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RANDOMIZED TRIAL OF PHACOEMULSIFICATION WITH AND WITHOUT PERIPHERAL IRIDOTOMY TO PREVENT INTRAOPERATIVE COMPLICATIONS IN CATARACT SURGERY WITH OCCLUDABLE ANGLES

Ophthalmology

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ABSTRACT

Introduction: Cataract surgery in patients with Primary angle closure or very narrow angles poses a unique set of challenges and risks. Laser peripheral iridotomy (LPI) relieves the pupillary block and is most effective intervention for the majority of cases of PAC.
Objectives: We conducted a prospective randomized controlled trial to compare the role of prophylactic LPI in cataract surgery with occludable angles.
Materials and methods: Total of 60 eyes of 60 patients were recruited with 30 eyes each in group. In group A, prophylactic LPI was done before the surgery, in Group B surgery was done without LPI. The outcome was intraocular miosis during the surgery including other intraoperative safety parameters like iris prolapse, difficulty in capsulorrhexis, increased AC fluctuation, rise in posterior vitreous pressure and PCR. The surgeons were given a questionnaire at the end of surgery to make a note of the above mentioned parameters. Intraoperative miosis was present in 13.3% patients in group A and 20% in group B. Surgeon comfortability was not there in 13 cases, out of which 9 (30%) were without LPI and 4 (13.33%) were with LPI.
Conclusions: This is the first prospective study to evaluate the role of YAG PI in preventing intraoperative complications in cataract patients with occludable angles, a preoperative LPI has potential to decrease intraoperative complications. The present study was conducted with experienced surgeons. So, a further study can be planned with different levels of surgeon experience to find out if a true benefit exists with prophylactic LPI.

KEYWORDS

Anterior Chamber(AC), Laser Peripheral Iridectomy(LPI), Primary Angle Closure(PAC)

INTRODUCTION

Cataract surgery is one of the most frequently performed ophthalmic surgeries all over the world. In most of the cases the outcomes are predictable. However, cataract surgery in patients with Primary angle closure (PAC) or very narrow angles poses a unique set of challenges and risks.[1,2] It has been reported that an anterior chamber depth of less than 2.5 mm increased the risk of surgical complications significantly by fivefold.[3] The anterior chamber in PAC eyes is characteristically shallow as they have thicker and more anteriorly positioned lenses than normal eyes [4,5]. This provides less room for maneuvering the nucleus, and also forces the surgeon to apply ultrasonic power closer to the corneal endothelium. Laser peripheral iridotomy (LPI) relieves the pupillary block and is the most effective intervention for the majority of cases of PAC [6,7]

As there is paucity of literature evaluating the utility of LPI performed preoperatively in reducing the intraoperative complications in patients presenting with cataract and occludable angle, we conducted a prospective randomized controlled trial to compare the role of prophylactic LPI in cataract surgery with occludable angles.

Materials and Methods:

The study was conducted at Dr. Shroff's charity eye hospital, New Delhi. Written informed consent was taken from all the participants before enrollment. The study was approved by the institutional review board and followed the declaration of Helsinki.**Inclusion criteria** were cataract grading between nuclear sclerosis grade II-III (as per LOCS classification[9]), occludable angle on gonioscopy (where ≥ 270° of the posterior trabecular meshwork could not be seen) with or without peripheral anterior synechiae (PAS) but without rise in IOP and anterior chamber depth of ≤ 2.7mm. **Exclusion criteria** were raised IOP (≥ 21mmhg), acute primary angle closure, glaucomatous damage of the optic disc and any other ocular pathology which can affect the visual outcome of the patient.

Randomization

All patients underwent comprehensive ophthalmologic evaluation by a glaucoma specialist which included visual acuity, slit lamp examination, IOP measurement by Goldmannn applanation tonometry, fundus evaluation and gonioscopy by Posner 4 mirror goniolens. Cataract was graded according to the Lens Opacities Classification System (LOCS) III [8] and the anterior chamber depth was recorded by immersion technique.

All eligible patients were randomized into two groups, Group A and Group B. In group A, prophylactic LPI was done before the surgery. In Group B, cataract surgery was done without LPI.

After randomization Group A patients underwent YAG PI, Laser peripheral iridotomy was performed using the sequential Neodymium:yttrium–aluminum–garnet (YAG) laser technique in the supero-temporal quadrant. The patients were prescribed Prednisolone acetate 1% eye drop, 4 times a day and Brimonidine eye drop 2 times a day for 7 days. The patients then underwent phacoemulsification after more than three weeks which is the washout period of Brimonidine.

