Original Research Article

Efficacy of plasma knife assisted posterior capsulotomy versus manual primary posterior capsulorhexis in preventing visual axis opacification in pediatric cataract surgery: A randomized controlled trial

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Abstract

Background: Posterior capsule opacification (PCO) is the commonest complication of extracapsular catraract surgery in pediatric patients with an incidence as high as 95%. But there is inadequate evidence on appropriate intervention to prevent PCO.

Aim: To compare the efficacy of plasma knife assisted posterior capsulotomy versus manual primary posterior capsulorhexis in Pediatric Cataract surgery.

Materials and methods: The current study was a randomized open labeled controlled study, conducted in the department of ophthalmology, All India Institute of Medical Sciences, New Delhi between July 2015 to June 2016. The study population included 32 children in each of < 2 years age, suffering from bilateral cataract and each eye was randomized to different intervention groups consisting of manual posterior capsulorhexis or and posterior capsulotomy using plasma knife. Anterior vitrectomy was performed in all the eyes. Visual acuity, axial length, Intra ocular pressure, and refraction etc. were measured using appropriate methods. The retro-illuminated clinical photograph was taken using NEW CARL ZEISS f340 CANON camera and was analyzed by EPCO software.

Results: There was no statistically significant difference in any of the ocular parameters at baseline and at 6 months following surgery. The log MAR visual acuity was significantly higher in intervention 1 (0.465±0.143) as compare to intervention 2 (0.397 ± 0.108) at 1 year, which was statistically significant (P value 0.036). There were no statistically significant differences in the proportion of Visual Axis Opacification (VAO) between the intervention groups.

Conclusion: Visual axis opacification after pediatric cataract surgery remains comparable in both techniques at one year (plasma knife assisted posterior capsulotomy and manual capsulorhexis). Hence it can be concluded that plasma knife assisted posterior capsulotomy does not have any added advantage over manual posterior capsulorhexis in preventing visual axis opacification.

Key words

Posterior Capsulotomy, Posterior Capsulorhexis, Pediatric Cataract, Visual Axis Opacification.

Introduction

Posterior capsule opacification (PCO) is the commonest complication of extracapsular catraract surgery in pediatric patients with an incidence as high as 95% [1]. It represents a considerable postoperative complication as the primary purpose of pediatric cataract surgery is to remove lens opacities and to create and maintain a clear visual pathway [2-4]. PCO is also referred to as 'secondary cataract' or 'after cataract', develops over the clear posterior capsule a few months to a few years after an uneventful cataract surgery.

A significant sequelae of PCO is that it reduces visual acuity [5] and increases the likelihood of deprivation amblyopia an [6]. In order to reduce the incidence and severity of posterior capsular opacification, various innovations and modifications of the technique of lens aspiration have been done by researchers.

If left untreated, a PCO membrane becomes an amblyopic issue that will limit the ultimate visual success of the primary IOL surgery [7, 8]. Even with a primary capsulotomy/capsulectomy, with or without an accompanying anterior vitrectomy, the anterior surface of the vitreous can still serve as a scaffold for lens epithelial cells to migrate across the visual axis and create a PCO membrane [9, 10]. Though such surgical techniques for IOL insertion do not eliminate secondary PCO membrane development, however, they do reduce the recurrence rate of PCO [2, 6, 8, 10].

It was found that posterior continuous curvilinear capsulorhexis and anterior vitrectomy (PCCC + AV) the only effective method of preventing or delaying the secondary cataract formation in infants or children [11]. The present study compares the efficacy of plasma knife assisted posterior capsulotomy versus manual primary posterior capsulorhexis in Pediatric Cataract surgery.

Materials and methods

The current study was a randomized open labeled controlled study, conducted in the department of ophthalmology, All India Institute of Medical Sciences, New Delhi between July 2015 June 2016.

The study population included children suffering from bilateral cataract and were categorized into two distinct subgroups based on the age of the child. The study group included 32 children aged < 2 years. Both eyes of a child were randomized to different intervention groups using computer generated random number pair sequence as follows.

Intervention I: lens aspiration with manual posterior capsulorhexis and anterior vitrectomy without PCIOL implantation.

Intervention 2: lens aspiration with posterior capsulotomy using plasma knife and anterior vitrectomy without PCIOL implantation.

The allocation sequence was concealed in serially numbered opaque envelops in the custody of an independent statistician. Considering the nature of the intervention, the investigator could not be blinded, the participant blinding was not done, considering the age group of the population, nature of the intervention and the objective method of outcome estimation.

Patients with an associated ocular pathology like traumatic cataracts, congenital glaucoma / IOP > 21mmHg, anterior segment disorders, systemic illness were excluded from the study. Also, the children with poorly dilated pupils, associated Nystagmus/ poor fixation and with H/o previous intraocular surgery were excluded from the study.

