Decreased postoperative endophthalmitis rate after institution of intracameral antibiotics in a Northern California eye department

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PURPOSE: To evaluate post-cataract-surgery endophthalmitis rates in relation to changing practice patterns in antibiotic administration.

SETTING: Kaiser Permanente, Diablo Service Area, California.

DESIGN: Ecological time-trend study.

METHODS: During 2007 through 2011, 3 time periods were identified based on increasing adoption of intracameral injections after phacoemulsification cataract surgery. In 2007, patients primarily received postoperative antibiotic drops without intracameral injection. During 2008 and 2009, in addition to the surgeons' usual postoperative topical drop regimen, patients received intracameral cefuroxime unless contraindicated by allergy or posterior capsule rupture (PCR). During 2010 and 2011, all patients received an intracameral injection of cefuroxime, moxifloxacin, or vancomycin while topical antibiotics were used according to surgeon preference. The rates of postoperative endophthalmitis during these 3 periods were calculated. Also evaluated separately were consecutive patients without PCR from a subgroup of 3 surgeons who used intracameral injection alone without perioperative topical antibiotics.

RESULTS: Nineteen cases of endophthalmitis occurred in 16 264 cataract surgeries. The respective rates per 1000 during the 3 time periods (2007, 2008 and 2009, 2010 and 2011) were as follows: 3.13 (95% confidence interval [CI], 1.43-5.93); 1.43 (95% CI, 0.66-2.72); 0.14 (95% CI, 0-0.78). One case of endophthalmitis was observed in 2038 patients without PCR who received intracameral injection only without topical antibiotics (rate per 1000: 0.49; 95% CI, 0.01-2.73).

CONCLUSIONS: The adoption of intracameral antibiotic injection coincided with a decline in the rate of postoperative endophthalmitis, and a low infection rate was observed with intracameral injection alone.

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Although endophthalmitis after cataract surgery is rare in the United States and Europe, these infections can be visually devastating. Recent reports of the rate of postoperative endophthalmitis after cataract surgery have ranged from 0.40 to 2.65 per 1000.[1–5] Antibiotic prophylaxis to prevent endophthalmitis after cataract surgery is well accepted and recommended; however, in the U.S. there is no consensus on the most preferred agents or routes of administration.[6] The European Society of Cataract & Refractive Surgeons (ESCRS) study of intracameral cefuroxime was the first randomized clinical trial showing the efficacy of antibiotic prophylaxis to prevent infection.[7] Despite this evidence, surveys of ophthalmologists practicing in the U.S. suggest that few have adopted intracameral antibiotic injection as a method of infection prophylaxis.[8,A]

In 2007, the rate of clinical endophthalmitis in our department (Kaiser Permanente Diablo Service Area) was similar to that in the control group in the ESCRS study. With the success of that study in mind, our department adopted intracameral injection of cefuroxime in uncomplicated, nonpenicillin-allergic patients in late 2007. Here, we report our evolving experience with intracameral injection alone and in combination with postoperative topical antibiotic agents from 2007 through 2011.

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PATIENTS AND METHODS

Study Design and Setting

This ecological time-trend study, which was approved by the Kaiser Permanente Institutional Review Board, was based on a consecutive case series of patients who had cataract surgery during 2007 through 2011 in the Diablo Service Area Department of Ophthalmology at Kaiser Permanente. The department is 1 of 31 cataract centers in the Kaiser Permanente Northern California health plan, which provides care to more than 3.2 million members. The department consists of 15 staff surgeons performing approximately 3000 cataract surgeries yearly. The study included patients of 14 of the 15 surgeons; 1 surgeon (670 surgeries) was excluded because he was not available to provide information on his panel.

During the study period, all surgeons performed phacoemulsification using a clear corneal approach. Other than outlined in this article, there were no additional significant department-wide practice changes during the study period of which we were aware. Povidone–iodine 5% was administered for at least 3 minutes before eyelid preparation to all patients without a history of allergy to topical iodine.

