Original Article

A Randomized Clinical Trial on Topical Ketorolac Administration Following Phaco-Surgery for Pseudoexfoliation Syndrome

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Abstract

The current randomized clinical trial was conducted to determine the influence of topical ketorolac combination with steroids on anterior segment inflammation and other adverse effects following phaco-surgery for pseudoexfoliation (PEX) syndrome. A total of eighty-eight patients with PEX and cataracts who had undergone phacoemulsification participated in the trial. They were randomly placed into one of two groups, which received betamethasone (0.1%) and chloramphenicol (5%) for two weeks, either with or without ketorolac eye drops (0.5%). The two groups' six-month post-operative differences in ACO (Anterior Capsule Opacification) and PCO (Posterior Capsule Opacification) were compared using SPSS 21 software. Measurements of BCVA (Best-Corrected Visual Acuity), IOP (Intraocular Pressure), and ACI (Anterior Chamber Inflammation) were taken on days 1, 3, 7, and 30 after surgery.

Between the 46 patients in the study group (who took ketorolac) and the 42 patients in the control group (who did not take ketorolac), there was no change in IOP or BCVA on days 30, 7, 3, and 1 following surgery ($P > 0.05$). The study group had reduced levels of PCO and ACO at six months postoperatively ($P < 0.05$), as well as decreased ACI on days 30, 7, and 3 postoperatively ($P < 0.05$). After cataract surgery, individuals with cataracts and PEX saw a synergistic effect on post-operative ACI reduction when ketorolac eye drops were combined with steroid eye drops. This combination also had further impacts on PCO and ACO reduction.

Keywords: Cataract, Ketorolac, Pseudoexfoliation syndrome, Phaco-surgery

Introduction

One in three blind people worldwide [1], particularly among the elderly [2], is blind due to cataracts, the most common cause of blindness worldwide. The front-line treatment strategy for cataracts is to replace the opacified intraocular lens (IOL) with an artificial crystalline lens via surgery [3] by multiple techniques, the most common of which is phacoemulsification [4]. In general, cataract surgery is safe and is associated with fewer serious complications, some of which are capsule rupture, retinal detachment, choroidal hemorrhage, and endophthalmitis. However, these adverse effects may lead to disturbed patient vision [5, 6].

A concomitant condition affecting the eyes is pseudoexfoliation syndrome (PEX), which weakens the zonular apparatus and capsule, increasing the risk of intraoperative and subsequent complications for those with it [7]. A distinct fibrillar substance that is deposited in the outer layer of the eye and other body segments is linked to this systemic condition. This condition raises the probability rate of anterior chamber inflammation (ACI), vitreous loss, lens dislocation, capsular phimosis, IOP spike, and corneal decompensation following surgery [8]." Accordingly, there is a need for further studies on this disease to reduce the risk of complications during and following phacoemulsification [9, 10]. According to specialists, experienced and skilled surgeons of phacoemulsification can eliminate the incidence rate of elevated adverse effects in eyes suffering from cataracts and PEX [11].

Another major complication following the cataract operation is inflammation, which can normally be prevented by prescribing post-operative eye drops, including NSAIDs (Non-Steroid Anti-Inflammatory Drugs) and steroids [12]. Various studies have examined and compared the effect of each of these two on post-operative adverse effects [12].

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Based on the literature review, limited scientists examined the effect of NSAIDs in combination with steroids in subjects suffering from PEX following phacoemulsification regarding the cataract. Multiple studies reported significant positive effects for the combination of NSAIDs with steroids [13], while others found insignificant differences [14]. This controversy in different reports with various follow-up durations and types of NSAIDs/steroids used led us to investigate the impact of ketorolac eye drops in combination with topical steroids on post-surgical inflammation and anterior segment adverse effects in PEX patients.

