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Surgical, antiseptic, and antibiotic practice in cataract surgery: Results from the European Observatory in 2013

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PURPOSE: To report the results from the first iteration of the European Observatory of Cataract Surgery, which was initiated to track changes in surgical, antiseptic, and antibiotic practices in cataract surgery over the coming years.

SETTING: Practicing European cataract surgeons (n = 479).

DESIGN: Internet-based declarative questionnaire or telephone questionnaire.

METHODS: The questionnaire comprised 37 questions divided into 8 categories as follows: screening, surgeon profile, surgical procedure used, product use before arrival at the operating room, techniques for mydriasis and anesthesia, product use during the surgery, product use after the patient leaves the operating room, and surgeon’s attitude to guidelines.

RESULTS: Cataract surgeons (n = 2700) were initially contacted, of whom 479 (17.7%) were included in the survey. The current baseline survey revealed considerable variation between countries in their implementation of infectious postoperative endophthalmitis (IPOE) prophylaxis. In some countries, adoption of intracameral cefuroxime is almost universal, whereas in others, the use of such prophylaxis is below one half. When intracameral cefuroxime is used, it is generally cefuroxime powder designed for parenteral use. A preparation specifically registered for intracameral use is now available, and this formulation is more commonly used in countries in which intracameral cefuroxime was most widely adopted.

CONCLUSION: The baseline results from this ongoing survey suggest a considerable level of heterogeneity between European countries in IPOE prophylaxis. Further iterations of this survey will monitor whether a consensus begins to emerge.

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Infectious postoperative endophthalmitis (IPOE) is among the most feared adverse events of cataract surgery and, although rare, is always serious and frequently sight-threatening. The European Team for the Prophylaxis of Infection in Cataract Surgery (ETHICS) group is a pan-European expert group established to examine procedures used for the prevention of endophthalmitis. Early in its deliberations, it became clear that there was considerable variation in practices and processes in cataract surgery between different European countries. In this context, a survey of cataract surgery practice, with particular emphasis on infection prophylaxis, was undertaken in 9 European countries.
The present report represents the results from the first iteration of the European Observatory of Cataract Surgery, a survey that will be repeated in subsequent years to monitor changes in practice in the light of such factors as the most recently published iteration of The European Society of Cataract and Refractive Surgeons (ESCRS) guidelines and the availability of new prophylactic treatments and processes.

Although the focus of this study is the use of intracameral antibiotics, many other factors during surgery are pertinent to the prevention of IPOE. Pre- and postsurgical procedures contribute to IPOE risk; the ESCRs study, for example, identified a number of factors, including the location of the incision, as risks for IPOE.

METHODS

Subjects

Survey subjects were identified from databases of ophthalmologists from specialized organizations and a recruitment organization (Stethos, Sevres, France) in France, the United Kingdom, Sweden, Spain, Italy, the Netherlands, Belgium, Poland, and Germany. The fieldwork was undertaken between April 15, 2013, and May 31, 2013. The survey was in accordance with the European Pharmaceutical Market Research Association code of conduct.

A total of 2700 ophthalmologists were contacted. To be eligible to participate, the surgeons were required to have at least 5 years of practice as an ophthalmic surgeon and to undertake at least 150 cataract operations each year. A maximum of 3 surgeons per center was allowed. A quota of surgeons was allocated pro-rata per country, according to the number of ophthalmologist surgeons in each country. A weighting adjustment was applied according to the number of cataract operations performed in each country.

The survey was undertaken via an Internet-based declarative questionnaire in all countries except in Poland, the Netherlands, and Belgium, where interviews by telephone were preferred.

Questionnaire

The questionnaire comprised 37 questions divided into 8 categories: screening, surgeon profile, surgical procedure used, product use before arrival at the operating room, techniques for mydriasis and anesthesia, product use during the surgery, product use after the patient leaves the operating room, and surgeon's attitude to guidelines.