Before September 2007, cataract patients in the department received topical postoperative antibiotic drops according to the preferred practice of the surgeon. No surgeon used intracameral injection.

Beginning in September 2007 and continuing through December 2009, the department adopted and began the practice of injecting intracameral cefuroxime 1 mg/0.1 mL at the conclusion of surgery to most patients. Intracameral injection was not performed in patients who were allergic to a penicillin or cephalosporin analogue or if there was posterior capsule rupture (PCR) because of concern about potential retinal toxicity. Most surgeons added intracameral injection to their usual postoperative topical antibiotic regimen, although 3 replaced their usual topical regimen with intracameral injection in most patients. Licensed pharmacists compounded all intracameral antibiotic agents on the morning of surgery.

In January 2010 through the end of this study in December 2011, the department expanded the policy of intracameral injection to include every patient, including those with allergy or PCR. Cefuroxime continued to be the first-line drug; moxifloxacin 0.1%/0.1 mL was injected into patients allergic to a penicillin or cephalosporin analogue; and vancomycin 1 mg/0.1 mL was injected into patients allergic to all the above antibiotic classes. This algorithm was implemented in cases with or without PCR, and topical antibiotics were used according to surgeon preference. For reinforcement and monitoring, the policy required operating room staff to report to the Risk Department any event of failure to inject 1 of these agents during a cataract procedure.

Three of 14 surgeons injected an intracameral antibiotic without prescribing additional perioperative antibiotic drops. Cefuroxime was injected in consecutive patients not allergic to penicillin with intact posterior capsules between September 2007 and December 2009. Beginning in 2010, these 3 surgeons followed the department's algorithm of intracameral injection in every patient. However, patients with PCR or corneal relaxing incisions performed at the time of surgery were prescribed postoperative topical antibiotic drops in addition to the intracameral injection.

Study Population

All Kaiser Permanente members who had phacoemulsification cataract surgery in the Diablo Service Area by the 14 surgeons under study during 2007 through 2011 were identified by searching Kaiser Permanente electronic medical records for procedure codes indicating cataract surgery (Current Procedural Terminology codes 66850, 66940, 66982, 66983, 66984).

Data Collection

Prophylactic Practices Information on perioperative antibiotic dispensing was obtained from the computerized medical records and the pharmacy information management system. In addition, practice patterns were confirmed with the operating surgeons.

Identification of Suspect Endophthalmitis Cases For all eligible cataract surgery cases, a search of the electronic medical records was performed for endophthalmitis diagnosis codes (outpatient or inpatient International Codes of Diseases-9 codes 360.00, 360.01, 360.03, 360.13, 360.19) for 12 months after the date of cataract surgery. Patients with 1 or more of these codes were considered suspect cases. In addition, operating surgeons as well as the Infection Control, Risk, and Quality departments were queried for reports of endophthalmitis during the study period.

Confirmation of Endophthalmitis Cases Using Medical Record Review For all suspect endophthalmitis cases, the lead author (N.S.) manually reviewed the electronic medical records to confirm the diagnosis and obtain additional details for each case, including risk factors for endophthalmitis such as surgical complications (eg, PCR), demographics, notes about antimicrobial therapy, and microbiological testing of aqueous or vitreous samples. The medical record review included progress notes from appointments with an ophthalmologist, optometrist, and other clinical health care providers at any Kaiser Permanente facility in Northern California as well as results from microbiological testing. The medical records were closely reviewed for the 8 weeks after surgery; the review was extended to 1 year if needed to confirm the diagnosis.

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A suspect endophthalmitis case was considered confirmed if clinical endophthalmitis was diagnosed by a Kaiser Permanente retinologist based on time of onset, visual acuity, degree of inflammation, vitreous cells, clinical appearance, and the administration of intravitreal antibiotics for treatment. On querying the retinologists for this study, no cases were believed to represent toxic anterior segment syndrome. Cases were considered culture-confirmed if aqueous or vitreous cultures were positive.

