

Complications of Pseudoexfoliation Syndrome with Special Reference to Cataract Surgery in a Teaching Institute in Western Maharashtra.

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ABSTRACT

Background: The purpose of the study is to assess demographic distribution, the incidence of glaucoma and complications during small incision cataract surgery and to assess the post-operative outcome in patients with Pseudoexfoliation syndrome (PEX), in a teaching institute in Western Maharashtra. **Methods:** Prospective study of patients, with PEX presenting to the Ophthalmic outpatient department of a teaching institute in India from Aug 2015 to May 2017. Small incision cataract surgery with intraocular lens implantation was performed on those with cataract. Intraoperative and postoperative complications and incidence of glaucoma were evaluated, as was final visual outcome. **Results:** The prevalence of pterygium was found to be 12.5%. It was more among the younger age group ($p=0.001$), those working outdoors ($p=0.001$) and those belonging to low income group ($p=0.001$). It was found to be equally distributed among the two sexes and also among tobacco smokers and non-smokers. Milder forms of the disease were found among low income groups and non-smokers whereas severer forms were found among people who worked outdoors. **Conclusion:** Pseudoexfoliation is a well-known disease of the elderly with an associated risk of developing secondary open angle glaucoma and complications during cataract surgery. The long-term control is important, as the disease has varied manifestations; medical treatment is effective only in early stages. The incidence of complications during cataract surgery has reduced with the advancement in cataract extraction techniques and better pre-operative evaluation and diagnosis. However, there is no substitute for the operating surgeon's skills. The major problem of inadequate pupillary dilatation remains, which can be effectively, tackled intraoperatively by various methods. In the hands of a competent surgeon, a good postoperative visual recovery is the rule today in most of the patients with pseudoexfoliation.

Keywords: Pseudoexfoliation syndrome (PEX), Pseudoexfoliative Glaucoma, prospective study, cataract surgery, intraoperative dilatation.

INTRODUCTION

Pseudoexfoliative syndrome (PEX) is a relatively common but easily overlooked cause of chronic open angle glaucoma. The prevalence of pseudoexfoliation varies in different populations ranging from 3.8% in a south Indian study to 6.0% in another rural population of southern India.^[1,2] A prevalence of 6.45% was reported in the Pakistani population.^[3] When an eye with PEX develops secondary glaucoma due to blockage of trabecular meshwork the condition is referred to as PEX glaucoma or glaucoma capsulare.^[4] It is a complex degenerative disturbance not very well understood.

Although no clear hereditary pattern has been established, PEX is associated with gene locus at 2p16.4. Nearly all pedigrees in the literature, and reports of PEX families in Iceland and Canada by Dhamji et al, suggest maternal transmission, raising the possibilities of mitochondrial inheritance, X-linked inheritance, and autosomal inheritance. It is possible that a combination of genetic and nongenetic factors may be involved in the etiology and pathogenesis of PEX, i.e. it may be a multifactorial disorder.^[5] External environmental factors like excess sun exposure has also been implicated for PXE.^[6]

Pseudoexfoliation is characterized by production and progressive accumulation of fibrillo-granular extra cellular matrix material in many ocular tissues. Light grey or white dandruff like flakes are most noticeable on pupillary margin and anterior lens capsule, but also on both surfaces of iris, zonules and ciliary body, anterior hyaloid, trabecular meshwork,

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and endothelial surface of the cornea. Its origin is multifocal and secondary to an abnormal basement membrane produced by aging cells. It is the most common identifiable cause of secondary glaucoma worldwide.^[7-9] It leads to both open and closed angle glaucoma, has been causatively associated with cataract, lens dislocation and central retinal vein occlusion (CRVO).^[7] Accumulation of locally produced PEX material in the juxtacanalicular tissue (JCT), followed by dysfunction of endothelial cells and disorganization of JCT and Schlemm's canal, appear to be causative factors in the development of a special type of secondary open-angle glaucoma in PEX syndrome.^[11] The amount of exfoliative material present within the JCT correlated with the severity of glaucoma, the elevation of intraocular pressure and axon counts of the optic nerve.^[12]

Glaucoma develops in up to 50% of patients with PEX and tends to be more difficult to control than primary open angle glaucoma, with higher intraocular pressures and a poorer response to medication.^[12]

Eyes with PEX have increased frequency of complications at the time of cataract extraction such as zonular dialysis, posterior capsular rent and vitreous loss.^[7] Pupillary diameter and zonular fragility have been suggested as the most important risk factors for capsular rupture and vitreous loss.^[9] The present study was undertaken to assess cataract surgery related complications, outcomes and glaucoma associated with PEX.

