



# Incidence of Acute Postoperative Endophthalmitis after Cataract Surgery

## A Nationwide Study in France from 2005 to 2014

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**Purpose:** To report the incidence of acute postoperative endophthalmitis (POE) after cataract surgery from 2005 to 2014 in France.

**Design:** Cohort study.

**Participants:** Patients undergoing operation for cataract surgery by phacoemulsification and presenting acute POE.

**Methods:** We identified acute POE occurring within 6 weeks after phacoemulsification cataract surgery and the use of intracameral antibiotic injection during the surgical procedure by means of billing codes from a national database.

**Main Outcome Measures:** Incidence of acute POE.

**Results:** From January 2005 to December 2014, 6 371 242 eyes in 3 983 525 patients underwent phacoemulsification cataract surgery. The incidence of acute POE after phacoemulsification decreased from 0.145% to 0.053% during this 10-year period; the unadjusted incidence rate ratio (IRR) (95% confidence interval) was 0.37 (0.32–0.42;  $P < 0.001$ ). In multivariate analysis, intracameral antibiotic injection was associated with a lower risk of acute POE 0.53 (0.50–0.57;  $P < 0.001$ ), whereas intraoperative posterior capsule rupture, combined surgery, and gender (male) were associated with a higher risk of acute POE: 5.24 (4.11–6.68), 1.77 (1.53–2.05), and 1.48 (1.40–1.56) ( $P < 0.001$ ), respectively.

**Conclusions:** Access to a national database allowed us to observe a decrease in acute POE after phacoemulsification cataract surgery from 2005 to 2014. Within the same period, the use of intracameral antibiotics during the surgical procedures increased. *Ophthalmology* 2016;■:1–7 © 2016 by the American Academy of Ophthalmology.

Acute postoperative endophthalmitis (POE) is a dreaded complication after cataract surgery. The incidence of acute POE varies from 0.04% to 0.26% according to recent reports.<sup>1–5</sup> This incidence is declining over time throughout the world, with Sweden observing a decrease in acute POE incidence from 0.048% in 2002–2004 to 0.029% in 2005–2010, for example.<sup>6</sup> A similar trend has been reported in the United States among Medicare beneficiaries.<sup>7</sup>

Prophylaxis against POE is of paramount importance because 34% of affected patients achieved a final visual acuity of 20/200 or worse.<sup>7</sup> The most robust means to decrease POE is the use of povidone-iodine,<sup>8</sup> which “appears to be nearly universal.”<sup>9</sup> The publications of the results of the European Society of Cataract and Refractive Surgeons (ESCRS) Endophthalmitis study have shed new light on the prophylaxis of acute POE after cataract surgery, showing a 5-fold decrease of acute POE after an anterior chamber injection of 1 mg of cefuroxime.<sup>10</sup> This study has been criticized and challenged, and the use of intracameral cefuroxime is not widely accepted.<sup>11,12</sup> Various surveys have shown

low-to-moderate acceptance of this prophylaxis depending on the country.<sup>13,14</sup> Although many European cataract surgeons have adopted this antibiotic prophylaxis,<sup>11</sup> in the United States the predominant antibiotic treatment for the prophylaxis of POE is based on fourth-generation fluoroquinolones.<sup>15</sup>

Most reports on POE have been based on data from 1 or several institutions or with the use of health insurance data,<sup>16</sup> but few data exist for an entire country. The Swedish National Cataract Register is probably unique because it contains 98% of all cataract extractions performed in Sweden.<sup>6</sup> Access to big data allows investigators to process large numbers of procedures and patients. The French national administrative database, Programme Médicalisé des Systèmes d’Information (PMSI), provides a huge amount of epidemiologic information concerning hospitalized patients in France.<sup>17</sup> In this study, we sought to report the incidence of acute POE after cataract surgery by phacoemulsification in France from 2005 to 2014 and to evaluate the potential impact of intracameral antibiotic injection use on this incidence.

