Efficacy and safety of intravitreal injection of triamcinolone-moxifloxacin after cataract surgery in a low to middle income country — a one-year audit

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Abstract

Objective: To evaluate the safety and efficacy of intravitreal injection of triamcinolone and moxifloxacin regime administered immediately following cataract surgery.

Method: The retrospective study was conducted from January to June 2021 at a tertiary care referral centre in Karachi and comprised record of all patients who underwent dropless cataract surgery from April 2018 to June 2019. Data included slit lamp examination, dilated fundal exam, uncorrected visual acuity, best corrected visual acuity, and intraocular pressure. Cataract assessment and anterior chamber reaction were graded according to the World Health Organisation cataract grouping system. Efficacy of the regime was defined as the ability to prevent postoperative endophthalmitis. Stratification analysis was done to note if gender has any role in terms of effectiveness. Data was analysed using Microsoft Excel version 16.0 and IBM SPSS version 27.

Results: Of 240 eyes of 161 patients analysed, 114(47.5%) were of men who had a mean age of 57.89±14.32 years, and 126(52.5%) were of females with a mean age of 58.02±10.85 years. Overall, 2(1.75%) male subjects and 1(0.8%) female subject developed breakthrough inflammation within one week of the procedure. They were treated with anti-inflammatory drops and in 1(33%) of the cases antibiotic drop for 1 week. At day 90, no patient had residual inflammation or new onset inflammation. Also, 15(6.25%) patients developed raised intraocular pressure from day 7 to day 30. Most cases 10(66.7%) resolved within 1 week of using intraocular pressure-lowering drops. No patient developed endophthalmitis postoperatively.

Conclusion: Dropless cataract regime was found to be an effective and safe alternative that was easy to administer.

Keywords: Dropless cataract surgery, Safety of cataract surgery, Innovations in cataract surgery, Endophthalmitis after dropless. (JPMA 73: 92; 2023) **DOI: 10.47391/JPMA.5207**

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Introduction

Cataract surgery is one of the most commonly performed surgeries in the world, and is associated with improved quality of life (QOL).[1] Postoperative care is an important aspect of cataract surgery management. Cataract surgeries have inherent risk of potentially sight-threatening postoperative complications, like persistent inflammation, macular oedema or infective endophthalmitis, that can increase due to poor postoperative care.[2] Postoperative measures to reduce the above complications are important aspects of cataract surgery management. However, the most effective prophylaxis methodology is considered extremely difficult to determine, given the large number of patients required for conducting a clinical trial.[2]

A low- to middle-income country (LMIC), such as Pakistan, with limited medical facilities and heavy burden of disease often addresses this issue with high-volume cataract surgery owing to limited postoperative care facilities. The current standard of prophylaxis against postoperative complications in many parts of the world, including Pakistan, involves preoperative povidone iodine and postoperative topical antibiotics and steroid eyedrops for 2-4 weeks.[1,2] In most European countries, the addition of intracameral antibiotics at the end of the surgery is considered the standard of care.[2] However, postoperative antibiotics and steroid eyedrops are still given for a couple of weeks.

Topical eyedrops have inherent challenges of compliance, cost and contamination. It can be a challenge in post-paediatric cataract surgery and in patients with compromised dexterity. A study reported that 92.6% patients following surgery showed incorrect technique of instilling the topical eye medication, forgetting to instil the medication (31.5%), using wrong volume of eyedrops (64.0%), touching the eyelashes resulting in medication vehicle tip contamination (57.4%), or not remembering to clean the hands before medication instillation (78.0%).[3] The above can result in reduction in the efficacy and safety of this method.

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Intravitreal antibiotics techniques involve injection of immediate-acting high-concentration drugs in anterior vitreous, which results in longer persistence of medication in the eye in order to provide longer protection against inflammation and infection.[4,5] The intravitreal route is increasingly being utilised in many developed healthcare systems as the choice of prophylaxis against postoperative complications.[4] There is limited data from Pakistan on the prophylaxis to prevent postoperative infections following cataract surgery.