The study was approved by the institutional human ethics committee and informed written consent was obtained from the parents or guardian of the child. All the patients underwent surgery under general anesthesia. Preoperative visual acuity of the patients had been assessed by using Cardiff visual acuity chart. The rest of the parameters were measured during examination under anesthesia. The axial length of the eye was measured using USG A scan. Keratometry have been measured by using auto-keratometer. The corneal diameter of the patient was measured using a caliper and the horizontal diameter of the eye was considered for evaluation. Intra ocular pressure (IOP in mmHg) was measured using Perkin's applanation tonometer. Fundus examination was done by both direct and indirect ophthalmoscopes. Refraction – objective refraction was assessed by retinoscopy and auto-refractometer. The retro-illuminated clinical photograph was taken using NEW CARL ZEISS f340 CANON camera with a fixed magnification of 11X, fixed retro-illumination under a same operating microscope. The image had been subjected to the visual axis opacification analysis/quantification using EPCO software.

Patients were followed up for week 1 after surgery to rule out any infection and routine postoperative assessment. The patients were called up for examination under anesthesia (EUA) after 1 month postoperatively and all the evaluation parameters were measured as before and suture removal was done. The patients were advised to follow up on the third month during which routine ocular examination was done. Then the patients were called up on the 6^{th} month and at the end of 1 year for examination under anesthesia (EUA) during which all the parameters had been measured. The parameters were entered in the following proforma during every follow up.

Statistical analysis was done using IBM SPSS software version 21. The separate comparative analysis was done between interventions I and II in each of the two subgroups i.e. less than 2 years and 2 to 5 year age groups. Both the study groups were compared with respect to all the baseline parameters. All the relevant parameters were compared at 6 months and at 1 year. The quantitative parameters were compared using mean and standard deviation and the statistical significance was tested by unpaired t-test. Categorical parameters were compared between the two groups using chi square test. P value < 0.05 was considered statistically significant.

Results

A total of 32 eyes were included in each of the intervention groups. Both the interventions were compared separately in the study population.

No statistically significant differences were observed in any other baseline visual parameters including the log MAR BCVA, axial length, corneal diameter and IOP (**Table - 1**).

There were no statistically significant differences between the two interventions in visual acuity (0.945±0.234 Vs 0.948±0.257, p value 0.961),

Axial length (19.291±0.541 Vs 19.291±0.557, p value 1.00), Corneal diameter (10.870±0.670 Vs 10.838±0.597, p value 0.841) or IOP (13.323±4.792 Vs 12.709±4.213, p value 0.588) at 6 months follow up period (**Table - 2**).

Table - 1: Comparison of baseline parameters in the study groups.

Parameter at baseline	**I**	**II**	**p value**
Visual acuity	1.410 ± 0.130	1.423±0.1283	0.689
Axial length	18.941±0.629	18.9±0.643	0.797
Corneal D	10.46±0.515	10.45±0.489	0.937
IOP	11.29±2.425	11.26±2.097	0.958

Table - 2: Comparison of various visual parameters at 6 months post-operative period.

At 6 months	**I**	**II**	**p value**
Visual acuity	0.945±0.234	0.948±0.257	0.961
Axial length	19.291±0.541	19.291±0.557	1.00
Corneal D	10.870±0.670	10.838±0.597	0.841
IOP	13.323±4.792	12.709±4.213	0.588

Table - 3: Comparison of various visual parameters at 1 year post-operative period.

At 1 year	**I**	**II**	**P value**
Visual acuity	0.465±0.143	0.397 ± 0.108	0.036
Axial length	19.661±0.452	19.657±0.482	0.973
Corneal D	11.177±0.556	11.193±0.477	0.902
IOP	11.613±1.874	11.258±1.182	0.368
Refractive error	17.709±1.064	17.721 1.062	0.964
Posterior capsulorexis	3.922 ± 0.373	3.865 ± 0.282	0.493
IOL power		26.629±3.071	

Table - 4: Comparison of VAO at 6 months and 1 year between the two study groups.

VAO	**I**	**II**	**P value**
At 6 months			
GRADE 0	22(67.7%)	20(61.3%)	0.859
GRADE 1	7(22.6%)	8(25.8%)	
GRADE 2	3(9.7%)	4(12.9%)	
GRADE 3	0%	0%	
At 1 year			
GRADE 0	18(54.8%)	16(48.4%)	0.957
GRADE 1	9(29.0%)	11(35.5%)	
GRADE 2	3(9.7%)	3(9.7%)	
GRADE 3	2(6.5%)	2(6.5%)	

The log MAR visual acuity was significantly higher in intervention 1 (0.465±0.143) as compare to intervention 2 (0.397 ± 0.108) at 1 year, which was statistically significant (P value 0.036). There were no statistically significant differences between the two interventions in, Axial length (19.661±0.452 Vs 19.657±0.482, p value 0.973), Corneal diameter (11.177±0.556

Vs11.193±0.477, p value 0.902) or IOP (11.613±1.874 Vs 11.258±1.182, p value 0.368), Refractive error (17.709± 1.064 Vs 17.721± 1.062, p value 0.964), Posterior capsulorexis **(**3.922 ± 0.373 vs 3.865 ± 0.282, p-value 0.493) at 1 year follow up period.

