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RESEARCH ARTICLE

EVALUATION OF CAPSULAR TENSION RING IMPLANTATION IN PHACOEMULSIFICATION OF CATARACTS WITH PSEUDOEXFOLIATION SYNDROME

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ABSTRACT

Purpose: To study the safety and efficacy of capsular tension ring in cataracts with pseudoexfoliation syndrome in terms of intraoperative and postoperative complications and to assess the visual acuity postoperatively in CTR and non CTR implanted patients.

Method: This prospective study included 100 patients with cataracts with pseudoexfoliation syndrome. Patients were randomized into two groups comprising 50 each. Group I underwent CTR implantation Group II had no CTR implanted. Intraoperative variables such as small pupil, extension of capsulorhexis, zonular separation, posterior capsule rupture and vitreous loss were assessed. Postoperative best corrected visual acuity was also assessed.

Results: In our study we found that 1(2%) patient out of 50 patients who underwent CTR implantation had zonular dialysis compared to 6(12%) out of 50 patients in non CTR group which was statistically significant (p=0.013) and also there was decrease in incidence of posterior capsular rupture noted in 2(4%) in CTR group and 8(16%) in non CTR group which was statistically significant (p value=0.042).

Conclusion: We found that, CTRs ensure safe removal of crystalline lens and stable placement of the IOL during phacoemulsification of eyes with pseudo exfoliation syndrome, thus preventing the risk of intraoperative & postoperative complications & improve patient outcomes.

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INTRODUCTION

Pseudoexfoliation syndrome (PXS) is a common and clinically important systemic condition characterized by the pathological production and accumulation of fibrillar extracellular material on many intraocular and extraocular tissues including muscles, heart, lungs, liver, kidney and meninges (Schlotzer-Schrehardt *et al*., 1992). It results in deposition of exfoliative material on ciliary body, ciliary zonules, lens capsule and corneal endothelium and presents as white flecks on the pupillary margin with loss of iris pigments which can be diagnosed on slit lamp examination (Allingham *et al*., 2011). It is most commonly seen between 60 and 70 years (Duke-Elder, 1969). It is frequently associated with open angle glaucoma and poor pupillary dilatation (Brooks and Gillies, 1988; Carpel, 1988). Cataract surgery in the presence of PXS has been associated with an increased incidence of intraoperative complications because of weak zonules (Naumann *et al*., 1998).

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In PXS, lysosomal proteinases destroy the normal basement membrane, so the basement membrane structure loosens the zonule-lens capsule complex. The rotational and anterior-posterior forces created during nucleus emulsification may lead to zonular separation, posterior capsular rent and vitreous loss (Bayraktar *et al*., 2001). Capsular Tension Rings (CTRs) are used to stabilize the capsular bag of the crystalline lens both during and after cataract surgery. CTR works by imparting a centrifugal force to the equator of the capsular bag. This force is equalized throughout the entire zonular- capsular apparatus, thereby transmitting the tension from intact and normal zonules to those areas of zonule laxity or absence. By increasing the overall bag stability the risk of intraoperative complication is reduced (Gimbel *et al*., 1997). In addition, CTR decreases postoperative capsular contraction, posterior capsular opacification and improves intraocular lens (IOL) centration (Lee *et al*., 2002). In this study, we evaluated the efficacy of capsular tension ring implantation on intraoperative complications resulting from zonular weakness during phacoemulsification of cataract associated with pseudoexfoliation syndrome.

MATEIALS AND METHODS

This prospective randomized study conducted between June 2013 to December 2013 comprised 100 eyes diagnosed as having cataract associated with PXS. Patients were randomly assigned into 2 groups. 50 eyes (Group I) underwent phacoemulsification with CTR implantation. The other 50 eyes (Group II) had no CTR implanted and served as a control group. All patients provided informed consent. Patients with cataract associated with pseudoexfoliation syndrome were included in the study. The criteria for exclusion were complicated cataract, traumatic cataract and cataracts secondary to systemic diseases. All the patients had similar protocol for standard cataract evaluation which consisted of recording of visual acuity, slit lamp examination for diagnosis of pseudoexfoliation syndrome and detailed fundus evaluation. All patients were put on oral Tab Ciprofloxacin 500mg twice daily and Ciprofloxacin 0.3% eye drops hourly one day prior to the surgery. Preoperatively, the operating eye was instilled with Tropicamide with Phenylephrine 0.5% drops and Flurbiprofen 0.3% drops alternatively every 15 min for dilatation of pupil.

The surgical technique was standardized and performed by a single surgeon. After subtenon's or peribulbaranaesthesia , a 3.2 mm temporal clear corneal incision was made with a crescent blade. The anterior chamber was filled with sodium hyaluronate 3.0%- chondroitin sulphate 4.0%. A continuous curvilinear capsulorhexis (CCC) performed with bent 26 G cystitome needle. All capsulocortical attachments were loosened by careful, thorough hydrodissection. A polymethyl methacrylate (PMMA) CTR was implanted with a forceps in the capsular bag through the CCC. Nuclear phacoemulsification was performed and intraocular lens was implanted in the capsular bag in all the eyes after ensuring complete cortical removal by automated irrigation/ aspiration. Stromal hydration was performed by injecting fluid into the sides of the clear corneal incision. The surgery was concluded with a subconjunctival injection of gentamycin and dexamethasone.