Intravitreal moxifloxacin provides immediate-acting high-concentration medicine in anterior vitreous for longer prophylaxis against infection. Moreover, reduced topical treatment results in decreased cost for postoperative eyedrops, decreased ocular surface toxicity and reduced need of compliance, including correct eyedrop instillation technique. The potential side effect of this technique is floaters, increased eye pressure, postoperative inflammation and hyphema that can result in reduced patient satisfaction.[3-8]

The dropless technique has been extensively studied in developed countries, but, to the best of our knowledge, its safety and efficacy have not been studied in Pakistan. The current study was planned to fill the gap by addressing the safety and efficacy of dropless cataract surgery in the local population.

Materials and Methods

The retrospective, cross-sectional study was conducted from January to June 2021 at the Aga Khan University Hospital (AKUH), which is a tertiary care referral centre in Karachi, and comprised record of all patients who underwent dropless cataract surgery with intravitreal injection of moxifloxacillin and triamcinalone (IVTM) from April 2018 to June 2019. All the surgeries had been done by a single eye surgeon. Data was retrieved using non-probability consecutive sampling technique after approval from the institutional ethics review committee.

The records of all consecutive patients who underwent phacoemulsification cataract surgery with implantation of an intraocular lens (IOL) and IVTM were reviewed. Data related to eyes and patients having extracapsular cataract extraction, posterior capsular tear, uncontrolled glaucoma, advanced glaucoma, allergy to any component of IVTM drug formulation and with incomplete or missing records was excluded. Informed consent had been obtained pre-surgery from all patients and they were counselled about the possibility of floaters post-IVTM.

The formulation of intravitreal injection was 0.1ml of moxifloxacin 0.16mg/0.1ml and 0.1ml of triamcinolone 4mg/0.1ml.[3,5] Aseptic protocol USP 797 (United States Pharmacopeia) was followed at the institution's pharmacy during the preparation to ensure sterility in a controlled environment.[9]

Standard surgical protocols were used in all cases. A 10% povidone-iodine solution was applied to the skin around the operative site, and a 5% solution was applied to the conjunctival sac 5min before surgery. Cataract surgery was performed by a standard clear corneal phacoemulsification technique using the Centurion Vision System (Alcon Laboratories, Inc.). A foldable IOL was implanted (Alcon Laboratories, Inc.) after which 0.2ml of triamcinolone and moxifloxacillin was injected 3.5mm from the limbus at pars plana after implantation of IOL and before the removal of viscoelastic.

Medical record review (MRR) method was used to extract data from the selected clinical cases. MRR data extraction form was predeveloped and the opinion from an expert from international universities was subsequently taken. The data was extracted related to age, concomitant conditions, intraocular pressure (IOP), cataract density, uncorrected visual acuity (UCVA) documented preoperatively, on days 1, 7, 30 and 90, and best corrected visual acuity (BCVA) on preoperative visit, days 1, 7, 30 and 90 in Snellen and logarithm of the minimum angle of resolution (logMAR) values. Postoperative anterior chamber reaction, flare or cells in the anterior chamber and IOPs were also noted on all the visits. In case any drops were medications, such as steroids, non-steriodal anti-inflammatory drugs (NSAIDs), antibiotics or IOP-lowering medications, were started for a patient, the data was noted separately. Fundus examination was carried out on each visit and any complications or findings were documented.

Safety of the dropless regime was defined by postoperative complications directly resulting from the dropless surgery technique, including raised IOP, damage to the zonules, iris prolapse or trauma, hyphaema or reflux of medication.

Efficacy of the regime was defined as the ability to prevent endophthalmitis after the cataract surgery. Postoperative inflammation and toxic anterior segment syndrome (TASS) were also noted as part of efficacy measurement. High IOP was defined as >21mmHg or >10mmHg from the preoperative value. Presence of symptomatic postoperative floaters was also recorded.

Data was analysed using Microsoft Excel version 16.0 and IBM SPSS version 27.

