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Original Article

Comparison of Manual Small Incision Cataract Surgery between the Patients of Cataract with Pseudoexfoliation and Those without Pseudoexfoliation

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ABSTRACT

Purpose: To compare the risk factors, intraoperative complications and postoperative visual outcome between patients of cataract with pseudoexfoliation (PXF) and those without pseudoexfoliation undergoing manual small incision cataract surgery (MSICS) with posterior chamber intra ocular lens implantation.

Study Design: Quasi experimental study.

Place and Duration of Study:

Methods: Fifty-six eyes of patients with cataract and PXF and 56 eyes of patients with cataract without PXF were recruited. Complete history and ocular examination was performed. Pre-operative pupillary dilation of the eye to be operated was measured. Manual small incision cataract surgery was performed with implantation of posterior chamber intraocular lens. Patients were examined on 1st post-operative day then on45th day. Risk factors for per-operative complications and visual outcomes were compared between two groups.

Results: Mean age in the PXF group was 55 ± 5 years and in the control group was 45 ± 5 years. PXF group showed female preponderance. Preoperative risk factors (higher in the PXF group) included poor pupillary dilatation, iridodonesis, zonular weakness/phacodonesis and subluxation. PXF was associated with raised intraocular pressure (10.6%). In 5% cases of PXF, intraoperative posterior capsular rent and vitreous loss occurred. Best-corrected visual acuity on the 45th postoperative day was significantly better in patients without PXF (p-value < 0.05).

Conclusion: Cataract patients with PXF have higher preoperative risk factors for intra-operative complications as compared to patients without PXF. This can result in compromised visual outcome as compared to the eyes without PXF.

Key Words: Cataract, Pseudoexfoliation, manual small incision cataract surgery, iridodonesis, phacodonesis.

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INTRODUCTION

Age-related cataract is the leading cause of visual impairment in India.[1] The only current treatment modality for cataract is the surgical removal of cataractous lens and implantation of an artificial intraocular lens, as non-surgical treatment options are

still in their nascent research phases.[2,3] Pseudoexfoliation (PXF) is an independent age-related disorder that enhances the progression of nuclear sclerotic cataract and presents with multiple preoperative risk factors for cataract surgery. It is still a matter of conflict whether those risk factors lead to an impaired visual outcome following cataract surgery.[4]

PXF was originally defined by the presence of grayish-white material on the anterior lens capsule near the pupillary margin and on the anterior surface of iris. With improved understanding of the pathology, PXF is now believed to be a multisystem disorder with varied ocular and extraocular manifestations.[5] The disorder is characterized by the production and accumulation of extracellular fibrillary material in the ocular and visceral structures due to a dysregulation of the lysyl oxidase like-1 (LOXL-1) gene, leading to systemic endothelial and vascular dysfunction and its attendant complications.[6]Within the eye, fibrillary PXF material deposits on virtually all tissues but more commonly in the anterior segment as seen on corneal endothelium, trabecular meshwork, iris surface, pupillary border, anterior lens capsule and the zonules.[7]

Due to the ubiquitous deposition of fibrillary material in the eye, PXF can lead to complications during and after cataract surgery such as increased per-operative endothelial cell loss, intraoperative floppy iris, iridodialysis, posterior capsular rent (PCR), zonular dialysis and vitreous loss.[8] It also predisposes to ocular hypertension and pseudo-exfoliative glaucoma.[9] Early postoperative complications such as persistent anterior chamber reaction, pigment dispersion and IOL deposits, corneal edema, IOP spikes and anterior capsular phimosis have been reported.[10] Late postoperative complications such as dislocation of the IOL-bag complex have also been observed.[11]

Pseudoexfoliation thus poses a challenge to cataract surgeons, especially in resource limited settings where MSICS, with its inherent requirement of a larger capsulorrhexis, is the routinely performed cataract extraction procedure. Use and availability of assistive surgical techniques and devices that have been shown to improve surgical outcome in these cases such as dispersive-cohesive ocular viscoelastic devices (OVDs), pupil expanders and capsular bag stabilizing devices is also a limitation in such settings.

Present study was undertaken in patients of senile cataract undergoing MSICS with PCIOL implantation under the National Program for Control of Blindness.[12] We studied the risk factors for complications during cataract surgery and compared the final visual outcomes between PXF and non-PXF patients undergoing a standardized MSICS procedure by a single experienced surgeon, with minimal use of assistive devices and techniques to maintain uniformity and increase the applicability of results to resource limited settings.

