ORIGINAL RESEARCH PAPER

Ophthalmology

EFFECT OF 0.06% TRYPAN BLUE DYE (IRRIGATION IN THE CAPSULAR BAG) - TO PREVENT POSTERIOR CAPSULAR OPACIFICATION

KEY WORDS: PCO, Trypan blue dye

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ABSTRACT

PURPOSE: To study the effect of trypan blue dye (0.06%) on posterior capsular opacification (PCO) during capsular bag irrigation in eyes undergoing phacoemulsification and also compare its effect as against BSS used in same manner after 12 months of surgery.

METHODS: The observational study was conducted on 200 patients who underwent ECCE (phacoemulsification with intraocular lens implantation) in the department of Ophthalmology, Mathura Das Mathur Hospital, Dr. SN Medical College, Jodhpur. Patients with age 40-60 years are included whose visual acuity is of 6/60 or less.

RESULTS: The mean age of patient in Dye group was 52.3 years and in control group mean age was 52.9 years. The mean Total PCO score in Dye group was 0.16±0.23 with mean area was 100±0. In control group the mean Total PCO was 0.31±0.40 with mean area was 100±0. There was a significant difference between group as the p value is <0.05.

CONCLUSION: Capsular opacification, in particular, PCO, still remains a physiological complication of an uneventful cataract surgery. Our study shows that the injection of trypan blue dye under air in a capsular bag is not a difficult technique. This study gives a strong evidence of relating the cause (LECS) to the effect (PCO).

INTRODUCTION

Modern day cataract surgery (ECCE i.e. extracapsular cataract extraction eg. phacoemulsification) entails leaving behind an intact posterior lens capsule and a part of anterior capsule, comprising the capsular bag, for intraocular lens (IOL) implantation. Proliferation and differentiation of cells in the pre equatorial lens bow and their subsequent migration towards the posterior capsule leads to posterior capsule opacification (PCO).[1] The term PCO is actually a misnomer. The capsule itself does not opacify; an opaque membrane develops as a result of proliferation and migration of regenerative lens epithelial cells towards the posterior capsule. Posterior capsular opacification, 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.

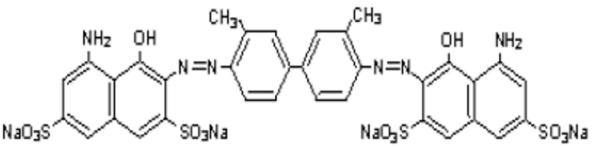
The incidence of PCO is known to range from as high as 50% to as low as <5% in eyes undergoing cataract surgery for uncomplicated senile cataracts.[2] PCO reduces visual acuity when the central area (inside the pupillary aperture) is involved. The amount of PCO and the size of the area analyzed are relevant since this could interfere with the appropriate interpretation of findings on scanning with a laser polarimetry.[3]

The PCO has two forms, fibrous and pearl.[4] Sometimes a combination of both is also found. The LECs that line the anterior capsule are believed to be responsible for fibrous PCO. Clinically it is seen as a wrinkling on the posterior capsule at the site of fusion of the anterior and posterior capsules. The LECs lining the pre-equatorial zone are responsible for the pearl or proliferative PCO. On examination it shows clusters of swollen, opacified differentiated LECs called bladder or Wedl cells.

Several systemic and ocular associations have been cited for influencing the development of PCO. The review of case records to evaluate the risk factors for PCO has revealed no correlation between PCO and gender, or axial length.[5]

The incidence of PCO is also high in eyes with uveitis. In these eyes, hydrophobic acrylic IOLs have shown to provide a better visual outcome and lower incidence of PCO than silicone, PMMA, or heparin-surface-modified PMMA IOLs. Patients with myotonic dystrophy have required multiple capsulotomies following cataract surgery.[6]

TRYPAN BLUE (an acid di-azo group dye). The drug substance trypan blue has the chemical name 3,3'-[(3,3'-dimethyl-4,4' biphenylylene) bis (azo)] bis (5-amino-4-hydroxy 2, 7-naphthalenedisulfonic acid) tetra sodium salt, a molecular weight of 960.8, a molecular formula of $C_{34}H_{24}N_6Na_4O_{14}S_4$, and has the following chemical structure:



Most clinical and experimental use indicates it is safe if used upto 0.1%.[7] It is approved by FDA for intraocular use and widely used already for the following-

1. Staining of the anterior capsule during phacoemulsificati on allows for successful completion of capsulorhexis when the red reflex is absent or insufficient.
2. In posterior segment surgery (viterectomy) and facilitate removal of epiretinal membrane.
3. In donor corneal grafts for vital staining of endothelial cells of cornea.

