

## Efficacy of Intracameral moxifloxacin in Cataract surgery to prevent post-operative Endophthalmitis

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### Abstract

**Purpose:** To establish the efficacy of intracameral injection of moxifloxacin 0.5% (0.5mg/ml or 500 µg) ophthalmic solution in patients having routine cataract surgery as prophylaxis to endophthalmitis.

**Setting:** Department of Ophthalmology, Sindh Government Qatar Hospital Orangi Town, Karachi.

**Study Design:** Prospective Case Series.

**Method:** A prospective study was conducted from the period of February 2009 to November 2009 in department of ophthalmology Sindh Government Qatar Hospital Orangi Town, Karachi. Total 530 patients were treated with intracameral injection of 0.5% moxifloxacin solution in 0.1 (500µg) ml dose at the conclusion of the surgery with IOL implantation either by doing phacoemulsification or conventional method. Safety parameters included VA, IOP, corneal clarity & edema, aqueous cells and flare were evaluated preoperatively and postoperatively for 3 months in patients who received intracameral injection.

**Results:** Five hundred eyes completed the study while 30 patients were excluded from the study because of poor follow up. Aqueous cells and count on first and third postoperative days were insignificant in all patients who were given intracameral injection of moxifloxacin at the last step of surgery. All eyes had a postoperative best corrected visual acuity of 20/30 or better. No stromal edema was observed. No drug related adverse effects were reported. No case of endophthalmitis was reported during and after the 3 months follows up period.

**Conclusion:** Intracameral injection of moxifloxacin 0.5% (0.5mg/ml or 500 µg) ophthalmic solution appears to be nontoxic in terms of visual rehabilitation, anterior chamber reaction and corneal edema. It is found very effective for the prophylaxis of endophthalmitis at the conclusion of routine cataract surgery.

**Key Words:** Endophthalmitis, Postoperative complication of cataract surgery, Intracameral moxifloxacin, Endophthalmitis prophylaxis

### Introduction

Postoperative Endophthalmitis continues to be a problem despite pre- and postoperative antibiotic prophylaxis. Though it occurs infrequently but it is one of the most feared complications as its consequences are sight threatening<sup>1,2</sup> It is a devastating complication that occurs in about 1:10000 cases.<sup>3</sup> Despite early treatment, about 50% cases become blind. After cataract surgery, Endophthalmitis cases increased from 1994 to 2001; with a reported incidence of 2.15 per

1000 cases.<sup>4</sup> Various regimens for prophylaxis are in practice since long like antibiotics in irrigation solution and sub conjunctival injections (SCI) etc.

Study by the European Society of Cataract and Refractory surgery (ESCRS) provided a strong evidence that intracameral injection (IC I) of an antibiotic agent at the close of cataract surgery was reported to decrease the incidence of post-operative endophthalmitis by almost 5-fold.<sup>5,6,7</sup>

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It provides immediate high antibiotic level that are sustained for a period of time.<sup>5</sup>

Among the antibiotics used intracamerally, the most common are vancomycin and cefuroxime<sup>8</sup>. However Vancomycin has shown to increase the risk of cystoid macular edema after cataract surgery.<sup>9</sup> Moreover there are reports of emergence of resistant strains of many bacteria.<sup>10</sup> Both of these are available as systemic preparation. They have to be reconstituted before delivery into the eye. Reconstitution of the drug increases the risk of toxic anterior segment syndrome (TASS).<sup>11</sup> Incorrect PH and incorrect osmolality can also cause TASS. Another problem with vancomycin and cephalosporin is that they have time dependent efficacy. As the concentration of the drug in AC decreases four times in first hour, so, this makes them poor choice for ICI. use.<sup>12,13</sup> Considering the possible complication with vancomycin and cefuraxime, moxifloxacin seems to be the better choice of antibiotic for endophthalmitis prophylaxis because of its broad spectrum coverage and mode of action. Moxifloxacin is a fourth generation fluoroquinolone antibacterial agent that is active against a broad spectrum of gram positive and gram negative ocular pathogens, atypical microorganism and anaerobes.<sup>14-16</sup> It is easily available, and needs not to be reconstituted (0.5% moxifloxacin eye drops as Vigamox by Alcon). SCI are effective but causes pain and sometimes sub conjunctival hemorrhage. Therefore we carried out a study in our department to evaluate the safety of injecting intracameral moxifloxacin in human eyes having cataract surgery.

#### **Patients and method:**

This is a prospective case series. The study was carried out at the Ophthalmology Department, Sindh Govt. Qatar Hospital Orangi Town Karachi. The study was conducted from February 2009 to November 2009. A total of 530 patients were included in the study.