Data Analysis

Incidence rates were calculated for each of the 3 practice periods (no intracameral policy, 2007; intracameral in those without allergy or PCR, 2008 to 2009; and intracameral in every patient, 2010 to 2011) and for the subgroup of 3 surgeons who replaced topical antibiotic use with intracameral injection in their patients without PCR during 2007 through 2011. Rates were computed using the number of cases of postoperative endophthalmitis as the numerator and the number of cataract surgeries as the denominator. In a separate analysis of the 3 surgeons who replaced topical antibiotic use with intracameral injection, patients who received both intracameral injection and a topical antibiotic were excluded. Exact 95% confidence intervals (CIs) and *P* values were estimated assuming a Poisson distribution.[9]

RESULTS

The study evaluated 16 264 consecutive phacoemulsification surgeries. The median patient age was 74 years. Of the 16 264 surgeries, 12 609 (78%) involved intracameral injection. Cefuroxime was injected in 10 644 cases (84%), moxifloxacin in 1890 cases (15%), and vancomycin in 75 cases (1%); 2038 patients (13%; median age 76 years) received intracameral injection alone. No adverse drug reactions were reported from administration of intracameral antibiotics during the entire study period, and there were no Risk Department reports of failure to administer an intracameral antibiotic injection in 2010 or 2011, the period during which the policy dictated 100% injection.

Trends in Prophylactic Practices

Intracameral injection (cefuroxime during 2007 through 2009; cefuroxime, moxifloxacin or vancomycin during 2010 and 2011) increased from 2007 to 2011. The proportions of patients who received intracameral injection were as follows: 2007, 11% (308 cases); 2008, 80% (2459 cases); 2009, 86% (2734 cases); 2010, 100% (3430 cases); and 2011, 100% (3678 cases) (Figure 1). The increase was especially sharp between 2007 and 2008, when cefuroxime injection was completely adopted by all ophthalmologists in the group but limited to nonpenicillin-allergic, non-PCR patients. It rose sharply again between 2009 and 2010, when an intracameral injection of antibiotic was provided to every patient.

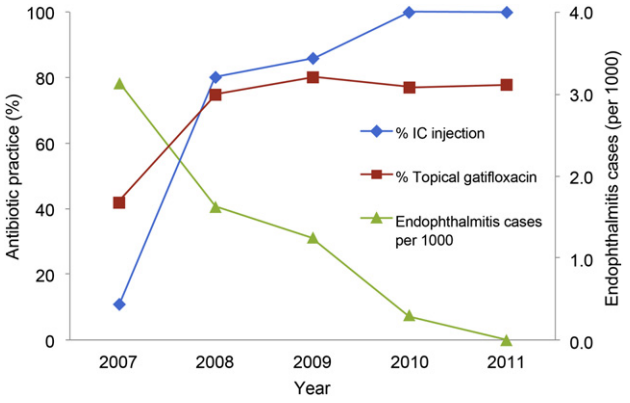

Figure 1. Trends in intracameral injection, postoperative topical gatifloxacin, and endophthalmitis in 16 264 phacoemulsification procedures performed by 14 surgeons during 2007 through 2011 in the Kaiser Permanente Diablo Service Area. The percentage of topical gatifloxacin is the percentage of patients prescribed topical gatifloxacin postoperatively, with the remainder being topical tobramycin, ofloxacin, less common agents, or nothing. From 2007 through 2009, intracameral injection was used in only patients without PCR and without allergy to penicillin and cephalosporin. In 2010 and 2011, intracameral injection was used in all patients (with and without PCR) (IC = intracameral).

Also during the study period, 5 surgeons switched postoperative prescribing from tobramycin to gatifloxacin drops (Zymar). Of the patients who received postoperative topical antibiotic, the proportions who received gatifloxacin were as follows: 2007, 42% (1210 cases); 2008, 75% (2324 cases); 2009, 80% (2568 cases); 2010, 77% (2645 cases); and 2011, 78% (2868 cases) (Figure 1). The increase was sharp between 2007 and 2008 but stable thereafter.

