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Safety And Efficacy Of Intracameral Moxifloxacin Prophylaxis For Endophthalmitis After Cataract Surgery- A Randomised Control Trial.

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ABSTRACT

Current practice methods are unclear as to the most safe and effective prophylactic pharmacotherapy and method of delivery to reduce postoperative endophthalmitis occurrence. To evaluate the safety and efficacy of intracameral moxifloxacin at the end of cataract surgery in preventing endophthalmitis. The case and control groups were age, gender, eye, and Best Corrected Visual Acuity(BCVA) matched and were evaluated without bias. There was no incidence of endophthalmitis in both groups. 95%(285) in group A and 93% (279) in group B had a BCVA better than 6/12. There was no difference in mean Intraocular Pressure (IOP). The mean endothelial cell density loss in Group A was 183.8 cells/mm^3 (7%) and in Group B was 199 cells/mm^3 (7.5%), which was not clinically significant. Fundus examination showed no significant change. There were no adverse events during the study. The results suggest that intracameral moxifloxacin is safe and efficient in preventing post-cataract surgery endophthalmitis.

Keywords: Cataract, Endophthalmitis, Glaucoma, Prophylaxis, Trabeculectomy

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INTRODUCTION

Cataract surgery is one of the leading ophthalmic surgical procedures performed all over the world. Post operative endophthalmitis is a serious and potentially vision-threatening complication following cataract surgery, with only 35% of patients achieving visual acuity better than ≥6/60 [1]. Strict preoperative, intraoperative, and postoperative protocols are being followed to prevent endophthalmitis. The injection of intracameral antibiotics for endophthalmitis prophylaxis has gained popularity in recent years. The use of topical antibiotics alone is less effective when compared to additional intracameral use, primarily due to limited anterior chamber penetration because of the intact corneal epithelium [2]. Among the antibiotics given intracamerally, cefuroxime, vancomycin, and moxifloxacin are the most commonly used [3]. Various studies have been done evaluating the efficacy and toxicity of these antibiotics. Intracameral antibiotics like cefuroxime and vancomycin are now not routinely used because of their side effects and the risk of contamination during dilution [4]. Intracameral moxifloxacin 0.5%, a fourth-generation fluoroquinolone, a broad-spectrum antibiotic, has been used worldwide in recent years for endophthalmitis prophylaxis. The purpose of this study was to determine the efficacy and safety parameters of intracameral moxifloxacin in reducing the incidence of endophthalmitis six weeks after cataract surgery.

MATERIALS AND METHODS

This prospective study was in the year June 2019 to May 2020 at Regional Institute Of Ophthalmology, Chennai, Tamil Nadu, India. Totally 600 patients who presented to our tertiary eye care centre and were diagnosed with cataracts and for whom surgery is indicated were registered, evaluated and randomized into two groups namely Group A and Group B by simple randomization (Random number table). The Institutional Research Ethical Committee approved the study, and the study was conducted according to the principles outlined in the Declaration of Helsinki. An informed consent was obtained from all patients. The inclusion criteria included patients with visually significant cataract, aged 30-70 years, with pre-operative IOP <21 mmHg. Patients with a history of allergy to fluoroquinolones, advanced glaucoma, previous corneal surgery, cataract surgery associated with other procedures, such as glaucoma filtering surgery, vitreoretinal surgery, and cornea surgery, and those with signs of ocular or periocular infections were excluded. A detailed history, uncorrected visual acuity, best corrected visual acuity, slit lamp biomicroscopy, IOP by Goldmann applanation tonometry, fundus examination, keratometry and specular microscopy for corneal endothelial cell density (CECD) were done for all the patients pre operatively. Preoperative patient details are summarized in Table 1. Preoperative pupil dilation was performed using topical 5% phenylephrine and 0.8% tropicamide. The anesthetic technique used was peribulbar anesthesia. Skin sterilization was performed using an aqueous solution of 10% povidone-iodine. After the sterile surgical field was established, 2 drops of 5% povidone-iodine were administered in the conjunctival sac with subsequent irrigation after 3 minutes [5]. The surgical technique was clear corneal phacoemulsification or m-SICS depending on the grade of cataract. In situations where the surgical wound was not self-sealing and in which there was consequent aqueous leak, the incision was sutured using Mononylon 10.0. 0.1 ml of 0.5% Moxifloxacin available as an ophthalmic solution was aspirated by aseptic technique and injected into the anterior chamber as the last step in the surgery. 0.5% moxifloxacin eye drops were instilled after the surgery was completed, and a bandage was applied. Postoperatively, all patients received 0.5% moxifloxacin and 1% prednisolone acetate eye drops and were gradually tapered over 6 weeks according to each individual's inflammatory response. Postoperatively, the patients were followed up for 6 weeks (1st, 7th, 30th, and 45th postoperative day). Slit lamp examination and Visual acuity documentation were done on all visits. IOP was measured on POD 7,14,30, and 45 by applanation tonometry. Fundus examination, BCVA by snellens chart, CECD by specular microscopy was recorded on the 45th postoperative day. The outcomes were the incidence of acute postoperative endophthalmitis, postoperative BCVA, mean change in CECD, and mean IOP before and after surgery. The collected data were analysed with IBM. SPSS Statistics software 23.0 Version. To find the significant difference between the bivariate samples in Independent groups the Unpaired sample t-test was used. To find the significance in categorical data Chi-Square test was used. Statistical significance was set at 0.05.