## Methods

### Data Source

The national administrative database (PMSI) was inspired by the American diagnosis-related group model. It was established in France in 1991 and extended in 1997 to the 1546 French healthcare facilities, both private and public. This coding system initially was designed to analyze hospital and clinic activity and to contribute to the elaboration of strategic healthcare plans. Since 2004, all public and private hospital budgets have depended on the medical activity described in a specific program, which compiles discharge abstracts related to all admissions (inpatient and outpatient settings) in all French public and private healthcare facilities. Information in these abstracts is anonymous and includes both medical and administrative data. Diagnoses identified during the hospital stay are coded according to the 10th edition of the International Classification of Diseases. All procedures performed during the hospitalization are coded according to the French Common Classification of Medical Procedures (CCAM). Each facility produces its own standardized anonymous data set, and these are then compiled at a national level. The fact that these national data are used for healthcare facilities' budget allocation encourages improvement in data quality in terms of coherence, accuracy, and exhaustiveness.

### Data Extraction

This study is a retrospective study based on a nationwide PMSI database collected between 2005 and 2014. The use of this database was approved by the National Commission for Data Protection (CNIL No. 1576793), and this study adhered to the tenets of the Declaration of Helsinki. We included all patients who were admitted to healthcare facilities during this period for phacoemulsification cataract surgery. For each patient, cataract surgery was identified by the CCAM code BFGA004 corresponding to "cataract extraction performed by phacoemulsification with intraocular lens implantation in a capsular bag." We did not consider the codes for other modalities of cataract extraction, such as manual extracapsular or intracapsular extraction. Combined procedures (i.e., cataract extraction concomitant with glaucoma or corneal surgery or vitreoretinal procedures) were included. Sociodemographic variables including age and gender were recorded.

For patients admitted from 2005 to 2014 for cataract surgery, all hospitalizations within 42 days of cataract surgery<sup>18</sup> with a billing code of endophthalmitis (10th edition of the International Classification of Diseases code H440 or H441) were selected. In France, endophthalmitis is treated only in hospitals, either public or private. The recommended treatment is intravitreal injections of antibiotics, and this is only performed during a hospitalization and never in the office for several reasons: The vitreous tap is performed in the operating room, and the preparation of intravitreal antibiotics requires the skills of a trained team. Moreover, because endophthalmitis is acknowledged as a nosocomial infection, lawsuits may occur if the treatment is not delivered according to the recommendations. All the procedures coded with the CCAM code BELB001, indicating an injection of an organic or inert substance in the anterior chamber of the eye (a surrogate for intracameral antibiotic injection) and concomitant to the BFGA004 procedure (cataract extraction performed using phacoemulsification), were identified. The intraoperative anterior vitrectomy associated with posterior capsule rupture was identified with the code BGFA008. Before extraction of the cohort, 0.76% of hospital stays for cataract surgery were not included because of patient identification errors.

### Statistical Analysis

Incidence corresponded to the number of eyes presenting with acute endophthalmitis during a 42-day period after cataract surgery (recurrences during this period were excluded) divided by the number of operated eyes. No confidence intervals were estimated because we studied the entire French population. Each variable was included as the only explanatory variable in a Poisson regression analysis and tested for significance using log-likelihood ratio statistics. The number of cataracts was used as a population offset. We also studied factors that may be associated with endophthalmitis after cataract surgery. For each variable (intracameral antibiotic injection, intraoperative posterior capsule rupture, combined surgery, age  $\geq 85$  years, and gender), incidence rate ratios (IRRs) were estimated using Poisson regression. The 5 variables were included in a multivariate Poisson regression analysis to obtain the adjusted IRR to explain the incidence of acute POE after cataract surgery. Analyses were performed with the SAS 9.2 software for Windows (SAS Institute Inc., Cary, NC). All the tests were 2-sided and *P* values  $< 0.05$  were considered significant.

### Results

During the 2005–2014 period, 3 983 525 patients were identified in the national administrative database as being admitted to a healthcare facility for cataract surgery by phacoemulsification. These patients underwent a total of 6 371 242 procedures for cataract surgery. Table 1 shows the distribution of cataract surgery from 2005 to 2014 for the entire country, according to age and gender. Combined cataract surgery with glaucoma or corneal or vitreoretinal procedures accounted for 1.61% ( $n = 102\,763$ ) of these 6 371 242 procedures during this 10-year period.