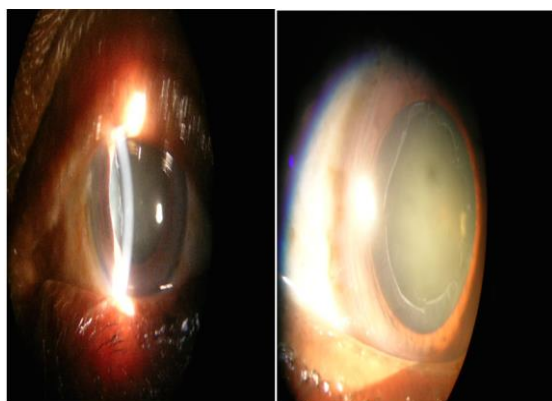


Figure: Slit Lamp Photograph of Left Eye of Patient with Pseudoexfoliation Syndrome

MATERIALS AND METHODS

This prospective study was carried out at Hridayasamrat Balasaheb Thakeray Medical College & Dr R. N. Cooper Hospital Mumbai. 84 patients with Pseudoexfoliative syndrome were selected from the hospitals outpatient department.

The study period was from August 2015 to May 2017. All patients with Pseudoexfoliative material on iris or lens capsule on clinical slit lamp biomicroscopic examination and those with cataract

who were found to have Pseudoexfoliation were included in the study.

Patients with congenital cataract, history of trauma, pre-existing iritis or iridocyclitis, or complications unrelated to PEX were excluded.

The patients underwent a thorough ophthalmic examination as follows:

Visual acuity using Snellen's chart, unaided as well as best corrected.

Intra-ocular pressure measured with Applanation tonometry.

Slit lamp examination with special attention to the following:

- Anterior chamber depth
- Integrity of zonules (phacodonesis)
- Maximal Pupillary dilatation
- Pseudoexfoliative material on the corneal endothelium, lens capsule, pupil, angle or iris
- Grade of cataract

Indentation gonioscopy was done using Goldmann two mirror gonioscopes. Angle was graded according to Schaffer's grading system.

Fundus was examined with slit lamp biomicroscopy using 90 D lens and indirect ophthalmoscope with 20 D to note the cup-disc ratio, depth of optic cup, and neuroretinal rim.

Automated perimetry was advised if required when glaucoma was suspected on basis of IOP and optic nerve head changes. It was deferred if patient had poor vision or advanced cataract.

Cataract surgery was advised for those with diagnosed cataract.

Preoperative preparation was carried out as follows:

- Keratometry
- Axial length calculation (name of machine)
- Intraocular lens (IOL) power calculation by A-scan biometry.
- Systemic and local antibiotics started on the day prior to surgery
- Pre-operative dilatation was done with tropicamide 0.8 % and phenylephrine 5 % eye drops instilled every 15 minutes starting one hour prior to surgery
- Flurbiprofen 0.03 % eye drops were instilled every 15 minutes to maintain the pupillary dilatation
- Pupil was considered small or non-dilating if pupillary diameter was less than 6 mm on slit lamp examination

Patients underwent small incision cataract surgery (SICS) with intraocular lens (IOL) implantation by the faculty or senior registrar. Intra-operative pupillary dilatation, if required, was done by sphincterotomies and intra-cameral adrenaline. Intra-operative complications like zonular dialysis, posterior capsular rent and vitreous loss were noted. Positioning of IOL was also noted.