RESULTS

600 patients participated in the study. Age distribution showed that majority of the population were between 50-59 years(41.8%) with a mean age of 56+/-8 years. The mean age in Group A was 56 years, and the mean age in Group B was 57 years. 52.3% of the patients were female. 62.2% of patients underwent

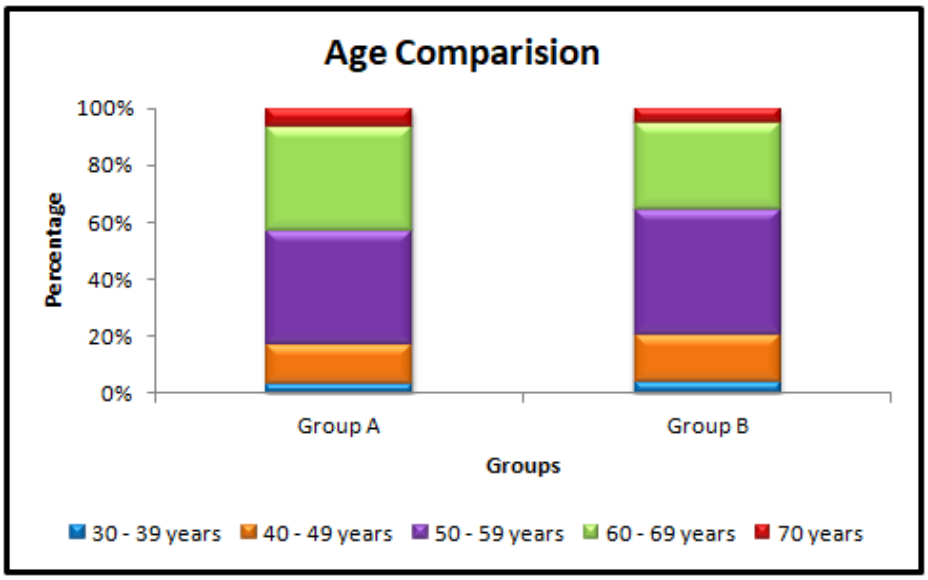
SICS and 37.8% underwent Phacoemulsification. Pre operative BCVA comparison between both groups by Pearson's chi-squared test shows no highly statistical significance between both groups. Thus, the case and control groups were age, gender, eye, and BCVA matched and can be evaluated without bias. There was no incidence of endophthalmitis in both groups. Preoperatively 2.7% and 3.7% of patients in group A and B had best corrected visual acuity of 6/6-6/12 respectively. On Post operative day 45, the best corrected visual acuity significantly improved and 95% in group A and 93% in group B had a best corrected visual acuity of 6/6-6/12. 4% in group A and 3% in group B had a best corrected visual acuity of 6/18-6/60. Only 1 % patients in both groups had a visual acuity <6/60. This was attributed to the posterior segment pathology in all patients. Fundus Examination of the other patients did not show any signs of endophthalmitis. The mean Preoperative IOP was 14.6 mmHg in group A and 13.4 mmHg in group B. The mean Postoperative IOP was 14.5 mmHg in group A and 13.6 mmHg in group B. There was a mild raise in IOP in the first postoperative visit which later returned to pre operative values by 6 weeks. IOP comparison between both groups by Unpaired t-test in all the time durations shows statistically significant difference at $p<0.05$. But the change in IOP from the preoperative value in both the groups is not clinically significant. CECD comparison between both groups shows no statistically significant difference between both the groups preoperatively and postoperatively. Post-operative change in CECD comparison between both groups shows a highly statistically significant difference between the groups. The mean endothelial cell density loss in Group A was 183.8 cells/mm^3 (7%) and in Group B was 199 cells/mm^3 (7.5%), which is not clinically significant. There were no adverse events during the study.

