

# Adherence to European Society for Cataract and Refractive Surgery recommendations among Italian cataract surgeons: a survey

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## ABSTRACT

**Purpose:** To survey the surgical routines with regards to prophylactic strategies in a sample of Italian hospitals and compare these with European Society for Cataract and Refractive Surgery (ESCRS) guidelines.

**Methods:** Six private and 18 public hospitals were included in this clinical-based retrospective study. The overall volume of cataract operations in the 24 centers in 2013 was 43,553. Main outcome measure was incidence of endophthalmitis per 1,000. An incidence of less than 0.13% was considered acceptable.

**Results:** Our study provides the first Italian data on the use of intracameral antibiotics in cataract surgery as recommended by the ESCRS. Thirteen centers (54%) used intracameral cefuroxime at the end of surgery. Of the 13 centers that used cefuroxime, 8 (62%) had an incidence of endophthalmitis less than 0.13%. Of the 7 (29%) centers that did not use intracameral cefuroxime, all had an endophthalmitis rate of greater than 0.13%. This difference was statistically significant ( $p < 0.05$ ). Among the 4 centers not included, 2 used vancomycin in the infusion bottle, 1 a fluoroquinolone, and the last a combination of antibiotics. The majority of surgeons (71%) used preoperative antibiotic eyedrops, but this measure was not shown to be significantly protective.

**Conclusions:** Slightly more than half of the centers surveyed in this study adhered to the recommendations of the ESCRS and routinely employed prophylactic intracameral cefuroxime. An incidence of endophthalmitis greater than 0.13% was encountered significantly more frequently among centers that did not employ intracameral cefuroxime.

**Keywords:** Cataract surgery, Endophthalmitis, Prophylaxis, Survey

## Introduction

Endophthalmitis remains one of the most challenging and devastating complications of surgery. Postcataract endophthalmitis incidence ranges from 0.04% to 0.13% with differences in regional microbiological spectrum (1-4).

The European Society for Cataract and Refractive Surgery (ESCRS) has recently updated its recommendations for

prevention and management of postcataract endophthalmitis (5, 6). Since the routine introduction of intracameral injection of cefuroxime 6 years ago, the rate of endophthalmitis has been significantly reduced (7-11). Furthermore, a commercially available formulation of cefuroxime (Aprokam<sup>®</sup>) approved for intracameral prophylaxis was introduced to the European market in 2013.

Recently, the Italian Society of Ophthalmology issued recommendations to prevent endophthalmitis following cataract surgery, but left antibiotic use to the individual surgeon's discretion (12).

What the Choosing Wisely paradigm in medicine would imply for perioperative prophylaxis in cataract surgery remains controversial (13), because surgical settings, techniques, and preferences may be different in various settings. Topical preoperative antibiotics remain popular despite the recognition that overuse and repeated exposure to topical antibiotics can lead to the emergence of bacteria that

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do not respond readily to available treatments. Mounting evidence suggests that ocular surface organisms are becoming more resistant to fluoroquinolones, with up to 30% of cultured ocular isolates being resistant (14, 15). Also, the efficacy and safety profile of intracameral cefuroxime during cataract surgery remains controversial since there are conflicting results in the literature about the additional protective effect of cefuroxime when added to the standard of care (16-18).

The purpose of our study was to conduct a survey and collect data on the attitudes and methods used to prevent postcataract endophthalmitis in selected Italian hospitals and to compare practice with ESCRS guidelines and best available evidence.

## Methods

A multiple-choice questionnaire survey was designed and e-mailed to a broad cross-section of different settings across the country. Six private and 18 public Italian hospitals participated in this survey.

Among public hospitals, 10 were teaching hospitals. Institutional review board approval was obtained for retrospective review of databases.

The aggregate incidence of endophthalmitis was established from a retrospective analysis of a coding database at the respective institutions (number of postoperative endophthalmitis codes/number of cataract surgery codes at that institution). An incidence of postcataract endophthalmitis of less than 0.13% was chosen as an acceptable level of endophthalmitis, since a systematic review found an aggregate incidence of endophthalmitis occurring after cataract surgery of 0.13% (3).

The purpose of the first part of the questionnaire was to collect information about the surgical routines with regards to prophylactic strategies.

The purpose of the second part of the questionnaire was to determine the incidence of endophthalmitis after cataract surgery in 2013 in each hospital and to assess whether the ESCRS recommendations with regards to intracameral cefuroxime were followed. Furthermore, allergic or toxic reactions with intracameral cefuroxime were queried.

