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ORIGINAL ARTICLE

Safety and efficacy of intracameral injection of dexamethasone and moxifloxacin at the end of cataract surgery

Hani A. Albialy[1 *], *Mostafa. M. Wagih*[1], *Doaa. M. Guda* [2]
[1]*Ophthalmology Department, Faculty of Medicine, Zagazig University, Zagazig, Egypt*
[2]*Zagazig Ophthalmic Hospital, Zagazig, Egypt*

***Corresponding author:**

Hani A Albialy
Ophthalmology Department, Faculty of Medicine, Zagazig University, Zagazig, Egypt

E-mail:

hani_bialy 2000@yahoo.com

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ABSTRACT

Background: To evaluate whether intracameral dexamethasone – moxifloxacin can safely and effectively reduce postoperative inflammation, guard against endophthalmitis, and improve surgical outcomes after cataract surgery.

Methods: Prospective simple randomized comparative control study included 200 eyes of 200 Patients who underwent uncomplicated phacoemulsification (PE). One hundred eyes were injected intracamerally with 0.1 ml moxifloxacin 0.5% and 0.4 mg dexamethasone at the end of surgery while the other 100 eyes used as a control group received an intracameral placebo injection. Outcomes were measured on the first postoperative day and weekly for one month by visual acuity assessment, slit lamp biomicroscopic examination, intraocular pressure (IOP), endothelial cell density (ECD), and presence of any postoperative complications.

Results: 200 eyes of 200 patients were included in the study. The mean age was 56.22± 10.62y (range 34-82y). Regarding aqueous cells recorded on the first postoperative day in group I, five eyes had 2 and 7 eyes had 1+ with no eyes of +3 or more. After a 1-week follow-up examination, all eyes had no anterior chamber cells. In group II, the first postoperative day showed 11 eyes with 3+, 15 eyes had 2+, 8 eyes had 1+. One week postoperatively, only 3 eyes had +1 aqueous cells. All eyes of both groups had no detected anterior chamber cells at subsequent follow-up visits. The effective phacoemulsification time was 3.89±0.93. The mean endothelial cell density (ECD) in group I was 2474.02 cells/mm2 ±348.21 preoperatively and in 2274.15 cells/mm2 ±330.09. In group II preoperative ECC was 2369.16 cells/mm2 ±394.13, and postoperative was 2200.96 cells/mm2 ± 351.12 one month postoperatively (P≤0.001). There was no significant effect on IOP values with no detected long-term complications.

Conclusions: Intracameral dexamethasone- moxifloxacin injected at the end of cataract surgery reduces the postoperative AC cells significantly and improves patient's compliance in early postoperative follow period with no significant risk of IOP elevation.

Keywords: Cataract surgery; intracameral; dexamethasone; moxifoxacin

INTRODUCTION

Cataract surgery is considered one of the most common surgical procedures performed all over the world. As with any intraocular surgery, phacoemulsification is subjected to postoperative complications' risks, although recent advances in surgical tools, surgical manipulation techniques, and intraocular lens (IOL) engineering had reduced the chance of postoperative inflammation after cataract extraction [1]. Persistent inflammation after cataract surgery can delay patient recovery, elevate intraocular pressure (IOP) and increase the rate of cystoid macular edema (CME) and posterior capsule opacification (PCO) [2,3]. Postoperative endophthalmitis is another serious vision-threatening complication and is considered the most feared complication of any intraocular surgery as it may significantly compromise visual function and even the anatomical integrity of the eye [4,5].Different prophylactic therapies were used to decrease the risk of postoperative inflammation and endophthalmitis. Preoperative topical povidone-iodine combined with perioperative topical antibiotic therapy is considered the standard way to decrease the rate of postoperative endophthalmitis [6-9]. Topical corticosteroids and NSAIDs are also available to guard against the incidence of postoperative