Cataract surgery by phacoemulsification increased by 52.9% from 2005 to 2014. Although the age of the patients undergoing operation statistically decreased from 2005 to 2014 ( $73.78 \pm 10.01$  years vs.  $73.76 \pm 9.82$  years;  $P < 0.001$ ), this difference was not clinically relevant. During this 10-year period, the proportion of men undergoing operation for cataract increased from 37.8% to 40.9% ( $P < 0.001$ ). Among these cataract surgeries, 6668 were associated with endophthalmitis within a 6-week period after the surgical procedure (Table 2).

The mean incidence of acute POE from 2005 to 2014 was 0.105% (Table 2). This decrease in incidence was statistically significant from 2009 to 2014 when taking 2005 as the reference year in a Poisson regression analysis (Table 3).

The use of intracameral antibiotic injection at the end of cataract surgery (identified by the CCAM code BELB001) sharply increased in France from 0.60% in 2005 to 80.03% in 2014 (Table 2, Fig 1). In univariate and multivariate analyses, intracameral antibiotic injection was associated with a lower risk of acute POE after cataract surgery by phacoemulsification, whereas intraoperative posterior capsule rupture, combined surgery, and gender (male) were associated with a greater risk (Table 4). The time period of cataract surgery was associated with acute POE in univariate analysis, when comparing the 2008–2011 period with the 2005–2007 period (IRR, 0.83; 95% CI, 0.78–0.87;  $P < 0.001$ ) and 2012–2014 with 2005–2007 (IRR, 0.45; 95% CI, 0.42–0.48;  $P < 0.001$ ). Because of colinearity between the time period and the intracameral antibiotic injection, only the latter variable was introduced in the multivariate analysis.

### Discussion

The 2 major findings of this study were the growing incidence of cataract surgery and the decreased incidence of

Table 1. Number of Phacoemulsification Cataract Surgeries Performed in France from 2005 to 2014

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2005–2014
<40 yrs											
n	3295	3301	3534	3343	3480	3427	3538	3612	3472	3452	34 454
Sex, female (%)	47.3	44.8	45.2	45.1	43.7	43.5	43.2	45.2	43.4	43.4	44.1
40–49 yrs											
n	8282	8626	8728	8861	9185	9345	9335	9272	9408	9473	90 515
Sex, female (%)	47.8	48.7	49.2	50.0	49.0	48.6	49.7	48.7	50.2	49.1	49.3
50–59 yrs											
n	32 689	35 298	37 391	38 347	40 328	41 313	42 547	43 915	43 536	44 495	399 859
Sex, female (%)	49.7	49.1	49.4	50.9	50.5	51.4	52.0	51.5	52.3	51.9	51.3
60–69 yrs											
n	84 495	93 443	99 726	107 071	117 806	129 017	140 691	153 239	161 530	170 476	1 257 494
Sex, female (%)	56.5	56.3	55.7	55.6	55.5	55.6	55.8	56.4	56.1	56.6	56.0
70–79 yrs											
n	220 073	239 761	245 756	250 966	266 252	275 120	280 333	287 894	292 147	300 682	2 658 984
Sex, female (%)	63.7	63.2	62.6	62.4	61.8	61.7	61.4	61.0	60.3	59.9	61.3
80–89 yrs											
n	134 964	150 446	160 070	167 989	180 646	189 802	197 191	203 242	206 560	211 685	1 802 595
Sex, female (%)	66.8	66.1	65.5	64.9	64.7	64.1	63.6	63.2	62.4	61.8	63.7
≥90 yrs											
n	11 967	10 974	9841	9131	9486	11 549	14 161	15 607	16 895	17 730	127 341
Sex, female (%)	70.8	69.7	69.8	68.6	68.4	67.4	66.9	66.5	65.4	65.3	66.9
Total											
n	495 765	541 849	565 046	585 708	627 183	659 573	687 796	716 781	733 548	757 993	6 371 242
Sex, female (%)	62.2	61.7	61.1	60.9	60.5	60.3	60.2	59.9	59.4	59.1	60.1