### Statistical analysis

The results were analyzed using StataMP11 statistical software (Stata Corp., College Station, TX, USA; 2011). First, a descriptive analysis of the centers was conducted, considering the number of infectious endophthalmitis cases per 1,000 cataracts, as well as the hospital type. Results were expressed in frequencies and percentages. Endophthalmitis incidences at the various participating institutions were dichotomized as <0.13% vs >0.13%. A descriptive analysis of the use of perioperative antibiotics and/or intracameral antibiotics, possible side effects, and the use of postoperative antibiotics was then carried out. Finally, a univariate analysis was performed in order to highlight which outcomes were related to a rate of endophthalmitis higher or lower than the expected acceptable value of 0.13%. For all analyses, the  $\alpha$  level was set at 0.05.

## Results

Our survey mirrors real-world practice patterns to prevent postcataract endophthalmitis among a spectrum of private and academic settings with varying surgical volumes in 2013.

The overall volume of cataract operations in the 24 centers in 2013 was 43,553.

Center characteristics are shown in Table I: 8 hospitals were public, 10 were academic, and 6 were private operating within the Italian National Health System. Eleven centers showed an incidence of postcataract endophthalmitis lower than 0.13% and 13 centers showed an incidence higher than 0.13%.

Table II shows the methods used to prevent postoperative endophthalmitis. All surgeons used preoperative conjunctival povidone-iodine. The use of subconjunctival antibiotics was not reported and only in 2 centers was vancomycin used in the infusion bottle. The majority of surgeons (71%) used preoperative antibiotic eyedrops and 63% of them recommend starting a perioperative topical antibiotic 3 days before the scheduled cataract surgery. Fluoroquinolones were the preferred preoperative topical antibiotic for cataract surgery (ofloxacin, ciprofloxacin, and levofloxacin, in order of frequency). Thirteen centers (54%) used intracameral cefuroxime at the end of surgery. Surgeons used more than one antibiotic as a postoperative prophylaxis according to local microbiological surveillance (chloramphenicol + fluoroquinolones, netilmicin + fluoroquinolones). The majority of cataract surgeons did not taper antibiotics during follow-up.

TABLE I - Description of the centers

	No. (%)
Annual surgical procedures volume	
≤1,999	5 (20.8)
2,000-3,999	13 (54.2)
≥4,000	6 (25.0)
Annual cataract volume	
≤999	4 (16.7)
1,000-1,999	13 (54.2)
≥2,000	7 (29.2)
Number of infectious endophthalmitis cases per 1,000	
<0.13	11 (45.8)
≥0.13	13 (54.2)
Geographic area	
Northwest	4 (16.7)
Northeast	9 (37.5)
Central	5 (20.8)
South	6 (25.0)
Hospital type	
Public	8 (33.3)
Teaching	10 (41.7)
Private operating with the National Health System	6 (25.0)

TABLE II - Description of the therapies used

	No. (%)
Your preferred perioperative topical antibiotic	
Don't use	5 (20.8)
Ofloxacin or ciprofloxacin	11 (45.8)
Levofloxacin	6 (25.0)
Gatifloxacin or moxifloxacin	-
Other	2 (8.3)
When do you start perioperative topical antibiotic?	
Don't use	4 (16.7)
3 days before	15 (62.5)
1 day before	1 (4.2)
Upon arrival at hospital	4 (16.7)
Use of intracameral antibiotics	
Don't use	8 (33.3)
Cephalosporin (e.g., cefuroxime) direct injection	10 (41.7)
Cephalosporin (infusion bottle)	-
Vancomycin (direct injection)	1 (4.2)
Vancomycin (infusion bottle)	2 (8.3)
Quinolone (direct injection)	-
Quinolone (infusion bottle)	-
Other antibiotic (direct injection)	1 (4.2)
Other antibiotic (infusion bottle)	-
More than one choice	2 (8.3)
How do you give antibiotics at the end of the surgery?	
Topical	8 (33.3)
Subconjunctival	-
Intracameral	7 (29.2)
None of the above	1 (4.2)
More than one choice	8 (33.3)
Who prepares your intracameral antibiotics?	
Nursing staff	15 (65.5)
Pharmacy	-
Surgeon	1 (4.2)
Don't use intracameral antibiotic	8 (33.3)
Have you ever had a complication from using "homemade" intracameral antibiotics?	
Don't use them	9 (37.5)
No, despite using them	14 (58.3)
Infection	-
Inflammation	1 (4.2)
Corneal endothelial injury	-
Do you administer antibiotics at the conclusion of the surgery?	
Topical application	13 (54.2)
Subconjunctival injection	-
Collagen shield	-
Intracameral injection	5 (20.8)
None of the above	1 (4.2)
More than one choice	5 (20.8)