Post-operative regime and follow up was as follows:

- Locally antibiotic-steroid combination eyes drops 6 times a day for 2 weeks and then tapered over a period of one month
 - Oral antibiotics continued for five days
 - Other necessary treatment like anti- glaucoma medications and oral steroids were given as per the individual patient requirement and responses to surgery
 - Post-operative visual recovery and inflammation were assessed on day one
- Post-operative inflammation was graded as follows:

Grade	Inflammation	Aqueous flare
Grade 0	<5 cells	Absent
Grade 1	5-10 cells	Just detectable, faint
Grade 2	11-20 cells	Iris details clear
Grade 3	21-50 cells	Iris details hazy
Grade 4	50 cells	Intense fibrinous exudates
Grade 5	Hypopyon	

- Patients were followed up on day 8 and one month after surgery
- Patients were asked to report immediately in case of any untoward symptoms or diminution of vision
- Patients diagnosed with glaucoma were followed up at one week, one month and then as required
- Postoperative refraction, as required was given after one and a half month for those operated for cataract

RESULTS

Table 1: Distribution of Age

Age group (years)	No. of patients	Percentage (%)
<50	3	3.57
50-59	11	13.09
60-69	28	33.33
70-79	35	41.66
81-90	7	8.33

Table 2: Sex distribution

Sex	No. of patients	Percentage (%)
Female	44	52.38
Male	40	47.61
Total	84	100

Table 3: Unilateral or bilateral PE

	No. of patients	Percentage (%)
Unilateral	39	46.42
Bilateral	45	53.57
Total	84	100

Table 4: Incidence of glaucoma in patients with PEX

Glaucoma	No. of patients	Percentage (%)
Present	10	11.90
Absent	74	88.09
Total	84	100

Note: Of the 10 patients detected with glaucoma 6 were males and 4 were females.

Table 5: Type of glaucoma

Glaucoma	No. of patients	Percentage (%)
Narrow angle	5	50
Open angle	5	50
Total	10	100

Total number of cataract surgeries done by SICS- 75
One of the patients underwent SICS with Trabeculectomy.
Intra-operative pupillary dilatation done in- 20

Table 6: Methods of intra-operative pupillary dilatation used in the patients undergoing cataract surgery.

Intra-op pupillary dilatation	No. of patients	Percentage (%)
Sphincterotomy	7	9.09
Adrenaline	12	15.9
Mechanical stretching	5	6.81
None required	55	79.54
Total surgeries	75	100

Note: More than one method was used in three patients. Hence the above result.

Table 8: Intra-complications during cataract surgery.

Complications	No. of patients	Percentage (%)
Rupture of PC	3	4
Vitreous loss	9	12
Zonulodialysis	14	18.66
No complications	58	77.33
Total surgeries	75	100

Note: There were intra-operative complications in 17 patients. 9 had more than one complication.

Table 9: Postoperative visual recovery

BCVA	Day1 (%)	8mDay (%)	1 Month (%)
≥6/12	30(40)	47(62.66)	55(73.33)
6/36-6/18	32(42.66)	19(25.33)	14(18.66)
6/60-3/60	5(6.66)	9(12)	6(8)
<3/60	8(10.66)	0	0

Table 10: Post-operative inflammation on day 1

Grade	No. of eyes (%)
0	48 (64)
1	15(20)
2	7(9.33)
3	3(4)
4	2(2.66)
Total eyes	75

DISCUSSION

Pseudoexfoliative syndrome is a disease that has increased incidence with advancing age.^[2,13] This study shows that of the patients diagnosed to have PEX, those between 70 to 80 years of age (41.66%) were affected more than the younger age groups [Table 1]. There was a gradual increase in the

number of patients affected as the age increased. Significantly fewer patients were observed to have the disease after 80 years of age. This may be due to decreased attendance of this group of patients in the OPD.