Materials and Methods

Patients with grade 3 cataracts with PEX and indications of phacoemulsification who were sent to the Hospital of Amir-al-Momenin in Rasht (Iran) between October 2016 and May 2019 were the subjects of the current endeavor. The research protocol, IRCT20160919029871N3, which was filed on the Iranian registry of clinical trials, was approved by the Guilan University of Medical Sciences Ethics Committee.

All patients were treated by the same ophthalmic surgeon. The OCCCGS (Oxford Clinical Cataract Classification and Grading System) was used to determine the cataract grade. The PEX was detected during slit lamp examination. An inclusion criterion was at least grade 3 cataracts with PEX and an indication of phacoemulsification. The exclusion criteria were hypersensitivity to any NSAIDs, ocular inflammation or trauma, chronic uncontrolled ocular or systemic disease, undergoing other cataract surgeries such as extracapsular or intracapsular techniques, history of oral, inhaled or locally taking NSAIDs a week before surgery or steroids by 2 weeks before surgery.

Patients were randomly allocated into the study group (topical ketorolac, additional to chloramphenicol and betamethasone) or the control group (chloramphenicol and betamethasone). Eligible patients were explained the research goals and methods and provided informed written consent to participate in the study voluntarily. Based on a 99% confidence interval and 90% test power, Coassin *et al*. [14] calculated the sample size to be 92. Forty-six patients in the study group and forty-six in the control group were removed from the trial because they did not receive a referral and did not cooperate.

The same surgeon performed standard phacoemulsification for all patients via a temporal incision (2.8 mm) and insertion of *enVista*® acrylic hydrophobic IOL in the lens capsule having 5-6mm-capsulorhexis. All patients underwent chloramphenicol (5%, Chlobiotic; Sina Company; Iran) plus betamethasone (0.1%, Chlobiotic; Sina Company; Iran) on the day after surgery every 4 hours two drops for each eye within 2 weeks and subsequently every 8 hours within 2 other weeks (a month in total). The research units were allocated into two groups by simple randomization, with a block size of 4 and a ratio of 1:1. Patients were blind to group allocation, and the study had a single-blinded design. These two and the ketorolac (study) group received ketorolac tromethamine (0.5%, Sinarolac, the same company) plus every 6 hours within 15 days.

The recorded demographic profiles of the participants were age and gender. The patients were examined at 1, 3, 7, and 30 days and 6 months postoperatively. The main results were tests of the anterior and posterior segments, such as IOP, ACI, and BCVA (Best Corrected Visual Acuity). At 1, 3, 7, and 30 days following surgery, ACI was assessed using slit-lamp examination data on cell counts and flare categorization. Based on the protein level, the number of individuals with this complication was calculated and ranged from 0 to 4. The working group of Standardization of Uveitis Nomenclature [15] classified the cases as follows: 0 represents none, 1+ represents faint, 2+ represents moderate (lens and iris details clear), 3+ represents marked (lens and iris details hazy), and 4+ represents intense (plasmoid or fibrin aqueous). Through the Snellen chart, Goldman Applanation Tonometry and BCVA were used to calculate the IOP, which was then reported using Log MAR.

The slit lamp test was used to examine the degree of ACO (Anterior Capsule Opacification) and PCO (Posterior Capsule Opacification) six months following surgery. The results were scored from 0 to 4. In terms of PCO, grade 0 (none) denotes the absence of any PCO, grade 1 (trace) denotes the presence of a few discrete epithelial pearls, grade 2 (mild) denotes the presence of several discrete epithelial pearls, grade 3 (moderate) denotes the presence of many coalescent epithelial pearls, and grade 4 (severe) denotes the presence of thick sheets [16]. When it comes to the ACO, grade 0 (clear) denotes a transparent anterior capsule, grade 1 denotes opacification on the capsulorhexis's edge, grade 2 denotes occasionally diffuse and moderate opacification with capsular folding, grade 3 denotes intense opacification with capsular folding, and grade 4 denotes constriction (phimosis) of the capsulorhexis opening with a diameter of less than a mm. The same anterior segment surgeon (M.A.) performed all examinations of the research units and surgical protocols and follow-up examinations.

