ARTICLE

Comparative analysis of intravitreal triamcinolone acetonide–moxifloxacin versus standard perioperative eyedrops in cataract surgery

Saman Nassiri, MD, FICO, Frank S. Hwang, MD, Jason Kim, MD, Bronson LeClair, MD, Eden Yoon, MD, Michael Pham, DO, Michael E. Rauser, MD

Purpose: To compare the effectiveness of intravitreal injection of triamcinolone acetonide–moxifloxacin (Tri-Moxi) to a standard eyedrop regimen in controlling postoperative inflammation, corneal edema, and the rate of high intraocular pressure (IOP) among cataract patients.

Setting: Loma Linda University Eye Institute, California, USA.

Design: Retrospective longitudinal comparative study.

Methods: The electronic medical records of patients who underwent cataract surgery using triamcinolone acetonide–moxifloxacin injection along with a postoperative nonsteroidal antiinflammatory drug drop were reviewed (Group 1). Group 1 was compared with patients who received a standard eyedrop (Group 2) in terms of intraocular inflammation and corneal edema severity, and the rate of high IOP, postoperatively.

Results: A total of 1195 consecutive eyes (Group 1 [681 eyes], Group 2 [514 eyes]) of 919 patients were included in the study. The anterior chamber cell reaction severity decreased by 34.0% and 35.7% at 1 week and 1 month, respectively, after surgery following triamcinolone acetonide–moxifloxacin injection compared with standard eyedrop therapy ($P = .001$ and $P = .02$, respectively). Group 1 was associated with increased severity of corneal edema (odds ratio, 1.48; $P = .001$) on postoperative day 1, with no statistically significant difference at 1 week and 1 month postoperatively ($P = .25$ and $P = .48$, respectively). There was no statistically significant difference in the rate of high IOP between the two groups at different timepoints postoperatively.

Conclusions: Triamcinolone acetonide–moxifloxacin injection is an effective method to control intraocular inflammation after cataract surgery. It is a promising substitute for standard eyedrop therapy, especially for patients who have poor compliance with eyedrop usage.

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Cataract surgery is among the most common surgical procedures performed in the world.[1] Advances in technology and improvements in techniques such as the clear corneal incision, small incision surgery, and the use of a femtosecond laser have made this procedure safe with successful outcomes in most cases.[2] Among the most common concerns regarding cataract patients are reducing postoperative inflammation and preventing microbial proliferation through the use of steroids, nonsteroidal antiinflammatory drugs (NSAIDs), and antibiotics.[3]

Cystoid macular edema (CME) and postoperative infectious endophthalmitis are caused by uncontrolled inflammation and microbial proliferation, respectively, which can lead to suboptimal or even devastating outcomes.[4] Therefore, every effective measure should be taken to prevent these complications.

Traditionally, eyedrop therapy throughout the perioperative period has been the mainstay in inflammation control and infection prevention after cataract surgery. Despite the advances in other aspects of cataract surgery, this has remained unchanged as the standard of care throughout many years. The major drawbacks of topical therapy are ocular surface toxicity, high expenses, unpredictable effective dose delivery, and concerns associated with instilling

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From the Loma Linda University Eye Institute (Nassiri, Hwang, Kim, LeClair, Yoon, Rauser), Loma Linda, California, and the George Washington University (Pham),

eyedrops, especially among inexperienced and poorly compliant patients, or those who need multiple drug administrations.[5,6] As a result, "dropless" cataract surgery has become an interesting concept in recent years.

A study conducted by the European Society of Cataract and Refractive Surgery (ESCRS) Endophthalmitis Study Group,[7] found a reduced occurrence of postoperative endophthalmitis with the use of intracameral cefuroxime at the end of cataract surgery. Recently, the introduction of triamcinolone acetonide–moxifloxacin (Tri-Moxi), which contains 15 mg/mL of triamcinolone acetonide and 1 mg/mL of moxifloxacin, has made "dropless" surgery a new option. This compound drug is injected into the anterior vitreous, through either a transzonular or pars plana approach.[8] Tri-Moxi 0.2 mL (for a total drug delivery of 3 mg of triamcinolone acetonide and 0.2 mg of moxifloxacin) can also be accompanied by vancomycin (10 mg/mL) as Tri-Moxi-Vanc, for a total vancomycin delivery of 2 mg. There are also other types of injectable compound drugs such as dexamethasone–moxifloxacin (Dex-Moxi) and dexamethasone–moxifloxacin–ketorolac (Dex-Moxi-Ketor).

