

PHACOTRABECULECTOMY WITH INTRAOCULAR LENS (IOL) IMPLANTATION IN PATIENTS WITH CO-EXISTING PSEUDOEXFOLIATIVE GLAUCOMA AND CATARACT

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ABSTRACT

PURPOSE

To evaluate the efficacy of phacotrabeculectomy with Intraocular Lens (IOL) implantation in patients with pseudoexfoliative glaucoma.

MATERIAL AND METHODS

This study included 46 eyes of 46 patients diagnosed with pseudoexfoliative glaucoma and clinically significant cataract. All eyes underwent phacotrabeculectomy with intra ocular lens implantation. Efficacy was measured by evaluating the changes in mean intraocular pressure, mean logMAR BCVA, drug number, bleb status and complications.

RESULT

Postoperative reduction of IOP was very satisfactory for the whole group. The mean pre-operative IOP \pm SD was 31.27 \pm 7.82 mmHg. After the procedure, the mean IOP decreased to a level of 14.05 \pm 4.22 mmHg at first week and 13.68 \pm 9.27 mmHg at 1 month. The mean IOP values at 3 months were 13.77 \pm 3.52 and 14.12 \pm 3.19 mmHg at 6 months. The mean IOP at final visit was 14.57 \pm 3.44 mmHg. The mean value of pre-operative logMAR BCVA was 0.98 \pm 45. It improved to a mean value of logMAR BCVA 0.36 \pm 37 at one month, logMAR BCVA 0.37 \pm 37 at 6 months and logMAR BCVA 0.39 \pm 65 at the final visit after one year.

CONCLUSION

Phacoemulsification, IOL implantation and trabeculectomy is an efficacious and safe procedure for treating eyes with co-existing pseudoexfoliation glaucoma and cataract.

KEYWORDS

Phacotrabeculectomy, Pseudoexfoliation Syndrome, Pseudoexfoliation Glaucoma.

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INTRODUCTION

Glaucoma, is a leading cause of irreversible blindness throughout the world. WHO statistics 1997, indicate glaucoma accounts for 15% of total global blindness. Glaucoma refers to a group of diseases that have in common a characteristic optic neuropathy with associated visual field loss for which elevated intraocular pressure is one of the primary risk factors.⁽¹⁾ Glaucoma has been classified by several systems. According to classification based on initial events, glaucoma has been classified as: (A) Open angle, (B) Angle closure, (C) Developmental and (D) Glaucomas associated with other ocular and systemic disorders.⁽²⁾ Pseudoexfoliation syndrome belongs to the last group of above classification.

Pseudoexfoliation syndrome is defined as a discrete clinical entity characterized by synthesis and progressive accumulation of fine white granular material in many ocular tissues.

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The first description of this condition appeared in Scandinavian literature in 1917, when Lindbergh described flaky material at the pupillary border in some patients with glaucoma.⁽³⁾ Throughout the anterior segment including the lens, iris, trabecular structures, conjunctiva, corneal endothelium, ciliary body and zonules the exfoliative material may be detected histopathologically.⁽⁴⁾ It is overall the most common identifiable cause of glaucoma worldwide and in some countries accounts for the majority of glaucoma.⁽⁵⁾ The reported mean age of pseudoexfoliation syndrome patients ranges from 69 to 75. And most epidemiological surveys demonstrate an increasing prevalence with increasing age. Men and women are probably equally affected.⁽⁶⁾ It leads to both open angle and angle closure glaucoma and has been causatively associated with cataract, lens dislocation and central retinal vein occlusion.

Eyes with pseudoexfoliation have a greater frequency of complications at the time of cataract extraction, such as zonular dialysis, capsular rupture and vitreous loss. Based on the identification of accumulations in orbital tissues, skin specimen and visceral organs, pseudoexfoliation syndrome appears to be a generalised disorder of the extracellular matrix.