Intraoperative observations such as small pupil, extension of capsulorhexis, zonular separation, posterior capsular rupture and vitreous loss were documented. Intraoperative zonular separation was defined as zonular dialysis of at least 90 degrees with or without lens drop into vitreous cavity. The standard postoperative drug regime included a combination of moxifloxacin and prednisolone eye drops, one drop hourly for a week and 4 times a day for 1 month with weekly tapering. Postoperative follow-up examinations were conducted at 1day, 1 week, 1month, 3rd month and 6 months. During the follow up visits, a complete ophthalmic examination was performed including visual acuity, slit lamp examination, tonometry and fundus examination. The best UCVA and BCVA in each patient was recorded throughout the followup.

Statistical Analysis

Data was analysed using the statistical program for social sciences (SPSS) software. Student t test (two tailed, independent) has been used to find the significance of study parameters. Chisquare/ Fisher Exact test has been used to find the significance of study. A probability value (p value) <0.05 will be considered statistically significant.

RESULTS

The most common presenting age group was 61-70 years with a mean age of 66.06±8.97 and 63.72±7.28 years in group I and group II respectively

Intraoperative complications

In the present study intra operative complications was documented in both the groups. Small pupil was present in 10 (20%) patients in group I and 11(22%) patients in group II, which was not statistically significant (p =0.247). Extension of capsulorhexis was seen in 2(4%) patients in group I and group II with p value 0.614 which was not statistically significant. 1(2%) patient in group I had zonular separation while 6 (12%) patients in group II had zonular separation, with p value 0.013 which was statistically significant. Posterior capsular rupture was observed in 2(4%) patients in group I and 8(16%) patients in group II which was statistically significant (p=0.042). There was 1(2%) vitreous loss observed in group I and 4(8%) in group II which was not statistically significant (p = 0.173).

Postoperative visual acuity

Best corrected visual acuity was documented in both the groups. On the 1stpost operative day, 32(64%) patients in group I had visual acuityin the range of 6/6-6/9 and 25(50%) patients in group II had visual acuity in the range of 6/6-6/9.
At end of six month postoperative period, 46(92%) patients out of 50 patients in CTR group had postoperative visual acuity ranging between 6/6 -6/9 as compared to 44(88%) patients out of 50 patients in non CTR group. No statistical significant differences was noted between two groups in terms of visual outcome.

Postoperative complications

Corneal edema and iritis was observed in 5(10%) cases in group I and 8(16%) cases in group II (p value=0.372), which was not statistically significant. Also postoperatively there was rise in IOP in 4(8%) patients in group I and 5 (10%) patients in group II (p value = 0.632), which was not statistically significant.

DISCUSSION

Cataract surgery is considered to be a challenge and associated with an increased incidence of complications in eyes with pseudoexfoliation syndrome. It is associated with an increased incidence of glaucoma, cataract, phakodonesis. These factors are believed to increase the rate of intraoperative zonular separation, vitreous loss, postoperative IOP spikes, corneal edema, and fibrin reaction in the anterior chamber, affect the site of IOL placement and reduce postoperative visual acuity.
Capsular tension ring implantation was first described by Legler and Witschel in 1993. When the ring is inserted in the capsular bag, it stretches the capsule equator and distributes the force equally to all the zonules.

In the regions in which zonular support is absent or inadequate, the ring supports the capsular bag and facilitates surgery. The most common presenting age group was 61-70 years with a mean age of 66.06±8.97 and 63.72±7.28 years in group I and group II respectively. Epidemiological studies of PXS have shown that it is more common in patients older than 60 years and prevalence further increases with age (Jawad *et al*., 2009). In our study, 43 (43%) were males and 57 (57%) were females. Studies regarding the sex distribution of PXS are conflicting. Some studies showed male preponderance while Aravind *et al*. in 2003 showed no sex predilection (Arvind *et al*., 2003).

Among the 100 patients, 65 patients were operated for right eye and 35 patients were operated for left eye.Preoperative visual acuity recording in both group I and group II was done. After all necessary preoperative investigations patients were posted for phacoemulsification surgery. In group I CTR was implanted which was followed by phacoemulsification with foldable IOL implantation. In group II, patients underwent routine phacoemulsification with foldable IOL implantation. Intra operative complications was documented in both the groups (Table 1). Small pupil was present in 10(20%) patients in group I and 11(22%) patients in group II with p = 0.247, which was not statistically significant. Extension of capsulorhexis was seen in 2(4%) patients in group I and group II with p value 0.614 which was not statistically significant. 1(2%) patient in group I had zonular separation during surgery. In group II, zonular separation occurred in 6 eyes (12%). The rate of intraoperative zonular dialysis was statistically significant between the 2 groups (p= 0.013). Posterior capsular rupture was found in 2(4%) patients in group I and 8(16%) patients in group II, which was statistically significant (p=0.042). Our data indicates 2% vitreous loss in group I and 8% in group II, which is related to capsular rupture, which was not statistically significant (p = 0.173).