Table 1: Summary of the patient details

PARAMETERS	GROUP A	GROUP B
Total number of patients	300	300
Total number of eyes included	300	300
Mean age of patients	57+/- 5 years	56+/- 5 years
Number of males	144 (48%)	142(47.3%)
Number of females	156 (52%)	158(52.7%)
Mean Pre operative Intraocular Pressure	14.6 mmHg	13.4 mmHg
Mean CECD	2625 cells/mmsq	2630 cells/mmsq
Number of SICS	189(63%)	184(61.3%)
Number of emulsification	111(37%)	116(38.7%)

CECD- Corneal endothelial cell density, SICS- Small Incision Cataract Surgery

Graph 1: Comparison of Age Between Both Groups



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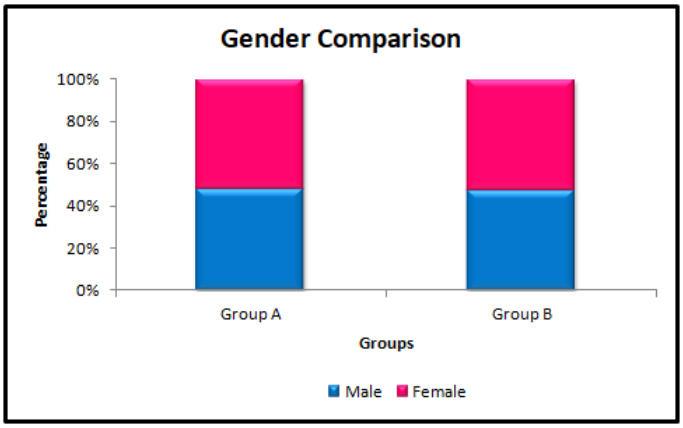
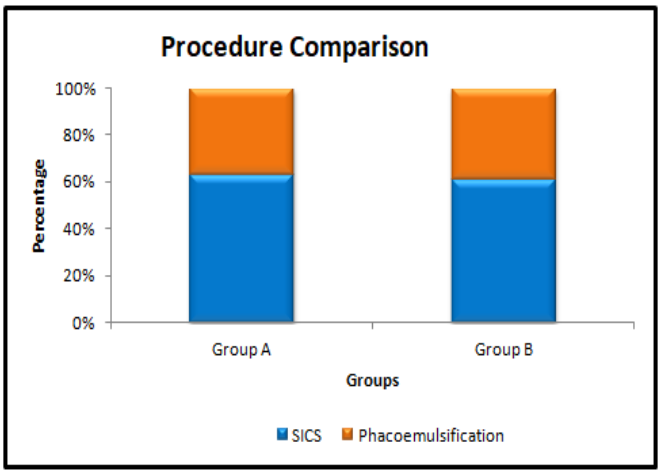
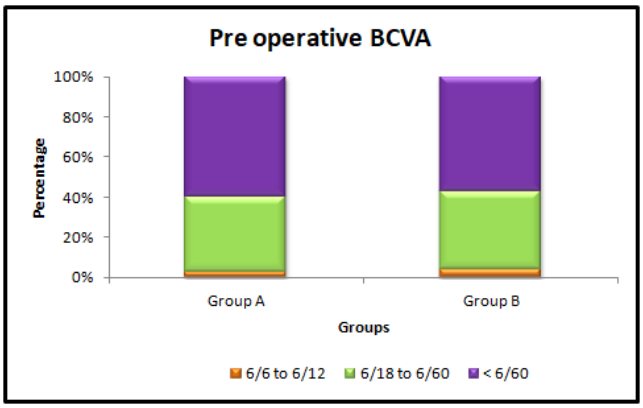
Graph 2: Comparison of Gender Between the Groups