Glaucoma occurs more commonly in eyes with pseudoexfoliation syndrome than in those without it. Elevated intraocular pressure with or without glaucomatous damage

occurs in approximately 25% of persons with pseudoexfoliation syndrome or about 6 to 10 times the rate in eyes without pseudoexfoliation syndrome. Pseudoexfoliation glaucoma has more serious clinical course and worse prognosis than primary open angle glaucoma.⁽⁷⁾ There is significantly higher frequency and severity of optic nerve damage at the time of diagnosis, worse visual field damage, poorer response to medications, more severe clinical course and more frequent necessity for surgical intervention.⁽⁸⁾

All patients with pseudoexfoliation syndrome and raised intraocular pressure should be treated even in presence of normal fields and discs, because if untreated a large percentage of cases will develop damage. Glaucoma associated with pseudoexfoliation syndrome is basically treated on same lines as chronic open angle glaucoma, although it responds less well to medical therapy than does primary open angle glaucoma.⁽⁹⁾ When conventional surgical intervention becomes necessary, filtering surgery is generally advocated.⁽¹⁰⁾ In the new millennium of rapid advancements and modifications in all fields of science and technology, the treatment of coexisting cataract and glaucoma by combined procedure (Cataract extraction, intraocular lens implantation and trabeculectomy) has produced favourable results. Combined procedure not only improves Visual Acuity (VA) and control of Intraocular Pressure (IOP), but also decreases post-operative pressure spikes.⁽¹¹⁾

MATERIAL AND METHODS

This was an observational case series carried out in the Department of Ophthalmology, Government Medical College, Srinagar, Jammu and Kashmir, India; 46 eyes of 46 patients diagnosed with pseudoexfoliation glaucoma and clinically significant cataract were taken up for this study. Studied subjects included 32 males and 14 females. Patients with exfoliation syndrome and cataract were included in this study if they had no associated ocular disease, previous surgery or trauma. Pre-operative assessment included detailed examination including Best Corrected Visual Acuity (BCVA) (Snellen's test types), which was later converted to logMAR values, slit-lamp biomicroscopy for presence of exfoliative material and cataract, intraocular pressure using Goldmann applanation tonometry, gonioscopy, detailed fundus examination for cup-disc ratio and other changes on the disc and A – Scan biometry. Selected cases also underwent visual field analysis depending on the maturity of cataract. Indications for trabeculectomy were uncontrolled IOP despite maximum tolerated medication and disease progression.

PROCEDURE

Consent for surgery was duly obtained from the patient or close relative of the patient. Pre-operative IOP was expressed as value measured at the visit immediately prior to the surgery. All surgeries were performed under peribulbar anaesthesia using 2% lidocaine. A single site was used for phacoemulsification and trabeculectomy. Limbal conjunctival peritomy performed at the 12 o'clock and a fornix based conjunctival flap was fashioned. Two millimetres posterior to the limbus at 12 o'clock position, a partial-thickness tangential scleral incision was made for 2.5 to 3 mm. Then with a 2.6 mm Crescent knife a half-thickness scleral tunnel, which extended 1 mm into clear cornea was dissected. No antimetabolite was applied. Two limbal paracentesis were made at 10 and 2

o'clock positions. Anterior chamber was entered with 2.6 mm Keratome and anterior chamber was filled by methylcellulose and then a 5 mm anterior continuous curvilinear capsulorhexis was performed. The nucleus was removed by phacoemulsification using the chop technique and a soft acrylic intraocular lens was placed in the bag.

Corneoscleral block excision was performed by Kelly punch. A peripheral iridectomy was performed, anterior chamber was reformed. The scleral incision was sutured and watertight suturing of the conjunctiva was performed by two 10-0 nylon. Post-operatively, after 24 hrs. patients were put on antibiotic steroid eye drops every 2 hours and then tapered gradually over following 4-6 weeks. Post-operative followup was done on first post-operative day, first post-operative week, first month and then after 3 months, 6 months and one year post-operatively. Followup assessment included BCVA, IOP, slit lamp examination for status and type of bleb, fundus examination and field of vision. Patients having post-operative IOP >21 mmHg were put on medical treatment and followed up.