Küchle found an intraoperative complication rate of 13.4% in the eyes with an anterior chamber depth less than 2.5 mm and 2.8% in eyes with an anterior chamber depth of 2.5 mm or more (Kuchle *et al*., 2000). In a study by Bayraktar *et al*, there were no cases of zonular dialysis reported in CTR group while 5 eyes (12.8%) in the control group had intraoperative zonular dialysis. Posterior capsule rupture occurred in 2 eyes (5.2%) in CTR group and 3(7.7%) in control group.[7]Vitreous prolapse in 21 (10.5%) patients and posterior capsular rupture in 18 (9%) patients were the most common complications seen in pseudoexfoliation in a study conducted by Jawad *et al*. (2009) In a study by Naumann GO, vitreous loss in patients with pseudoexfoliation has been reported to be five times more common than in patients without this disorder (9.0% vs.1.8%) which is related to an increased incidence of zonular dialysis, lens subluxation and capsular rupture (Naumann, 1988).

At end of six month postoperative period, 46(92%) patients out of 50 patients in CTR group had postoperative visual acuity ranging between 6/6 -6/9 as compared to 44(88%) patients out of 50 patients in non CTR group. No statistical significant differences was noted between two groups in terms of visual outcome. Our study findings were similar to the study by Bayraktar, who found no statistical significance in BCVA between CTR group and control group (Bayraktar *et al*., 2001). In our study, postoperative complications were noted in both the groups (Table 2). One day postoperatively, corneal edema and iritis was present in 5 eyes (10%) in group I and 8 eyes (16%) in group II (Table 10). The difference was not statistically significant (p=0.372). Corneal edema resolved in 2 to 7 days in all eyes. The intraocular pressure (IOP) was measured both preoperatively and postoperatively. On the 1st postoperative day, transient IOP spikes were observed in 4(8%) patients in group I and 5 (10%) patients in group II (p value = 0.632), which was not statistically significant.

Table 1. Intraoperative complications

Intraoperative Complications	Group I (n=50)		Group II(n=50)		P value
	No	%	No	%	
Small pupil	10	20	11	22	0.247
Extension of capsulorhexis	2	4	2	4	0.614
Zonular separation	1	2	6	12	0.013
Posterior capsule rupture	2	4	8	16	0.042
Vitreous loss	1	2	4	8	0.173

Table 2. Postoperative complications

Postoperative Complications	Group I (n=50)		Group II (n=50)		P value
	No	%	No	%	
Corneal edema	5	10.0	8	16.0	0.372
Iritis	5	10.0	8	16.0	0.372
Increased IOP	4	8.0	5	10.0	0.632

The decreased incidence of zonular dialysis in group I (CTR group) is evidence that the ring is effective in preventing zonular separation during phacoemulsification in eyes with PXS.The CTR was implanted successfully in all eyes in group 1. It can be inserted at any stage of cataract surgery. However, the optimal timing remains controversial. To support the area of zonular weakness and distribute the forces equally over all zonules, the CTR is usually inserted after hydrodissection and before phacoemulsification.

Early post-operative rise in IOP was because of inflammation which subsided with treatment after 1-2 weeks. In a study by Bayraktar, corneal edema was present in 14 eyes (35.9%) in the CTR group and 12 eyes (30.8%) in the control group, which was not statistically significant. Postoperative fibrin reaction in the anterior chamber was seen in 3 eyes (7.7%) in the CTR group and in 7 eyes (17.9%) in control group. Transient IOP spikes were observed in more control eyes than in eyes with a CTR but at the last visit, mean IOP was not

significantly different between the 2 groups (2001). Intraocular lens decentration is more common even when the lens is entirely in the capsular bag, primarily due to decentration of the entire bag. In our study, no such cases were reported. Early follow up of CTR use in loose zonules found excellent IOL centration 2 to 11 months postoperatively in the study by Gimbel *et al*. (1997). Our study had limitations. The mean follow-up was short; thus, we could only assess the influence of the CTR intraoperatively and in the early postoperative period. Several studies report high rates of posterior capsule opacification (PCO) and anterior capsule contraction resulting in late IOL dislocation in eyes with pseudoexfoliation syndrome (Davison, 1993).A minimum of 1 to 2 years of follow-up will be needed to confirm that CTR implantation reduces the rates of IOL decentration and PCO.

Conclusion

In our study, we found that zonular separation and posterior capsular rupture occurred more in non CTR group than in CTR group which was statistically significant.At the end of six month postoperative period, both the groups had better visual outcome which was not statistically significant. Postoperative complications like iritis, corneal edema and rise in IOP were noticed in both the groups which resolved after 1 month, which also had no significant statistical differences. So, CTR implantation in cataracts with pseudoexfoliation syndrome stabilizes the zonules and ensures safe surgery with reduced intraoperative and postoperative complications. Thus, increasing the rate of well centered in the bag IOL implantation.

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