

Cohort Study of Intracameral Moxifloxacin in Postoperative Endophthalmitis Prophylaxis

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ABSTRACT: We conducted a cohort study to evaluate post-cataract surgery endophthalmitis rates in relation to prophylactic intracameral moxifloxacin administration. A total of 2332 patients (2674 eyes) who underwent phacoemulsification by a single surgeon from January 2007 through December 2012 were included in the study. A total of 1056 eyes did not receive intracameral prophylactic moxifloxacin and the antibiotic was injected in 1618 eyes. The incidence of presumed postoperative endophthalmitis in the 2 groups was calculated. The rate of presumed infectious endophthalmitis after cataract surgery between January 2007 and June 2009 (without intracameral moxifloxacin) was 0.094%. The rate in the second period, from July 2009 to December 2012 (with prophylactic intracameral moxifloxacin), was 0%. In our patients, a decline in the incidence of presumed infectious postoperative endophthalmitis appeared to be associated with the application of intracameral moxifloxacin.

KEYWORDS: cataract surgery, endophthalmitis, intracameral antibiotics

CITATION: Galvis et al. Cohort Study of Intracameral Moxifloxacin in Postoperative Endophthalmitis Prophylaxis. *Ophthalmology and Eye Diseases* 2014;6:1–4
doi: 10.4137/OED.S13102.

RECEIVED: August 28, 2013. **RESUBMITTED:** November 21, 2013. **ACCEPTED FOR PUBLICATION:** December 2, 2013.

ACADEMIC EDITOR: Joshua Cameron, Editor in Chief

TYPE: Original Research

FUNDING: Author(s) disclose no funding sources.

COMPETING INTERESTS: Author(s) disclose no potential conflicts of interest.

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Introduction

Endophthalmitis is a rare but potentially serious complication of cataract surgery. Within the literature, its incidence varies substantially.^{1–29} The incidence has been reported to be as low as 0%,^{3,11,19} and as high as 0.8% and 1.24%.^{15,26} Even with the best treatment, endophthalmitis can result in severe visual loss. Published studies have reported final visual acuity of 20/400 or worse in up to 47% of patients and that up to 25% of eyes required enucleation/visceration.^{16,22,30–32}

The objective of the present study was to describe the incidence of presumed infectious postoperative endophthalmitis after phacoemulsification and intraocular lens implant in a Colombian group of patients of a single surgeon (VG) for a period of 6 years (2007–2012). Furthermore, this study sought to compare incidences before and after intracameral moxifloxacin use (0.05 mL Vigamox®) as a prophylactic antibiotic applied at the end of the procedure.

Patients and Methods

The study included patients at Fundación Oftalmológica de Santander (FOSCAL), Floridablanca, Colombia. A retrospective review was completed of the medical records of all patients who underwent cataract surgery by phacoemulsification at FOSCAL by one surgeon (VG) between January 2007 and December 2012. All cases of presumed infectious postoperative endophthalmitis in the first two weeks after surgery, according to the diagnosis made by the treating physician, were identified. The diagnosis was based on clinical findings of pain, decreased vision, and intraocular inflammatory signs. The Institutional Ethics Committee of Fundación Oftalmológica de Santander (FOSCAL) approval was obtained. This retrospective study adhered to the tenets of the Declaration of Helsinki.

Prophylactic measures

As prophylaxis for postoperative infection, each patient received the following: 1) topical 4th generation fluoroquinolone



(gatifloxacin or moxifloxacin) four times per day, beginning the day before surgery and until 8–10 days after surgery; 2) periocular and eyelid surgical scrub using povidone—iodine 10%; 3) application of povidone—iodine 5% in the inferior cul-de-sac between 5 and 15 min before surgery. Additionally, each patient from July 2009 onward received an intracameral injection of 0.05 mL of undiluted moxifloxacin 0.5% (Vigamox[®], Alcon laboratories, Fort Worth, TX, USA). Patients were divided into two groups: group 1 (without IC moxifloxacin), surgery from January 2007 to June 2009 and group 2 (with IC moxifloxacin), surgery from July 2009 to December 2012.

Surgical Technique

Surgical technique was consistent among the entire group: topical anesthesia, clear cornea incision, and prechopping-assisted divide and conquer phacoemulsification without sutures.

Data Analysis

Accumulated incidences were calculated for each of the periods (January 2007 to June 2009 without IC moxifloxacin, and from July 2009 to December 2012 with IC moxifloxacin). *P*-values (Fisher's exact test, Stata v11.0) were estimated; *P* < 0.05 was considered significant.