In this study, we compared the postoperative outcomes of Tri-Moxi versus standard eyedrop therapy after cataract surgery. We hypothesized that intravitreal triamcinolone acetonide–moxifloxacin injection can effectively control infection and inflammation after cataract surgery and be at least comparable to standard eyedrop therapy. To our knowledge, there is limited data available in the literature about the effectiveness of this new compound drug in cataract surgery.

PATIENTS AND METHODS

Study Participants

This retrospective longitudinal study was performed at Loma Linda University Eye Institute, California, USA. Institutional Review Board approval was obtained. The electronic medical records were reviewed of all patients who underwent cataract surgery by two surgeons (M.E.R. and F.S.H.) at Loma Linda University Eye Institute from February 2015 to May 2018. The study groups included patients who received pars plana intravitreal injection of triamcinolone acetonide–moxifloxacin accompanied by a topical postoperative NSAID (Group 1) and those who received standard eyedrop medications of an antibiotic, corticosteroid, and NSAID (Group 2). Postoperative care was based on surgeon and patient preferences, and there were no formal criteria to assign patients to one of the postoperative care methods. Patients had at least a 1-month postoperative follow-up. The following types of patients were excluded from the study: those with uncontrolled intraocular pressure (IOP), steroid-responsive glaucoma, advanced glaucoma, and/or a history of intraoperative complications (eg, posterior capsule tear and vitreous loss). Patients with a known allergy to moxifloxacin were treated with the standard eyedrop regimen and a non-fluoroquinolone antibiotic substitute.

Procedures

A subset of patients operated by one surgeon (M.E.R.) was pretreated with a topical NSAID (Group 1 [540 eyes]) and a topical

Group 1 underwent pars plana intravitreal injection of triamcinolone acetonide–moxifloxacin (0.2 mL), 3.5 mm posterior to the limbus in the superotemporal or inferotemporal quadrant after intraocular lens implantation and before ophthalmic viscosurgical device removal. Postoperatively, the patients in Group 1 received one of the following NSAID regimens for a total of 4 weeks: diclofenac 0.1% (4 times a day); ketorolac 0.5% (4 times a day); flurbiprofen 0.03% (4 times a day); nepafenac 0.3% (once a day); bromfenac 0.07% or 0.09% (once a day). Patients in Group 2 received topical moxifloxacin 0.5% (4 times a day), and prednisolone acetate 1% (4 times a day) along with one of the above NSAID regimens for 1 week, and then the steroid was tapered and the NSAID was administered consistently over the next 3 weeks (4 weeks total).

Assessment

Different demographic and clinical data at baseline (preoperative), 1 day, 1 week, and 1 month postoperatively were collected. Assessment included uncorrected (UDVA) and corrected (CDVA) distance visual acuities, standard slitlamp evaluation, IOP, and fundus examination. Anterior chamber cell reaction and corneal edema were graded on a scale of 0 to 4+. High IOP was defined as IOP of 24 mm Hg or higher. Any postoperative complications were also recorded. The presence of postoperative clinical CME was defined as a recorded clinical finding (visual acuity of 20/40 or worse with an evidence of macular edema on funduscopic examination) confirmed by retinal thickening on optical coherence tomography.

Statistical Analysis

Statistical analyses were performed using SPSS Statistics software (version 22, IBM Corp.). A Shapiro-Wilk test was used to check the normal distribution of the study variables. Summary statistics were computed for continuous (mean, median) and categorical (counts, percentages) variables. A Student t test and analysis of variance (ANOVA) statistics were used for parametric analyses. Mann-Whitney, Wilcoxon, Friedman, MacNemar, Cochran Q, and ordinal regression statistics were applied for nonparametric analyses. The chi-square test was used to compare categorical variables. Somers' d statistics was used for nonparametric trend analysis. Cohen's d was used to estimate the effect size in the t test. A P value less than 0.05 was considered statistically significant.

