Safety of Prophylactic Intracameral Moxifloxacin Injection after Uncomplicated Phacoemulsification Surgery

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ABSTRACT

Purpose: Endophthalmitis is a serious inflammation that affect the eye and represents a major threat after cataract operation in the form of postoperative endophthalmitis (POE). With more than 10 million cataract operation performed yearly all over the world, effective POE prophylaxis is essential. Many postoperative prophylactic measures are available including Intracameral (IC), topical, subconjunctival and oral antibiotic preparations. Currently, although IC administration is widely accepted, there is no consensus on the best prophylactic therapy or route of administration for POE prevention.

Objective: Determine the safety of prophylactic intracameral injection of moxifloxacin after uncomplicated phacoemulsification surgery.

Patients and Methods: This prospective randomized study included 60 eyes of patients who had uncomplicated phacoemulsification cataract operation selected from Mansoura ophthalmic center, Mansoura University, Egypt, in the period from August 2017 to August 2018. After the surgery the cases were classified into two groups. The first group (30 eyes) received ordinary postoperative systemic and topical ocular treatment (Control group) and the second group (30 eyes) received ordinary postoperative systemic and topical ocular treatment in addition to injection with IC moxifloxacin at the end of operation. The cases were followed up at the following up at; first day,1 week, 1 month & 3 months after surgery

Results: There was statistically significant difference in the BCVA, but there was no statistically significant difference in the central corneal thickness and endothelial cell count in the cases within the two groups 1 and 3 months of surgery. There was a statistically significant decrease in the central corneal thickness, endothelial cell count and number of cells in anterior chamber in the cases within the two groups along the follow up period after the surgery as compared with the preoperative value.

Conclusion: The current study supported the safety of IC injection of undiluted moxifloxacin in a concentration of 0.5 mg /0.1 ml (vigamox) in terms of anterior chamber reaction, central corneal thickness, endothelial cell count and visual rehabilitation.

Key words: Intracameral, Moxifloxacin, Phacoemulsification, Endophthalmitis, Cataract.

INTRODUCTION:

Cataract extraction with intraocular lens implantation is the most commonly performed operation worldwide, with more than 10 million patients operated every year. The majority of cases experience uncomplicated postoperative courses with improving visual acuities[1]. However, one of the most serious adverse events after cataract surgeries is the development of endophthalmitis[2].

Preoperative povidone–iodine antisepsis combined with preoperative and postoperative topical antibiotic therapy is considered the standard of care[3]. The utilization of prophylactic antibiotic preparation in elective cataract operation is still controversial[4]. In spite of a lack of evidence that antibiotics prevent post-operative infection, several surgeons routinely administer IC antibiotics to prevent POE[5].

Reconstituting the drug for IC administration might enhance the risk of toxic anterior segment syndrome (TASS) as an erroneous concentration might be inadvertently injected if a mistake has occurred during the preparation or dilution processes[6].

Fluoroquinolones were introduced to treat corneal and conjunctival infections; but, they had a better role for prophylaxis prior to operation for prevention of POE[7].

Considering the potential adverse effects of vancomycin and cefuroxime, moxifloxacin appears to be a better choice for POE prophylaxis due to its broad-spectrum action and mechanism of action[8].

Several studies demonstrated moxifloxacin, to be more potent. It has the lowest MIC for the majority of endophthalmitis caused by bacteria;it offers potent and rapid bactericidal activity against the most common Gram-positive and Gram-negative POE pathogens. It has excellent ocular penetration following topical administration and is available in a self-preserved ophthalmic formulation without added preservative. therefore, it appears to be a better choice for prophylaxis[9-11].

PATIENTS AND METHODS

This is a prospective randomized study that was conducted in the period between August 2017 to August 2018 in Mansoura ophthalmic center, Mansoura University, Egypt.