The medications of those undergoing prostaglandin analogs to treat glaucoma were substituted with another anti-glaucoma agent. The excluded ones were the subjects with intraoperative adverse effects like vitreous loss and posterior capsule rupture and the patients requiring systemic NSAIDs or corticosteroids because of severe inflammatory responses after surgery.

Statistical Analysis

Data were described as percentage frequency and mean (± SD or standard deviation). Numerical data between the two groups were compared using the Mann-Whitney test or t-test, and the normality of the data was evaluated using the Kolmogorov-Smirnov test. Fisher's exact and Chi-square tests were used to compare the classified data between the two

groups. The impact of time was evaluated using ANOVA repeated measurements or Friedman's test, an analogous non-parametric test. To perform a pairwise comparison for significant differences, we used Tukey's post hoc test. The SPSS21 program was used to analyze the data (Armonk, NY: IBM Corp.; IBM Corp., 2012). P<0.05 was regarded as the statistically significant threshold.

Results and Discussion

Forty-six (46) patients participated in the study group (with ketorolac), and 42 patients in the control group (without ketorolac). **Table 1** presents the participants' demographic characteristics. The two groups were homogenous for the average age, age distribution, and gender (P>0.05).

Table 1. The participants' demographic details and a comparison of them between the study's two groups

Variables	Categories	Total	The group of Ketorolac (N=46)	The group of Control (N=42)	p-value
Age categories (years), No.(%)	≤60	9(10.23)	3(6.52)	6(14.29)	0.486*
	61-70	27(30.68)	14(30.43)	13(30.95)	
	>70	52(59.09)	29(63.04)	23(54.76)	
Age (years), mean ± SD		71.58±7.82	71.96±7.06	71.17±8.65	0.639†
Sex, No (%)	Male	41(46.59)	21(45.65)	20(47.62)	0.853‡
	Female	47(53.41)	25(54.35)	22(52.38)	

* Results of Fisher's exact test of independent samples of t-test; The Chi-squared test findings

According to the BCVA test data **(Table 2)**, there was no significant difference in this regard between the groups at the intervals measured (P>0.05), and the Friedman test data displayed the significant impact of time (P<0.001) and a better post-operative BCVA in both groups (P<0.001). Comparison of mean differences in BCVA values between pre- and post-operative status **(Table 2)** revealed a significant improvement on days 3 and 7 postoperatively (both P = 0.022), whereas not on months 1 and 6 postoperatively (P> 0.05).

Table 2. Contrasting the two research groups' greatest corrected visual acuity in the tested intervals based on Log-MAR

Variables		Total	The group of Ketorolac (N=46)	The group of Control (N=42)	p-value*
Before surgery	mean±SD	1.11±0.39	1.15±0.36	1.15±0.36	0.449
	Median	1.04	1.13	1.00	
One day after surgery	mean±SD	0.73±0.29	0.81±0.27	0.85±0.31	0.326
	Median	1.00	1.00	1.00	
Compared to the status before surgery	mean±SD	-0.30±0.26	-0.35±0.19	-0.25±0.31	0.171
	Median	-0.30	-0.30	-0.30	
After surgery (Three days)	mean±SD	0.73±0.28	0.70±0.27	0.77±0.29	0.301
	Median	0.70	0.70	1.00	
Compared to the status before surgery	mean±SD	-0.40±0.29	-0.46±0.25	-0.32±0.31	0.027
	Median	-0.39	-0.48	-0.30	
After surgery (Seven days)	mean±SD	0.61±0.28	0.57±0.25	0.66±0.30	0.141
	Median	0.70	0.52	0.70	
Compared to the status before surgery	mean±SD	-0.51±0.26	-0.58±0.19	-0.43±0.30	0.027
	Median	-0.48	-0.48	-0.48	
After surgery (One month)	mean±SD	0.45±0.22	0.42±0.21	0.48±0.23	0.173
	Median	0.40	0.40	0.52	
Compared to the status before surgery	mean±SD	-0.67±0.29	-0.74±0.26	-0.60±0.30	0.155
	Median	-0.70	-0.70	-0.66	
After surgery (Six months)	mean±SD	0.34±0.20	0.33±0.19	0.36±0.20	0.488
	Median	0.30	0.30	0.30	
Compared to the status before surgery	mean±SD	-0.77±0.32	-0.83±0.29	-0.77±0.32	0.191
	Median	-0.78	-0.78	-0.74	