To be continued

TABLE II - continued

	No. (%)
When do you start postoperative topical antibiotic?	
Don't use	-
The day of the surgery	16 (66.7)
Postop day 1	8 (33.3)
For how long do you continue postoperative topical antibiotic?	
Don't use	-
One week or less (no taper)	11 (45.8)
Several weeks (no taper)	6 (25.0)
Taper off during several weeks	7 (29.2)
What intracameral antibiotics do you use?	
I don't use intracameral antibiotics	7 (29.2)
Cefuroxime	13 (54.2)
Vancomycin	2 (8.3)
Quinolone	1 (4.2)
More than one	1 (4.2)
If you do not currently use intracameral cefuroxime, which of the following have contributed to this decision?	
Risk of dilution errors	-
Risk of bacterial contamination	-
Risk of endothelial toxicity	3 (30.0)
Lack of commercially available preformulated preparation	4 (40.0)
More than one choice	3 (30.0)
If a commercially available preformulated preparation of cefuroxime for intracameral use were available, would you use it?	
Yes	19 (82.6)
No	4 (17.4)
If you use intracameral cefuroxime, do you consider penicillin allergy a contraindication?	
Yes	10 (50.0)
No	10 (50.0)

Table III shows the association of endophthalmitis by therapy used. Thirteen centers (54%) used intracameral cefuroxime at the end of surgery. Of the 13 centers that used cefuroxime, 8 (62%) had an incidence of endophthalmitis less than 0.13%. Of the 7 (29%) centers that did not use intracameral cefuroxime, all had an endophthalmitis rate greater than 0.13%. This difference was statistically significant ( $p < 0.05$ ). Among the 4 centers not included, 2 used vancomycin in the infusion bottle, 1 a fluoroquinolone, and the last a combination of antibiotics. In one of the centers where vancomycin was used, the incidence of endophthalmitis was lower than 0.13%. In the center where a fluoroquinolone was used and in the center where a combination of cefuroxime + vancomycin was used, the incidence of endophthalmitis was found to be lower than 0.13%. The use of preoperative antibiotics was not shown to be significantly associated with a reduction in the incidence of endophthalmitis. Our data showed no differences in the incidence of postcataract endophthalmitis between high-volume and low-volume centers.

TABLE III - Univariate analysis

	Infectious endophthalmitis cases per 1,000		
	<0.13	≥0.13	p
Annual cataract volume			
≤999 (n = 4)	2 (50.0)	2 (50.0)	0.974
1,000-1,999 (n = 13)	6 (46.1)	7 (53.8)	
≥2,000 (n = 7)	3 (42.9)	4 (57.1)	
How do you give antibiotics at the end of the surgery?			
Topical (n = 8)	1 (12.5)	7 (87.5)	0.057 <sup>a</sup>
Subconjunctival (n = 0)	-	-	
Intracameral (n = 7)	3 (42.9)	4 (57.1)	
None of the above (n = 1)	1 (100.0)	-	
More than one choice (n = 8)	6 (75.0)	2 (25.0)	
What intracameral antibiotics do you use?			
I don't use intracameral antibiotics (n = 7)	-	7 (100.0)	0.048 <sup>a</sup>
Cefuroxime (n = 13)	8 (61.5)	5 (38.5)	
Vancomycin (n = 2)	1 (50.0)	1 (50.0)	
Quinolone (n = 1)	1 (100.0)	-	
More than one (n = 1)	1 (100.0)	-	
Who prepares your intracameral antibiotics?			
Nursing staff (n = 15)	9 (60.0)	6 (40.0)	0.050 <sup>a</sup>
Pharmacy	-	-	
Surgeon (n = 1)	1 (100.0)	-	
Don't use intracameral antibiotic (n = 8)	1 (12.5)	7 (87.5)	
Your preferred perioperative topical antibiotic			
Don't use (n = 5)	2 (40.0)	3 (60.0)	0.315
Ofloxacin or ciprofloxacin (n = 11)	7 (63.6)	4 (36.4)	
Levofloxacin (n = 6)	1 (16.7)	5 (83.3)	
Gatifloxacin or moxifloxacin (n = 0)	-	-	
Other (n = 2)	1 (50.0)	1 (50.0)	
When do you start perioperative topical antibiotic?			
Don't use (n = 4)	1 (25.0)	3 (75.0)	0.091 <sup>a</sup>
3 days before (n = 15)	9 (60.0)	6 (40.0)	
1 day before (n = 1)	1 (100.0)	-	
Upon arrival at hospital (n = 4)	-	4 (100.0)	
Do you administer antibiotics at the conclusion of the surgery?			
Topical application (n = 13)	5 (38.5)	8 (61.5)	0.585
Subconjunctival injection (n = 0)	-	-	
Collagen shield (n = 0)	-	-	
Intracameral injection (n = 5)	3 (60.0)	2 (40.0)	
None of the above (n = 1)	-	1 (100.0)	
More than one choice (n = 5)	3 (60.0)	2 (40.0)	0.148
Don't use (n = 0)	-	-	
The day of the surgery (n = 16)	9 (56.2)	7 (43.7)	
Postop day 1 (n = 8)	2 (25.0)	6 (75.0)	
For how long do you continue postoperative topical antibiotic?			
Don't use (n = 0)	-	-	0.544
One week or less (no taper) (n = 11)	6 (54.5)	5 (45.4)	
Several weeks (no taper) (n = 6)	3 (50.0)	3 (50.0)	
Taper off during several weeks (n = 7)	2 (28.6)	5 (71.4)	