For all continuous variables, mean ± standard deviation and median values were calculated, while for categorical data, frequencies and percentages were used. Stratification analysis was used to note if gender made any difference in the effectiveness. For inferential statistics, chi-square test of independence was used. Information related to patient demographics and clinical assessment of preoperative visit, postoperative visit on days 1, 7, 30 and 90 were recorded. Data also included slit lamp examination, dilated fundal exam, UCVA, BCVA and IOP. Cataract assessment and anterior chamber reaction were graded according to the World Health Organisation (WHO) cataract grouping system Nuclear Scelrotic Cataract.10 P value of 0.05 was considered statistically significant.

Results

Of the 240 eyes of 161 patients analysed, 114(47.5%) were of men who had a mean age of 57.89±14.32 years, and 126(52.5%) were of females with a mean age of 58.02±10.85 years. There was no significant difference along gender lines in terms of mean age (p=0.941) and mean presenting IOP (p=0.115) (Table-1).

Mean logMAR UCVA and BCVA increased after the surgery. There was a significant improvement between preoperative UCVA and UCVA at day 1 (Table-2). This difference improved further and remained statistically significant (p<0.01) on day 90 postoperatively. Clinically, there was an improvement in postoperative UCVA at day 1 from the preoperative UCVA (logMAR 0.52) which further improved (logMAR 0.61) by day 90 postoperatively.

Table-1: Patient demographics.

	Characteristics	Male	Female
1	Number of eyes (n = 240)	114	126
2	Age (n = 240)		
	Mean	57.89±14.32	58.02±10.85
	Median	61	59
3	Concomitant condition (n = 165)	75	90
	Diabetes	34	38
	Glaucoma	6	2
	Others	61	79
4	IOP (baseline) (n = 235)	111	124
	Mean	14.74±2.80	15.27±2.39
	Range	8-28	10-21
5	Cataract Density (n=240)		
	NS +	12	12
	NS ++	50	68
	NS +++	40	35
	Brown cataract	8	5
	RLE	4	6

RLE: Refractive lens exchange, IOP: Intraocular pressure (measured in mmHg), NS: Nuclear Sclerotic Cataract (WHO grading).

*Patient with 28 was a known case of glaucoma with a baseline IOP of 28

* Others included systemic disorders such as hypertension, ischemic heart disease, thyroid disorders, malignancies, dementia, and neurodegenerative disorders.

Table-2: Uncorrected visual acuity (UCVA).

	Scheduled visit	Mean Visual acuity Snellen (Mean)	LogMar Mean	LogMar Median	LogMar Mode
1	UCVA				
	Preoperative	20/109	0.72 ± 0 .60	0.54	0.3
	Day 1	20/32	0.20 ± 0.30	0.1	0.1
	Day 7	20/26	0.13 ± 0.24	0.1	0
	Day 30	20/25	0.11 ± 0.23	0	0
	Day 90	20/25	0.11 ± 0.24	0	0
2	BCVA				
	Preoperative	20/54	0.43 ± 0.53	0.3	0.1
	Day 1	20/29	0.17 ± 0.30	0.1	0.1
	Day 7	20/24	0.08 ± 0.20	0	0
	Day 30	20/23	0.08 ± 0.20	0	0
	Day 90	20/23	0.08 ± 0.20	0	0

BCVA: Best Corrected Visual Acuity.

Table-3: Postoperative inflammation.

		Male (n)	Female (n)
1	Number of cases	2	1
2	Concomitant condition	0	0
3	Medications prescribed	2	1
	Steroid drops	2	1
	NSAID	0	0
	Antibiotic drops	1	0
	Others	0	0

NSAID: Non-steroidal anti-inflammatory drugs, some patients may be prescribed more than one type of medications.
All cases of breakthrough inflammation resolved with 1 week of steroids.

Overall, 2(1.75%) male subjects and 1(0.8%) female subject developed breakthrough inflammation within one week of the procedure (Table-3). They were treated with anti-inflammatory drops and in 1(33%) of the cases antibiotic drop for 1 week. All cases resolved within 2 weeks of the commencement of the drops and at day 90, there were no persistent case of inflammation, and there were no new cases. None of these individuals had underlying comorbid condition. Patients having a preoperative diagnosis of glaucoma did not develop postoperative inflammation postoperatively.