**Inclusion Criteria:** All patients requiring cataract surgery, over the age of 20 with no other ocular pathology that would prevent achievement of at least 20/30 best corrected visual acuity postop-

eratively with informed consent were included in the study.

**Exclusion Criteria:** Patients with glaucoma, retinopathy, maculopathy, media opacities other than cataract (cornea or vitreous) and visual pathway problem, patients with uveitis, diabetes with advanced retinopathy, corneal endothelial disease or psuedoexfoliation with evidence of glaucoma, patients taking systemic immunosuppressants or anticoagulants, patients with other ocular pathologies that would prevent achievement of at least 20/30 best corrected visual acuity, patients with previous ocular trauma or allergy to flouroquinolones. Patients taking prostaglandins analogue agents. Cataract surgery cases with intraoperative complications including vitreous loss or posterior capsule breakage and prolonged surgery time.

#### **Method:**

All patients of either sex were admitted in the ward for the study. A careful history was taken from each patient and recorded on a proforma which included: name, age, sex, address, presenting complaints and their duration. Written consent was obtained from the patients or their parents.

Complete ocular examination was done and findings were recorded, which included uncorrected and corrected visual acuity, slit lamp examination, tonometry, fundoscopy and biometry.

**Surgical Technique:** All patients were admitted one day prior to surgery. On the day of surgery pupil was dilated with 1% tropicamide and 10% phenylephrine. All surgeries were performed using retro bulbar or topical anesthesia. The prophylactic regimen to reduce the risk of infection included topical 10% povidone-iodine on the periorbital skin, 5% povidone iodine in the conjunctival sac and eye lashes, draping of the eyelashes and perorbital region, topical antibiotic drops one day prior to and on the day of surgery. At the start of operating day, a new bottle of moxifloxacin (vigamox) was opened and the contents of newly opened bottle were



Figure 1: (Burney, Ali & Baig) Moxifloxacin (Vigamox-Alcon) is being aspirated 1cc through a new bottle at the start of surgery in 3cc syringe



Figure 2: (Burney, Ali & Baig) Pure moxifloxacin 0.1ml of is aspirated in tuberculin syringe from 3cc syringe

aspirated in 3cc syringe by the operating assistant (Figure 1). Then 0.1 ml of 0.5% pure moxifloxacin was aspirated in 1cc tuberculin syringe (Figure 2) before starting surgery in every case and put on the surgery trolley aside. No solution including saline was added to dilute commercial preparation. Uneventful phacoemulsification or planned ECCE was performed in a standardized fashion through a 3.2 mm clear corneal incision and IOL was implanted after enlarging the incision. The prefilled 0.1 (500 $\mu$ g) ml of 0.5% pure moxifloxacin solution in 1cc tuberculin syringe was injected using 27-gauge cannula through the side port into the capsular bag as the last step of cataract extraction and IOL implantation. Post-operative antibiotics included oral ciprofloxacin 500mg, 1 tablet twice a day for 5 days and topical moxifloxacin (Vigamox eye drops by Alcon) every two hours. Topical dexamethasone 0.1% was also given. The patients were scheduled for follow-up 1 day, 1 week and 1 month after surgery. On each visit visual acuity was recorded, slit lamp examination was done for anterior

chamber cells and flare.

### Results:

Total of 530 patients were included in the study. However 30 patients were excluded from the study because of poor follow-up. One eye of each patient was enrolled in the study. There were 298 females patients and 202 were males. The age varied from 20 to 80 years, average being 55 years. Three hundred and fifty two (352) surgeries were done by phacoemulsification and 148 by conventional ECCE method. All patients completed the follow up. All patients were examined on pre schedule interval and undergone visual acuity recording slitlamp examination followed by tonometry. All eyes had a postoperative best corrected visual acuity of 20/30 or better, 78 % had visual acuity of at least 20/20 (Table 1). Seventy-five (75) patients had mild corneal edema on the first day postoperatively. There were trace to +2 cells and flare anterior chamber reaction only on the first day after cataract surgery. All had quite anterior chamber at subsequent follow-up examination. No drug related adverse effects were reported. No post-operative epithelial defect or stromal edema was observed. All patients were kept on antibiotic and steroid drops for four weeks.