## Discussion

We present information on current prophylactic antibiotic use for cataract surgery in Italy.

Despite the existence of internationally validated standardized protocols, there is heterogeneity regarding surgeons' efforts to prevent endophthalmitis in the real world.

It is controversial whether preoperative antibiotics or intracameral cefuroxime play a role in the routine prophylaxis of postcataract endophthalmitis (16, 17). The majority of Italian cataract surgeons use topical fluoroquinolones in the perioperative period. As no significant association was found in our survey, we cannot recommend or discourage the use of preoperative antibiotics. The overuse and repeated exposure to antibiotics may lead to the emergence of bacteria that do not respond readily to available treatments.

Our survey provides the first Italian data on the use of intracameral antibiotics in cataract surgery. There is already strong evidence that intracameral prophylaxis with cefuroxime may be effective in lowering the incidence of endophthalmitis (7-11). The ESCRS has been recommending administering cefuroxime in the anterior chamber in all cataract surgery cases since 2007 (5). However, the additional protective role of cefuroxime over the standardized protocols is a matter of debate. According to our survey, cefuroxime seems to have a protective effect. Given the low rate of incidence of endophthalmitis, it is difficult to demonstrate a greater efficacy of a preventive protocol that includes intracameral cefuroxime vs a prophylactic protocol that does not include cefuroxime; however, when the ESCRS guidelines are followed, 62% of centers that routinely use intracameral cefuroxime had an incidence of postcataract endophthalmitis lower than the acceptable 0.13% and similarly acceptable rates were found significantly less frequently among centers that did not routinely employ intracameral cefuroxime. Nevertheless, in 5 centers that routinely used intracameral cefuroxime, the incidence of postcataract endophthalmitis was higher than 0.13%. There may have been other factors than just intracameral antibiotics that contributed to higher endophthalmitis rates, including the use of perioperative topical antibiotics (type of molecule and duration of prophylaxis) and the clinical characteristics of the patients operated.

In the sample of selected hospitals included in this survey, only 13 centers (54%) used intracameral cefuroxime at the end of surgery. However, with preformulated cefuroxime now being readily available, the number of Italian cataract surgeons who use cefuroxime is increasing, as shown in Table II. Intracameral use may have gained slow acceptance by surgeons in Italy over other means of administration of antibiotics (subconjunctivally or in the infusion bottle) for technical reasons (risk of dilution errors and bacterial contamination) and concerns about endothelial corneal toxicity.

The choice of cefuroxime as an ideal prophylactic antibiotic to cover the most frequent microbiological pathogens derives from the conclusion of the Endophthalmitis Vitrectomy Study (19). Microbiological surveillance is mandatory to validate the current role of cefuroxime. When we compare microbiological surveillance (18, 20) among different studies in the United States and Europe, the list of germs involved is stable and similar, with the majority of them in the Gram+category: coagulase-negative *Staphylococci*, *Staphylococcus aureus*,

*alpha-hemolytic streptococci*, and *Streptococcus pneumoniae*. Among Gram- organisms are *Pseudomonas spp*, *enterobacteriaceae*, *Haemophilus influenzae*, *Moraxella*, and *Klebsiella*. A recent microbiological review (18) of all culture-proven cases of endophthalmitis in the last 25 years at one large institution, even though this study did not specifically look at this aspect, supported cefuroxime vs ceftazidime and/or other antibiotics that have higher resistant rates.

As far as allergic or toxic reactions are concerned, it was recently reported (21) that a patient developed an anaphylactic reaction several minutes after intracameral injection of cefuroxime at the end of uneventful phacoemulsification and intraocular lens implantation surgery. In our survey, 50% of surgeons were concerned about toxic or allergic reactions.

