure (trabeculectomy with small incision cataract surgery with rigid PCIOL) within a week of diagnosis, after reducing initial IOP.

10 eyes were converted to surgical management at a mean of 3 months from diagnosis, due to failure of control of IOP despite maximal tolerated medical therapy. The mean IOP at presentation was 28.4 mm of Hg for both eyes and at the end of 12 months after triple was 14.8 and 14.4 mm of Hg respectively for right eye and left eye. The mean decrease in IOP was 13.6 mm of Hg and 14 mm of Hg respectively for right eye and left eye ($P < 0.001$, ANOVA: Two factor without replication test) which is statistically significant.

The trend of IOP at 1 month, 3 months, 6 months and 12 months is (Chart 3) as follows.

DISCUSSION

Pseudoexfoliation syndrome is the most common identifiable cause of open angle glaucoma worldwide.¹ It has also been reported to be a risk factor for narrow angles and angle closure glaucoma.¹ It was first described in 1917 by Finnish ophthalmologist John Lindberg.^{2,3} Pseudoexfoliation is rarely seen before the age of 40, and its prevalence increases markedly with age.⁷ In studies carried out by Rao V. et al.⁷ Onochie C et al.³ Shazley.A. Tarek,⁸ H. Arvind et al.¹ the mean age of subjects was found to be 65.5 years. 60.8 ± 9.3 years, 68.15 years, 64.7 years respectively which corresponds to results of mean age of 68 years in our study. A male predominance of 63 % was seen in our study which is same as results obtained with Rao V. et al.⁷ and Onochie C.³ This could be attributed to higher levels of outdoor activities and occupational hazards to which men are exposed more than women. While Shazley A. Tarek⁸ and H. Arvind et al.¹ found no predilection towards either gender.

In study done by Rao A et al.⁴ 625 patients were having bilateral disease (1250 eyes) at presentation while 525 had unilateral disease at presentation. In our study, 55 (81 %) presented with bilateral pseudoexfoliation glaucoma while only 7 (10 %) in right eye alone and 6 (9 %) in left eye alone. In our study 85 (69 %) eyes had a baseline pressure of > 21 mm of Hg, 38 (31 %) eyes were in normal range of 10 – 21 mm of Hg. Majority of cases, in our study, presented with pseudoexfoliative material deposited over the pupil margin and anterior capsule of lens, that is, 38 (62 %) in left eyes, 47 (76 %) in right eye respectively followed by deposition of fibrillary material on pupil margin alone i.e., 16 (26 %) in left eye and 10 (16 %) in right eye.

Gonioscopic examination revealed open angle in 32 out of 50 subjects in study conducted by Rao V. et al.⁸ H. Arvind et al.¹ found 9 cases had open angles and 5 had occludable angles. Desai A et al.⁹ reported occurrence of angle closure was found to be 2.2 %. Prevalence of occludable angles varied from 9 % - 18 % in different studies. In study done by Rao A et al.⁴ glaucoma type was closed angle in 13 % eyes and 81 % presenting as open angle glaucoma.

In our study, 97 (79 %) eyes had open angles, 22 (18 %) had closed angles, 4 (3 %) eyes had occludable angles. Open angle glaucoma has been widely described as a result of accumulation of pseudoexfoliative material, which obstructs the trabecular meshwork,⁹ blockage of meshwork by pseudoexfoliation syndrome liberated pigment and concomitant primary open angle glaucoma.⁹ A number of mechanisms may create a tendency toward pupillary block and angle closure, which includes zonular weakness causing anterior movement of the lens iris diaphragm, lens thickening from cataract formation, increased adhesiveness of the iris to the lens due to exfoliative material and iris rigidity from hypoxia.

Eyes with closed and occludable angle were started on medical therapy and laser peripheral iridotomy was done to relieve/ prevent the pupillary block respectively. Fundus examination with +90D after dilatation of pupil with 1 % tropicamide and 5 % phenylephrine eyedrops revealed 4 (3 %) of eyes had cup disc ratio < 0.5 , 49 (40 %) of eyes had cup disc ratio of 0.5 - 0.7, 64 (52 %) had 0.7 - total cupping, 6 (5 %) had no view of disc due to cataract. Higher intraocular pressures and cup disc ratio at time of presentation may be due to late presentation and lack of awareness about the disease. Onochie C³ found a higher proportion of optic disc cupping and visual field damage was observed among pseudoexfoliation glaucoma patients in comparison to primary open angle glaucoma. Similar observation was made by Drosalum L et al.¹⁰

Regardless of its aggressive and often refractory course, medical or laser treatment is usually recommended as first line therapy^{2,11} before surgical management is planned. Medical management is same as for POAG and includes use of aqueous suppressants, prostaglandin analogues and miotic agents. Drug therapy is based upon target IOP to be achieved, cup disc ratio and Humphrey's visual field changes. The topical drug such as latanoprost, dorzolamide - timolol combination yield a good response in the first period of medical treatment. Preferred drug is prostaglandin agonist for initial medical treatment because of its high efficacy for lowering IOP and longer duration of action, which may be helpful in blunting pseudoexfoliation glaucoma associated diurnal pressure spikes.¹¹