### Discussion:

Endophthalmitis is a serious vision threatening postoperative complication of cataract surgery. Various regimes are available for its prophylaxis. Recently intracameral injection is viewed with increasing interest for the benefits of providing

Table 1: Table demonstrating postoperative visual outcome after ICI moxifloxacin in 500 cases

Parameters	First Day	One Week	One Month
Aqueous flare	22% (N=110)	8% (N=40)	Nil
Aqueous cell count	21% (N=105)	9% (N=45)	Nil
IOP (mmHg)	22m.mHg In 11% (N=75)	25 m.mHg In 3%	25 m.mHg 1% (N=5)
Corneal edema	15% (N=75)	6% (N=30)	Nil
VA	85% 6/18 to 6/12 (N=425)	90% 6/18 to 6/12 (N=450)	98% 6/9 to 6/6 (N=490)

an instantaneous high level of antibiotic in the anterior chamber after cataract surgery to prevent postoperative endophthalmitis. Contamination during surgery from the patient's own conjunctival flora and imperfections in wound architecture pose the risk that an inoculum of bacteria sufficient to cause infection may enter the eye at the close of, or shortly after cataract surgery. Anterior chamber fluid contamination rates from 5% to 43% after routine cataract surgery are reported, with the patient's own conjunctival flora often identified as the source.<sup>17-19</sup> Older patients over 75 years, demographic sector most likely to present for cataract surgery, have been found to carry high rates of bacterial contamination on their conjunctiva.<sup>20</sup> As this patient population ages worldwide, the number of cataract surgeries performed annually is expected to increase substantially and the need to identify effective prophylactic measures to reduce endophthalmitis following cataract surgery becomes essential.<sup>21</sup>

Of the prophylactic methods for cataract surgery only povidone iodine is recommended.<sup>22</sup> If applied alone it reduces conjunctival flora by 91% for colony forming and 51% for species. If it is used along with topical antibiotic, it produces synergistic effect and leads to sterilization of 83% of the eyes.<sup>23</sup> Despite its efficacy the rate of endophthalmitis increased after 1994. So there was a need for prophylactic antibiotic to check this rise in the rate of endophthalmitis. Contemporary standards of care for surgical prophylaxis include not only povidone iodine but also topical antibiotic drop therapy.<sup>24</sup> Topical antibiotic which gained popularity in last few years for infection prophylaxis after cataract surgery were fluoroquinolone.<sup>11</sup> Moxifloxacin is a fourth-generation fluoroquinolone antibiotic agent that provides broader spectrum antimicrobial action and enhanced activity against gram positive bacteria than earlier fluoroquinolone antibiotic agents such as ciprofloxacin, ofloxacin, and levofloxacin. Moxifloxacin is rapidly bactericidal against ocular isolates resistant to older generations of fluoroquinolones.<sup>25-28</sup> Because of the self-preserved nature of moxifloxacin 0.5% ophthalmic solution, its physiologic pH and the ease

of availability and preparation, our objective in the current study was to evaluate the safety of intracameral moxifloxacin as an adjunct to topical therapy. Our concern was to check the effect of intracameral moxifloxacin on cornea for which we examined the cornea clinically for striate after surgery. The other concern was effect of moxifloxacin on blood aqueous barrier and whether it causes inflammation or not. The patients were examined for aqueous flare and cells on the first postoperative day and on the scheduled visits.

Intracameral injections of 50 to 500 mg doses were evaluated in a rabbit model to assess the bactericidal efficacy and safety of the undiluted moxifloxacin 0.5% ophthalmic solution (Vigamox).<sup>29</sup> No toxicity was noted by slitlamp examination, indirect ophthalmoscopy, or corneal ultrasound pachymetry. These studies in animal models, together with clinical reports, support the safety profile of moxifloxacin for intraocular use. The objective of the intracameral injection is to deliver high drug levels to the anterior chamber instantaneously as high peak antibiotic levels are most closely associated with an antimicrobial effect.<sup>24</sup>

This route of injection delivers very high concentration of an antibiotic agent to the anterior chamber at the close of surgery with the presumed effect of eradicating bacteria before wound closure and in the immediate postoperative period. Several studies<sup>15, 28, 30, 31</sup> found moxifloxacin to be superior in terms of potency. It has the lowest mean inhibitory concentration (MIC) for most bacterial Endophthalmitis isolates<sup>28</sup>, thus it seems to be a better choice for prophylactic antibiotic. Our choice to analyze the data 4 weeks after surgery is supported by observations in previous studies of intracameral instillation of the drug.<sup>12, 21, 24</sup>

The successful use of intracameral moxifloxacin in cataract patients was recently described by Espiritu et al.<sup>32</sup> The results in our study provide further support to the safety profile of an intracameral injection of moxifloxacin for the prophylaxis of endophthalmitis.



**Conclusion:**

Intracameral moxifloxacin 0.1(500µg) ml of 0.5% pure solution appears to be nontoxic in terms of visual rehabilitation, anterior chamber reaction and corneal edema. It is easy to use, doesn't need reconstitution and cheaper, as one bottle can be used in more than 25 cases. Injected at the conclusion of routine cataract surgery, this treatment modality, using the broad-spectrum antimicrobial activity of moxifloxacin, may prove useful in evolving prophylactic regimens against postoperative endophthalmitis.

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