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STATISTICS

Statistical software SPSS 16.0 was used to carry out the statistical analysis of data. Data was analysed by means of descriptive statistics, viz. means, standard deviations and percentages and presented by Bar diagrams. Paired 't' test was

employed for comparing preoperative IOP with postoperative IOP. A p value of < 0.05 was considered statistically significant.

RESULTS AND OBSERVATIONS

Baseline Data

Our study included 46 eyes of 46 patients diagnosed with pseudoexfoliation glaucoma with clinically significant cataract. Mean age and standard deviation of studied subjects was 66.2 ± 8.8 years. The distribution was not statistically significant (Table 1); 32 (69.5%) of studied subjects were males and 14 (30.5%) were females (Table 2). Right eye was operated in 24 (53.5%) patients and left eye was operated in 22 (47.5%) patients (Table 3). Exfoliation material was present on the pupillary border in 78% cases, while as 38% had exfoliation material present on anterior lens capsule at the time of diagnosis (Table 4). More than one site was involved at the time of diagnosis in majority of patients. Pre-operative CD ratio was in the range of 0.3-0.5 in 30% of cases, 0.6-0.8 in 46% cases and 0.9 in 24% cases (Table 4).

Intraocular Pressure

Preoperative IOP was taken as IOP of the patient one day prior to the surgery whether on medical treatment or not. Almost all patients 44 (95.5%) were on medical treatment before trabeculectomy, except 2 (4.5%) patients in whom primary trabeculectomy was done. Pre-operatively 18 (40%) cases were in the range of 21-30 mmHg on medical treatment, 11 (24%) cases were in the range of >15-20 mmHg, who though medically controlled had to undergo trabeculectomy either due to progressive loss of visual field or intolerance to medical therapy and 13 (28%) cases were in preoperative IOP range of 31-40 mmHg. Also 2 (6%) cases had IOP in the range of 41-50 mmHg and 1 case (2%) had pre-operative IOP of 60 mmHg.

The mean pre-operative IOP \pm SD was 31.27 ± 7.82 mmHg. After the phacotrabeculectomy with IOL implantation was performed the mean IOP decreased to a level of 14.05 ± 4.22 mmHg at first post-operative week and 13.68 ± 9.27 mmHg at first post-operative month. The mean IOP value at 3 months was 13.77 ± 3.52 mmHg, while as at 6 months the mean value was 14.12 ± 3.19 mmHg.

The mean IOP at final visit was 14.57 ± 3.44 mmHg. The changes were statistically significant ($p < 0.001$) (Table 6) (Fig. 1). Post-operative reduction of IOP was very satisfactory for the whole group with about 39 patients (85%) having a post-operative IOP of 10-20 mmHg in first week. Moreover 4 (9%) patients had post-operative IOP of less than 10 mmHg making the total percentage of controlled cases as 94% in first week. However, in overall followup, 5 cases showed unsatisfactory post-operative IOP reduction. Three amongst them showed controlled IOP on postoperative medical treatment and 2 maintained a post-operative IOP >25 mmHg, despite continuation of medical treatment.

The mean pre-operative anti-glaucoma drug number was 3.09 ± 2 . It was significantly reduced to a mean value of 0.31 ± 7 at 6 months and 0.38 ± 3 at 1 year ($p < 0.001$) (Table 7) (Fig. 2).

At the end of first week blebs were formed in 43 cases, out of which 31 (67%) were flat diffuse type, while as 12 (26%) were thin polycystic type. Remaining 3 (7%) cases showed no bleb.

At final visit post-operative cup-disc ratio remained same in 39 (85%) cases and deteriorated in 7 (15%) cases. However, none of the cases showed any improvement.