RESULTS

Demographics

A total of 2700 surgeons were initially contacted; after screening and allocation according to national populations of ophthalmologists 479 (17.7% of the total contacted), European surgeons representing 243,927 cataract operations were recruited in 9 countries (Table 1). They had been undertaking cataract surgery for a mean of 16.8 years. Only 3% had been operating for more than 30 years. Of the 243,927 cataract surgeries represented by the cohort, the mean number of operations per year was 509, with 33% of surgeons undertaking between 201 and 400 operations per year (Table 2).
Surgery was most frequently performed in the context of a general hospital (40%) or university hospital (18%), with 26% of the procedures being performed in private practice. The great majority (81%) of respondents were hospital doctors, with 19% being either head of clinic or head of department. Those in their middle age dominated the age distribution.

**Surgical Technique**

Of all surgeries, 97.9% used phacoemulsification. Only 0.5% of the procedures were performed with femtosecond laser. There were no differences of note between the countries. A clear corneal incision was used in 65% of operations and limbal in 31%, the remainder being scleral. There was a considerable degree of heterogeneity between countries in terms of preferred positioning of the incision; whereas the temporal approach was preferred in 40% of cases overall, in Sweden it accounted for 72% of cases, and in the Netherlands, only 12% of surgeons used this approach. Similarly, the Spanish cohort reported using the supero-temporal approach in 47% of cases (versus a group mean of 18%). Surgical technique was predominantly coaxial (65% overall) rather than bimanual. The size of the main incision was between 2.2 and 2.7 mm in the majority (62%) of surgeries and relatively consistent between countries.

Additional incisions were required in 86% of operations overall, with highest frequencies in the United Kingdom, Belgium, and the Netherlands (99%). The number of additional incisions varied considerably; in the United Kingdom, France, Spain, and Sweden, only one single extra incision was typically performed (58%, 76%, and 82%, respectively), whereas in Germany, Poland, Belgium, and the Netherlands, more than one extra incision was used to a higher extent.

**Anesthesia**

Anesthesia was almost entirely local rather than general, with eyedrops being used most frequently (67%) either alone or with intracameral (21%), peribulbar (19%), sub-tenon (9%), gel (6%), retrobulbar (5%), and subconjunctival (1%) anesthesia. Intracameral anesthesia is also frequently used (35% to 40%) in the United Kingdom, Spain, and Poland.

**Product use Before Arrival in the Operating Room**

The use of antibiotics (topical and oral), ocular antiseptics, eyelid hygiene, skin hygiene, and anti-inflammatory agents is summarized in the first panel of Figure 1.

Antibiotics (all routes of administration) were used in 42% of cataract surgeries and anti-inflammatory drugs (all routes of administration) by 32%. Eyelid hygiene was the least common procedure (23%), but large differences between countries were observed (58% of surgeries in Spain).

**Antibiotics**

Before arrival at the operating room, systemic or topical antibiotic was used in only rarely in the United Kingdom (3.5%) and in Sweden (7.3%) (versus a group mean of 42%), with much higher figures for Spain, Italy, Poland, and the Netherlands (all greater than 65%). In the great majority of cases, antibiotics were administered as eyedrops (93%); use of systemic antibiotics was reported in 14% of cases. Ofloxacin was the most commonly used antibiotic overall (32%), but it was very rarely used in Sweden (0.3%), Belgium (0%), and the Netherlands (5%).

**Ocular Antisepsis**

Ocular antiseptic use before entering the operating facility was higher in the United Kingdom (60% compared with a group mean of 31%) and lower in Sweden and Poland (5.5% and 7.9%, respectively). Povidone iodine was the most frequent choice of antiseptic overall (25.8%); however, in Sweden, where the use of ocular antiseptic was the
lowest in the group (5.5% of cases), chlorhexidine was dominating (5.5%). Picloxydine, although rarely used elsewhere, was commonly used by French surgeons (15%).

Eyelid Hygiene Of the 23% of surgeries in which eyelid hygiene was used, 51% used a cleaning detergent, 48% used eyelid pads, and 7% used gel. Use of skin hygiene in France was more than twice the group mean (69% versus 26%).