Results

This cohort study included 2674 eyes of 2332 patients (59.2% women) who underwent phacoemulsification and intraocular lens implantation (50.3% in the right eye). The mean age was 67.2 ± 11.3 years. The overall rate of presumed postoperative endophthalmitis after phacoemulsification in the entire group of eyes studied was 0.037%. Group 1 (without IC moxifloxacin) included 982 patients (1,056 eyes). Group 2 (with IC moxifloxacin) included 1,350 patients (1,618 eyes). Endophthalmitis incidence in group 1 was 0.094% (1 eye of 1,056). In group 2, there were no cases of endophthalmitis (0% incidence). *P* = 0.395 (Fisher's exact test, Stata v11.0).

The patient with endophthalmitis in group 1 was a 49-year-old male who underwent phacoemulsification and intraocular lens implantation in his left eye. There were no intraoperative complications. He presented the next day after surgery referring very poor vision and severe intraocular inflammation involving cells and membranes in anterior chamber. A sample from anterior chamber showed gram-positive cocci, and intravitreal vancomycin and ceftazidime were injected. A coagulase-negative *Staphylococcus* was isolated from the aqueous humor samples. On the fourth postoperative day, inflammatory signs worsened, including vitreous haze, and a posterior vitrectomy and new application of intravitreal antibiotics was performed. The postoperative course was satisfactory and final visual acuity with correction, four months later, was 20/30.

Discussion

In 2007, a large multicentric clinical trial conducted by the European Society of Cataract and Refractive Surgeons showed an incidence of postoperative endophthalmitis in a group that received intracameral cefuroxime to be significantly lower than in control groups.¹⁰ Recently, large studies have been published showing low incidence rates in eyes receiving intracameral antibiotics. Arshinoff et al.¹⁹ in 2011 reported an incidence of 0.01% in a group of 45,873 cases using intracameral cefuroxime and 0% in a group of 19,722 eyes with intracameral vancomycin. Additionally, in 2011, a Chinese study by Lin et al.²¹ that included 94,650 eyes using intracameral vancomycin reported an incidence of 0.01%. In 2013, Friling et al.²⁹ reported the largest prospective study on acute endophthalmitis following cataract surgery based on the National Cataract Register in Sweden. They found that in 455,054 eyes receiving intracameral cefuroxime, the rate of endophthalmitis was approximately 0.03%, while the rate was 0.39% in 2,804 eyes that did not receive intracameral antibiotics.²⁹

The commercial packaging of these antibiotics (cefuroxime and vancomycin) is in vials for intravenous infusion, which requires the antibiotic to be diluted in balance saline solution prior to being injected into the anterior chamber. This procedure carries risks of dilution errors, with possible toxic effects on intraocular tissues.^{33–37} In a report of six cases in France, which received 40–50 mg of cefuroxime rather than the recommended 1.0 mg, all eyes presented intraocular inflammation, including extensive macular edema. However, the eyes responded to a topical steroid, reaching a final best corrected visual acuity of 0.2–0.05 logMAR (Snellen notation between 20/32 and 20/22).³⁷

A study in 2005 indicated that moxifloxacin, a fourth-generation fluoroquinolone, was safe and effective for preventing experimental endophthalmitis in rabbits.³⁸ An experimental study showed that the toxic effects of moxifloxacin on corneal endothelial cells (500 µg/mL during 30 days) were not significant and that at a concentration of 150 µg/mL for 24 h, trabecular meshwork and retinal pigment epithelium cells were not affected.³⁹

Moxifloxacin has advantages over cefuroxime; while cefuroxime eliminates bacteria in a time-dependent manner, moxifloxacin exhibits biphasic behavior, including an initial concentration-dependent elimination, which may lead to an eradication of microorganisms if a very high concentration of the substance is attained, even for a short period of time.^{40–43}

Recently, Matsuura et al.⁴⁴ assessed intraocular concentrations of moxifloxacin following simple injection and flushing and measured drug kinetics in humans and rabbits. In humans, they obtained a sample of aqueous humor 2 min after administration and found that following the injection of 0.05 mg/0.1 mL of moxifloxacin underwent a 3.3-fold dilution and following flushing with 33.33 micrograms/mL underwent a 1.13-fold dilution. The half-life of intracameral