This study included 60 eyes of patients who had uncomplicated phacoemulsification cataract surgery. The cases with the following conditions were excluded; Patients with glaucoma, uveitis, media opacities other than cataract (cornea or vitreous), patients with visual pathway problems, patients taking prostaglandin analogue agents, systemic immunosuppressants or anticoagulants, cataract surgery cases with intraoperative complications including posterior capsule rupture, vitreous loss and at last any patients who had a prior eye operation.

After approval from the institutional review board of Mansoura Faculty of Medicine and obtaining an informed written consent from the participants, all cases were subjected to complete history taking and through full general.

In the preoperative stage, full detailed ophthalmic examination was done for all the cases including assessment of the visual acuity (VA) using Landolt's VA chart and then transformed for statistical analysis to logarithm of minimal angle of resolution units (Log MAR).

Slit lamp biomicroscopy (Haag Streit BP 900) (Haag-Streit, Koeniz, Switzerland) was used to assess corneal clarity, anterior chamber for depth and regularity, pupil shape, size, regularity and reactivity and state of the lens. Intraocular pressure was measured using Keeler pulsair intellipuff tonometer and patient's refractive error was measured using Topcon RM-800 autorefractometer.

Posterior segment examination was conducted using indirect ophthalmoscope and slit lamp biomicroscopy with auxiliary contact lens.

Tomey EM-3000 non-contact specular microscope was used to measure endothelial cell count (ECC) and Nidek US-4000 echo scan ultrasound pachymetry was used to measure central corneal thickness (CCT).

The cases were randomly divided (using computer generated tables) into two groups; the first group (30 eyes) received ordinary postoperative systemic and topical ocular treatment (Control group) and the second group (30 eyes) received ordinary postoperative systemic and topical ocular treatment in addition to injection.

Preoperative preparations:

We explained to every patient nature of the study, its purpose, follow up duration, nature of procedures, possible complications, benefits as well as any discomfort might occur. A written consent was obtained from every patient.

Pupil dilatation: One drop of topical Cyclopentolate 1% eye drops 1 hour before the scheduled time for surgery then every 15 min., no phenylephrine or topical NSAIDs eye drops were used before operation.

Operative technique:

Anesthesia:

All Surgeries were done under local anesthesia (retrobulbar anesthesia) using 2ml mepivacaine HCL3%.

Surgical technique:

All surgeries were done by the same surgeon using the same phaco technique and machine.

1. Adequate Sterilization using povidone iodine (10% for skin and 5% for conjunctiva).
2. Two corneal side ports were performed using 20-G MVR blade at 2 & 10 o'clock.

3. A corneal incision was performed using keratome, 3.2 mm width at 12 o'clock.
4. Then a viscoelastic material underwent injection in the form of methyl cellulose to protect corneal endothelium and heal on to keep the AC formed .
5. Rhexis forceps was used to adjust anterior capsulorrhexis (5 mm in diameter).
6. Hydrodissection of the lens was done using BSS.
7. Phacoemulsification of the nucleus was done by stop and chop technique.
8. Irrigation & aspiration of remaining soft cortex using I/A system.
9. Healon was then injected to fill the AC and the capsular bag before implantation of the hydrophobic foldable acrylic IOL, which was introduced into the capsular bag using an injector.
10. Removal of any remaining viscoelastic material was done through irrigation and aspiration with the aid of a bimanual procedure.
11. The main corneal incision and the 2 side ports were closed by hydration.
12. Intra cameral injection was done to Group B eyes.

Technique of injection:

The contents of a newly opened bottle of moxifloxacin ophthalmic solution 0.5% (Vigamox) was aspirated into a sterile tuberculin syringe, a volume slightly in excess of 0.1 mL (0.3-0.4 mL) of the pure undiluted moxifloxacin 0.5% ophthalmic solution. The excess amount was discarded, leaving 0.5 mg/0.1 mL of the nonpreserved moxifloxacin in the tuberculin syringe ready for injection into the anterior chamber. The solution prepared in the syringe was injected using a 27-gauge cannula through the side port into the capsular bag after hydration of the side ports and water tightness of corneal incisions controlled.