METHODS

This study was conducted with the primary objective to compare the visual outcome between senile cataract patients with and without PXF undergoing MSICS. It was a Quasi experimental study including 112 participants (56 cases and 56 controls) aged > 40 years. The study was approved by the institutional review board and ethics committee and written informed consent was obtained from all participants. Primary outcomes that were assessed prospectively included the perioperative complication rates as well as best-corrected visual acuity at 45 days post-surgery.

Patients of either sex, more than 40 years of age, diagnosed with either senile cataract or senile cataract with PXF on slit lamp examination, and consenting for study and follow-up were included. Patients less than 40 years of age, with complicated cataract, glaucomatous changes, previous history of ocular trauma or surgeries and presence of any systemic complications like diabetes mellitus, hypertension or stroke were excluded from the study.

Patients with cataract and clinically apparent PXF were included in cases and age-matched controls consisted of patients who had cataract without PXF.

Pupillary dilation was achieved by topical instillation of a combination of 5% phenylephrine and 0.8% Tropicamide, three times, once every 10 minutes. Cataract grading was done as per the Lens Opacification Classification System III (LOCS III). In patients with mature cataract, a B-scan was done to rule out gross posterior segment pathology and fundus evaluation was planned postoperatively.

An assessment of visual acuity using self-illuminated Snellen box, thorough examination of anterior and posterior segments on slit-lamp biomicroscope and measurement of intraocular pressure (IOP) using Goldmann applanation tonometer

were done preoperatively. PFX was identified by the presence of white granular material on the lens surface, iris, or pupillary margin. The preoperative risk factors that were assessed were raised IOP, poor pupillary dilatation, frank lens subluxation as assessed by irregular AC depth or visibility of lenticular margin through dilated pupil, and/or zonular weakness as assessed by phacodonesis or iridodonesis. Pupillary diameter of less than 6mm after dilation was graded as poor while 8-9 mm of pupillary dilation was graded as good. Patients with raised IOP were given aqueous suppressant (Timolol Maleate 0.5% BD) and proceeded for surgery only when IOP reduced to < 20 mm Hg.

The patients were admitted one day prior to surgery and prophylactic Moxifloxacin 0.5% was given topically every 6 hours. Pupillary dilation on the day of the surgery was achieved with a combination of topical phenylephrine 5% and Tropicamide 0.8% along with topical Flurbiprofen 0.03% to maintain pupillary dilation. The eye to be operated was marked and locally anesthetized with a combination of 3mL of 2% lignocaine and 3mL of 0.5% bupivacaine injected in the peri-bulbar space. Painting and draping was done. Eye speculum was placed. A 5% povidone-iodine solution was instilled in the conjunctival sac. All patients underwent MSICS with polymethylmethacrylate (PMMA) posterior chamber intraocular lens (PCIOL) implantation in the bag. A superior fornix based conjunctival flap was raised and frown shaped scleral incision given 2mm away and superior to the limbus with #15 blade. A sclerocorneal tunnel was then made with a crescent blade. Side port was made at 9 o'clock position. Trypan Blue dye, available as 0.1% solution, was then injected into the anterior chamber. The dye was washed with balanced salt solution. In eyes with poor pupillary dilation, 2% hydroxypropylmethylcellulose (HPMC) was used to dilate the pupil. A 26G ½ inch needle cystitome was used to make a continuous curvilinear capsulorrhexis. Hydrodissection was then performed to separate the nucleus from the cortex. Nucleus was prolapsed out of capsular bag using hydro-prolapsing method and delivered out of the anterior chamber with Wire Vectis. Irrigation and aspiration of residual cortical matter was done with Simcoe's two-way cannula. A single piece, biconvex, PMMA PCIOL lens was placed in the bag. In cases with zonular dialysis or bag dialysis, use of capsular tension rings was avoided and the PCIOL was placed in the sulcus.

Post-operative treatment consisted of topical Prednisolone 1% 4 hourly, Moxifloxacin 0.5%, and Carboxy-methylcellulose 0.5% 6 hourly tapered as required. Cycloplegics and anti-glaucoma medications were added at the first follow-up if indicated. The patients were given refractive correction and the best-corrected visual acuity (BCVA) was noted on the 45th day postoperatively.

Number of cases and controls having preoperative risk factors and intraoperative complications were documented along with the BCVA at 45th postoperative day. The data was analyzed qualitatively and quantitatively using appropriate statistical tests.

The data was collected in tabulated form and analyzed with student's t-test for quantitative variables and chi-square test for qualitative variables. The data was presented in terms of means and percentages. P value < 0.05 was considered as significant.

RESULTS

Cataract with PXF was most commonly seen in 60 to 70 years age group which composed of 27 (48.2%) out of 56 patients. Majority of non-PXF cataract patients belonged to 51 to 60 years age (41%) (Table 1).