acute POE after phacoemulsification cataract surgery in France from 2005 to 2014. Our findings are in agreement with a recent publication reporting a 14% increased incidence of cataract surgeries in France from 2009 to 2012.<sup>19</sup> This trend has been observed in several countries<sup>20,21</sup> and is related to the aging process and to surgical technique refinements resulting in an effective procedure with a rapid recovery of vision in most cases.<sup>19</sup> The decrease of acute POE after cataract surgery observed in the current article is in line with the published literature.<sup>6,22</sup> Respecting good antisepsis with povidone-iodine certainly has played a key prophylactic role against acute POE.<sup>8,22</sup> However, the use of antibiotic prophylaxis remains controversial. A 10-year study conducted in the United States between 1997 and 2007 reached the conclusion that the adoption of

fourth-generation fluoroquinolones led to a 3.5-fold decrease in acute POE.<sup>23</sup> In the United States, most cataract surgeons use topical fourth-generation fluoroquinolones,<sup>24</sup> whereas in Europe an increasing number of surgeons use intracameral cefuroxime.<sup>25</sup> In a single academic center in France, a multivariate analysis demonstrated that the lack of cefuroxime use was strongly associated with acute POE.<sup>26</sup> In Sweden, a multivariate analysis showed that not using intracameral cefuroxime was identified as an independent risk factor for acute POE with an odds ratio of 2.6; the 2 other risk factors reaching statistical significance were age 85 years or older and intraoperative communication with the vitreous.<sup>6</sup> Outside Europe, 2 studies mentioned the benefit of intracameral cefuroxime as a prophylaxis for acute POE after cataract

Table 2. Incidence of Acute Postoperative Endophthalmitis after Cataract Surgery by Phacoemulsification in France from 2005 to 2014

	No. of Cataract Surgeries	No. of Acute POE Cases	No. of Intracameral Antibiotic Injections	Overall Incidence of Acute POE (%)	Incidence of Acute POE with Intracameral Antibiotic Injection (%)	Incidence of Acute POE without Intracameral Antibiotic Injection (%)
2005	495 765	719	2989	0.145	0.100	0.145
2006	541 849	779	33 835	0.144	0.103	0.146
2007	565 046	773	54 706	0.137	0.110	0.140
2008	585 708	777	57 061	0.133	0.119	0.134
2009	627 183	809	61 976	0.129	0.115	0.131
2010	659 573	768	73 159	0.116	0.111	0.117
2011	687 796	649	97 570	0.094	0.099	0.094
2012	716 781	553	231 037	0.077	0.053	0.089
2013	733 548	436	471 429	0.059	0.048	0.080
2014	757 993	405	606 586	0.053	0.046	0.082
Total	6 371 242	6668	1 690 348			

POE = postoperative endophthalmitis.

Table 3. Unadjusted Incidence Rate Ratios of Acute Postoperative Endophthalmitis after Cataract Surgery by Phacoemulsification in France from 2005 to 2014, Derived from Poisson Regression Analysis, According to Year of Surgery

Variable	Univariate Poisson Regression	
	IRR (95% CI)	P Value*
Year of surgery overall		<0.001
Year of surgery (reference = 2005)		
2006	0.99 (0.90–1.10)	0.86
2007	0.94 (0.85–1.04)	0.26
2008	0.91 (0.83–1.01)	0.08
2009	0.89 (0.80–0.98)	0.022
2010	0.80 (0.73–0.89)	<0.001
2011	0.65 (0.59–0.72)	<0.001
2012	0.53 (0.48–0.59)	<0.001
2013	0.41 (0.36–0.46)	<0.001
2014	0.37 (0.32–0.42)	<0.001

CI = confidence interval; IRR = incidence rate ratio.

\*Log-likelihood ratio statistics from Poisson regression.

surgery in the United States (a 22-fold decline in the rate of acute POE) and South Africa.<sup>27,28</sup>