Graph 3: Comparison of Surgical Procedure between both groups



Graph 4: Comparison of pre-operative BCVA between both groups



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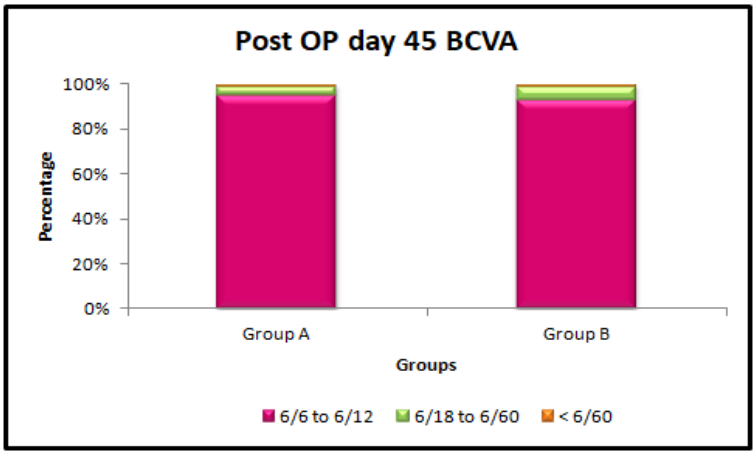
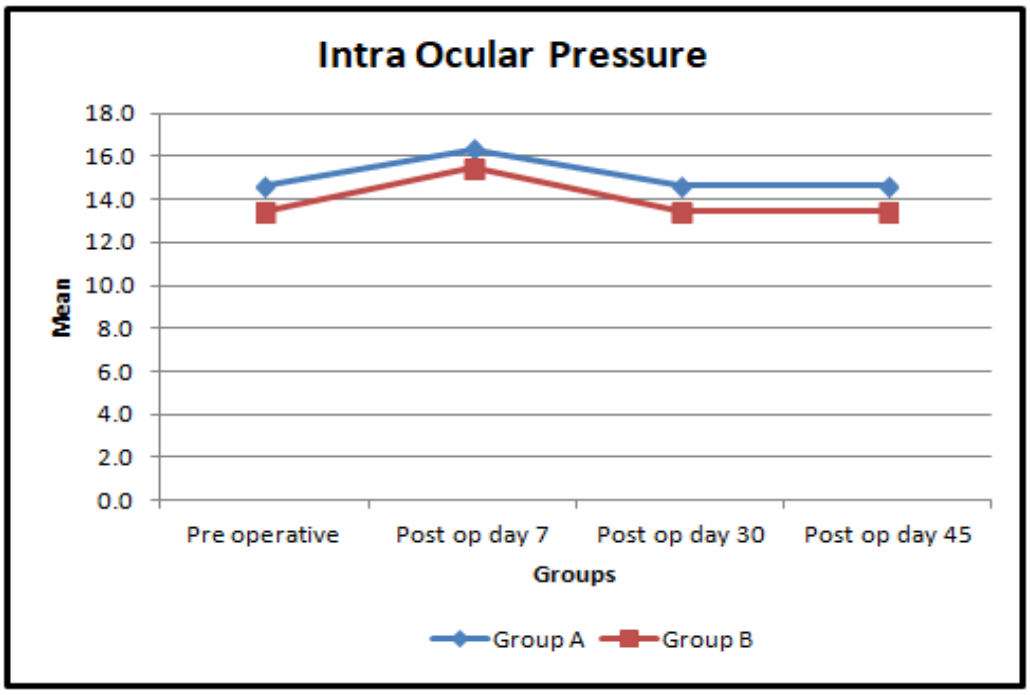
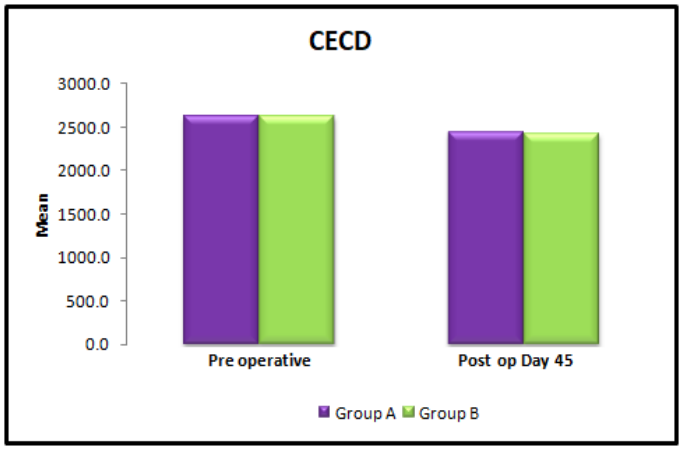
Graph 5: Comparison of Post Operative Day 45 BCVA between both groups