The posterior capsulorhexis/capsulotomy along with anterior vitrectomy is found to be the most accepted method to reduce visual axis opacification. The posterior capsulorhexis of patients enrolled in group 1 was done by manual technique whereas in the patients of group 2 posterior capsulotomy was done using Fugo blade/plasma knife. The average posterior capsulorhexis / capsulotomy margin size (mm) in group I and II was 3.922 ± 0.373 and 3.865 ± 0.282 mm respectively. Two patients (6.45%) were found to have a rise in IOP at 6 months follow up without any fundus changes of glaucoma. Both the patients were aphakic and they underwent cataract extraction at an early age. There was no statistical significance (p = 0.246) between the groups or between the techniques (manual versus fugo blade). Membranectomy had been done for 2 patients (6.45%). The posterior capsular opacification had been graded clinically into none, mild, moderate and severe. The severe PCO required immediate surgical intervention to clear the visual axis to prevent amblyopia. The patients who developed severe PCO underwent membrane to my and secondary IOL implantation in sulcus under general anesthesia. The rate of re-surgery between the techniques was not statistically significant (p = 1.0) (**Table - 3**).

The proportion of subjects with grade I, II and III VAO was 67.7%, 22.6%, and 9.7% respectively in an intervention I at 6 months. In intervention II group the proportions were 61.3%, 25.8%, and 12.9% respectively. None of the subjects in either group had grade III VAO. The difference in VAO between two intervention groups was statistically not significant (P value 0.859). The proportion of subjects with grade I, II, III and IV VAO was 54.8%, 29% 9.7% and 6.5% respectively in intervention I at 2 years. In intervention II group the proportions were 48.4%, 35.5%, 9.7% and 6.5% respectively. The difference in VAO between two intervention groups was statistically not significant (P value 0.957) (**Table - 4**).

Discussion

In children, the visual disability caused by a cataract is higher than any other form of treatable blindness. Children with untreated, visually substantial cataracts face a lifetime of blindness at awful quality of life and socioeconomic costs to the child, the family, and the society. Additionally, many other children suffer from partial cataracts that may slowly worsen over time, with progressive visual difficulties as the child grows. Evidence suggests that the cumulative risk of cataract during the growing years is as high as 1 per 1000 [12]. WHO has incorporated childhood blindness as a major priority in its 'vision 2020-the right to sight' initiative. The postoperative complication of pediatric cataract surgery includes posterior capsular opacification, glaucoma, retinal detachment, cystoid macular edema, decentration of the intraocular lens.

Posterior continuous curvilinear capsulorhexis (PCCC) with anterior vitrectomy (AV) is the most accepted method to reduce the visual axis ossification (VAO). The Fugo plasma blade (MediSurg Research and Management Corp., Norristown, PA, USA) has recently been approved for performing capsulotomies, iridotomies and trans ciliary filtration [13-15]. The Fugo Blade tip comes in different lengths and is flexible enough to be bent in various directions. The blade's extreme tip only gets activated for cutting. Plasma blade uses pulses of plasma, generated around the tip to cut and cauterize tissue without much collateral tissue damage.

The present study included two groups of children: first group aged less than 2 years while the second group had children between 2-5 year

group. In contrast, Sinha R, et al. [16] had children between the age range of 5 to 28 months.

Cadmak, et al. [17] evaluated the 132 eyes, 76 patients, retrospectively who underwent congenital cataract surgery. The commonest complications they reported were secondary cataract (24.2%), posterior synechiae (9.1%) and glaucoma (3%). The frequent complication in our study at the end of one-year follow-up was posterior capsular opacification (severe) in 6.5 % among group A and group B, moderate PCO in 9.7% of group A and 22.6-35.5% in group B. Other complications were a rise in IOP (6.45% of group A) and extension of posterior capsular margin in 6.45% of group 2B.

Horizolan, et al. [18] studied the comparison between vitrecto-rhexis versus forceps capsulorhexis for anterior and posterior capsulotomy after congenital cataract surgery. They found that both the techniques appeared to be equally safe and effective for the achievement of anterior and posterior capsulorhexis. In our study, we had done anterior capsulorhexis using forceps manually in all groups and the posterior capsulotomy by plasma knife in one group and manual forceps in another group.

The axial growth after cataract surgery is attributed to the normal growth of eyeball, age at surgery, visual input, presence or absence of IOL, laterality, genetic factors and inter-ocular AL difference [19]. In our study, we found that the axial length increases gradually during 1 year follow up in all four sub-groups. The mean axial length of the patients in both the study groups reported were comparable between two groups and with findings rom other similar studies. The primary outcome of the study was assessing the efficacy of Fugo blade in preventing VAO compared to manual technique. The study results showed that the efficacy of the both techniques was comparable all follow up visits and that. Hence the preferential use of Fugo blade may not provide any additional advantage in preventing VAO in pediatric cataract surgery compared to the manual technique. Newer techniques have to be developed in future to prevent VAO in pediatric cataract surgery.

Conclusion

Visual axis opacification after pediatric cataract surgery remains comparable in both techniques at one year (plasma knife assisted posterior capsulotomy and manual capsulorhexis). Plasma knife assisted posterior capsulotomy does not have any added advantage over manual posterior capsulorhexis in preventing visual axis opacification.

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