According to a US survey, the main obstacle to the use of intracameral antibiotics is the lack of availability of a commercially approved drug, and more cataract surgeons would consider this practice if the antibiotic were available.<sup>24</sup> This concern also was noted in a survey among European cataract surgeons; 74% of them continued to use

intracameral antibiotics (82% of them used cefuroxime) during cataract surgery, and 90% would use cefuroxime if an approved single-unit dose were commercially available.<sup>25</sup> An online survey conducted in 1147 members of the American Society of Cataract and Refractive Surgery indicated that 84% of them would adopt this prophylaxis if the commercial availability of an approved antibiotic were established in their country. Such a commercial preparation of cefuroxime is on the market in 24 European countries (Aprokam, Lab Théa, Clermont-Ferrand, France). In France, cefuroxime was officially approved on September 26, 2012. The average price is 11.62 Euros per unit, and the drug is reimbursed by the insurance system. It is interesting to note that in the present study, the IRR of acute POE was nearly halved when a commercial preparation of cefuroxime became commercially available in the country: 0.83 for the 2008–2011 period versus 0.45 for the 2012–2014 period. In fact, the results of the ESCRS endophthalmitis study showing a 5-fold decrease of POE when cefuroxime was used during the surgical procedure were published in 2007.<sup>10</sup> One could suspect that the “kitchen pharmacy” preparations of cefuroxime used between 2008 and 2012 in France did not reach the optimal concentration of antibiotic necessary to achieve a bactericidal effect in the anterior chamber on completion of surgery. The potential dilution hazards of such in-house preparations are reinforced by the fact that inaccurate high dosages of cefuroxime have led to severe ocular complications.<sup>29,30</sup>

We attempted to identify risk factors for acute POE after cataract surgery. Unfortunately, some operating parameters, such as side, incision location, and silicone intraocular lenses, or general morbidity indicators, such as diabetes, which have already been identified as risk factors for POE,<sup>31,32</sup> were not available or not reliable in our national database. In multivariate analysis, age more than 85 years was not a risk factor, unlike in other reports.<sup>6,31</sup> Male gender and posterior capsule rupture were associated with a higher risk of POE, in agreement with several reports.<sup>6,31</sup> Combined cataract surgery as a risk factor for acute POE is poorly documented in the literature. This study found that intracameral antibiotic injection was associated with a lower risk for acute POE (IRR, 0.53). However, it could not be fully ascertained that this benefit was related to cefuroxime. In fact, the code demonstrates the use of an intracameral injection without specifying the exact nature of the drug injected. It is possible that other antibiotics such as cefazolin<sup>33</sup> or vancomycin,<sup>14</sup> despite the warnings about emerging resistance,<sup>34</sup> were used in France. Other classes of drugs are highly unlikely. Indeed, the manufacturer of the ready-to-use preparation of cefuroxime (Aprokam) reported that the sales of cefuroxime units increased from 19 000 in 2012 to 577 000 in 2014. Therefore, there is a strong presumption that the substance used was cefuroxime from 2012 to 2014 in the majority of intracameral antibiotic injections in France.

### Study Limitations

We acknowledge several limitations to this study. First, coding may not be fully accurate. The surgeons code

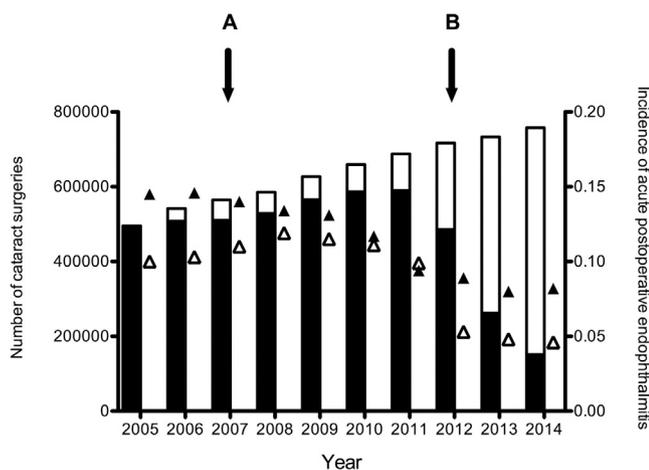


Figure 1. Number of phacoemulsification cataract surgeries, number of intracameral antibiotic injections, and incidence of acute postoperative endophthalmitis (POE) after phacoemulsification cataract surgery in France from 2005 to 2014. A, 2007, publication of the ESCRS endophthalmitis study.<sup>10</sup> B, 2012, commercialization in France of an approved preparation of cefuroxime. Dark bars represent the number of cataract surgeries without intraoperative antibiotic injection in the anterior chamber. White bars represent the number of cataract surgeries with intraoperative antibiotic injection in the anterior chamber. Dark triangles represent the incidence of acute POE after cataract surgery in eyes without intraoperative antibiotic injection in the anterior chamber. White triangles represent the incidence of acute POE after cataract surgery in eyes with intraoperative antibiotic injection in the anterior chamber.