*The Mann-Whitney U test results

According to the IOP test results **(Table 3)**, there was no difference in this regard between the two groups at any of the intervals measured (P>0.05). Hence, the Friedman test results revealed a significant impact of time (P<0.001) and a better post-operative IOP in both groups (P<0.001). Comparison of mean differences in IOP values between pre- and post-operative status **(Table 2)** revealed significant IOP values in the study group on month 1 after surgery (P=0.027) but not in other time points (P> 0.05).

Table 3. Making a comparison between the groups' intraocular pressures at the recorded periods

Variables		Total	The group of Ketorolac (N=46)	The group of Control (N=42)	p-value*
Before surgery	mean±SD	16.23±2.92	16.54±2.65	15.88±3.19	0.675
	Median	16.00	16.00	16.00	
One day after surgery	mean±SD	17.72±2.46	17.67±2.68	27.76±2.23	0.679
	Median	17.00	17.00	17.50	
Compared to the status before surgery	mean±SD	1.49±2.43	1.13±1.15	1.88±3.28	0.641
	Median	1.00	1.00	1.00	
After surgery (Three days)	mean±SD	17.45±2.19	17.35±2.29	17.57±2.09	0.478
	Median	17.00	17.00	17.00	
Compared to the status before surgery	mean±SD	1.23±2.42	0.80±1.20	1.69±3.22	0.302
	Median	1.00	1.00	1.00	
After surgery (Seven days)	mean±SD	17.06±1.84	16.87±1.96	17.26±1.70	0.235
	Median	17.00	17.00	17.00	
Compared to the status before surgery	mean±SD	0.83±2.52	0.33±1.16	1.38±3.38	0.095
	Median	1.00	1.00	1.00	
After surgery (One month)	mean±SD	16.81±1.81	16.67±1.93	16.95±1.68	0.370
	Median	16.5	16.00	17.00	
Compared to the status before surgery	mean±SD	0.58±2.25	0.13±1.20	1.07±2.95	0.022
	Median	0	0	1.00	
After surgery (Six months)	mean±SD	16.70±1.92	16.62±1.98	16.78±1.86	0.517
	Median	16.00	16.00	17.00	
Compared to the status before surgery	mean±SD	0.49±2.24	1.19±0	2.95±1.00	0.055
	Median	1.00	1.00	1.00	

*The Mann-Whitney U test results

Based on the categorization of cell count and flare at 3, 7, and 30 days postoperatively, **Table 4** illustrates the considerable differences in ACI distributions between the two groups. Higher degrees of inflammation were more frequently seen in the controls. The Friedman test results showed that time significantly impacted groups (P<0.001). There were also important differences between the two groups seven (P<0.001) and one (P<0.001) days after surgery, one month (P<0.001) and one day (P<0.001), and one month (P<0.001) and three days (P<0.001) after surgery, and between those two groups.