There was a reduction in IOP for both male and female subjects compared to the presenting IOP reading, but it was not statistically significant on post-operative day 1 (p=0.670). However, it was significantly lower than the presenting IOP on days 7, 30 and 90 (p=0.001, p=0.002 and p<0.01 respectively).

Also, 15(6.25%) patients developed raised intraocular

Table-4: Mean IOP.

Schedules Visit	Male				Female			
	Mean	Std Deviation	Minimum	Maximum	Mean	Std Deviation	Minimum	Maximum
Preoperative (M=111, F=124)	14.74	2.80	8	28	15.27	2.39	10	21
Day 1 (M=111, F=123)	14.61	4.22	8	32	15.10	4.11	8	42
Day 7 (M=109, F=123)	14.01	3.83	7	31	14.43	3.39	8	36
Day 30 (M=109, F=121)	13.89	2.95	9	31	14.51	3.76	8	35
Day 90 (M=109, F=118)	13.26	2.10	9	19	13.59	2.17	6	20

IOP: Intraocular pressure.

pressure from day 7 to day 30. Of them, 7(46.66%) were male and 8(53.33%) were female subjects. Most spikes occurred (n=12) between days 7 and 30, and most cases 10(66.7%) resolved with 1 week of IOP-lowering drops. Besides, 4(1.67%) patients were prescribed drops for 2 weeks and 1(0.42%) for 21 days postoperatively. IOP was controlled for all patients by day 90 and none of the patients suffered any long-term complications of raised IOP. No surgical intervention was required for any of the cases of raised IOP (Table-4).

All cases were administered IVTM immediately after surgery. There were no major intraoperative complications. There were no reported cases of hyphema, iris prolapse, zonular disruption, retinal tear or detachment or vitreous haemorrhage. In 1(0.8%) female subject, there was a small corneal abrasion for which antibiotic drops were prescribed for 2 weeks, leading to complete resolution. The abrasion did not affect her postoperative vision.

No patient developed endophthalmitis postoperatively, while 2(0.83%) patients reported TASS which resolved within 1 week. Further, 5(2.08%) patients complained of peripheral floaters in the early postoperative phase. All patients reported resolution of floaters, with 3(1.25%) patients reporting resolution after 1 week and 2(0.83%) after 2 weeks. The floaters did not affect postoperative visual acuity.

Discussion

Postoperative inflammation is one of the common complications following cataract surgery with varied reported rates.[11] Steroid drops are administered postoperatively to prevent this occurrence.[11,12] Kristin et al. reported the rate of postoperative iritis to be 1.75%, and persistent iritis in 0.32% patients.[13] In the current study, the rate of postoperative inflammation was 1.25% and no patient had persistent inflammation.

Intracameral antibiotics is used in high-income countries (HICs) as well as in LMICs following cataract surgery to reduce the incidence of postoperative endophthalmitis.[14,15] Despite strong evidence for its efficiency and safety, it is not a regular practice in most places. The safety of intracameral injections has encouraged the evolution of dropless cataract surgery which can be performed using trans-zonular or intravitreal approaches. Trans-zonular approach involves introducing the cannula from the cataract incision site, advancing it under the iris on top of the anterior capsule, passing through the ciliary zonule to administer the drug into the anterior vitreous.[16] Though highly effective, the technique involves manipulation around iris and ciliary zonules and has a risk of iris trauma, hyphema, zolunar damage and reflux of the medicine in the anterior chamber.[16] Intravitreal approach involves going through the pars plana to inject the medicine directly into the vitreous. Though it has rare risk of retinal detachment, it is considered easier to perform than the trans-zonular approach.[16] In the current study, the intravitreal approach was used and none of the patients developed retinal detachment.

The current study had data of 240 cataract surgeries that received IVTM immediately before the completion of surgery. Although the sample size is small, the absence of endophthalmitis in the series suggested safety with the use of prophylactic IVTM in patients undergoing cataract surgery. Kishore et al. reported 4 cases of endophthalmitis from a sample of 2000 eyes. Tyson et al. reported no case of endophthalmitis among 1541 eyes.[6,17] Bardoloi et al. conducted a trial of dropless cataract surgery on 200 eyes and reported no cases of endophthalmitis.[18] Most such studies, however, had limited patient population compared to trials done for conventional cataract surgeries.[19] Hence, the evidence for dropless cataract surgery is still limited.