MATERIAL AND METHODS

The observational study was conducted on 200 patients who underwent ECCE (phacoemulsification with intraocular lens implantation) in the department of Ophthalmology, Mathura Das Mathur Hospital, Dr. SN Medical College, Jodhpur with due permission from the institutional ethical committee and review board and after taking written informed consent from patients.

INCLUSION CRITERIA: Age criteria 40 - 60 yrs. Visual acuity of 6/60 or less. Cataract types grade nucleus II/III cataract & nuclear sclerosis.

EXCLUSION CRITERIA: Patient with ocular pathology like glaucoma, pseudoexfoliation, uveitis. Patients with subluxated cataractous lens. Any previous intraocular surgery. History of any ocular trauma. Patients with systemic illness like hypertension, diabetes mellitus.

TECHNIQUE

In our study instead of staining anterior capsule for capsulorhhexis we used trypan dye 0.06% by injecting into the capsular bag after cortical wash under air and evaluated the effect of this capsular bag injection on prevention of posterior capsular opacification and compared it to the control group in which we had not used trypan dye and only washed with equivalent amount of balanced salt solution (BSS) injected into the capsular bag in a similar manner.

In my study all surgeries were done by well experienced single surgeon and all the other parameters remained fixed viz.

- Type of IOL used is aspheric hydrophilic made of premium quality biocompatible acrylic material.[9]
- Technical specifications:
- Overall length 13.00 mm
- Optic diameter 6.00 mm
- Optic design Equi – Biconvex[10]
- Aspheric optics and 360^0 square edge and haptic angulation of 0^0
- A constant 118.0

RESULTS

The patients were divided into two groups with 100 patients each.

DYE group - 100 patients
CONTROL group - 100 patients.

TABLE 1: DEMOGRAPHIC DATA

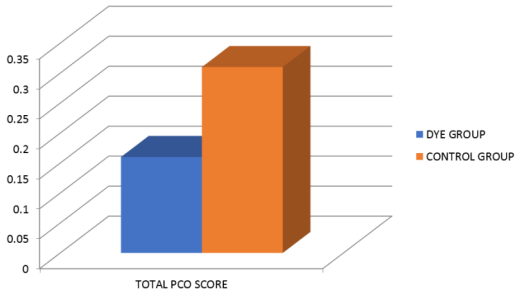
Parameter	Cases	Control
Age	52.3±4.8 years	52.9±4.8 years
Gender (M/F)	73/27	56/44

the mean age of patient in Dye group was 52.3 years and in control group mean age was 52.9 years. There is no significant difference between age in both group with a p-value of 0.809. 73 were males and 27 females in Dye group and in control group there were 56 males and 44 males.

TABLE 2: Distribution of patients in Dye and Control group with grade

Grade	Cases	Control
GRADE 0	100	100
GRADE 1	37	52
GRADE 2	25	39
GRADE 3	9	19
GRADE 4	0	6

Here, in Dye group 100 out of 100 patients are present with grade 0 and in control group 100 out of 100 patients are present with grade 0. in Dye group 37(37%) out of 100 patients are present with grade 1 and in control group 52(52%) out of 100 patients are present. in Dye group 25(25%) out of 100 patients are present with grade 2 and in control group 39(39%) out of 100 patients are present. in Dye group 9 (9%) out of 100 patients are present with grade 3 and in control group 19 (19%) out of 100 patients are present. in Dye group 0 (0%) out of 100 patients are present with grade 4 and in control group 6 (6%) out of 100 patients are present.



GRAPH 1: Total PCO score in Dye and Control group.

The mean Total PCO score in Dye group in graph 1 was 0.16±0.23 with mean area was 100±0. In control group the mean Total PCO was 0.31±0.40 with mean area was 100±0. There was a significant difference between group as the p value is <0.05.