inflammation and CME [10]. Despite being the current standard of postoperative care, these eye drops regimens are often associated with patient non-compliance as multiple eye drops must be applied multiple times daily at regular intervals over the course of weeks. Poor compliance interferes with the efficacy of topical drugs. It is further limited by corneal absorption with variable intraocular drug concentrations during the postoperative therapeutic course. Furthermore, there was a potential fear for intraocular pressure (IOP) rise with the use of frequent corticosteroid eye drops [11,12]. Results above suggest the need for other simple, safe, effective, and well-tolerated prophylactic therapy that reduces or eliminates the patient dependence on postoperative eye drops. Direct single-use injections into the eye during surgery have been developed to meet this need [13,14].Intracameral injection of antibiotic substances at the end of surgery had increased the attention as it provides immediate high drug levels that are sustained for a long period of time. Vancomycin, cefuroxime, and moxifloxacin are the most commonly used antibiotics given intracamerally [15,16].Clinical studies also support the intracameral use of corticosteroids for the prophylaxis against inflammation and CME after cataract surgery [17]. It was observed that intracameral injection of triamcinolone acetonide (TAA) sustain a lesser degree of anterior chamber inflammation and corneal edema on the critical period of first postoperative days. However, the particulate structure of the TAA and its tendency to raise the IOP in many patients forced surgeons to replace it with intracameral dexamethasone [18,19].This study evaluates the safety and efficacy of intracameral injection of moxifloxacin-dexamethasone at end of phacoemulsification surgery for the prophylaxis of postoperative infection and inflammation.

METHODS

In this prospective study, 200 eyes of 200 patients underwent elective uncomplicated phacoemulsification and foldable intraocular lens implantations during the period from November 2016 to December 2018. All patients were informed about the design of the study and the procedure involved. Written informed consent was given from all patients. A full personal, medical and ocular history was taken. Inclusion criteria were the presence of a significant cataract with a moderate hardness that was suitable for phacoemulsification, visual acuities 0.4 or lower and intraocular pressures of 21 mmHg or lower. Exclusion criteria included: Diabetes retinopathy, uveitis, glaucoma, corneal disease, current use of topical or oral steroidal or non-steroidal anti-inflammatory agents, history of steroid responsiveness, or cystoid macular edema. A detailed preoperative ophthalmic evaluation including slit-lamp examination, Goldman applanation tonometry for IOP measurement, endothelial cell density (ECD) and dilated fundus examination was performed.Written informed consent was obtained from all participants and the study was performed and approved by the research ethical committee of Alfath eye hospital, Zagazig. The work has been carried out in accordance with the Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.Surgery was performed under local peribulbar anesthesia. A 2.8 mm clear corneal incision was made, 4% sodium chondroitin sulfate - 2% sodium hyaluronate (Viscoat, Alcon, Pharmaceuticals Ltd) was injected into AC, and capsulorhexis was performed. Standard phacoemulsification was performed using the stop and chop technique. After bimanual lens cortex removal, the capsular bag was expanded with sodium hyaluronate 1% (Healon, Abbott Medical Optics), and a foldable hydrophilic acrylic intraocular lens was implanted in the capsular bag. Using abimanual irrigation/aspiration system, the viscoelastic substance was removed from the bag, and the anterior chamber was formed and secured by stromal hydration.At the end of the procedure, patients were randomly divided into two groups. In group, I (n = 100 eyes), 0.1 ml dexamethasone (Dexamethasone, Amria Pharmaceuticals) 0.4 mg/0.1 ml & 0.1 ml moxifloxacin 0.5% (Vigamox, Novartis, Ltd) was injected using a single 27-gauge syringe into the anterior chamber through a paracentesis. In group II (n =100 eyes), placebo medications (PSS) were injected intracamerally at the end of surgery. For both groups, postoperative medication included 0.5% moxifloxacin eye drops (Vigamox, Novartis, Pharmaceuticals Ltd) five times daily for 2 weeks, and prednisolone acetate 1% eye drop (Orchapred, Orchidia, Pharmaceuticals Ltd) five times per day for one week, then tapered gradually over the next three weeks.Patients were examined on the first postoperative days and weekly for one month. Postoperative follow-up included patient history reporting any ocular discomfort, visual acuity (VA) assessment, slit-lamp examination, IOP measurement, and fundus examinations. The evaluation was based on efficacy, and safety criteria. On each visit, the major efficacy parameters were assessed clinically by recording the anterior chamber cells and conjunctival hyperemia. Grading scores for consistent inflammation were obtained accordingly and recorded for each visit. Anterior chamber cells were graded as: 0 = <5 cell; 1+ = mild, 5-10 cells; 2+ = moderate, 11-20 cells; 3+ = marked, 21-50