Pseudoexfoliation glaucoma is usually recalcitrant to medical therapy. Alternate therapy is argon laser therapy with responses similar to that of filtering surgery. However, once affects laser trabeculectomy starts to wear off, patients with pseudoexfoliation glaucoma tend to demonstrate a more rapid IOP increase than POAG patients. There are indications that primary laser trabeculectomy has a higher success rate in pseudoexfoliation glaucoma than in primary open-angle glaucoma¹⁰ if medications and laser treatment do not control IOP adequately, a guarded filtration procedure may be performed.¹²

The most frequent incisional procedure done is trabeculectomy. In one study, the proportion of pseudoexfoliation glaucoma patients undergoing trabeculectomy was as high as 87.8 %.¹¹ Since pseudoexfoliation glaucoma was age related disease seen more commonly in older age group another good option is also to do combined trabeculectomy with cataract surgery.

Indication for filtering surgery includes late presentation with advanced disease, non-compliance to drug therapy or intolerance to medical therapy and inadequate IOP control despite maximal medical therapy.

In our study, 38 eyes responded well to topical antiglaucoma medication. 14 eyes had occludable/closed angles and were taken up for Nd YAG laser peripheral iridotomy on the same day as presentation, on subsequent gonioscopy angles were found to be open and pressure were controlled with topical antiglaucoma medication. 2 eyes underwent cataract surgery with surgical PI and were further managed with topical antiglaucoma medication.

In total, 54 (44 %) eyes were treated medically with topical antiglaucoma treatment.

- The mean intraocular pressure of the RE and LE was 22.1 mm of Hg and 21.1 mm of Hg respectively at presentation.
- The mean intraocular pressure at the end of 12 months for eyes on medical therapy was 14.7 mm of Hg in RE and 14.1 mm of Hg in LE.
- The mean change in IOP was 7.4 mm of Hg and 7 mm of Hg RE and LE respectively ($P < 0.001$) which was statistically significant.

59 (48 %) eyes presented with initial high IOP with advanced disc cupping. They were planned for triple procedure (trabeculectomy with small incision cataract surgery with rigid PCIOL) within a week of diagnosis, after reducing initial IOP.

10 eyes were converted to surgical management at a mean of 3 months from diagnosis, due to failure of control of IOP despite maximal tolerated medical therapy

- The mean IOP at presentation was 28.4 mm of Hg both eyes.
- The IOP at the end of 12 months after triple was 14.8 and 14.4 mm of Hg respectively for RE and LE.
- The mean decrease in IOP was 13.6 mm of Hg and 14 mm of Hg respectively for RE and LE respectively ($P < 0.001$) which is statistically significant.

Mietz et al.¹³ evaluated the trabeculectomy outcomes of 709 eyes from 506 patients with variable types of glaucoma at the end of a mean 27.9 month follow-up period. They concluded that there was no difference in surgical success between pseudoexfoliation glaucoma and POAG cases. Törnqvist and Drolsum¹⁴ reported that in 43 % of cases with POAG and 64 % of patients with PXG, no additional treatment was required for 10 year after trabeculectomy.

Fernández et al.¹⁵ found surgical success rates of 99.3 % at the end of 1 year, 90.6 % at the end of 5 year, 76.7 % at the end of 10 year, 70.1 % at the end of 15 year, and 45.9 % at the end of 20 year in 956 eyes that had undergone trabeculectomy and been followed for 3 – 20 years. This study included POAG, PXG, and primary angle closure glaucoma (PACG) patients.

Antifibrotic agents such as Mitomycin C or 5 fluorouracil are commonly used to enhance the success rate of this procedure.^{2,16} In our study, majority of patients were taken up for trabeculectomy with cataract surgery with mitomycin C. It has now been widely considered as the gold standard surgery in advanced or progressing PXG.¹⁷ Furthermore,

exfoliation patients may progress at a lower rate than POAG patients after filtering surgery.^{14,17,18}

The major drawback of our study was that we were unable to document reliable visual fields in many of our patients with visually significant cataract. Hence, visual field could not be used as a reliable indicator of disc damage caused by raised IOP. Therefore, these data were ignored in the analysis. Another major drawback of our study was we were unable to document reliable visual fields due to visually significant cataract. Visual fields could not be used as a reliable indicator of disc damage caused by raised IOP. However, the optic disc was carefully evaluated in all subjects and as disc changes usually precede visual field loss, it is unlikely that the results were altered significantly.

CONCLUSIONS

Pseudoexfoliation glaucoma has a higher prevalence in older population with higher IOP levels and more severe optic nerve damage. If aggressive therapy is not advocated it can progress leading to visual impairment. Therefore, a careful assessment is warranted, and regular follow-up of patients is desired to minimize the extent of optic nerve damage. The response to medical therapy is poor and needs early surgical intervention.

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

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