Choosing Wisely also is a patient-specific choice. For example, elderly patients with blepharitis, poor tear film, or anticipated prolonged surgery may be more prone to infection and therefore good candidates for intracameral or preoperative antibiotics.

It would be of clinical interest to investigate whether a correlation between specific types of germs in immunocompromised patients may be demonstrated, such as those with diabetes, cancer, or long-term treatment with steroids.

Cost-effectiveness analyses are also warranted. A retrospective study carried out at the University of Udine, Italy, in 2013 showed that the use of commercially available intracameral antibiotics is not cost-effective in the prevention of postcataract endophthalmitis compared to the costs of vitrectomy for endophthalmitis, given the rare occurrence of postcataract endophthalmitis (Prof. P. Lanzetta and coworkers, personal communication, Pordenone, Italy, September 2014).

Strengths of our study are the enrollment of a variety of private, public, and academic settings across Italy. This is the first Italian survey on the subject to employ e-mail questionnaires for data collection. The method offers advantages over postal surveys and telephone interviews, as direct dialogue among the epidemiologists (F.B., R.G., R.S.), the principal investigator (A.G.), and cataract surgeons (complete list reported in the Appendix) allows clarification of query answers and additional queries, and leaves time for a better retrospective analysis. Each center involved in the survey was blind regarding the participation of the other centers.

Limitations include the retrospective nature of our study. There may have been other factors than just intracameral antibiotics that contributed to lower endophthalmitis rates. Randomized controlled trials with rare outcomes require very large sample sizes and are costly or even cost-prohibitive to conduct. Further, we could not perform a health technology assessment analysis given the absence of uniform data and sufficient studies. We are aware that case-control studies or models could have provided more solid scientific data than a survey. A high cutpoint for an acceptable level of endophthalmitis was decided on (0.13%): in a systematic review, an aggregate incidence of endophthalmitis occurring after cataract surgery of 0.128% was found (3). Further, the cutoff decided in our survey was lower than the level found in the cefuroxime study (5). We are aware that it would have been desirable to have a lower than reported average level of endophthalmitis; however, dealing with rare clinical events, the choice of lower cutpoint may have weakened the association.

In conclusion, when we compare routine clinical practice in the sample of Italian hospitals enrolled in this survey with ESCRS guidelines and best available evidence, the use of cefuroxime at the end of surgery was lower than expected. Our survey shows that an incidence of endophthalmitis greater than 0.13% was encountered significantly more frequently among centers that did not employ intracameral cefuroxime. The majority of surgeons in our survey (83%) said they would use cefuroxime if a preformulated preparation of cefuroxime for intracameral use were commercially available (22).

## Appendix

List of centers examined by region (from north to south)

- Piemonte  
Torino (NHS and University): Claudio Panico, MD, Francesco Faraldi, MD, and Savino D'Amelio, MD  
Borgomanero (NHS): Vito Belloli, MD, Vincenzo Ferrara, MD
- Lombardia  
Milano (University): Paolo Nucci, MD, Edoardo Villani, MD  
Brescia (University): Francesco Semeraro, MD  
Milano (University): Matteo Cereda, MD  
Brescia (private hospital operating with NHS): Barbara Parolini, MD  
Milano (private hospital operating with NHS): Mario Romano, MD
- Veneto  
Venezia (NHS): Antonella Franch, MD  
Verona (University): Giorgio Marchini, MD, Piero Ceruti, MD  
Treviso (NHS): Giuseppe Scarpa, MD  
Negrar (private hospital operating with NHS): Grazia Pertile, MD, Guido Prigione, MD
- Emilia Romagna  
Reggio Emilia (NHS): Luigi Fontana, MD  
Ravenna (NHS): Cesare Forlini, MD  
Parma (University): Nicola Ungaro, MD
- Marche  
Ancona (University): Cesare Mariotti, MD
- Toscana  
Pisa (NHS): Stanislao Rizzo, MD, Francesco Barca, MD  
Pisa (University): Michele Figus, MD
- Umbria  
Perugia (NHS): Tito Fiore, MD
- Lazio  
Roma (NHS): Tommaso Rossi, MD
- Campania  
Acerra (private hospital operating with NHS): Aldo Gelso, MD  
Napoli (private hospital operating with NHS): Otello Gallo, MD  
Napoli (NHS): Beniamino Mastursi, MD  
Pompei (private hospital operating with NHS): Dario Furguele, MD
- Calabria  
Catanzaro (University): Vincenzo Scoria, MD
- Sardegna  
Sassari (University): Francesco Boscia, MD

NHS = National Health System.

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