Table 4. Unadjusted and Adjusted Incidence Rate Ratios of Acute Postoperative Endophthalmitis after Phacoemulsification Cataract Surgery in France from 2005 to 2014, Derived from Poisson Regression Analysis, According to Intracameral Antibiotic Injection, Posterior Capsule Rupture, Combined Surgery, Age, and Gender

Variable	Univariate Poisson Regression		Multivariate Poisson Regression	
	IRR (95% CI)	P Value*	IRR (95% CI)	P Value*
Intracameral antibiotic injection	0.52 (0.49–0.56)	<0.001	0.53 (0.50–0.57)	<0.001
Posterior capsular rupture	5.74 (4.56–7.23)	<0.001	5.24 (4.11–6.68)	<0.001
Combined surgery	1.99 (1.74–2.29)	<0.001	1.77 (1.53–2.05)	<0.001
Age ≥85 yrs	1.01 (0.94–1.10)	0.73	1.05 (0.97–1.14)	0.60
Gender male vs. female	1.48 (1.41–1.56)	<0.001	1.48 (1.40–1.56)	<0.001

CI = confidence interval; IRR = incidence rate ratio.

\*Log-likelihood ratio statistics from Poisson regression.

themselves, and errors may have occurred.<sup>34</sup> However, the national health service regularly checks coding accuracy on the basis of samples of patient charts and doctors, and healthcare facilities can be fined in case of excessive errors. Second, the code for endophthalmitis encompasses both culture-positive and culture-negative cases, and the definition of endophthalmitis was based on clinical suspicion rather than a more strict bacteriological definition. However, the majority of studies report on a diagnosis of endophthalmitis based on clinical suspicion.<sup>6</sup> Third, it is not possible to exclude cases hospitalized for noninfectious severe inflammation, such as toxic anterior segment syndrome, because the clinical presentation can be mistaken for acute POE. Fourth, the findings reported may not apply to other countries because the current practices for the prevention of postoperative ocular infection may vary. Fifth, we cannot exclude that other factors besides intracameral antibiotic injections could have played a role in the decline of acute POE observed in this study. However, because no changes have occurred for antisepsis or topical antibiotics, and major surgical technique changes had already been implemented, this is unlikely. Sixth, we have excluded cataract extraction modalities other than phacoemulsification, the gold standard for cataract surgery for at least the last 3 decades. On the one hand, it has been shown that these procedures—other than phacoemulsification—led to a higher rate of acute POE with a 2.19 odds ratio.<sup>31</sup> On the other hand, it has recently been reported that these procedures accounted for only 0.7% of all the procedures used for cataract surgery in France.<sup>19</sup>

The very high number of surgical procedures collected in this study counterbalances these caveats. We did not work on a sample of the population but on all the cases recorded in a country with 66 million inhabitants over a 10-year period. In an important contribution titled “How Big Data Informs Us About Cataract Surgery,” Coleman<sup>35</sup> pointed out the intrinsic limitations of big data use. The large volume and rapidly growing variety of data, known as the “3 Vs rule,” are counterbalanced by the paucity of clinical data, which is a limit to including all the variables involved in a specific event or disease.<sup>35</sup>

In conclusion, during a 10-year period, the number of people in France undergoing phacoemulsification for

cataract surgery increased by 52.9% and the incidence of acute POE was cut nearly in half. The increased number of cefuroxime intracameral injections and the availability of a commercial preparation of cefuroxime occurred at the same time as a substantial decrease in acute POE after phacoemulsification cataract surgery in France. This finding deserves further study in randomized trials on the use of intracameral antibiotics for cataract surgery.

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*Creuzot-Garcher et al* • Incidence of Acute Postoperative Endophthalmitis

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Abbreviations and Acronyms:

**CCAM** = Classification Commune des Actes Médicaux; **IRR** = incidence rate ratio; **PMSI** = Programme Médicalisé des Systèmes d'Information; **POE** = postoperative endophthalmitis.

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