Postoperative phase :

After the surgery, all the cases received topical steroids eye drops (prednisolone acetate 1% 6times /day which were tapered gradually and discontinued after 2 weeks). ,antibiotics eye drops (Moxifloxacin 0.5%) every two hours in the first day then 6 times /day for 2 weeks and lubricants eye drops 6 times for two weeks.

Patients were examined at1 week, 1 month & 3 months after surgery with assessment of the following parameters, unaided visual acuity, refraction and assessment of aided visual acuity, slit lamp biomicroscopy examination, IOP, endothelial cell count (ECC) and central corneal thickness (CCT).

Statistical analysis

Data entered and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS 21.0, IBM/SPSS Inc., Chicago, IL) software for analysis. Baseline characteristics of the study population were presented as frequencies and percentages (%) or mean values and standard deviations (SD) or median and interquartile range (IQR) (after testing of normality by Kolmogorov-Smirnov and Shapiro-Wilk's tests).

For comparison of data, Chi-Square test (or Fisher's exact test) was used to compare two independent groups of qualitative data and McNemar test was used to compare two related groups of qualitative data at different time points. For quantitative data, independent-Samples t-test and Mann-Whitney U test were used to compare two groups of parametric and non-parametric quantitative data respectively. For comparison of quantitative data between two related groups, paired-samples t-test. or Wilcoxon test were used for parametric and non-parametric data respectively. Probability (p value) ≤ 0.05 was considered to be statistically significant.

RESULTS

As shown in table (1), The mean age of subjects in the control group is 58.77 ± 4.43 years and the mean age of the cases in the injected group was 59.2 ± 5.05 years with no statistically significant difference between the two groups (p=0.725). There were 16 males (53.3%) and 14 females (46.7%) in the control group while there were 19 males (63.3%) and 11 females (36.7%) in the cases group with no statistically significant difference in the sex distribution within the two groups (p=0.432).

There was no statistically significant difference in the UCVA and BCVA in the cases within the two groups (Data not shown).

There was no statistically significant difference in the ECC and CCT between the cases in the two study groups (p=0.138 and 0.487 respectively).

Table (1): Demographic data and preoperative examination in the two study groups

Items	Group A (control) n=30	Group B (injected group) n=30	P value
Age (years)	58.77 ± 4.43	59.2 ± 5.05	0.725
Sex			
Male	**16 (53.3%)**	**١9 (63.3%)**	0.432
Female	**14 (46.7%)**	**11 (٣6.7%)**	
ECC [Median (IQR)]	2597.5 (2368.25-2753)	2536.5 (2382.25-2608)	0.183
CCT (Mean ± SD)	522.27 ± 35.36	515.60 ± 38.38	0.487

Table (2) shows that there was no statistically significant difference in the BCVA in the cases within the two groups after 1 week of surgery. The median number of ECC in the cases in the control group was 2328.5 (IQR 2228.75 and 2529.75) while in the cases in the injected group, the median number of ECC was 2402.5 (IQR 2299 and 2544.75) with no statistically significant difference between the two groups (p=0.501). The mean CCT in the cases in the control group was 553.77 ± 50.50 µm while in the cases in the injected group, the mean CCT was 550.40± 49.24 µm with no statistically significant difference between the two groups (p=0.495). The number of cells in AC was 0 in both groups.

Table (2): Analysis of different parameters of the first postoperative week in the studied groups

Items	Group A (control) n=30	Group B (injected group) n=30	P value
BCVA			
6/9	13 (43.3%)	9 (30%)	0.276
6/12	8 (26.7%)	5 (16.7%)	
6/18	5 (16.7%)	6 (20%)	
6/24	2 (6.7%)	2 (6.7%)	
6/36	2 (6.7%)	8 (26.7%)	
AC	0	0	1
ECC [Median (IQR)]	2328.5 (2228.75-2529.75)	2402.5 (2299-2544.75)	0.501
CCT (Mean ± SD)	553.77 ±50.50	550.40 ± 49.24	0.495

Table (3) shows that, at 1-month post-surgery, there was statistically significant difference in the BCVA in the cases within the two groups (p=0.045). The median (IQR) ECC in the cases in the control group was 2241 (2126-2518) while in the cases in the injected group, the median (IQR) ECC was 2340 (2092.75-2438.5) with no statistically significant difference between the two groups (p=0.668). The mean CCT in the cases in the control group was 536.90 ± 41.32 µm while in the cases in the injected group, the mean CCT was 527.77 ± 59.43 µm with no statistically significant difference between the two groups (p=0.492). The number of cells in AC was 0 in both groups.

