

A Retrospective Comparative Clinical Trial for the safety and efficacy of Intracameral moxifloxacin amongst the patients undergoing cataract surgery (MSICS or PHACO) at an Eye care centre in Himachal Pradesh.

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Citation this Article: Shailender Minhas, Gaurav Sharma, Dr. Anita Thakur, “A Retrospective Comparative Clinical Trial for the safety and efficacy of Intracameral moxifloxacin amongst the patients undergoing cataract surgery (MSICS or PHACO) at an Eye care centre in Himachal Pradesh.”, IJMSIR- May - 2020, Vol – 5, Issue -3, P. No. 259 – 263.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: Intracameral antibiotic use, worldwide including India has emerged as another effective method of endophthalmitis prevention. Despite using preoperative antibiotics and PVI prophylaxis and aseptic guidelines, the rate of intraocular bacterial contamination is very high.

Aim: To compare safety and efficacy of Intracameral moxifloxacin amongst the patients undergoing cataract surgery (MSICS or Phaco) at an Eye care centre in Himachal Pradesh.

Patients and Methods: Eight-hundred patients (800 eyes) were randomly divided into 2 groups; group A receiving intracameral moxifloxacin while group B did not receive the antibiotic. Patients with adnexal or pre-existing eye infection or with uncontrolled diabetes or hypertension were excluded from the study.

Results: 75% patients in each group underwent MSICS and 25% patients each underwent phacoemulsification. None of the patients who received intracameral moxifloxacin reported endophthalmitis while endophthalmitis was observed in 3 patients who did not

receive intracameral moxifloxacin. The incidence of endophthalmitis was statistically non-significant ($P>0.05$) between both the groups.

Conclusion: Although, the incidence of endophthalmitis is statistically insignificant, number of patients with endophthalmitis is high and advocates the use of intraocular preservative free sterile antibiotic.

Keywords: Intracameral, Moxifloxacin, Endophthalmitis

Introduction

Cataract is the cause for 62% of blindness in our country and cataract surgery is one of the most widely performed surgeries in the world. The incidence of endophthalmitis after cataract surgery is reported to be 0.04-0.15%.¹Endophthalmitis is a devastating sight threatening condition that involves the internal structures of the eye. With increasing cases of cataract and cataract surgery volume, effective endophthalmitis prophylaxis is the need of the hour.

Prevention of postoperative endophthalmitis can be achieved by using preoperative topical antibiotics, perioperative intracameral antibiotics and postoperative

antibiotics. Preoperative antisepsis of the periocular area with topical povidone-iodine (5-10%) is considered the standard of care for endophthalmitis prevention.²

Topical antibiotic prophylaxis is another common and effective method to decrease the conjunctival bacterial load. Various topical antibiotics like aminoglycosides, fluoroquinolones, cephalosporins and chloramphenicol are widely used in the preoperative period for 3-4 days and in the postoperative period for 4-6 weeks until the incision completely heals.

Intracameral antibiotic use, worldwide including India has emerged as another effective method of endophthalmitis prevention. The commonly used antibiotics for intraocular use are moxifloxacin, vancomycin and cephalosporins. Despite using preoperative antibiotics and PVI prophylaxis and aseptic guidelines, the rate of intraocular bacterial contamination is as high as 31%.^{3,4} Hence, the present study was aimed to retrospectively evaluate safety and efficacy of Intracameral moxifloxacin (preloaded, preservative free and sterile) amongst the patients undergoing cataract surgery at an Eye care centre in Himachal Pradesh.

Patients and Methods

Eight hundred patients (800 eyes) who underwent cataract surgery during the period of one year were included in the study. Patients with adnexal or pre-existing eye infection or with uncontrolled diabetes or hypertension were excluded from the study. The patients were randomly divided into 2 groups. Patients in group A (400 eyes) received intracameral Moxifloxacin (preloaded, preservative free and sterile) at the end of the cataract surgery (MSICS and Phaco) and the patients in group B did not receive intracameral moxifloxacin (preloaded, preservative free and sterile) at the end of the cataract surgery (MSICS or Phaco).

All surgeries were performed under standard aseptic techniques and procedures as followed worldwide.

The patients were examined over slit lamp on the 1st and 5th post-operative day and then at 1 month, to look for any drug precipitates, infection and reaction.

Data were presented as frequency and percentages. Chi-square test with or without Yate's correction was used to compare categorical variables between the groups. P value <0.05 was considered statistically significant. Statistical analysis was performed using SPSS v21.0.

Results

In our study, there was equal distribution of patients who underwent manual small incision cataract surgery (MSICS) or phacoemulsification (P=1.000). Out of 400 eyes in group A, 75% patients MSICS while remaining 25% patients underwent phacoemulsification. Similar trend was observed in group B (Figure 1).

Our study observed that on day-1 post-operatively, endophthalmitis was observed in none of the patients who received intracameral moxifloxacin while in group B, endophthalmitis was observed in 3 patients. We observed that the incidence of endophthalmitis was not statistically significantly between the groups (P=0.247) (Table 1).

We further analyzed and found that the incidence of endophthalmitis was also comparable in the patients who underwent MSCIS in group A and group B (P=0.317). Similarly, incidence of endophthalmitis was not statistically significant in the patients who underwent phacoemulsification in group A and group B (P=0.478).