cells; +4 = severe, >50 cells, and 5+ = hypopyon. The major safety parameters were assessed by postoperative IOP monitoring & endothelial cell density (ECD). The IOP was measured using a Goldmann applanation tonometry, 1 day before surgery and postoperatively in 1 day, 7 days, and 30 days after surgery. Endothelial Cell Density (ECD) was measured one month after surgery using aspecular microscope (Topcon SP-3000). Visual acuity was measured using the Snellen VA chart and converted to logMAR values for statistical analysis.**Statistical analysis:**

All data were analyzed using IBM SPSS Statistics Version 23 (SPSS Inc., Chicago, III, USA).

RESULTS

The study included 123 women and 77 men with an average age of 56.22± 10.62 (34-82) years.

All eyes had improved postoperative BCVA (Table 1). The mean BCVA was 0.65±0.15 preoperatively and 0.15±0.13 postoperatively in group I & 0.65±0.13 preoperatively and 0.17±0.11 postoperatively in group II There were no statistically significant differences in mean VA between the two groups at any postoperative visit (P > 0.05). Effective phacoemulsification time (EPT) was 3.87±0.93 seconds (ranges from, 2.5-5.9) in group 1 & 3.72±0.84 seconds (ranges from, 2.3-5.4) in group 2.

The first group showed significantly fewer subjective complaints of discomfort, pain, redness, blurred vision, foreign body sensation, photophobia, and tearing. It occurred only on the first postoperative day in 5 eyes in group I and in 37 eyes in group II. While there were no subjective complaints on subsequent follow-up visits.

One day after surgery, five eyes had 2+ anterior chamber aqueous cells, seven eyes had 1+ with no eyes showed +3 or more in group I. No anterior chamber aqueous cells were detected one week & one month postoperatively. There was a statistically significant difference between first post-operative day aqueous cells on one side and, one week and one month (on the other side) postoperatively, while there was no statistically significant difference between cells later on one week and one month postoperatively.

In group II, eleven eyes had anterior chamber aqueous cells 3+, 15 eyes had 2+, 8 eyes had 1+ in the first postoperative day. One week postoperatively, only 3 eyes had +1 aqueous cells with no eyes showing +2 or more. One month postoperatively, no evidence of aqueous cells (figure, 1). There was a statistically significant difference between aqueous cells in the first post-operative day on one side, and one week and one month postoperatively on the other side, while there is no statistically significant difference between cells one week & one month postoperatively (Table 2).

There was a statistically significant difference between the 2 groups on the first day postoperatively, while there is no difference between the 2 groups after one week and I month postoperatively.

Group I IOP showed that preoperative IOP =14.1±2.2 (9.7-20.2) mmHg, one day postoperative=16.0±2.6 (10.3-21.1) mmHg, one-week IOP=14.7±2.5 (9.2-20.4) mmHg and one-month postoperative IOP= 14.5±1.9 (9.5-19.9) mmHg (figure, 1). Group II IOP showed that preoperative IOP =14.8 ±2.4 (9.1-19.7) mmHg, one day postoperative=15.8 ±2.5(9.5-21.3) mmHg, one-week IOP=14.5±1.7(9.9-18.4) mmHg and one-month postoperative IOP= 14.3±2.4 (9.7-19.4) mmHg (Table, 3). There were no statistically significant differences in IOP values between the two groups, and between preoperative and postoperative in both groups (P > 0.05).

