A Cataract is the clouding or opacity of the normally clear, natural crystalline lens of the eye, which lies behind the iris and the pupil. There are an estimated 9-12 million blind in India, half of which can be attributed to cataract. Endophthalmitis is a potentially sight-threatening complication of cataract surgery. Fluoroquinolones penetrate vitreous better than other antibiotics and is used by many clinicians, but have not been suggested to rigorous blinded trials.

Objectives: The main objective of this study is to compare the efficacy and penetration ability of topically applied 0.5% Moxifloxacin and 0.5% Levofloxacin ophthalmic solutions into human aqueous humor before routine cataract surgery.

Materials and Method: Microbiological study was carried out on patients' conjunctival smear before and after administration of antibiotic. Fifty patients that underwent cataract extraction were divided randomly into two groups with Moxifloxacin (25 Patients) and Levofloxacin (25 Patients).

Result: Based on the penetration study, the mean concentration of Moxifloxacin in the aqueous humor was significantly greater than that of Levofloxacin in both types of regimens namely regime A and B. The MIC90 value of Moxifloxacin was found to be lower than that of Levofloxacin for most key ocular pathogens.

Conclusion: This study provides an evidence based conclusion that cataract surgery can be done as an out patient procedure without any complication to the patients and that Moxifloxacin has a better penetrating power than Levofloxacin in the aqueous humor.

Keywords: Moxifloxacin, Levofloxacin, Endophthalmitis.
sensitivity to any of the ingredients in the study medications or any quinolone compound, had a condition that may confound the study results, or may interfere significantly with the subject’s participation in the study, had abnormal eyelid function, had only one eye, would require the use of any systemic antibiotic during the study period, was exhibiting a corneal ulcer, keratitis, or had a history of herpetic keratitis, had any ocular disease that would interfere with the evaluation of the study treatments, received previous intraocular silicone oil was pregnant or nursing were excluded.

Method of the study
The clinical ethics committee of the institution approved of the study. The 50 patients undergoing cataract extraction were divided randomly into two groups with 0.5% Moxifloxacin - 25 patients and 0.5% Levofloxacin -25 patients.

Three days before surgery the patient’s conjunctival smear was taken as a baseline. Then the assigned drug was given randomly to each patient at a dose of a drop four times a day for three days. After three days of administration at the time of surgery a second smear was taken to assess the bacterial load to find the efficacy of the drugs.

Conjunctival swab material was inoculated into 0.3 ml of sterile saline in a sterile vial. The swab was repeatedly twirled in the saline. In the laboratory, 0.1ml of the saline was inoculated onto a plate of 5% sheep blood agar while 0.05 ml each was inoculated onto a plate of cystine-tryptone-agar and a plate of MacConkey agar.

Following inoculation, the plates were incubated in a bacteriological incubator at 37°C and after overnight incubation and after 48 hours the plates were checked. If bacterial growth was obtained on the plates, the colony count was first estimated by counting the number of colonies in the streaked area of the plate and multiplying the same by 10. A smear of an individual colony was prepared on a microscope slide, and this was stained by the gram method, dried and viewed under the oil immersion objective or a light microscope. If positive, with the presence of beta haemolysis on blood agar and growth on MacConkey agar, the growth was considered to be *Staphylococcus aureus*. If coagulase test was negative, with no beta haemolysis on blood agar and no growth on MacConkey agar, the growth was considered to be a coagulase-negative *staphylococcus*.

Penetration (Aqueous)
The patients were instructed to use their antibiotic drops according to regimen A or B to which they were assigned.

Regimen A: 1 drop four times a day for three days (12 drops) – 23 patients and

Regimen B: 1 drop – 6 doses delivered every 10 min in the hour immediately preceding surgery (6 drops)-15 patients.

During surgery 0.2 ml of aqueous fluid was aspirated with the help of a tuberculin syringe. The anterior chamber fluid was immediately placed into a sterilized cryogenic tube and stored at -40°C in an Ultra Low Freezer (Remi®5, Remi Instruments, Mumbai) and kept frozen until analysis was performed. Each tube was marked with a patient identification number (which indicated the antibiotic that the subject was randomly assigned), the subject’s initials, date of surgery, and eye. Concentrations of topically applied fluoroquinolones were determined by use of reverse-phase high-pressure liquid chromatography assay technique with ultraviolet-visible detector at a wavelength of 275 nm.