Trends in Endophthalmitis

The intracameral policy was introduced in September 2007. After this, when intracameral cefuroxime began to be injected except in penicillin/cephalosporin allergic and PCR patients, the endophthalmitis rate declined by a factor of 2.2 in 2008 and 2009 to a rate of 1.43 cases per 1000 (95% CI, 0.66-2.72) (Table 1). During 2010 and 2011, when intracameral cefuroxime, moxifloxacin, or vancomycin was provided to all patients including those with PCR, the infection rate declined by a factor of 10.2 to 0.14 per 1000 (95% CI, 0.00-0.78).

Over the 5-year study period, the group of patients who received intracameral injection at the time of cataract surgery had 4 cases of endophthalmitis, all culture negative, for an infection rate of 0.32 per 1000 (95% CI, 0.09-0.82). The corrected distance visual acuity (CDVA) after infection resolution was 20/30 in 3 of the 4 cases. One patient with preexisting postexudative macular degeneration in the index eye

Table 1. Incidence of postoperative endophthalmitis in relation to practice patterns during 3 time periods, Kaiser Permanente Diablo Service Area.

Period	Practice Pattern	Cataract Surgeries (n)	Endophthalmitis Cases (n)	Infection Rate per 1000	95% CI
2007	Individual surgeon's preference without IC injection	2878	9	3.13	1.43, 5.93
2008–09	IC injection with or without topical in patients without PCR; topical only in patients with PCR	6278	9	1.43	0.66, 2.72
2010–11	IC injection in all patients, with or without topical depending on surgeon's preference	7108	1	0.14	0.00, 0.78
Overall	All surgeons	16 264	19	1.17	0.70, 1.83
2008–11	Three surgeons, IC alone in patients without PCR	2038	1	0.49	0.01, 2.73

CI = confidence interval; IC = intracameral; PCR = posterior capsule rupture

achieved an improved postoperative CDVA after infection resolution of 20/70. During this same period, the group of patients who did not receive intracameral injection had 15 cases of endophthalmitis, an infection rate of 4.20 per 1000 (95% CI, 2.35-6.78). The post-infection CDVA was 20/20 to 20/40 in 8 patients (53%), 20/50 to 20/70 in 3 patients (20%), and no light perception in 3 patients (20%). One patient with preexisting proliferative diabetic retinopathy and retinal detachment had enucleation after the infection episode due to phthisis bulbi.

Three surgeons used intracameral injection without topical antibiotic in 2038 consecutive surgeries uncomplicated by PCR. Among these surgeries, there was 1 case of clinical endophthalmitis, a rate of 0.49 per 1000 (95% CI, 0.01-2.73) (Table 1).

Details of Endophthalmitis Cases

During the study period, 19 cases of endophthalmitis were identified. Table 2 shows the characteristics of these cases. The median time to onset after cataract extraction was 6 days (range 1 to 47 days). Regimens used for antibiotic prophylaxis varied for these cases; 10 (53%) received postoperative gatifloxacin drops, 8 (42%) postoperative tobramycin, and 3 (16%) intracameral antibiotic plus topical therapy, and 1 (5%) intracameral antibiotic alone.

Of the 19 cases, 8 (42%) were culture positive. None of these patients received intracameral antibiotic injection. The organisms cultured were coagulase-negative *Staphylococcus*, *Streptococcus viridans*, *S pneumoniae*, methicillin-resistant *S aureus*, and *Enterococcus faecalis*. Five patients (63%) had received postoperative gatifloxacin drops and 3 patients (38%) tobramycin drops. Six (75%) of the 8 culture-positive endophthalmitis patients were uncomplicated (no PCR). Of the 6, half received gatifloxacin and half received tobramycin. The 2 patients (25%) with culture-positive endophthalmitis who had PCR were treated with gatifloxacin topical eyedrops but not intracameral injection.