The mean preoperative ECC in group I was 2474.02±348.21 cells/mm2 and 2274.15±330.09 cells/mm2 one month postoperatively, while group II preoperative ECC was 2369.16±394.13 cells/mm2 and 2200.96±351.12 cells/mm2 one month postoperatively (Table 4). There was a statistically significant difference between preoperative and postoperative ECC in both groups, while there was no statistically significant difference between the two groups.

Table 1: Visual acuity measurements in both groups.

VA	Intracameral injection				Placebo				P-value
	Mean	SD	Minimum	Maximum	Mean	SD	Minimum	Maximum	
Preop_VA	0.65	0.15	0.30	1.00	0.65	0.13	0.4	1.00	
Postop 1day	0.22	0.17	0.2	0.5	0.23	0.14	0.2	0.6	0.134
Postop 1week	0.17	0.14	0.0	0.6	0.19	0.17	0.0	0.4	0.164
Postop 1month	0.15	0.13	0.0	0.4	0.17	0.11	0.0	0.4	0.279

The test was done by independent sample T-test between the 2 groups and paired sample T-test between preoperative & postoperative

Table 2: Anterior chamber cells in both groups.

Anterior chamber cells	Baseline		Day 1		Day 7		1 month	
	Intracameral injection	Control	Intracameral injection	Control	Intracameral injection	Control	Intracameral injection	Control
N	100	100	100	100	100	100	100	100
0 = Less than 5 cells	100 (100.0%)	100 (100.0%)	88 (88%)	66 (66%)	100 (100%)	97 (97%)	100 (100%)	100 (100%)
1 = Mild: 5-10 cells	0 (0.0%)	0 (0.0%)	7 (7%)	8 (8%)	0 (0.0%)	3 (3%)	0 (0%)	0 (0%)
2 = Moderate: 11–20 cells	0 (0.0%)	0 (0.0%)	5 (5%)	15 (15%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
3 = Marked: 21–50 cells	0 (0.0%)	0 (0.0%)	0 (0%)	11 (11%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
4 = Severe: Greater than 50 cells/hypopyon	0 (0.0%)	0 (0.0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Mann-Whitney test was used for analysis between the 2 groups and the Friedman test for pre and post-analysis.

Table 3: Intraocular pressure values (in mmHg) in both groups.

IOP	Intracameral injection				Placebo			P-value
	Mean	SD	Minimum	Maximum	Mean	SD	Minimum	Maximum	
Preop_IOP	14.1	2.2	9.7	20.2	14.8	2.4	9.1	19.7	
Postop 1day	16	2.6	10.3	21.1	15.8	2.5	9.5	21.3	0.602
Postop 1week	14.7	2.5	9.2	20.4	14.5	1.7	9.9	18.4	0.683
Postop 1month	14.5	1.9	9.5	19.9	14.3	2.4	9.7	19.4	0.618

The test was done by independent sample T-test between the 2 groups and paired sample T-test between preoperative & postoperative.

Table 4: Endothelial cell count in both groups.

ECC	Intracameral injection				Placebo			P-value	
	Mean	SD	Minimum	Maximum	Mean	SD	Minimum	Maximum	
Preoperative	2474.02	348.21	1751	3465	2369.16	394.13	1674	3492	
Postoperative	2274.20	330.09	1592	2990	2200.96	351.12	1433	3274	0.130
P-value between pre and postop	Group 1	<0.001							
	Group 2	0.01							

The test was done by independent sample T-test between the 2 groups and paired sample T-test between preoperative & postoperative