Table (3): Analysis of different parameters at 1 month postoperative in the studied groups

Items	Group A (control) n=30	Group B (injected group) n=30	P value
BCVA			
6/9	13 (43.3%)	8 (26.7%)	**0.045**
6/12	7 (23.3%)	4 (13.3%)	
6/18	2 (6.7%)	3 (10%)	
6/24	8 (26.7%)	15 (50%)	
AC	0	0	1
ECC [Median (IQR)]	2241 (2126-2518)	2340 (2092.75-2438.5)	0.668
CCT (Mean ± SD)	536.90 ± 41.32	527.77 ± 59.43	0.492

Table (4) shows that, at 3 months post-surgery, there was statistically significant difference in the BCVA in the cases within the two groups (p=0.045). The median (IQR) ECC in the cases in the control group was 2214 (2111.25-2496.25) while in the cases in the injected group, the median (IQR) ECC was 2299 (2091.25-2367.75) with no statistically significant difference between the two groups (p=0.626). The mean CCT in the cases in the control group was 529.90 ± 39.63 µm while in the cases in the injected group, the mean CCT was 524.73 ± 48.36 µm with no statistically significant difference between the two groups (p=0.653). The number of cells in AC was 0 in both groups.

Table (4): Analysis of different parameters at 3 months postoperative in the two studied groups

Items	Group A (control) n=30	Group B (injected group) n=30	P Value
BCVA			
6/9	13 (43.3%)	8 (26.7%)	**0.045**
6/12	7 (23.3%)	4 (13.3%)	
6/18	2 (6.7%)	3 (10%)	
6/24	8 (26.7%)	15 (50%)	
AC	0	0	1
ECC [Median (IQR)]	2214 (2111.25-2496.25)	2299 (2091.25-2367.75)	0.626
CCT (Mean ± SD)	529.90 ± 39.63	524.73 ± 48.36	0.653

There was a statistically significant decrease in the AC in the cases with the two study groups in the first week of surgery as compared to the values in the first day (completely disappeared at 1 week). No reported change in the number of cells at 1 months and 3 months. There was a statistically significant decrease in the number of ECC in the cases with the two study groups in the first week, first month and 3 months as compared to the preoperative values (p< 0.001) (Data no shown).

Table (5) shows that there was a statistically significant increase in the CTT in the cases with the two study groups in the first week postoperatively (p< 0.001). At 1 month postoperatively, the CCT started to decrease again in both groups, but the values were still statistically significant higher as compared with the preoperative values (p=0.002 and 0.026 for the control and moxifloxacin treated group respectively). The values of CCT continued to decrease again in the two groups at three months with no significant difference as compared to the preoperative values.

Table (5): Assessment of CCT along the study duration in the two studied group

Time	*Group A (control) n=30*	*Group B (injected group) n=30*	*P Value*
Preoperative	*522.27 ± 35.36*	*515.60 ± 38.38*	*0.487*
At 1 week	*553.77 ±50.50*	*550.40 ± 49.24*	*0.495*
P1	***< 0.0001***	***< 0.000***	
At 1 months	*536.90 ± 41.32*	*527.77 ± 59.43*	*0.492*
P1	***0.002***	***0.026***	
At 3months	*529.90 ± 39.63*	*524.73 ± 48.36*	*0.653*
P1	***0.067***	***0.108***	

In this study, no cases with retinal vascular toxicity due to intracameral injection of moxifloxacin were reported.