RESULTS

The study comprised 1195 consecutive eyes of 919 patients (Group 1: 681 eyes and Group 2: 514 eyes) with a median age of 72 years (range 3 to 99 years). Table 1 shows the baseline characteristics of the study participants.

At baseline, both study groups were statistically comparable except for age (Table 1). The patient population was older in Group 1 than Group 2 (median 74 vs. 70, $P < .001$). The CDVA improved about 2 lines on average in both groups 1 month after surgery compared with the preoperative values ($P < .001$). Furthermore, the UDVA improved significantly in both groups throughout the first month follow-up visits (repeated-measures ANOVA, $P < .001$). The difference between UDVA at 1 week and 1 month postoperatively was not statistically significant in Group 2 ($P = .13$). Moreover, the UDVA in Group 1 was better than in Group 2 at 1 week and 1 month postopera-

Table 1. Baseline characteristics of the study participants.

Parameter	Group 1 (681 Eyes)*	Group 2 (514 Eyes)†	*P* Value
Age (y)			
Median	74	70	<.001
Range	40, 99	3, 97	
Sex, n (%)			
Female	406 (59.7)	305 (59.3)	.90
Male	275 (40.3)	209 (40.7)	
Eye laterality, n (%)			
Right	357 (52.4)	255 (49.6)	.34
Left	324 (47.6)	259 (50.4)	
Cataract density (%)			
1-2+	48.2	48.1	.99
3-4+	51.8	51.9	
Preop IOP (mm Hg)			
Median	16	15	.06
Range	5, 22	8, 20	
Preop mean CDVA (logMAR)	0.326	0.309	.12

CDVA = corrected distance visual acuity; IOP = intraocular pressure; logMAR = logarithm of the minimum angle of resolution
*Triamcinolone acetonide–moxifloxacin injection
†Standard eyedrop therapy

significant IOP elevation rates during the postoperative visits in Group 1 compared with Group 2.

The trend analysis showed Somers' *d* of −0.56 and −0.54 in decreasing postoperative intraocular inflammation severity in Group 1 and Group 2, respectively, throughout the follow-up visits (both statistically significant, $P < .001$). The postoperative anterior chamber cell reaction severity was lower by 34.0% and 35.7% at 1 week and 1 month, respectively, after cataract surgery in Group 1 compared with Group 2 ($P = .001$ and $P = .02$, respectively). The intraocular inflammation severity was not statistically significantly different between the two groups on postoperative day 1 (OR, 0.94; $P = .57$).

The corneal edema severity decreased on a trend of −0.34 and −0.27 throughout the postoperative period in Group 1 and Group 2, respectively (Somers' *d*, both statistically significant; $P < .001$). Patients in Group 2 had a lower degree of corneal edema by 32.4% on postoperative day 1 compared with Group 1 ($P = .001$). There was no significant difference in corneal edema severity between the two groups at later follow-up visits.

The statistical analysis showed that pretreatment of a major subset of patients with eyedrops (as a function of preference of one of the surgeons) compared with the other group did not affect the final conclusion in terms of statistically significant *P* values (ordinal regression; adjusted for "surgeon's preferred treatment protocol" factor). The adjusted *P* values were .84, less than .01, and .04 for the difference in anterior chamber inflammation severity between the two groups at postoperative day 1, week 1, and month 1, respectively. Furthermore, the adjusted *P* values were less than .01, .54, and .83 for the difference in corneal edema severity between the two groups at the same corresponding postoperative timepoints, respectively.

Figure 1 depicts IOP at baseline and different follow-up visits in both groups. On average, the IOP increased by 15.7% (95% confidence interval [CI], 10.0-22.5; $P < .001$) in Group 1 and 14.8% (95% CI, 6.3-24.6; $P < .01$) in Group 2, on postoperative day 1 compared with the preoperative values. Although the increase was more prominent in Group 1 than Group 2, the difference was not statistically significant (mixed ANOVA, $P = .74$).

The difference between IOP preoperatively and 1 week postoperatively was not statistically significant ($P = .99$). Furthermore, there was no statistically significant difference in IOP between the two groups at 1 week and 1 month postoperatively ($P = .10$ and $P = .40$, respectively).