DISCUSSION

We examined changing trends in cataract surgical prophylaxis and computed the endophthalmitis rates in a large community-based ophthalmology practice over a 5-year period. During this time, we documented an increase in the use of intracameral antibiotics from 11% to 100% and a concurrent 22-fold decline in the rate of clinical endophthalmitis. The patients who received intracameral injection over the course of the 5-year study had a 13-fold lower rate of infection, were culture negative, and had a good visual outcome, factoring out preexisting ocular disease. In addition, we documented a low incidence rate of endophthalmitis with the use of intracameral antibiotics alone in the absence of preoperative or postoperative antibiotic drops. Our study supports the findings in the ESCRS randomized controlled trial and other studies that found intracameral antibiotic use was associated with lower endophthalmitis risk.[7,10,11]

A key element of the study that provides a critical clue about the relative effectiveness of gatifloxacin and intracameral injection stems from the timing of the practice changes under study. The marked increase in the adoption of gatifloxacin from tobramycin occurred in late 2007. During that same time, intracameral cefuroxime injection was initiated in patients without PCR or allergy to penicillin or cephalosporin analogues. The rate of endophthalmitis declined by a factor of 2, although the decrease was not statistically significant ($P = .09$).

From 2010 to 2011, gatifloxacin-prescribing practices remained essentially constant. In January 2010, after a review of the available literature on the safety of intracameral antibiotics.[12–15] the group changed its practice to begin injecting all cataract surgery patients,

Table 2. Detailed characteristics of 19 endophthalmitis cases that developed in a consecutive series of 16 264 phacoemulsification surgeries in 2007 through 2011, Kaiser Permanente Diablo Service Area.

Year/Patient ID	Culture	IC Injection	PCR	Postoperative Agent	CDVA
2007					
1	No growth	No	No	Tobramycin	20/25
2	No growth	No	No	Tobramycin	20/60
3	*Strep viridans*	No	No	Tobramycin	NLP
4	*Staph* coag neg	No	No	Tobramycin	20/40
5	No growth	No	No	Gatifloxacin	20/40
6	No growth	No	No	Tobramycin	20/40
7	No growth	No	No	Tobramycin	20/20
8	*Strep pneumoniae*	No	No	Gatifloxacin	Enuc
9	No growth	No	No	Gatifloxacin	NLP
2008					
10	No growth	Cefuroxime	No	Gatifloxacin	20/70
11	No growth	No	No	Gentamicin	20/25
12	No growth	Cefuroxime	No	Gatifloxacin	20/30
13	MRSA	No	No	Tobramycin	20/70
14	*Staph* coag neg	No	No	Gatifloxacin	20/40
2009					
15*	No growth	Cefuroxime	No	Gatifloxacin	20/30
16	*Staph* coag neg	No	No	Gatifloxacin	20/25
17	*Staph* coag neg	No	Yes	Gatifloxacin	20/50
18	*Enteroc faecalis*	No	Yes	Gatifloxacin	NLP
2010					
19	No growth	Moxifloxacin	No	None	20/30
2011					
No cases	—	—	—	—	—

CDVA = corrected distance visual acuity; coag neg = coagulase negative; *Enteroc* = *Enterococcus*; Enuc = enucleated; IC = intracameral; ID = identifier; MRSA = methicillin-resistant *Staphylococcus aureus*; NLP = no light perception; PCR = posterior capsule rupture; *Strep* = *Streptococcus*; *Staph* = *Staphylococcus*
*Endophthalmitis was diagnosed 22 days after surgery after a fingernail scratch.

including (and especially) those with PCR. The addition of moxifloxacin as a second-line alternative and vancomycin as a third-line alternative to cefuroxime brought the percentage of patients injected to 100%. With this change, the risk for endophthalmitis declined 10-fold ($P<.01$). This suggests that adoption of intracameral injection was the key practice change reducing endophthalmitis rates and that intracameral injection may be especially effective in patients with PCR, which is important because the risk for infection increases by 5- to 10-fold after PCR.[7,16] It was because of this increased risk that the subgroup of 3 surgeons whose usual practice was to inject intracameral antibiotics as the only means of prophylaxis for infection prescribed additional topical antibiotics in cases complicated by PCR.