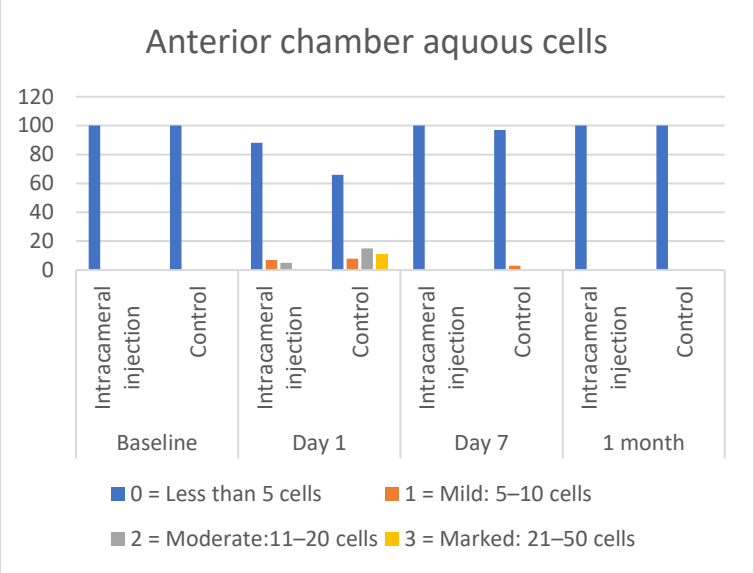

Figure 1: Anterior chamber aqueous cells in both groups

DISCUSSION

In this study, we discuss the role of intracameral dexamesathone added to moxifloxacin at the end of cataract surgery in controlling postoperative inflammation and enophthalmitis prophlaxis as the most feared postoperative hazards. Two hundered eyes of 200 patients underwent uncomplicated phacoemulsification (PE) were enrolled. One hundered eyes were injected intracamerally with 0.1 ml moxifloxacin 0.5% and 0.4 mg dexamethasone at the end of surgery, while the other 100 eyes used as a control group received intracameral placebo injection. The mean BCVA was 0.65±0.15 and 0.65±0.13 preoperatively and 0.15±0.13 & 0.17±0.11 postoperatively, respectively for both groups with no significant difference between the two groups. With regard to other studies, the postoperative visual acuity did not differ significantly in eyes receiving intracameral dexamesathone (DXM) compared to those that received topical steroids. Notably, no eye lost best corrected visual acuity with either intracameral or topical DXM use [20]. Intracameral dexamethasone use was associated with significantly fewer subjective complaints of discomfort, pain, redness, blurred vision, foreign body sensation, photophobia and tearing. It occurred only on the first postoperative day in 5 eyes in group I and in 37 eyes in group II. While, there were no any subjective complaints on subsequent follow up visits. Studies have shown that postoperative inflammatory symptoms were generally fewer in patients treated with intracameral dexamethasone in the first week postoperatively, while negligible statistical differences are reported after the first week when compared to eyes receiving dexamthasone eye drops [21,22]. We found significant reduction in the quantity of aqueous inflammatory cells in the first group during the follow up period. One day after cataract surgery, five eyes had had 2+, seven eyes had 1+. Second group showed more cells; eleven eyes had 3+, fifteen eyes had 2+, eight eyes had 1+. One-week postoperatively, group II showed 3 eyes with +1 cells with no other detected anterior chamber cells at subsequent follow up visits in both groups. There are many studies that report that injection of intracameral DXM significantly reduces postoperative anterior chamber cells and flare effectively [21-25]. While, Tan [22] stated no significant differences in anterior chamber cell and flare between intracameral dexamethasone treated eyes and topical dexamethasone throughout each postoperative interval.One of the major problems with intraocular steroids administration is intraocular pressure (IOP) control. In our study, the mean IOP values were 16.0±2.6 mmHg (range: 10.3-21.1 mmHg) at the first postoperative day. There was no significant change in IOP values on postoperative days 7 and 30. Since direct administration into the anterior chamber requires a lower drug concentration, it may be noticed that intracameral drug use may not elevate IOP as much as topical dexamethasone. This is may be explained by the short half-life of intraocular DXM (~3 hours) with rapid aqueous volume turnover, reducing the risk of steroid-induced ocular hypertension[24].Gungor[23]comparedintracameral DXM to intracameral triamcinolone. They detected a mild intraocular pressure elevation in the early postoperative period with triamcinolone use. Chang et al reported the same conclusion that intracameral dexamethasone had little effect on IOP rise compared to triamcionolne acetonide [25]. Topical administration of DXM has known to increase the mean IOP. Pleyer [26] demonstrated that 0.1% of topical DXM drops administered four-