moxifloxacin in rabbit eyes was found to be longer than 1 h, reaching a concentration of 38 µg/mL 2 h after flushing in the anterior chamber, which is beyond the minimum inhibitory concentration to inhibit the growth of 90% of bacteria for the most resistant microorganisms. Additionally, in many countries preservative-free eye drops containing moxifloxacin 0.5% are available which can be used intraocularly without dilution (Vigamox®). In 2007, Espiritu et al.⁴³ reported the application of intracameral 0.5% moxifloxacin (Vigamox®) without complications. The same year, Arshinoff⁴⁵ presented a poster indicating that intracameral moxifloxacin did not show secondary effects in more than 1,000 eyes. Subsequently, several groups reported that intracameral moxifloxacin is safe in the anterior and posterior segments of the eye.^{42,46–47} There have been few studies regarding the incidence of postoperative endophthalmitis when applying intracameral moxifloxacin. A large multicenter cohort study published in 2011 by Arshinoff et al.¹⁹ reported one case out of 35,194 operated eyes, a very low rate of this complication (0.003%). Moreover, in 2012 Shorstein et al.^{28,48} reported one case out of 1,890 operated eyes with intracameral moxifloxacin (0.053%). Friling et al.²⁹ in 2013 reported that in 6,897 patients in which intracameral moxifloxacin was used, the rate of acute postoperative endophthalmitis was 0.029%.

Endophthalmitis prophylaxis remains a controversial issue.^{49–55} In a recent systematic review on perioperative antibiotics for the prevention of acute endophthalmitis after cataract surgery in adults, Gower et al.⁵⁵ identified only two randomized controlled trials with sufficient power to detect valid differences between treatments and that showed statistically significant differences with intervention. One of these, performed by Christy et al.⁵⁶ in 1979 in Pakistan in patients undergoing intracapsular cataract extraction, compared periocular penicillin versus topical antibiotics and found a risk ratio of 0.33 (95% confidence interval 0.12–0.92). The second randomized controlled trial was a study conducted in Europe by ESCRS, which was described above.¹⁰ In 2007, this prospective randomized partially-masked trial that recruited 16,603 patients showed that intracameral cefuroxime at the end of the procedure was associated with a 4.92-fold decrease in the risk of postoperative endophthalmitis with an incidence of 0.07% versus 0.34% in the control group [risk ratio 0.21 (95% confidence interval 0.06–0.74)].^{10,55} With regard to preoperative antisepsis, in 1991 a nonrandomized trial including 8,083 eyes demonstrated that preoperative application of povidone-iodine 5% to the ocular surface was more effective than silver protein solution in reducing the incidence of culture-positive endophthalmitis (0.06% versus 0.24%; $P < 0.03$).⁵⁷ However, although there is virtually a universal consensus regarding the preoperative application of povidone-iodine 5% to the ocular surface, there is no unified criterion for intracameral use of prophylactic antibiotics in cataract surgery.^{49–54}

The endophthalmitis incidence in Group 1 in the present study (without intracameral moxifloxacin) was 0.09%, an

intermediate point compared with other published studies. In the group treated with intracameral moxifloxacin, the incidence was zero. However, difference was not statistically significant ($P = 0.395$), possibly due to the small number of events (only one endophthalmitis case) in the group of eyes without intracameral moxifloxacin. Thus, a weakness of our study was that although the sample included 2674 eyes, it was not large enough to demonstrate that the use of intracameral moxifloxacin diminished presumed endophthalmitis incidence rate with a statistically significant difference. To achieve statistically a significant difference, approximately 21,000 eyes treated with intracameral moxifloxacin should be examined, but this would delay the publication of results that may be very useful for the clinicians. In conclusion, in our institution, a reduction in the rate of presumed endophthalmitis cases appeared to be related to the introduction of an intracameral injection of moxifloxacin (0.5%/0.05 mL) at the end of cataract surgery in addition to preoperative antisepsis with povidone iodine 5% and pre- and postoperative topical fluoroquinolones, measures which were previously implemented. We will perform additional studies in the future to include a larger sample size to confirm this trend; we will also analyze the presence or absence of intraoperative complications to evaluate their potential relationship.

Author Contributions

Conceived and designed the experiments: VG, AT. Analyzed the data: AT, MAS, PAC. Wrote the first draft of the manuscript: AT, MAS. Contributed to the writing of the manuscript: VG, PAC. Agree with manuscript results and conclusions: VG, AT, MAS, PAC. Jointly developed the structure and arguments for the paper: VG, AT, MAS, PAC. Made critical revisions and approved final version: VG, PAC. All authors reviewed and approved of the final manuscript.

DISCLOSURES AND ETHICS

As a requirement of publication the authors have provided signed confirmation of their compliance with ethical and legal obligations including but not limited to compliance with ICMJE authorship and competing interests guidelines, that the article is neither under consideration for publication nor published elsewhere, of their compliance with legal and ethical guidelines concerning human and animal research participants (if applicable), and that permission has been obtained for reproduction of any copyrighted material. This article was subject to blind, independent, expert peer review. The reviewers reported no competing interests.

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