The incidence rate of high IOP in Group 1 versus Group 2 was 6.9% versus 5.5%, 0.9% versus 1.2%, and 1.0% versus 1.0% at the postoperative follow-up visits of day 1, week 1, and month 1, respectively. There was no statistically significant difference between the two groups at each follow-up visit (χ^2; $P = .32$, $P = .61$, and $P = .97$, respectively).

Thirty-nine (5.7%) of the 681 eyes in Group 1 and 22 (4.3%) of the 514 eyes in Group 2 had corticosteroids either added or increased in dosage within their eyedrop regimen to better control intraocular inflammation during the postoperative period, respectively. Therefore, more patients in Group 1 required an alteration in the planned therapeutic regimen, although the difference was not statistically significant ($P = .26$).

There were two cases (0.29%) of clinically significant CME in Group 1 and three cases (0.58%) in Group 2, confirmed by retinal thickening on optical coherence tomography. The difference was not statistically significant between the two groups ($P = .44$). Furthermore, there were 2 eyes with postoperative endophthalmitis, 1 (0.14%) in Group 1 and 1 (0.19%) in Group 2. The difference in the rate of postoperative

Table 2. Odds ratios with 95% CI during the postoperative visits in Group 1* compared with Group 2 (reference).†

Parameter	Day 1			Week 1			Month 1		
	OR	95% CI	*P* Value	OR	95% CI	*P* Value	OR	95% CI	*P* Value
Anterior chamber inflammation	0.94	0.76, 1.16	.57	0.66‡	0.51, 0.85‡	.001‡	0.64‡	0.45, 0.93‡	.02‡
Corneal edema	1.48‡	1.19, 1.84‡	.001‡	1.23	0.86, 1.75	.25	1.22	0.70, 2.14	.48
IOP ≥ 24 mm Hg	1.28	0.79, 2.07	.32	0.74	0.24, 2.31	.61	1.02	0.32, 3.23	.97

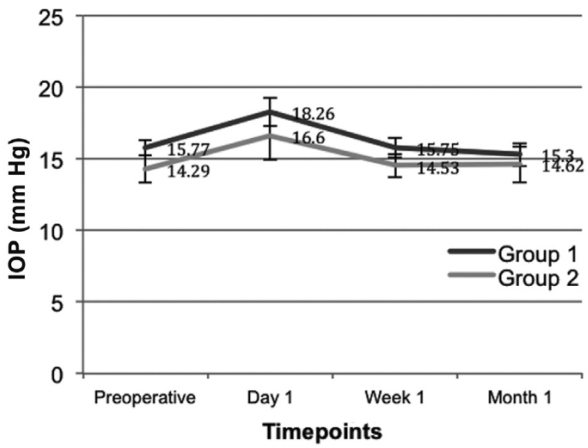

Figure 1. Mean IOP ± 95% confidence interval at different timepoints in Group 1 (triamcinolone acetonide–moxifloxacin injection) and Group 2 (standard eyedrop therapy) (IOP = intraocular pressure).

endophthalmitis was not statistically significant between two groups ($P = .84$). No significant relevant risk factors for infectious endophthalmitis were found in these cases.

DISCUSSION

To the best of our knowledge, this is the first large-scale comparative study assessing intravitreal Tri-Moxi in terms of postoperative inflammation control on a grading-based analysis compared with standard eyedrop therapy. The results in our study showed that postoperative intraocular inflammation decreased at a faster pace in the triamcinolone acetonide–moxifloxacin group versus the standard eyedrop group. Hence, the degree of intraocular inflammation was lower in triamcinolone acetonide–moxifloxacin group compared with the standard group at 1 week and 1 month after surgery, respectively, but not on postoperative day 1.

Uncontrolled postoperative inflammation and infection can be associated with CME and infectious endophthalmitis, respectively. These, along with IOP rise and corneal decompensation/edema, are among the most common concerns regarding postoperative care of cataract patients.