times per day for more than six weeks result in a mean IOP rise by 8.6 mmHg. It has shown also that ocular hypertension refractory to maximum antiglaucoma medical therapy was recorded following sub-Tenon's injection of triamcinolone [27,28].An expected complication of an intra-cameral drug injection is the loss of corneal endothelial cells. In healthy eyes that have not undergone operation, endothelial cell density declines at about 0.6% per year [29]. After cataract extraction, the rate increases to 2.5% per year from 1-10y after operation, whether or not an intraocular lens was implanted [30].Significant reduction of the endothelial cell count causes impairment of the endothelium pumping, resulting in stromal edema. In present study, the effective phacoemulsification time (EPT) was 3.87±0.93 sec (range 2.5-5.9s). The mean endothelial cell density (ECD) in group I was 2474.02±348.21 cells/mm2 preoperatively and 2274.15±330.09 cells/mm2 one month postoperatively. Group II showed that mean endothelial cell density (ECD) was 2369.20±394 cells/mm2 preoperatively and 2200.75±351 cells/mm2 one month postoperatively with no significant difference in ECC loss between both groups.Jamil [21] studied the effects of intracameral dexamesathone on corneal endothelial cell loss. They found no significant difference in endothelial cell count after intracameral injection compared to a subconjunctival dexamesathone injection. Three months postoperatively, they record a mean endothelial cell count of 2471 cells/mm2 in intracameral DXM-treated eyes whereas subconjunctival DXM demonstrated a mean endothelial cell count of 2496 cells/mm2 proving that intracameral DXM was safe for corneal endothelium. Other studies [21-25] demonstrated no significant cell loss after intracameral DXM compared to those that received placebo [31].Current progress in the use of intracameral antibiotics appears to help in minimizing the risk of postoperative endophthalmitis especially after cataract surgery [32]. Direct intracameral injection of antibiotic has an advantage over topical drops regimens, as it delivers very high concentrations of an antibiotic agent to the anterior chamber at the end of surgery with the desired effect of eradicating bacteria before wound closure and in the early critical postoperative period [33]. Unlike topical antibiotics in which bacterial resistance may develop with frequent administration over long period, intracameral route with one time and highly concentrated dose of antibiotic injected into a physiologically isolated space (AC) is extremely rare to promote bacterial resistance [34,35].In this study, the other molecule injected to fulfill this object is moxifloxacin (Vigamox) which is a commercially available fourth-generation fluoroquinolone that offers a broad activity spectrum. Compared with cefuroxime, which contain benzalkonium chloride (BAK) as a preservative agent, moxifloxacin is a preservative free ophthalmic drug, containing no preservatives known to have toxic effects on ocular tissues. It also does not require any special preparation for intracameral injection, thus decreasing the risk for toxic anterior segment syndrome (TASS) [36].

No cases of infectious endophthalmitis were reported in our study. Arshinoff [37] in a large multicenter cohort study reported one case of postoperative endophthalmitis among of 35,194 operated eyes, (0.003%) with intracameral moxifloxacin. Shorstein [38] reported also only one case out of 1,890 operated eyes with intracameral moxifloxacin (0.053%). The incidence of of postoperative endophthalmitis was 0.029% in Friling study [39]. Inclusion of bilateral cases in the study could be a potential source of bias.

CONCLUSION

In conclusion, the ideal route of a postoperative drug is one that remains confined to a specific target region, minimizes the dose needed to reach the acquired therapeutic level minimizes systemic and local side effects, improve patient's compliance, and maximizes visual rehabilitation. Intracameral dexamesathone moxifloxacin nearly provide all these benefits. This study demonstrates that intracameral moxifloxacin dexamethasone given at the end of cataract surgery improves subjective reports of recovery, significantly reduces postoperative inflammation and highly effective defense against infectious endophthalmitis. We found that it is safe, not toxic to corneal endothelium and did not increase the risk of IOP elevation or other complications in studied eyes. Although, it is unlikely replace topical eye drops totally as the standard postoperative care, its use offers another supplementary simple, safe and effective agent guard against post cataract inflammation and infectious endophthamliti

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