Table 1: *Age distribution of cases and controls.*

Age (in Years)	No. of Cases PXF (n=56)	No. of Controls Non-PXF (n=56)
40 to 50	07 (12.5%)	06 (10.7%)
51 to 60	13 (23.2%)	23 (41%)
61 to 70	27 (48.2%)	19 (33.9%)
71 to 80	08 (14.2%)	08 (14.2%)
> 80	01 (1.7%)	–
Total	56	56

Mean age of presentation for PXF-associated cataract was 64 ± 8.67 versus 62.4 ± 8.26 for non-PXF cataract (p = 0.25; student's t test). Cataract with PXF showed a slight female preponderance at 55.3% while majority (64.2%) of the control group comprised of males (p < 0.05; chi-square test).

PXF was commonly seen with Nucleus sclerosis (Nucleus opalescence grade II 55.3%, Nucleus opalescence Grade III & IV 21.4%) (Table 2). In control group 39.2 % patients were found to be with nucleus opalescence grade II, and 21.4% with Nucleus opalescence Grade III & IV (p-value was > 0.05) which indicate; cases and control groups were

comparable as per cataract grading. Cortical cataract was seen more frequently in controls than in cases (39.3% vs. 23.2%; p value= < 0.01; chi square test).

Table 2: *Grading of cataract in cases and controls.*

Grading	Cases	Controls
Nuclear Sclerosis (NS) II	31 (55.3%)	22 (39.2%)
NSIII	11 (19.6%)	11 (19.6)
NSIV	01 (1.7%)	1 (1.7%)
Cortical cataract	13 (23.2%)	22 (39.3%)
Total	56	56

Preoperative risk factors were noted more frequently in PXF group (Table 3). 78.6% of PXF patients had unilateral presentation while only 16.1 % of the non-PXF cases presented unilaterally (p < 0.001).

Table 3: *Preoperative risk factors among cases and controls.*

Preoperative Risk Factors	Cases (n = 56)	Control (n = 56)	P values
Poor pupillary Dilation (< 6 mm)	24 (42.8%)	1 (1.7%)	P < 0.0001
Mean Pupil Size	5.9 ± 1.2mm	8.14 ± 0.77mm	
Iridodonesis	7 (12.5%)	0	–
Raised IOP	6 (10.7%)	1 (1.7%)	P = 0.04
Zonular Weakness (Phacodonesis)	3 (5.35%)	0	–
Subluxation	1 (1.7%)	0	–

Intra-operative complication rate was 16.071% in the PXF group and there was no complication encountered in the control group (p < 0.01). Floppy iris 3 cases (5.35%), posterior capsule rupture (PCR) with vitreous loss 3 cases (5.35%), PCR without vitreous loss 2 cases (3.57%). PCR with vitreous loss were left aphakic and managed later with anterior chamber intraocular lens implantation. These were the cases with preoperatively diagnosed zonular weakness with or without subluxation.

On comparison of BCVA on postoperative day 45 between cases and controls, mean VA in cases was 0.3 ± 0.17 (logMAR VA) vs. 0.13 ± 0.1 in controls (p< 0.005). Within PXF cases, patients without any preoperative risk factors had a mean final BCVA of 0.15 ± 0.07 versus 0.39 ± 0.2 in cases with preoperative risk factors (p = < 0.01) (Table 4).

Table 4: *Comparison of BCVA.*

BCVA (Convert to logMAR)	PXF Group		Non-PXF
	Cases without Risk Factors	Cases with Risk Factors	
<0.47 (better than 6/18)	20	24	52
0.47 to 1 (6/18 to 6/60)	3	6	04
> 1 (worse than 6/60)	–	03	–
Total	23	33	56

DISCUSSION

In our study, cataract with PXF was seen mostly in 60 to 70 years age group (48.2%) whereas non-PXF related cataract tended to present earlier in the 50 to 60 years group (41%). However, on comparing the mean age of the two groups (64 ± 8.67 vs. 62.4 ± 8.26), the difference was not statistically significant (p = 0.25). This is in contrast to findings of previous authors like Turalba et al and Joshi et al, who reported a significantly higher age of presentation for PXF-associated cataract.[13,14]

A female preponderance (55%) was seen in pseudoexfoliation cases whereas a male predominance of 64% was seen in controls. Bangal et al, also reported a female preponderance (58%) of PXF among their study group of 50 patients.[15] Few studies reported that PXF was more common among male population, however, some studies also reported no significant difference in male and female incidence of PXF.[13,16,17]