**Moxifloxacin and Levofloxacin**

**Chromatographic Conditions**
Stationary Phase : Gemini 5u C18 (2) 100A 250 x 4.60 mm
Mobile Phase : Acetonitrile: Phosphate buffer (pH 5)
Mobile phase ratio : ≥20: 80 % v/v
Flow rate : ≥1.0 ml/min
Sample volume : ≥20µl

**Detection** : ≥275nm using UV Visible detector.

**Data station** : Class VP data station

**Calibration curve of Levofloxacin**

**Calibration curve of Moxifloxacin**

**Table 1: Mean VALUE representation of levofloxacin and Moxifloxacin**

<table>
<thead>
<tr>
<th>Dosing regimen</th>
<th>Levofloxacin (µg/ml)</th>
<th>Moxifloxacin (µg/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>0.18 ±0.05 (n = 8)</td>
<td>0.77 ±0.15 (n = 15)</td>
</tr>
<tr>
<td>B</td>
<td>1.34 ±0.33 (n = 9)</td>
<td>1.94 ±0.06 (n = 6)</td>
</tr>
</tbody>
</table>

**Fig. 1: Bar Graph**

**Statistical methods**
The collected data were subjected to statistical analysis and results analysis was done by using Anova test.
RESULTS

The average age of the 50 patients under study was 60.52 years. Male patients numbered 32 (64%) and female patients numbered 18 (36%). Among this the patients having associated disease of diabetes alone 22 (44%), hypertension alone 18 (36%) both hypertension and diabetes were 9 (18%), and patients with anemia 25 (50%). Microorganisms isolated were *Staphylococcus aureus* in 21 (42%) patients, *Staphylococcus epidermidis* in 18 (36%) patients.

DISCUSSION

Amongst 50 patients undergoing cataract extraction were divided randomly into two groups with 0.5% Moxifloxacin – 25 patients and 0.5% Levofloxacin – 25 patients. Three days before the surgery the patients’ conjunctival smear was taken to find the bacterial load as a baseline. Then the assigned drug was given to each patient at a dosage of 4 times a day for three days.

After 3 days of administration a second smear was taken and there was no growth in both the groups. So both the drugs were found to be effective on the surface as a prophylactic prior to phacoemulsification. In the microbiological aspect of this study, the two antibiotics Levofloxacin and Moxifloxacin were effective in eradicating the bacterial flora from the conjunctiva after 3 days of drug administration. Both the drugs registered no growth after drug treatment.

The new generation of fluoroquinolones addresses the problem of emerging bacterial resistance with a broader spectrum of activity. The most recent therapeutic agents include the fourth-generation fluoroquinolone moxifloxacin 0.5%. Unlike prior generation fluoroquinolones that predominantly inhibit topoisomerase IV or DNA gyrase and, therefore, only require 1 genetic mutation for bacteria to develop resistance, fourth-generation fluoroquinolones work on both bacterial DNA gyrase and topoisomerase IV. To become resistant to these agents, the bacteria must undergo 2 genetic mutations, resulting in a significantly decreased chance of an organism developing resistance.

The increased efficacy of fourth-generation fluoroquinolones against Gram-positive organisms makes these antibiotics important agents to evaluate for prophylaxis against post cataract surgery endophthalmitis.

In this study we have found that the mean concentration of Moxifloxacin in the aqueous humor was significantly greater than that of Levofloxacin in all the treatment groups (p < 0.0001).

In the regimen A, the mean ± SD for Moxifloxacin was found to be 0.77 ± 0.15 (n = 15) and that of Levofloxacin it was 0.18 ± 0.05 (n = 8). This represented a 4.28 fold difference in measured aqueous humor antibiotic concentration which was statistically significant (p < 0.001).

In the regimen B, the mean ± SD for Moxifloxacin was found to be 1.94 ± 0.06 (n = 6) and that of Levofloxacin it was 1.34 ± 0.33 (n = 9). This represented a 1.45 fold difference in the antibiotic concentration which was considered to be statistically significant (p < 0.001). Regimen B delivered more drug in the aqueous than Regimen A for both the drugs. In Moxifloxacin there was 2.52 fold difference (p < 0.001) and for Levofloxacin there was 7.44 fold difference (p < 0.001). The fourth generation fluoroquinolone eye drops have been developed to broaden the spectrum of antibiotic coverage, including resistant strain.

So we can come to an evidence based conclusion that cataract surgery can be done as an outpatient procedure without any complication to the patient by using regimen B and Moxifloxacin was found to have a better penetration than Levofloxacin in the aqueous humor.

REFERENCE