DISCUSSION:

In this study, we tried to determine the safety of prophylactic intracameral injection of moxifloxacin after uncomplicated phacoemulsification surgery. This prospective randomized controlled trial included 60 eyes of 60 patients who had uncomplicated phacoemulsification cataract surgery. The cases were divided into two equal groups, group A who received no treatment as a control group while group B who were injected with intracameral moxifloxacin at the end of surgery.

There were 16 males (53.3%) and 14 females (46.7%) in the control group while there were 19 males (63.3%) and 11 females (36.7%) in the injected group. there is no statistically significant difference in the basic demographic data of the cases within the two groups.

The right eyes were affected in 15 cases (50%) and left eyes in 15 cases (50%) in the control group while in the cases in the injected group, the right eyes were affected in 14 cases (46.7%) and the left eyes in 16 cases (53.3%).

Regarding the preoperative data in the two study groups, there was no statistically significant difference in the UCVA and BCVA in the cases within the two groups. There was no statistically significant difference in the median ECC and the mean CCT between the cases within the 2 groups (p = 0.138 and 0.487).

There was a statistically significant improvement in BCVA in the cases within the two study groups with the follow up as regards of the preoperative value. There was a statistically significant improvement in the injected group at 1 month and 3 months postoperative as compared with the control group.

This came in accordance with Koktejir and Aslan (2012) who showed that the mean pre-operative visual acuity was same in both groups, furthermore, mean post-operative visual acuity was also comparable. Therefore, the improved visual acuity was comparable in the 2 groups; there was no statistical difference at all[12].

Also in accordance with the results of this study, the preoperative VA range from HM to 6/12 This changed postoperatively in which mostly improved more than 6/18 with a total lines gained up to 12 lines in the two study groups with no significant difference between the two groups[13].

In this study, there was a statistically significant decrease in the aqueous cells (AC) in the cases with the two study groups in the first week of surgery as compared to the values in the first day (completely disappeared at 1 week). No reported change in the number of cells at 1 months and 3 months.

Similar results were shown by Arslan et al. (2014) who showed that no cells and flare were detected in all eyes at the 1wk postoperatively after treatment by injecting of moxifloxacin in a dose of 0.5 mg/0.1 mL[14]

This also came in agreement with Arbisser (2008) who reported that One day post-operatively, 4 eyes (2.0%) in the moxifloxacin- treated eyes and 11 eyes (11.0%) of controls had aqueous cell counts higher than 3 cells. The difference was statistically significant in favor of the moxifloxacin-treated eyes (P= 0.0007). At one week, there was no significant difference between the 2 groups in the number of patients with no or trace cells (95% and 96% in the moxifloxacin-treated patients and controls, respectively) (P = 0.6987). Likewise, there was no difference between groups in cases with 1+ or 2+ cells (5% and 4%, respectively)[15].

Within the same context, Espiritu *et al (2007) who* showed that moxifloxacin causes no inflammation in the anterior chamber and vitreous[11].

More recently, Albialy et al. (2019) showed that aqueous cells on the first postoperative day in the group of patients treated with injected intracamerally with moxifloxacin: five eyes had 2+, and 7 eyes had 1+ with no eyes of +3 or more. After 1 week, all eyes had no anterior chamber cells. In the control group, 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[16].

It was previously reported that in healthy eyes that have not undergone operation, endothelial cell density declines at about 0.6% per year [17]. After cataract extraction, the rate increases to 2.5% per year from 1-10y after operation, whether or not an intraocular lens was implanted[14].

*In this study, t*here was a statistically significant decrease in the number of ECC in cases with the two study groups in the first week, first month and 3 months as compared to the preoperative values (p< 0.001). However, there is no statistically significant difference in the number of ECC between the two groups at the preoperative, 1 week, 1 months and 3 months after the surgery.

In an Egyptian study conducted by Amer et al. (2013) the average endothelial cell density in controls was 2366.75cells/mm3 and altered to 2083.75 cells/mm3, whereas the average endothelial cell density in the moxifloxacin group was 2533.21 cells/mm3then one month post-operatively altered to 2006.29 cells/mm3. There was a reduction of 283 cells/mm3 in controls as compared with the 526.93 cells/mm3decrease in the moxifloxacin treated eyes[13].