Most patients in both the groups in our study presented with grade II nuclear opalescence (55.3% and 39.2%; case and control respectively). Both groups showed equal number of patients presenting with grade III and grade IV nuclear opalescence. However, cortical cataract was seen more frequently in the non-PXF group (39.3% versus 23.3%; p < 0.01). These findings corroborate with results of a study by Soni et al who reported a majority of grade II nuclear opalescence among their PXF cases.[9] Most studies, however, indicate increasing grade of cataract in association with PXF with majority of the patients presenting with mature or hypermature cataracts.[4,13,18] This discrepancy in results might be attributed to the wide range of sample sizes in the studies and some selection bias as studies reporting advanced grade of presentation of cataract were carried out in backward rural areas.[13]

An assessment of laterality among cases and controls showed predominance of unilateral cases with PXF (78.5%). Yildirim et al reported unilateral

involvement in 62% of PXF patients.[19] In a 10-year follow-up study conducted by Puska et al, on a cohort of 56 patients, 38% of the patients with initial unilateral involvement were seen to develop bilateral PXF by the end of the follow up period.[20]As unilateral PXF is considered a precursor for development of PXF in the other eye, and because most patients in our study had grade 2 nuclear opalescence, the results of our study may point towards our patients having presented early.

The most observed risk factor in PXF group in our study was poor dilatation of pupil. The mean pupillary dilatation amongst cases was 5.9 ± 1.2 mm and amongst control was 8.14 ± 0.77 mm ($p < 0.0001$). A poorly dilating pupil of < 6 mm was noted in 24 (42.8%) cases whereas in control group only 1 patient (1.7%) had <6 mm pupillary dilatation. Other preoperative risk factors were iridodonesis in 7 cases (12.5%), zonular weakness in 3 cases (5.35%), and lens subluxation in 1 case (1.7%); none of which were seen in control group. Sastry et al, found the mean pupillary dilation in PXF patients to be 5.1 mm ± 1.47 mm, with 86% of the patients having a maximum dilation of less than 6 mm.[18] Haripriya et al, reported a pupil size of ≤ 5.9 mm in 39.4% of PXF patients as compared to 19.1% in controls.[4]

Eleven percent of the PXF cases had raised IOP without glaucomatous changes at presentation as compared to only 1.8% in the control group ($p < 0.01$). Preoperative mean IOP among cases and control was 19.07 ± 8.8 and 16.03 ± 2.7 mm of Hg respectively ($p = 0.01$). Prevalence of raised IOP in PXF patients at the time of cataract surgery has been reported to be as high as 49% by Drolsum et al.[21] Turalba et al reported preoperative glaucoma incidence of 48% in cases versus 11% in controls.[14] Multiple studies conducted in South Indian population groups have also demonstrated increased incidence of preoperatively raised IOP in PXF patients.[16,17,22]

In the present study, intraoperative complications occurred in 9 patients (16%) in the PXF group as compared to none in the control group ($p < 0.01$). We encountered floppy iris, PCR with vitreous loss, PCR without vitreous loss and bag dialysis. Haripriya et al, reported PCR with vitreous loss as the most common complication (1.1%).[4] Other complications reported by them were PCR without vitreous loss (0.7%), zonular dialysis with or without vitreous loss (0.2% each), and capsulorrhexis tear with an intact posterior capsule in 0.6%.[4]

On assessment of BCVA on day 45, controls were seen to have a better outcome as compared to the PXF cases. The difference in final BCVA was also significant for PXF cases with and without preoperative risk factors. These findings are in contrast with those reported by Haripriya et al, where excellent final visual outcome was seen in both cases and controls with no difference in final BCVA post 1 month of follow-up.[4]This difference can be attributed to multiple factors, such as preferential patient selection with exclusion of known preoperatively complicated cases, their surgical technique (phacoemulsification), use of assistive devices (iris retractors, capsule tension rings) and high surgeon experience.[4] In the study by Turalba et al, better final visual acuity was reported in non-PXF versus PXF cases ($p = 0.0003$) although both groups had significant improvement from their respective preoperative visual acuities.[14]

Limitation of this study is the single center research. Results from different surgeons and different centers may show different results. The sample size was limited to only 56 which can also modify the outcomes.

CONCLUSION

Cataract patients with PXF have higher preoperative risk factors for intra-operative complications as compared to patients without PXF. This can result in compromised visual outcome as compared to the eyes without PXF.

Ethical Approval

The study was approved by the Institutional review board/Ethical review board **(SAIMS/IEC/16/40).**

Conflict of Interest

Authors declared no conflict of interest.

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