Table 4. Comparing the subjects' levels of inflammation in the two research groups' assessed intervals based on flare categorization and cell count

	Variables	Grade	Total	The group of Ketorolac (N=46)	The group of Control (N=42)	p-value
Flare classification	One day after surgery	0	20(22.73)	13(28.26)	7(16.67)	0.372*
		1	39(44.32)	17(39.96)	22(52.38)	
		2	24(27.27)	14(30.43)	10(23.81)	
		3	5(5.68)	2(4.35)	3(7.14)	

Cell count	Three days after surgery	0	18(20.45)	15(32.61)	3(7.14)	0.005*
		1	53(60.23)	26(56.52)	27(64.29)	
		2	17(19.32)	5(10.87)	12(28.57)	
	Seven days after surgery	0	39(45.88)	29(65.91)	10(24.39)	<0.001†
		1	43(50.59)	15(43.09)	28(68.29)	
		2	3(4.53)	0	3(7.32)	
	One month after surgery	0	60(73.17)	39(95.12)	21(51.22)	<0.001*
		1	22(26.83)	2(4.88)	20(48.78)	
	One day after surgery	0	6(6.82)	3(6.52)	3(7.14)	0.824†
		1	48(54.55)	24(52.17)	24(57.14)	
		2	31(35.23)	18(39.13)	13(30.95)	
		3	3(3.41)	1(2.17)	2(4.76)	
	Three days after surgery	0	6(7.06)	5(11.63)	1(2.38)	0.007†
		1	60(70.59)	34(79.07)	26(61.90)	
		2	18(21.18)	4(9.30)	14(33.33)	
		3	1(1.18)	0	1(2.38)	
	Seven days after surgery	0	25(32.89)	22(53.66)	3(8.57)	<0.001†
		1	46(60.53)	19(46.34)	27(77.14)	
		2	5(6.58)	0	5(14.29)	
	One month after surgery	0	54(73,97)	40(97.56)	14(43.75)	<0.001*
		1	19(26.03)	1(2.44)	18(56.25)	

* The Fisher's exact test results; the Chi-square test findings; all values are given as No. (%)

Based on **Table 5**, the two groups had an important difference in PCO (P=0.002) and ACO (0.001), and the study group experienced no ACO grades 3 and 4 and PCO grade 3.

Table 5. contrasting the subjects' anterior and posterior capsule opacities at the intervals that were assessed between the two research groups

	Grade	Total	The group of Ketorolac (N=46)	The group of Control (N=42)	p-value
Posterior capsule opacity	0	16(18.18)	12(26.09)	4(9.52)	0.002*
	I	53(60.23)	31(67.39)	22(52.38)	
	II	18(20.45)	3(6.52)	15(35.71)	
	III	1(1.14)	0	1(2.38)	
Anterior capsule opacity	I	63(71.59)	40(86.96)	23(54.76)	0.001†
	II	17(19.32)	6(13.04)	11(26.19)	
	III	7(7.95)	0	7(16.67)	
	IV	1(1.14)	0	1(2.38)	

* Following Fisher's exact test, the findings were: the Chi-square test findings; all values are given as No. (%)

Although PEX patients are advised to obtain a lower BCVA when compared with non-PEX ones following phacoemulsification, the results of this single-blinded RCT indicate that all study participants and control groups with similar demographic profiles demonstrated an improvement in visual acuity, confirming the surgical procedure efficacy suggested with the proposed drugs in improving the visual acuity of affected individuals [16, 17]. A study by Sastry and Singal found that the mean BCVA of PEX patients was 1.02±0.64 on the day after the cataract operation. This is higher than expected, and the average logMAR BCVA of this research unit at the same time point (0.73±0.29) indicates that the current study's BCVA is superior to the earlier study's BCVA.

According to our findings, the study group had a greater average change in BCVA postoperatively on days 3 and 7. However, no difference was found in the mean BCVA between the groups at the examined time points. The data clarified no significant change in post-operative visual acuity following the addition of ketorolac to steroids in PEX patients after phacoemulsification. In the research of Coassin *et al*. the PEX patients who were candidates for cataract surgery were randomly allocated into groups receiving dexamethasone (0.1%) and tobramycin (0.3%) with or without bromfenac (0.09%). Based on their findings, the two groups showed no difference in the post-operative visual acuity [14], in line with our results, although the type of prescribed NSAID and steroid were different. Reportedly, NSAIDs and steroids can effectively prevent inflammatory responses following cataract surgery, whereas predominantly, either of them is administrated [18]. The results of 15 RCTs overview revealed that the patient's visual acuity following the cataract operation had no significant difference between those undergoing steroids or NSAIDs [12]. Despite consistent with this study's results, this review did not consider PEX patients and assessed the individual impacts of the drugs, not the extra influences. Accordingly, there is a need for further research to explore the NSAID's additional effect on PEX patients' visual acuity after phacoemulsification.