These findings are in accordance with other published reports. According to Thomas R et al, the prevalence of PEX increased with increasing age: 3.01% in those 40 years of age or older and 6.28% in those 60 years of age or older.^[14] In Norway, Aasved reported prevalence of PEX of 0.4% between 50 to 59 years and 7.9% between 80 to 89 years. Mean age was 69-75 years.^[15]

Varied sex distribution has been reported in patients with PEX. Literature reports a higher incidence in females.^[4] According to Jeng SM et al 78% patients with PEX were females.^[16] According to Kozart&Yanoff, PEX is 3 times more common in females.^[17] Some studies have however reported no appreciable sex difference.^[1,18] or more prevalence in males.^[2]

The present study shows that the females (52.38%) were affected almost as equally as males (47.61%) [Table 2]

The presentation of PEX is usually bilateral. However the changes in one eye may precede the other. According to Puska P.M. et al within 10 years of diagnosis 38% of unilateral cases become bilateral.^[19] According to Becker Shaffer one third to one half of the cases of PEX are unilateral at detection but 14 to 43% of unilateral cases become bilateral over 5-10 years.^[13] The Blue Mountains Eye Study showed that the proportion of subjects with bilateral involvement increased markedly with age, from 0% of subjects aged younger than 60 years to 75% of subjects aged 80 years or older.¹⁸ According to H Arvind et al, PEX is unilateral in 49.1% & bilateral in 50.9%.^[1]

This study shows that PEX was bilateral in 53.57% of cases and the rest were unilateral with no evidence of PEX in the other eye even on gonioscopy.[Table 3]

Though PEX is more common in women, the risk of glaucoma is however higher in males. Of the ten patients detected with glaucoma six were males and four were females in this study. [Table 4]

Varied reports from different authors have reported incidence of glaucoma in PEX. Kozart&Yanoff reported glaucoma was present in 7% of the 100 patients of PEX in Philadelphia.^[17] H Arvind et al reported that pseudo exfoliative glaucoma was present in 13%.^[1] According to Blue Mountain Eye Study, glaucomatous damage was present in 14.2% eyes with PEX compared to 1.7% eyes without PEX.^[18]

According to this study, about 13 patients had high intraocular pressures (>20 mmHg), 7 patients had occludable angles, and 10 patients had pseudo exfoliation glaucoma.

Pseudo exfoliation is the most common identifiable cause of secondary open angle glaucoma worldwide. However PEX can also coexist with narrow angles contributing to glaucomatous damage. According to H Arvind et al, 14.8% of the PEX patients had occludable angles.^[1]

In this study, only 10 of the 84 patients were found to have glaucoma based on their IOP, disc changes and visual field defects. Five of them had narrow angles and five had open angles.[Table 5]

One of them had advanced narrow angle glaucoma with significant cataract and hence was posted for cataract extraction with intraocular lens implantation and trabeculectomy in the same sitting. The pressures dropped and were well controlled at 1 month follow up without any medication with a mean IOP of 19 mm Hg. The BCVA was 6/24 (partial).

The rest of the patients had mild to moderate glaucomatous damage with a mean IOP of 25 mm Hg. All of them were started on timolol maleate 0.5% eye drops twice a day and pressures were monitored. They underwent small incision cataract extraction. This modality of surgery was selected since it is a teaching hospital and all surgeons are equality proficient and trained to perform it. The intraocular pressures were maintained after the surgeries and four patients had to continue timolol maleate eye drops postoperatively. They were asked to follow up every month after the first month for monitoring of the intra-ocular pressures. However a longer follow up is essential to see the efficacy and long term control by anti-glaucoma medications as pseudo exfoliative glaucoma is said to be refractory to topical therapy in later stages.

Cataract surgery in pseudo exfoliation is considered to be difficult due to the associated risks of zonulodialysis, posterior capsule rupture and vitreous loss. Inadequate pupillary dilatation adds to the surgeon's woes. It warrants more skill and care during the surgery. In spite of the precautions, complications do occur, even in best of the hands due to the pathology inherent to the disease.

Various workers have reported different rates of complications.

According to Lumme et al, occurrence of vitreous loss was fourfold, and the need to use an anterior chamber intraocular lens instead of a posterior chamber lens because of loss of capsular support was tenfold as compared to eyes without PEX.^[20]

According to Naumann GO et al, the incidence of vitreous loss due to either rupture of zonules or posterior capsule was 11.1% in eyes with PES and 1.6% in eyes without PEX, a sevenfold increase that was statistically significant.^[21] On the other hand, Shastri L. and Vasavada A. noted that the intraoperative performance of Indian eyes with pseudoexfoliation was comparable to that in normal eyes apart from a higher flare response.^[22] According to Droloum L, Haaskjold E et al,

postoperative iritis, cellular precipitates were demonstrated in 16.2% and 11% respectively in eyes with PEX as compared to 3.8%, 3.2% in non PEX group. The frequency of an inflammatory reaction was highly correlated to small pupil size during operation in both groups.^[23]

We observed that in the patients with a postoperative inflammation of grade 2 or more, only one patient had good intraoperative pupillary dilation (better than 6mm).