Commonly identified pathogen in endophthalmitis are staphylococcus and pseudomonas along with other gram-positive and gram-negative organisms.[2] In dropless preparations, both vancomycin and moxifloxacin have been used along with triamcinolone. Moxifloxacin has shown greater bactericidal activity against staphylococci

when compared with cefuroxime, as well as broader coverage against gram-positive and gram-negative organisms to include enterococcus and pseudomonas, making this the antibiotic of choice in the postoperative management plan.[2] In Pakistan, IVTM preparations are not routinely available, and, hence, institutional pharmacy prepared the compounding medication in a sterile environment following relevant international guidelines for compounding pharmacy in the current study.

The was no visually significant postoperative cystoid macular oedema (CME) seen after IVTM in the current series as evident from the postoperative visual acuity. Existing literature shows about 2% incidence of visually significant CME after both topical postoperative medication and IVTM.[8] This complication was not identified in the current study. A large-scale study did not show a difference in CME or breakthrough inflammation between patients receiving IVTM and those receiving standard topical medication.[8]

IOP increase, defined as >21mmHg, was found in 15(6.25%) patients, and the matter was resolved in 10(66.7%) of them within 1 week of IOP-lowering medications. All cases were temporary and benign, and eventually there was a decrease in IOP from preoperative IOP which was similar to the reported reduction after surgery.[20] Triamcinolone has a half- life of 18.7±5.7 days. It can take up to 5 half-lives for the drug to be disintegrated in the vitreous which means it can persist for approximately 3 months postoperatively.[14] Hence, the resulting rise in IOP can be controlled by prescribing IOP-lowering medications.

Intravitreal triamcinolone can cause visual obscuration and floaters during the early postoperative period, which may cause concern among the patients. All patients were counselled preoperatively about the possibility. The small number of patients who did complain of floaters did not have any effect on visual quality secondary to floaters.

A study in Canada reported a significant number of patients (92.5%) using eyedrops incorrectly during their postoperative period. This included 78% not washing their hands before instillation, 57.4% contaminating the bottle tip, 64% applying incorrect dose and 31% missing the eye. It is widely accepted that noncompliance is an important variable in the development of endophthalmitis.[4] Pakistan is LMIC with a significantly lower literacy rate than Canada.[21] It also has a much higher cataract burden due to it large population and limited number of medical professionals. The reduced number of ophthalmic nurses to educate and instruct the proper drop instillation technique could result in a higher risk of contamination and non-compliance. Therefore, dropless cataract surgery could offer a safer alternative, particularly in large volume camps that has limited postoperative care facilities.

The current practice for prophylaxis in Pakistan is topical drops. The issue of reduced compliance and poor technique of instilling drops is a recognised challenge of this method. Moreover, this technique assumes that patient has excellent dexterity or has full-time carer for drops instillation.[8,22-25] The economic impact of topical drops has not been studied in Pakistani population either. The dropless technique offers a possible solution to counter the compliance, technique and cost issues that are inherent in the topical application method.[8]

The retrospective design is a limitation of the current study. Furthermore, the limited sample size might not be sufficient to show the true incidence of endophthalmitis following dropless cataract surgery.

Further studies with larger samples are needed to validate the findings of the current study. Besides, a randomised controlled trial (RCT) to evaluate clinical and cost effectiveness of the regime is proposed.

Conclusion

The dropless cataract regime was found to be an effective and safe alternative that was easy to administer. It did not affect the visual outcomes post-surgery.

Author Statement

Irfan Jeeva: Conceptualization, Writing - Reviewing and Editing, Supervision, Project administration.

Sidra Masud: Literature search, Methodology, Writing - Original draft and preparation with discussion, Writing - Reviewing and Editing, Formal analysis, Data curation.

Rehman Siddiqui: Conceptualization, Writing - Reviewing and Editing, Data curation, Supervision.

All the authors are responsible and accountable for the accuracy and integrity of the work.

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