In another study, the mean ECC was 2340.20±187.21 cells/mm^2 preoperatively and 1948.75±246.76 cells/mm^2 1 month postoperatively. The ECC was statistically significantly lower than preoperatively (P<0.001)[14].

In this study, there was a statistically significant rise in CTT in the cases with the two study groups in the first week postoperatively (p< 0.001). At 1 month postoperatively, the CCT started to decrease again in both groups, but the values were still statistically significant higher as compared with the preoperative values (p=0.002 and 0.026 for the control and moxifloxacin treated group respectively). The values of CCT continued to decrease again in the two groups at three months with no significant difference as compared to the preoperative values. However, there is no statistically significant difference in the ECC between 2 groups at the preoperative, 1 week, 1 months and 3 months after the surgery. The increase in the CCT could be explained by blood aqueous barrier (BAB) disturbance or secondary inflammatory response, which would have cause increased aqueous flare values and increased cell values, respectively[8].

Amer and his colleagues showed that the average pre-operative central corneal thickness in controls was 613 and altered to 613.75 one month post-operatively, whereas the average central corneal thickness in moxifloxacin treated eyes was 589 pre-operatively and altered to 611.21 one month[13].

In accordance to this current results, Arslan et al. (2014) showed that the mean CCT was 560.96±13.22 µm preoperatively and 582.05±17.21 µm 1 month postoperatively; the difference was highly statistically significant[14]

In another study, there was no single case of corneal oedema. In the 1st group (povidone iodine drop), pre-operative pachymetry was 523±44 and post-operative pachymetry was 536±45 µm, while in the 2nd group (treated with IC moxifloxacin (250 µg/0.050 mL) pre-operative pachymetry was 527±43 and post-operative pachymetry was 543±42 µm. Pre-operative and post-operative pachymetry alterations were not significantly different between the two groups[12].

On the other hand, O'Brien reported no statistical evidence of decreased endothelial cells or increased corneal thickness as early as one month post-operatively in comparison with pre-operatively. The authors explained this as they found no evidence that Vigamox caused increased BAB disturbance or secondary inflammatory response, which would have cause increased aqueous flare values and increased cell values, respectively[18].

Overall, our current study reported no cases of endophthalmitis with the use of intracameral moxifloxacin, however this didn't reveal a significant difference as compared with the ordinary prophylaxis regimen. On the other hand, Viera et al. reported a 7.3-fold lower ratio of POE following cataract operation in patients treated with moxifloxacin intraoperative[19].

An earlier study showed that the IC moxifloxacin was associated with an endophthalmitis rate of 1:6,265, which was a three-fold lower in comparison with the group which was not treated with antibiotics[20].

In an Indian study, a four-fold decrease in endophthalmitis was reported in cases that had small-incision cataract operation and received IC moxifloxacin following IOL implantation [21].

In spite of such promising findings, some studies revealed that other factors might explain the reduced rates of endophthalmitis with time, such as increased asepsis and antisepsis concerns, improved surgical time and procedures, equipment evolution, alterations in postoperative routines, or other unidentified factors[22].

CONCLUSION:

Phacoemulsification surgery is associated with postoperative complications especially endophthalmitis. Moxifloxacin is a fluoroquinolone antibiotic that is widely used in prophylaxis for postoperative endophthalmitis.

Intracameral injection of moxifloxacin didn't reveal superiority over ordinary prophylactic measures in decreasing signs of eye affection. Intracameral injection of moxifloxacin didn't show increase in the incidence of postoperative complications.

DATA AVAILABILITY

All data are included in this article.

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None

Conflict of Interest

Authors declare no conflicts of interest.

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Ethics declarations

Conflict of interest

Ahmad E. Hassaan, Eman A. Abd El-Hamed, Sherief E. El-Khouly, Hosam M. Ali El-fallal all authors have no conflicts of interest that are directly relevant to the content of this review.

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