In this study of the 75 patients who underwent SICS, 20 patients (26.66%) had insufficient pupillary dilation of 6 mm or less. [Table 6,7] They were all benefited by intraoperative pupil dilatation methods, which facilitated easier nucleus delivery into the anterior chamber, cortical clean-up and intra-ocular lens implantation. In the rest, the pupil dilated well.

Sphincterotomies, usually three in number were done for 7 patients undergoing SICS in very small pupils. Although there was slightly more inflammation in the immediate postoperative period following these methods, it was effectively controlled by use of topical steroids instilled every hour in the waking hours for one or two days. Thus, these methods are quite useful and should be carried out whenever required so as to ensure safety during cataract surgery, lest it may result in more postoperative inflammation due to increased iris handling or improper cortical clean up.

In one study, it was shown that occurrence of vitreous loss was fourfold, and the need to use a scleral fixated intraocular lens instead of a posterior chamber lens because of loss of capsular support was tenfold in eyes with exfoliation as compared to those without exfoliation.^[20]

According to Naumann GO, the incidence of vitreous loss was 11.1% in eyes with PEX and 1.6% in eyes without PEX, a sevenfold increase that was statistically significant.^[21]

The complications encountered are detailed as follows.[Table 8,9] Posterior capsular rent in 3 cases (4%). Two were associated with vitreous loss requiring limited vitrectomy. In one, the PCIOL was put in the sulcus, a scleral fixated lens was used in the second, while the third had to be left aphakic.

Overall 9 cases (12%) were associated with vitreous loss due to large posterior capsule rupture or zonulodialysis. It was effectively managed by vitrectomy. A PCIOL in sulcus was placed in one, a scleral fixated lens was placed in five and three were left aphakic.

Zonulodialysis occurred in 14 cases (18.66%). 7 were also associated with significant vitreous loss. 3 were left aphakic and 4 had a SFIOL inserted and PCIOL could be inserted in the rest.

The postoperative recovery was uneventful except for the initial inflammation.

On day 1:[Table 9]

30 patients (40%) achieved a BCVA of 6/12 or better.

32 patients (42.66%) had a BCVA of 6/18 to 6/36.

2 patients had BCVA 6/24p and 6/60 due to advanced glaucomatous damage

At the end of one month:

Of the 4 patients left aphakic three had BCVA 6/60 at the end of one month. All of them had been associated with intra-operative complications and post-operative inflammation.

Of The 5 patients with SFIOL, one had BCVA of 6/60 and others between 6/12 and 6/36 at the end of one month.

Of the 9 patients with vitreous loss only one had a BCVA of 6/9. The rest had a BCVA between 6/36 and 6/60.

CONCLUSION

Pseudoexfoliation is a well-known entity associated with glaucoma and complications during cataract surgery. The present study has pointed out that it is a disease of the elderly with an associated risk of developing secondary glaucoma. The progression of glaucoma can be retarded by initiating appropriate anti-glaucoma therapy, at least in the initial stages. Its long term control is known to be difficult and these patients need to be followed up regularly. Medical treatment is effective initially, followed up with trabeculectomy if required. The incidence of complications during cataract surgery has reduced with the advancement in cataract extraction techniques and better pre-operative evaluation and diagnosis. Complications can be effectively managed due to the availability of better operating microscopes, vitrectomy machines, scleral fixated intraocular lenses. However, there is no substitute for the operating surgeon's skills. The major problem of inadequate pupillary dilatation remains, which can be effectively, tackled by various intraoperative pupillary dilatation methods without compromising the postoperative recovery. In the hands of a competent surgeon, a good postoperative visual recovery is the rule today in most of our patients with pseudoexfoliation.

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