Best Corrected Visual Acuity (BCVA)

The mean value of pre-operative logMAR BCVA was 0.98 ± 45 . After phacotrabeculectomy the value improved to a mean of logMAR BCVA 0.36 ± 37 at one month, logMAR BCVA 0.37 ± 37 at 6 months and logMAR BCVA 0.39 ± 65 at the final visit after one year (Table 8) (Fig. 3). Thus showing an overall improvement in BCVA by 62% at 6 months and 60.2% at one year. The difference was statistically significant ($P < 0.001$).

COMPLICATIONS

Intraoperative complications include poor pupillary dilatation in 9 (20%) of cases and gross subluxation of the lens with implantation of anterior chamber intraocular lens in 1 (2%) case. Early post-operative complications included shallow anterior chamber in 5 (10%) cases, fibrin exudation and pupillary membrane formation in 4 (8%) cases, flat anterior chamber in 2 (4%) cases and hyphema in 2 (4%) of cases. Most common late post-operative complication included posterior capsular opacification seen in 14 (32%) of cases. Additional surgical procedures included anterior chamber reformation in 3 (7%) of cases and conjunctival resuturing in 2 (4%) cases (Table 9).

Age in Years	No. of Patients	% Age
<60	7	16%
60-70	26	56%
>70	13	28%
Mean Age: 66.2 ± 8.8 Years		
Table 1: Age Distribution of Studied Subjects		

Gender	No. of Patients	% Age
Male	32	69.5%
Female	14	30.5%
Total	46	100%
Table 2: Gender Distribution of Studied Subjects		

	No. of Patients	% Age
Right Eye	24	53.5%
Left Eye	22	47.5%
Total	46	100%
Table 3: Eye Operated		

	No. of Patients	% Age
Exfoliation Material on Pupillary Border	36	78%
Exfoliation Material on Anterior Lens Capsule	18	38%
Exfoliation Material in Angle with Pigmentation	8	16%
Exfoliation Material on Corneal Endothelium	8	16%
More than one site was Involved in Majority of Patients		
Table 4: Pre-Operative Type of Exfoliation as per SLE and Gonioscopy		

	No. of Patients	% Age
0.3-0.5	14	30%
0.6-0.8	22	46%
0.9	10	24%

Table 5: Pre-Operative CD Ratio

	Mean IOP (mmHg)	SD
Baseline	31.27	7.82
First Post-operative Week	14.05	4.22
One Month	13.68	9.27
Three Months	13.77	3.52
Six Months	14.12	3.19
One Year	14.57	3.44

Table 6: Changes in Intraocular Pressure over the Studied Period

	Mean	SD
Pre-Operative Drug Number	3.09	2
Drug Number at 6 Months	0.31	7
Drug Number at One Year	0.38	3

Table 7: Drug Number of Anti-Glaucoma Medication

	Mean	SD
Baseline BCVA	0.98	45
BCVA at one Month	0.36	35
BCVA at 6 Months	0.37	37
BCVA at One Year	0.39	65

Table 8: Changes in LogMAR BCVA over Studied Period

	Number	% Age
Poor Pupillary Dilation	9	20%
Gross Subluxation of Lens	1	2%
Shallow Anterior Chamber	5	10%
Fibrin Exudation and Pupillary Membrane Formation	4	8%
Flat Anterior Chamber	2	4%
Hyphema	2	4%
Posterior Capsular Opacification	14	32%

Table 9: Complications over the Studied Period

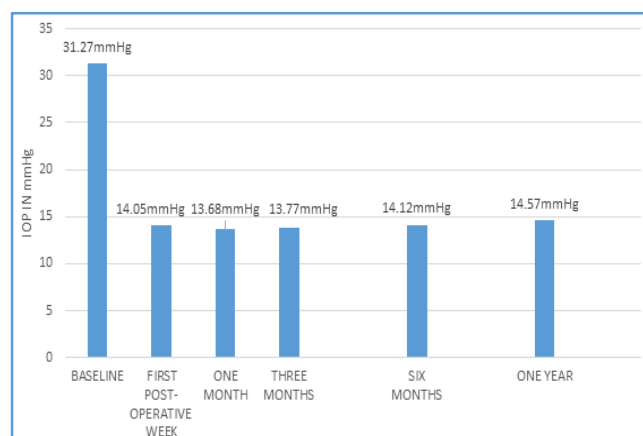


Fig. 1: A Demonstration of Changes in the Mean Intraocular Pressure over the Studied Period of Time. Note that a Statistically Significant Decrease has been observed in the IOP from a Mean Baseline IOP of 31.27 mmHg to IOP of 14.2 mmHg at the final visit.