CME results from the release of inflammatory mediators such as prostaglandins and leukotrienes. The rate of pseudophakic macular edema has been shown to be 1.17% among patients without operative complications or risk factors such as diabetes, and the relative risk is increased with the presence of these risk factors.[9] It might be lower with the advent of modern phacoemulsification techniques.[10] A major therapeutic approach for prophylaxis and treatment of CME is targeted against these inflammatory mediators.[11] Based on this, NSAID therapy alone or in combination with a corticosteroid has been shown to be the treatment of choice for pseudophakic CME.[12,13] In a recent multicenter trial of CME prevention after cataract surgery in 914 nondiabetic patients, supported by the ESCRS, the author study, the rate of CME was not statistically different between the triamcinolone acetonide–moxifloxacin group and the standard eyedrop group (0.29% and 0.58%, respectively). However, CME can develop several weeks after surgery[9], and a 1-month follow-up might be inadequate to detect all cases of CME amongst our patients.

Reports in the literature regarding the incidence of postoperative infectious endophthalmitis are diverse, and the incidence ranges between 0.04% and 0.2%.[15,16] Surgical complication remains a key risk factor for its occurrence because posterior capsule rupture can increase the risk up to 3.7-fold.[17] In our study, the rates were 0.14% and 0.19% in the triamcinolone acetonide–moxifloxacin group and the standard eyedrop group, respectively; the difference was not statistically significant. However, low-rate yet diverse incidence of postoperative infectious endophthalmitis in previous studies warrants a larger sample size for definitive conclusion on the rate of endophthalmitis. Of note, the endophthalmitis case in the standard group followed a more acute course compared with the patient in the triamcinolone acetonide–moxifloxacin group. Both responded well to antimicrobial therapy and vitrectomy, with a final CDVA of 20/25 and 20/80 in the triamcinolone acetonide–moxifloxacin group and standard group, respectively.

Alternatives to the standard eyedrop regimen for postoperative care of cataract patients are subconjunctival, intracameral, and newly introduced intravitreal drug deliveries, which might be associated with more efficient and predictable drug dose delivery.

Intracameral drug delivery has been convincingly shown to be effective in controlling inflammation and preventing microbial proliferation after cataract surgery across multiple clinical studies.[18,19] In a multicenter study conducted by the ESCRS,[7] the authors reported a statistically significant reduction in postoperative endophthalmitis following the use of intracameral cefuroxime at the end of surgery. Similarly, other studies reported decline in the rate of postoperative endophthalmitis using intracameral moxifloxacin and vancomycin.[20–23] Arbisser[22] found better outcomes in terms of lower aqueous cell count 1 day postoperatively with intracameral moxifloxacin injection compared with the non-injection group, with no untoward effect. Intracameral dexamethasone and triamcinolone acetonide have also been successfully used to control postoperative inflammation after cataract surgery.[24]

It is worth noting that in comparison to an intracameral injection of drug, methods of posterior segment drug delivery either through transzonular or pars plana injection might better guarantee effective and sustainable intraocular drug transfer.[8] In a study by Tyson et al.,[25] patients who received transzonular injection of Tri-Moxi-Vanc showed rates of infection and inflammation similar to rates with standard prophylactic approach of topical medications. In their retrospective review of 1541 eyes, they evaluated the rate of breakthrough inflammation, defined as ocular

acetonide–moxifloxacin–vancomycin injection, which was reported to be similar to topical ophthalmic corticosteroids.

In our study, we found a statistically greater severity of corneal edema on postoperative day 1 in the triamcinolone acetonide–moxifloxacin group. However, the severity of corneal edema was statistically similar between the two groups at 1 week and 1 month postoperatively. In a prospective contralateral eye study of 25 patients performed by Fisher et al.,[26] the authors showed similar outcomes for transzonular injection of Tri-Moxi-Vanc and a single drop compounded topical regimen. They did not find significant difference in terms of central corneal and macular thickness and change in IOP between these two approaches. In fact, the patients in the study preferred the injection most likely because of greater convenience. Espiritu et al.[27] reported that intracameral moxifloxacin 0.5% was nontoxic to corneal endothelium, and it did not increase corneal pachymetry statistically significantly after surgery. It is claimed that the "dropless" approach is significantly cost-saving because the cost to the patient and/or the healthcare system of prophylactic drugs can be reduced from hundreds of U.S. dollars to $20 to $25 per case.[8]