Table 1: Comparison of incidence of Endophthalmitis

	Endophthalmitis	P Value
Overall		
Group A (n=400)	0	0.247
Group B (n=400)	3	
MSCIS		0.317
Group A (n=300)	0	
Group B (n=300)	1	
Phacoemulsification		0.478
Group A (n=100)	0	
Group B (n=100)	2	

MSICS; manual small incision cataract surgery; Data expressed as frequency

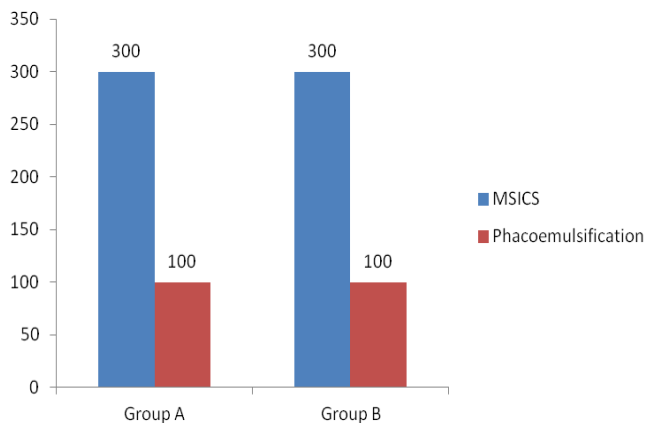


Figure 1: Distribution of patients underwent cataract surgery; Group A: received intracameral moxifloxacin; Group B: did not receive intracameral moxifloxacin; MSICS; manual small incision cataract surgery; Data expressed as frequency

Discussion

Moxifloxacin, a fourth generation Fluoroquinolone was approved for systemic use in the United States in 1999 and for topical ophthalmic use in 2003. It has good corneal penetration and reduced susceptibility to the emergence of bacterial resistance, which is dose-dependent as opposed to absolute.⁵ Intracameral moxifloxacin achieves bactericidal levels at least 10 times the minimum inhibitory concentration of the most

resistant bacteria for a limited time period but, because of its dose-dependent activity even at low injection concentrations, it remains bactericidal for a much longer duration than cefuroxime.⁶ In India, intracameral moxifloxacin is available since 2013.

In our eye care facility single use, prefilled, preservative free and sterile 0.2 ml of intracameral moxifloxacin (0.5%) was used at the end of the cataract surgery, (MSICS or Phaco) in one group of 400 eyes of 400 patients and in another group of 400 eyes of 400 patients undergoing cataract surgery intracameral moxifloxacin was not used. Injection of 0.1 ml containing 500ug of these ready to use commercial preparations achieves anterior chamber concentrations exceeding 1 mg/ml. The rationale behind using intracameral moxifloxacin was its easy availability, cost effectiveness, prefilled solution, single use and sterile preparation in a glass syringe. Another reason for using intraocular antibiotic was that sclerocorneal and corneal incisions and side ports may allow the fluid during surgery to enter the anterior chamber, even after hydration.

Moxifloxacin has a broad spectrum of action against Gram positive, gram negative, mycobacterial and atypical mycobacterial organisms. It acts by inhibiting DNA Gyrase enzyme. Fluoroquinolones produce both concentration dependent (peak MIC) and a combination of concentration and time dependent killing (AUC:MIC).

Studies from Aravind Eye Care System showed a 4 fold decrease in the cases of postoperative endophthalmitis that underwent MSICS. The overall endophthalmitis reduction was seen from 0.07% to 0.02% and that was separately true for both phacoemulsification(7-fold) and MSICS (3.5-fold).⁷

In our study, the group that was given intracameral moxifloxacin, no endophthalmitis was seen whereas in the group in which intracameral moxifloxacin was not given, 3 cases of postoperative endophthalmitis were noted (0.75%). The number is high and our observation advocates the use of intraocular preservative free sterile antibiotic. Prefilled syringe helps to reduce the chances of risk of dosing errors along with risk of contamination. Mixing antibiotics in the operating room or reconstituting them prior to surgery also increases the risk of contamination. Some authors have declined the use of routine intracameral antibiotics citing the reason of increased bacterial drug resistance. But a study from Naseriet al⁸ showed that highly concentrated dose of antibiotic injected into a physiologically isolated space is extremely unlikely to promote bacterial resistance.

In our study, we observed that injecting doses of 0.5 ml or more lead to endothelial deposition of the drug (in the pupillary area) and it was noted on the first postop day. This deposit disappeared after 2-3 days. Using intracameral antibiotic is highly recommended in patients having posterior capsular rent, in prolonged surgery time (>40 minutes), excessive iris manipulation, corneal surface disorders, elderly individuals (>80 years) and in individuals having diabetes and HIV.⁹

Conclusion

In India <40% surgeons are using intracameral antibiotic.⁹ The practice pattern of the ophthalmologists in India still does not show any inclination for the use of intracameral antibiotics. Worldwide surgeons are using intraocular, commercially available formulations approved by their countries. Our study supports the safety and efficacy of the intracameral use of moxifloxacin in the prevention of postoperative

endophthalmitis along with other routine measures followed by surgeons world over.

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