Phacoemulsification with IOL implantation were performed under peribulbar anesthesia by two expert surgeons who have >10 years of surgical experience and have done >15,000 phacoemulsification surgeries. All surgeries were done by a clear corneal incision of 2.8 mm. The surgeons were blinded to the group they were operating on.

Primary and Secondary Outcomes

The primary outcome of the study was intraocular miosis during the surgery. We also measured the surgeon comfort during the surgery by measurement of intraoperative safety parameters which were iris prolapse, difficulty in capsulorrhexis, increased anterior chamber fluctuation, rise in posterior vitreous pressure and posterior capsular rent. The intraoperative parameters were recorded as yes/no. The surgeons were given a questionnaire at the end of surgery to make a note of the above mentioned parameters.

The secondary outcomes included vision, intraocular pressure, anterior chamber reaction and degree of corneal edema at day 1, day 7 and day 28. The corneal edema was graded as mild (few Descemet's folds), moderate (stromal edema with clear AC details) and severe (stromal edema with AC details not clear). AC reaction was graded as mild, moderate and severe based on AC cells.

Statistical Methods

Data were analysed using SPSS software version 21 (IBM,USA). P ≤ 0.05 was considered statistically significant. Chi square test was used to calculate the defference between two groups.

Results

A total of 60 eyes of 60 patients were recruited with 30 eyes each in group A and group B. All patients completed the follow up period of 28 days. Figure 1 shows the flow of the study participants during the course of the study.

Participant flow

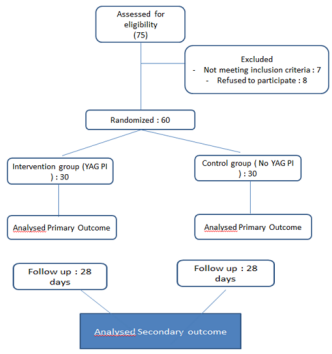

Figure 1

Table 1 : Baseline characteristics of the enrolled patients in each group

	Study Group		P value
	Group A (with PI) N=30	Group B (without PI) N=30	
Mean age ± SD	60.03 ± 6.79	59.01 ± 7.29	0.599
Sex (male/female)	11/19	9/21	
Mean BCVA ± SD (log Mar)	1.173 ± 1.02	1.080 ± 0.901	0.40
Mean IOP ± SD	14.5 ± 2.7	13.77 ± 2.50	0.8
Mean ACD ± SD	2.507 ± 0.16	2.60 ± 0.13	0.1
Mean axial length ± SD	23.01 ± 1.01	22.91 ± 1.5	0.1

There were no significant differences in the baseline characteristics in the two groups as shown in Table 1. The study groups were comparable in terms of age, sex, IOP, ACD and axial length.

Table 2 : Values of the intraoperative parameters during surgery

	Group A	Group B	P value
Iris prolapse	**1 (3.33%)**	**2 (6.66%)**	**0.35**
Miosis	**4 (13.33%)**	**6 (20%)**	**0.58**
Difficulty in capsulorrhexis	**0**	**1 (3.33%)**	**0.23**
Difficulty in nucleus rotation	**1 (3.33%)**	**1 (3.33%)**	**0.34**
AC fluctuation	**0**	**2 (6.66%)**	**0.23**
Posterior vitreous pressure	**1 (3.33%)**	**2 (6.66%)**	**0.35**
Surgical time in minutes	**16**	**15**	**0.12**

Intraoperative miosis was present in 13.3% patients in group A and 20% in group B. Miosis during surgery was not associated with disturbance in other safety intraocular parameters except in two cases. One patient in the group B who had an ACD of 2.3 mm had miosis associated with difficulty in nucleus rotation, AC fluctuation and PVP. The other patient was from group A with ACD of 2.6 mm who had associated iris prolapse with AC fluctuation.

The surgeon's comfort during the surgery was measured with respect to other intraoperative safety parameters. Based on that surgeon comfortability was not there in 13 cases, out of which 9 (30%) were without LPI and 4 (13.33%) were with LPI. If a single case had multiple intraoperative complications, it was still taken as one value.