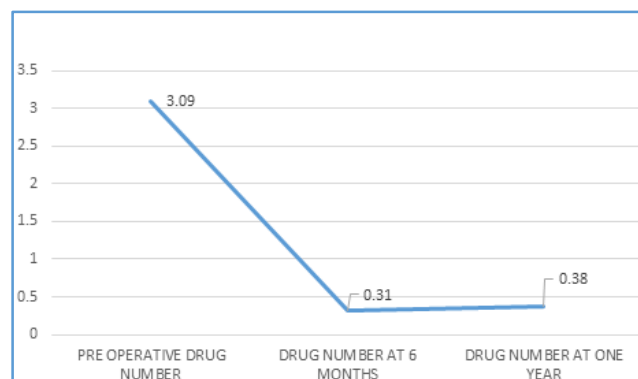


Fig. 2: Demonstrating a Statistically Significant Decrease in the Drug Number from 3.09 Preoperatively, to 0.31 at a Follow-Up Period of 6 months and 0.38 at the Final Visit

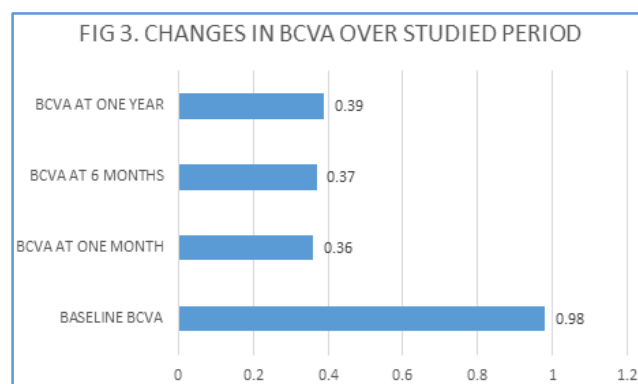


Fig. 3: Demonstrating the Improvement in logMAR BCVA where the BCVA Improves from Baseline Value of 0.98 to 0.37, 0.36 and 0.39 at one month, three months and one year respectively

DISCUSSION

Ophthalmologists have been facing the challenge of simultaneous management of cataract and glaucoma in our elderly population with pseudoexfoliation syndrome. The surgical management of coexisting glaucoma and cataract has changed a lot, raising critical management issues.⁽¹²⁾ The benefits of combined procedure include to avoid temporary increase in intraocular pressure in the initial postoperative period and to achieve long-term improvement in IOP control with one surgical procedure, while removing the visual impairment and save the patient one surgery.⁽¹³⁾ Although the optimal surgical approach for cataract patients with coexisting glaucoma is still under evolution, phacotrabeculectomy may be considered as the current standard option.

The pseudoexfoliation syndrome usually affects the elderly and steady increase in prevalence occurs with advancing age.⁽³⁾ Our study also supports this, as the mean age of the patients was 66.2 ± 8.8 years. Various studies have demonstrated that the clinical course in pseudoexfoliative glaucoma is likely to be more serious as compared with primary open angle glaucoma. Level of IOP, progression of visual defects and glaucomatous optic neuropathy are more pronounced in exfoliative glaucoma.⁽¹⁴⁾ Moreover, pseudoexfoliative eyes respond less readily to medical therapy, so that many of these require early surgery. Jacobi reported that after combined procedure in eyes with exfoliation syndrome, the mean IOP of 32.5 mmHg with a mean