DISCUSSION

Modern cataract surgery has progressed to a point where patients recover instant vision with least morbidity. There have been progressions in technology, IOL schemes and pharmacology. Phacoemulsification, suture less, self-sealing tunnel incision and foldable intraocular lenses (IOL) have transformed cataract surgery radically over the past two eras.[11] Postoperative astigamatism and inflammation are typically slight; visual recovery and patients restoration are enhanced. Notwithstanding developments in modern cataract surgery posterior capsule opacification (PCO) still leftovers a nagging postsurgical complication following phacoemulsification and intraocular lens (IOL) implantation.[5, 12,13-15]. Earlier onset and greater amblyogenic effect the rates of PCO in children ranged from 43.7% to 100% probably because of the high proliferations of LECs.[5,16,17]

The mean age of patient in cases was 52.3 years and in control group mean age was 52.9 years. There is no significant difference between age in both group with a p-value of 0.809. In a study by **Joshi et al**[18] the mean The average age of patients was 62.05 (±6.22) years in the trypan blue group and 64.92 (±7.16) years in the control group. There were 22 male and 28 female and an equal number of eyes (n = 50) were randomized into two groups. In our study there were 73 males and 27 females in case group and in control group there were 56 males and 44 males. PCO was found in total 37 eyes out of them 12 left eyes and 25 right eyes in Dye group and in control group PCO was found in total 52 eye out of them 22 left eyes and in 30 right eyes. In our study mean PCO score in Dye group was 0.16±0.23 with mean area was 100±0. In control group the mean PCO was 0.31±0.40 with mean area was 100±0. Here the use of trypan blue dye significantly lower PCO score in Dye group as compared control group with a p-value of 0.014. Our results correlates with the results of **Joshi et al**[18] they found that PCO score at 6 months is significantly lower in the dye group than in the control group. In their study the mean PCO score at 6 months was significantly lower in the dye group (0.10 ± 0.15) than in the control group (0.22 ± 0.30). Sharma and Panwar, in their study on PCO prevention by trypan blue dye, have shown that the PCO scores at 6 and 12 months were significantly lower in the dye group than in the control group.[9] The concentration of dye used in their study was 0.1% compared with 0.06% in our study. Sharma and Panwar found that the mean PCO scores at 6 months and 12 months were 0.10 and 0.15, respectively, in the trypan blue group (102 eyes) and 0.21 and 0.25, respectively, in the control group (103 eyes). The difference was statistically significant at 6 months (P=.042) and 12 months (P=.0227).[9] **Kothari et al**[19] study the efficacy and safety of 0.1% Trypan Blue dye to stain the anterior capsule for capsulorhexis in mature and hypermature cataracts. In all 25 eyes the capsulorhexis was completed. There was peripheral extension of the capsulorhexis in the eye with traumatic cataract and the stained edge of the anterior capsule helped identification and redirection of the capsulorhexis. Successful phacoemulsificat ion with intraocular lens implantation was performed in all eyes. Adverse reactions related to the dye such as raised intraocular pressure, anterior chamber inflammation and endothelial damage were not observed in the immediate postoperative period or at the end of mean follow-up of 3 months.

Trypan blue dye staining of the anterior capsule appears to be a very useful and safe technique that simplifies capsulorhexis in mature and hypermature cataracts.[19]

Thus in concurrence with other studies our study shows a strong evidence of trypan blue dye causes significant reduction in PCO when injected into the capsular bag.Though larger study with a longer follow up may be planned to see effects on longer term .

CONCLUSION

Capsular opacification, in particular, PCO, still remains a physiological complication of an uneventful cataract surgery. The quest for its eradication goes on. Different patient-related factors, ocular and systemic conditions, surgical techniques to remove the residual LECs, and residual cortical fibers and adjuncts influence the development of PCO.

The use of intraocular lenses with different biomaterials and edge designs can influence the progression of visually significant PCO. At present, meticulous use of surgical techniques and appropriate intraocular lens remain the mainstays for retarding the development of post-operative posterior capsule opacification in human. Our study shows that the injection of trypan blue dye under air in a capsular bag is not a difficult technique. This study gives a strong evidence of relating the cause (LECS) to the effect (PCO). Though the duration of the follow-up was only 12 months, a larger study with a longer follow up may be conducted to potentiate these findings.

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