Table 3: Postoperative vision, IOP in two groups (Independent samples test)

	P value	95% confidence interval	
		lower	upper
Day 1 vision	0.107	-0.126	0.125
Day 28 vision	0.367	-0.028	0.075
Postop IOP	0.533	-0.803	1.536

Table 3 shows the secondary outcomes for both group A and group B. There was no significant difference among the groups regarding the secondary outcomes in the post-operative follow-up visits. All patients had followed up to 28 days. On day 1, 16 patients had vision of 6/12, seven patients had 6/24 and the rest had vision of 6/6 – 6/9. On day 28, all patients had vision of 6/6. Mild corneal edema was present in 11(36.66%) in the group A versus 6 (20%) in group B on the first day but on day seven no corneal edema was noted in any patient. On day one, six patients had mild AC reaction and which resolved by one week. In all patients average IOP was 15.5 mm Hg on day 1.

DISCUSSION

PAC is characterized by shallow AC due to a thicker and anteriorly placed lens. Cataract surgery involves dilatation of the pupil which can further compromise the crowded angle. In a retrospective analysis [10] of 4923 cataract surgery, 451patients had shallow ACD (< 2.6 mm) and it was found that shallow ACD was associated with persistent postoperative corneal edema at 1 month (p value=0.02). LPI in PAC suspects is shown to increase the median limbal anterior chamber depth from 15% to 25% [11] of peripheral corneal thickness after treatment. By allowing aqueous to flow directly through the iridotomy site, LPI equilibrates the pressure between the anterior and posterior chambers. Eliminating this pressure gradient flattens the iris, allowing the peripheral iris to fall backward, resulting in a wider angle and a more stable anterior chamber. Therefore, a preoperative LPI has potential to decrease intraoperative complications during phacoemulsification.

This is to our knowledge the first prospective study to evaluate the role of YAG PI in preventing intraoperative complications in cataract patients with occludable angles.

In a meta-analysis done by Silverstein and colleagues[12] evaluating 40 studies that included 195,340 cataract procedures, the rate of complications related to intraoperative miosis ranged from 1% to 4%. The most common complications associated with intraoperative miosis were posterior capsule rupture, vitreous loss, corneal edema and cystoid macular edema[12]. In a study by Dada et al[13] the most common reason for converting phacoemulsification to extracapsular cataract surgery was miosis. In our study, intraoperative miosis was present in 13.3% patients in group A and 20% in group B. Though the difference between the two groups was not significant, it was higher in group B. In one patient where intraoperative miosis occurred sphincterotomy had to be done to proceed with phacoemulsification. We found that in Group A the surgeons were more comfortable than operating in group B patients (87% vs 70%) However the difference was not significant.

In our study, iris prolapse was encountered in 1 case of group A and 2 cases of group B. In patients with a narrow to closed anterior chamber angle, spontaneous prolapse of iris in the wound poses difficulty in repositioning. The surgeon may inadvertently tear or rip the iris, resulting in functional loss of the iris and non-formation of the anterior chamber during the surgery. ***Robert M. Mandelkorn,*** performed laser iridotomy preoperatively on a series of patients (not published) presenting for cataract surgery with narrow anterior chamber angles and the iris was observed to remain in excellent position within the anterior chamber at all times, allowing successful cataract surgery to be done[14].In our study, surgeon faced difficulty in capsulorrhexis in 1(3.33%) case of group B. In our study, intraoperative anterior chamber fluctuation was noted in 2 cases of group B and positive vitreous pressure was noted in 1 case of group A and 2 cases in group B. When a cataract database was analyzed, a shallow anterior chamber with vitreous bulge was also significantly more common in the ≤ 2.5mm ACD group i.e., 4.48% versus 1.2% in the >2.5 mm group.

CONCLUSION

Though the difference in intraoperative miosis was not statistically significant between the two groups, it had been observed that the surgeon comfortability was more in patients with a shallow AC undergoing cataract surgery with prophylactic PI. There are inherent risks while operating in a case with occludable angles and so a cataract surgery undertaken should be one with the best possible measures to prevent any undue complication. We recommend LPI in ACD < 2. 5 mm so that the pressure in the anterior and posterior chamber reaches an equilibrium which prevents the sudden total angle closure that can happen in these eyes.

The present study was conducted with experienced surgeons. So, a further study can be planned with different levels of surgeon experience to find out if a true benefit exists with prophylactic LPI. Also, a prospective study with a larger sample size may be able to detect a difference between the two groups in terms of the intra- and post-operative complications.

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