of 2.1 antiglaucoma medications was decreased to the mean IOP of 18.1 mmHg with a mean of 0.2 antiglaucoma medications after 6 months.⁽¹⁵⁾ The mean pre-operative IOP \pm SD in our study significantly decreased from a value of 31.27 \pm 7.82 mmHg at baseline and 14.57 \pm 3.44 mmHg at final visit, thereby showing an overall decrease by 16.7 mmHg (53.40%). Our results were comparable with Shingleton BJ et al.⁽¹⁶⁾ and L J Katz et al.⁽¹⁷⁾ The mean pre-operative antiglaucoma medication number in our study was 3.09 \pm 2 and was reduced to a mean value of 0.31 \pm 7 at 6 months and 0.38 \pm 3 at 1 year. Our results were similar to Eslami et al.⁽¹⁸⁾ and comparable with other studies.⁽¹⁶⁾⁽¹⁷⁾

Combining the two surgeries not only enhances the vision of the patients, but also provides independence from multiple glaucoma drugs and frequent follow ups, thus improving the quality of life.⁽¹⁹⁾ The mean value of pre-operative logMAR BCVA was 0.98. It improved to a mean value of logMAR BCVA 0.35 at one month, a mean value of logMAR BCVA 0.37 at 6 months and a mean value of logMAR BCVA 0.39 at one year. The difference was statistically significant ($p < 0.001$). Our findings are in agreement with studies done by L J Katz et al.⁽¹⁷⁾ and Eslami et al.⁽¹⁸⁾

Poor pupillary dilation is a well-known feature of pseudoexfoliation syndrome and can seriously hamper the surgeon's view. Phacoemulsification performed in patients with glaucoma is frequently challenging because of a number of factors including a small pupil that is resistant to pharmacologic dilation or even viscoelastic mechanical dilation.⁽¹⁹⁾ In our study, 10 (20%) patients presented with poor pupillary dilation. Local production and deposition of exfoliative material may lead to characteristic clinical and ultrastructural changes, which actively involve all structures of the anterior segment of the eye. These alterations may cause complication after surgical procedures. Many reports have mentioned increased rate of intraoperative complications that is, zonular dialysis, posterior capsular tear and vitreous loss. In our study, gross subluxation of the lens was encountered in 1 (2%) cases.

A number of studies have presented evidence of dysfunction of the blood aqueous barrier in pseudoexfoliation syndrome with consecutive increase of aqueous flare and protein. Clinical response of inflammatory reaction and fibrin formation in eyes with pseudoexfoliation following cataract extraction appears to be related to these ultrastructural changes.⁽²⁰⁾ Fibrin exudation and pupillary membrane formation was encountered in 4 (8%) patients in our study. The explanation elucidated for this is that the maintenance of a relatively controlled IOP during phacoemulsification incites less chamber reaction. Prior studies by Tezel et al.⁽²¹⁾ and Wishart et al.⁽²²⁾ that have compared ECCE trabeculectomy with phacotrabeculectomy also documented lesser anterior chamber inflammatory reaction in phacotrabeculectomy group.

Most common late post-operative complication included posterior capsular opacification seen in 32% of cases.

CONCLUSION

Trabeculectomy combined with phacoemulsification is considered a safe, effective and economical strategy in the management of cataract associated with pseudoexfoliative glaucoma. It prevents early IOP spikes responsible for visual field wipeout in advanced glaucoma and provides visual

rehabilitation with long-term IOP control. Also both the diseases are controlled in a single sitting, thus it eliminates the need for glaucoma medications and frequent follow-ups. This reduced incidence of complications and has made this surgery technically faster and superior. Other advantages include less induced astigmatism, early visual rehabilitation, reduced stimuli to wound healing, inflammation and postoperative bleb scarring and thus improving long-term filtration. The results obtained were promising; however, they do not permit us to draw definitive conclusions and further studies involving a larger number of patients are needed to confirm these results.

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