Graph 6: Comparison of IOP between both groups by Unpaired t-test



Graph 7: Comparison of CECD between both groups by Unpaired t-test



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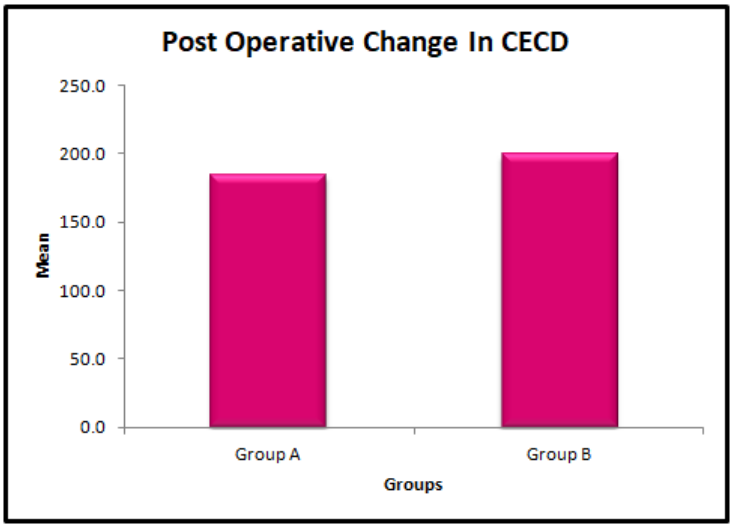
Graph 8: Comparison of post-operative change in endothelial cell density between both groups by Unpaired t-test



DISCUSSION

Endophthalmitis is a rare but potentially serious complication following cataract surgery. Its incidence varies substantially in the literature. Antibiotic penetration into the anterior chamber by using topical drops is relatively low when compared with intracameral administration due to the barrier posed by an intact corneal epithelium and dilution and removal by tears. Intracameral injection delivers very high concentrations 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. The peak aqueous humor levels of moxifloxacin in the anterior chamber after intracameral injection of 0.5mg/0/1ml was approximately more than 3000-fold above the tested MIC_{50} (minimum inhibitory concentration) of moxifloxacin against some of the common ocular pathogens such as Staphylococcus aureus (0.03 µg/mL), Staphylococcus epidermidis (0.06 µg/mL), Propionibacterium acnes (0.25 µg/mL), and Bacillus cereus (0.13 µg/mL) [7]. As a self-preserved solution, Moxifloxacin ophthalmic solution requires no special preparation for intracameral injection, reducing the risk for toxic anterior segment syndrome (TASS). Many studies have suggested that intracameral moxifloxacin would be a safe option for the prevention of endophthalmitis, but most of the data is from retrospective studies [13]. In a retrospective analysis of 600,000 surgeries at ten regional Aravind Eye Hospitals, Haripriya et al [8] observed that intracameral Moxifloxacin reduced the overall rate of endophthalmitis by 3.5-fold (three-fold for manual small-incision cataract surgery and nearly six-fold for phacoemulsification) [12]. Lira et al. compared the last 150 surgeries before and the first 150 surgeries after the introduction of intracameral moxifloxacin for the prevention of post-cataract endophthalmitis. They found no significant mean-change differences between the groups in terms of pachymetry, CDVA, or IOP from baseline to 2 years after surgery which was also proved to be true in our study [13, 14]. Lucena, Nelise de Paiva, et al studied 1016 cataract surgeries and suggested moxifloxacin is a safe option for intracameral use after cataract surgery [15]. Espiritu et al [16] and Lane et al [17] injected an intracameral dose of 0.5 mg/0.1 mL and 0.25 mg/0.05 mL of the commercially available undiluted moxifloxacin 0.5% ophthalmic solutions, respectively, and showed no increased safety risk associated with prepared doses of intracameral injection of moxifloxacin, which appears to be safe in the prophylaxis of endophthalmitis after cataract surgery [9, 10]. The ESCRS study from 2007 is the only masked randomised control trial with intracameral antibiotics that confirmed that the intracameral use of cefuroxime reduced the incidence of endophthalmitis approximately fivefold [11]. However, no controlled, randomized, and masked clinical trials have been performed with this objective using moxifloxacin. In the present study, we used a solution of moxifloxacin, injecting a dose of 0.5 mg/0.1 mL after cataract surgery. The results of our study give supportive evidence for the safety profile of intracameral moxifloxacin for the prophylaxis of endophthalmitis after cataract surgery.

CONCLUSION

Moxifloxacin is an easily available, self-preserved ophthalmic solution that can be used readily as an intracameral injection with no adverse effects. The main limitation of this study is that it has a relatively small sample size. Incidences of endophthalmitis vary from 0.04% to 0.5%; therefore, the absence of endophthalmitis could have occurred by chance. However, the other safety data results (CDVA, CECD, and IOP) are strong and encourage the routine use of intracameral moxifloxacin. The study shows intracameral injection of 0.1 ml of 0.5% moxifloxacin at the end of cataract surgery is safe and efficient in preventing endophthalmitis after cataract surgery. However, a randomized masked clinical trial with a larger sample size is recommended to prove this hypothesis.

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