Furthermore, we did not find any difference between the triamcinolone acetonide–moxifloxacin group and the standard group in terms of high IOP. In a meta-analysis, Jonas et al.[28] reported 41.2% of patients with IOP higher than 21 mm Hg after intravitreal injection of 20 mg triamcinolone acetonide. However, the injection of low-dose triamcinolone acetonide (up to 3 mg) has been shown to be associated with a lower incidence of IOP spikes than seen with postoperative drops.[29] Tyson et al.[25] reported that 0.9% of their cases had at least a 10 mm Hg increase in their preoperative IOP throughout the late postoperative period of triamcinolone acetonide–moxifloxacin–vancomycin injection. The rate reported in the literature for topical corticosteroid use (such as difluprednate 0.05%) is 2.8% for a 10 mm Hg increase in preoperative IOP (and IOP $\geq$ 21 mm Hg).[30]

Main concerns about the "dropless" protocol are unclear pharmacokinetics of triamcinolone acetonide–moxifloxacin after the intravitreal injection, potential contamination of the compound drug, technical issues with this type of injection, foggy vision and floaters for a few days postoperatively, emergence of antibiotic resistance, risk for steroid-induced ocular hypertension, and risks for intravitreal injection such as introducing microbial pathogens into the eye.[31–33] There were reports of temporary floaters among our patients attributable to the triamcinolone injection for a few days after surgery, which did not appear to affect long-term visual outcomes. Dexamethasone–moxifloxacin (Dex-Moxi) or dexamethasone–moxifloxacin–ketorolac (Dex-Moxi-Ketor) can be used as alternatives to Tri-Moxi because they do not cause as much floaters.

We used the pars plana approach for our intravitreal injection because our surgeons were more familiar with this did not observe these complications in our study. Although concern does exist regarding the possible risks for retinal injury through this more posterior drug delivery approach, we did not observe any retinal tear or detachment in patients included in this study.

In July 2017, the American Society of Cataract and Refractive Surgery and the American Academy of Ophthalmology Advisory issued a joint alert regarding possible retinal toxicity of intravitreal injection of triamcinolone–moxifloxacin from specific compounding sources.[A] We did not observe any such complication among our patients.

The current study has some limitations. First, our grading system was mostly subjective, which typically contains both systematic and random measurement errors. Second, a 1-month follow-up might be insufficient to assess complications such as CME, and the longer-term follow-up might better evaluate delayed sequelae of uncontrolled inflammation. Third, adjusting and stratification of intraocular inflammation postoperatively based on some concomitant medical conditions such as diabetes or glaucoma can better control possible confounders or effect modifiers, and is suggested for future studies. Fourth, our patients were not randomized between the triamcinolone acetonide–moxifloxacin versus standard eyedrop regimen for controlling confounders and selection bias. This decision was at the discretion of the surgeon, incorporating patient preference into the decision-making process. Last, the NSAID therapy was not standardized between our patients because insurance coverage for the patient often dictated the type of NSAID used. Thus, studies with controlling for factors such as type of NSAID regimen are warranted in the future.

In conclusion, intravitreal triamcinolone acetonide–moxifloxacin injection during cataract surgery along with a postoperative NSAID appears to be noninferior to standard eyedrop therapy in terms of postoperative inflammation control and the rate of high IOP. Corneal edema severity was equivalent at the 1-week and 1-month postoperative timepoints. Therefore, triamcinolone acetonide–moxifloxacin injection can be considered as a promising substitute for standard eyedrop therapy, especially in patients who have poor compliance with eyedrop use.

WHAT WAS KNOWN

- The triamcinolone acetonide–moxifloxacin compound has been used during cataract surgery to prevent infection and control postoperative inflammation after surgery.
- Concern exists regarding the risk for IOP elevation with intravitreal triamcinolone acetonide use.

WHAT PAPER ADDS

- Intravitreal injection of triamcinolone acetonide–moxifloxacin during cataract surgery was noninferior to standard eyedrop therapy in the control of inflammation and corneal edema after cataract surgery.

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First author:
Saman Nassiri, MD, FICO

Loma Linda University Eye Institute, California, USA

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