The IOP is also a key parameter following the cataract operation to indicate the susceptibility of patients to glaucoma [19]. Glaucoma is a main PEX comorbidity, and sub-clinically high IOP levels can elevate post-operative IOP risk and disrupt the surgical obtains [19]. Although the glaucoma risk decreases in PEX subjects following the cataract operation [20], the IOP continues to be a serious adverse effect in such individuals following the cataract operation, which can be followed by the PEX severity and the IOP values after the operation [17]. Our data clarified a significant impact of time and decreased average IOPs after surgery. In an effort by Vahedian *et al*. the IOP was significantly reduced after six months to 12.57±1.58 from 17.45±3.32 mmHg [21], in line with our results, although the values differ. In a study of Sastry and Singal, the mean IOP was 26.23±11.40 mmHg on day one following the cataract operation in PEX subjects, which is near to the average IOP of our controls (27.76±2.23). Still, there is no test in the work of Sastry and Singal on administering eye drops after the operation. Despite the average IOP in the people receiving ketorolac being lower a day following the operation (17.67±2.68), the IOP possessed a non-normal distribution, and no differences in medians exist between the groups. In the between-group comparison in our study, the average IOP data were identical to pre-operative circumstances at the examined time points with significantly greater average change in IOP on month one in the control.

In our study, the results of additionally measured PCO and ACO demonstrated that their frequency had differences between the groups, and no PCO grade 3 and ACO grades 3 and 4 were found among the members of the ketorolac group. PCO and ACO are the common adverse effects following cataract surgery, which can lead to secondary visual loss and need Nd-YAG capsulotomy or other measures [22]. Our data reported a decrease in the risk of high-grade PCO and ACO by adding ketorolac to steroids. In a study on 13368 candidates for cataract surgery, no benefit was found by combining NSAIDs and steroids with mere steroids regarding the capsulotomy rates [23]. This frequency had not been determined in our attempt to compare the findings.

The ACI was the other most significant side effect after the operation investigated in our work, which is important in PEX patients and is supposed to possess a great risk following phacoemulsification [11, 24]. We discovered 24 of 86 instances during the same period when Sastry and Singal reported that 11 of 35 PEX participants had an AC response of 2+, indicating ACI, on the first post-operative day. Only the day after the surgery showed no difference in the ACI grade frequency between the groups; nevertheless, at all other periods, there was a substantial difference in the ketorolac group favored by all (cell and flare) assessments. Coassin *et al*. reported that the mean flare was 31% and 43% lower on days 3 and 7 following the operation, sequentially, in the group treated with bromfenac (0.09%) plus dexamethasone (0.1%) and tobramycin (0.3%) when comparing with the group receiving steroids alone [14], in agreement with our results. There have been reports of the effectiveness of NSAIDs and steroids individually in decreasing post-operative inflammatory responses [13, 25, 26], whereas they did not investigate the extra influences of NSAIDs plus steroids.

There were a few limitations in the present RCT, including uncooperative patients during follow-up periods. Moreover, the inflammation was not objectively evaluated by standard equipment.

Conclusion

According to the current randomized clinical trial findings, ketorolac in combination with steroids could better control inflammation and decrease long-term adverse effects like capsular phimosis and PCO until six months postoperatively in PEX research units treated with phacoemulsification. However, there is a need for further research with a larger sample size and less bias to reach definitive conclusions.

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