This raises the question of whether topical antibiotics, when combined with intracameral administration, offer any marginal effectiveness. The subset of patients who received intracameral injection as the sole means of prophylaxis without topical agent had a low endophthalmitis rate (0.49 per 1000), although the number of patients receiving this prophylactic regimen was too small to allow us to draw a clear conclusion. This rate is very similar to, although less precise than, the rate of 0.45 per 1000 reported in Sweden, where 95% of 225 471 patients received intracameral cefuroxime without a postoperative topical antibiotic.[17]

An advantage of intracameral injection is that the dose of antibiotic achieved in the anterior chamber is much higher than with topical administration[18]; for dose-dependent antibiotics, this provides a higher kill. The use of topical fluoroquinolones is not without problems. Topical therapy itself may pose risks. Many patients are elderly,[19] a contaminated eye dropper tip[20] may contact the eye,[21] and topical fluoroquinolones have been implicated in emerging resistance.[22,23]

The better cost effectiveness of intracameral cefuroxime over topical fluoroquinolones has been shown.[24] The additional cost of a fourth-generation fluoroquinolone over intracameral cefuroxime is approximately $75 per bottle.[25] With 1.82 million

cataract procedures performed in the U.S. Medicare population,[6] the cost to Medicare is $136 million annually for postoperative topical agents alone. This figure may be a conservative estimate because some surgeons administer additional antibiotic units immediately before or after surgery. This estimate also does not include patients receiving their surgeries outside the Medicare program.

Although the choice of cefuroxime as first-line intracameral agent in our department was driven by the results in the ESCRS study when we first embarked on this practice improvement, moxifloxacin may have advantages as a first-line drug because it offers broader spectrum coverage and is available for injection without dilution. Its cost effectiveness in intracameral injection may approach that of cefuroxime as the number of doses obtained from 1 bottle increases. As our experience with cefuroxime as a first-line agent appears to be successful, no change in our current algorithm of antibiotics is being contemplated at this time. Vancomycin, however, should not be injected as a first-line drug to reduce the risk for emerging resistance.[26]

The design of this study is a potential weakness. Ecologic studies, such as country-level comparisons and time trends, use data collected at the population level rather than the patient level. They are often used to generate hypotheses and provide supportive evidence rather than show causality. Ecologic time-trend studies, such as this one, do not account for other population shifts that may be explanatory. It was because of this limitation that we carefully assessed trends in topical gatifloxacin use. Nonetheless, surgeon factors, such as wound construction,[27,28] stromal hydration,[29] and concluding intraocular pressure,[30] or systemic factors, such as declines in the PCR rate and improvements in environmental cleaning, may be important, and we could not control for these, directly or indirectly.

In conclusion, we observed that an increase in the use of intracameral injection coincided with a large decline in the risk for endophthalmitis. This decline coincided only modestly, if at all, with switching from postoperative topical tobramycin to gatifloxacin. Intracameral antibiotics appear to be safe and effective in preventing postoperative endophthalmitis. They may be particularly effective in the event of PCR. The marginal effectiveness of postoperative topical antibiotic when combined with intracameral administration requires further study. Without randomized controlled trials or other comparative studies, the relative effectiveness of topical gatifloxacin compared with intracameral cefuroxime, moxifloxacin, or other topical agents remains to be elucidated.

WHAT WAS KNOWN

- Intracameral antibiotic injection in the prevention of postoperative endophthalmitis has not generally been adopted in the United States. Skepticism about the design of the ESCRS study and difficulties compounding cefuroxime may be factors.
- There have been no published data describing a link between posterior capsule rupture and intracameral injection for prevention of endophthalmitis.
- There have been no published data on the endophthalmitis rate in patients who receive intracameral injection and no other perioperative antibiotic drops.

WHAT THIS PAPER ADDS

- Systematic adoption of intracameral antibiotic injection at the end of the cataract surgery was associated with a lower rate of endophthalmitis at a large surgery center in Northern California. This has not been demonstrated in any U.S. center.
- Intracameral injection may be particularly effective in patients who sustain PCR.
- Intracameral injection alone, without additional perioperative antibiotic drops, may be highly protective against endophthalmitis.

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