Anti-inflammatory Drugs Anti-inflammatory drugs were administered in 32.5% of surgeries overall; rates were higher in the Netherlands and Belgium (58% and 77%, respectively). The great majority of this anti-inflammatory use was accounted for by nonsteroidal anti-inflammatory drugs (NSAIDs), 84% overall, and considerably less by steroids (6%) and antibiotic combinations of NSAIDs (6%) or steroids (6%), although in Poland, and to a lesser extent Italy, NSAID combinations with antibiotics were popular preoperatively (21.8% and 12% respectively). In the United Kingdom, Sweden, Belgium, and the Netherlands, more than 95% of all patients given anti-inflammatory agents before surgery received an NSAID.

Mydriasis Mydriasis was most commonly initiated by a nurse in the ambulatory surgical center (82%); in 14% of cases, mydriasis was initiated at home by the patients, with the remainder initiated in the operating room.

Surgeons rated “stable dilation” and “largest size of dilation” as the most important factors in mydriasis.

Eyedrops were most commonly used when mydriasis was initiated in the surgical center (77% overall), although, drug inserts were more popular in this context (22% overall) than in mydriasis initiated at home. Inserts were the majority choice among surgeons in Belgium (79%) and also commonly used in France (55%) and the Netherlands (36%). The use of such inserts does not yet appear to be widespread in the other countries; the inserts are not available at all in Poland, for example. The comparative results should be interpreted with this in mind.

When mydriasis was initiated in the operating room, eyedrops were used in the majority of surgeries (56%), but intracameral injection was also commonly used (22%).

Additional mydriasis was reported in 18.3% of cataract operations overall and in up to 27% of cases in Sweden. When additional mydriasis was required, adrenaline (epinephrine) was the most commonly used drug (47% overall).

Product Use in the Operating Room

The use of antibiotics, ocular antiseptics, and eyelid and skin antisepsis is summarized in the middle panel of Figure 1.

Antisepsis Skin disinfection was used in the great majority of cataract surgery cases (83.9% overall), with some national variation from 100% in the Netherlands to less than 70% in Italy and Sweden. Povidone iodine was by far the most commonly chosen antiseptic for skin disinfection during surgery. A notable exception was Sweden, where it was not used at all, with
surgeons preferring chlorhexidine (used in 60.3% of all surgeries). Other antiseptics such as picloxydine, alcohol, and povidone were used much less frequently.

The use of antiseptics for eye disinfection followed a similar pattern to skin disinfection (instillation into the conjunctival sac), being used in 81.1% of surgeries overall.

**Antibiotics**

Antibiotics (regardless of route of administration) were used during surgery in 75.6% of all procedures (Figure 1, middle panel) and in more than 90% of surgeries in Spain, Poland, Belgium, and the Netherlands, although somewhat less frequently in the United Kingdom (63.8%) and Italy (54.6%). In Sweden, 51.2% of surgeons reported antibiotic use during surgery but 100% reported using intracameral antibiotics. This paradox is possibly caused by an ambiguous translation of this specific question into the Swedish language.

Cefuroxime was the antibiotic most frequently chosen for use during surgery (41.9% of all surgeries; 93% direct intracameral injection, 3% conjunctival, 2% by infusion in the irrigation bottle, and 1% each as eyedrops or intravenous), although in Germany there was a preference for gentamicin over cefuroxime (39.8% versus 14.6%, all routes of administration). In the operating room, no other antibiotic was used in more than 10% of surgeries overall, although vancomycin and levofloxacin were used more commonly in Germany than other countries (22.9% and 12.1%, respectively, versus group means of 8.3% and 7.1%, respectively, all routes of administration). Gentamicin, vancomycin, and levofloxacin were used with approximately equal frequency (11.4%, 9.8% and 11.6%, respectively, all routes of administration). In Poland cefuroxime, both intracameral and topical was used in 27.3% of cases only, and levofloxacin, moxifloxacin, and ofloxacin were used more commonly than in the group as a whole.

The great majority of cefuroxime use was by direct intracameral injection (93%); vancomycin and gentamicin were also administered by direct intracameral injection (31% and 10% respectively), but the majority of their use was in the irrigation fluid (69% and 41% respectively). Tobramycin/dexamethasone was given predominantly as an ointment (91%) and levofloxacin as eyedrops or intravenously (83% and 15%, respectively) (Table 3).

Intracameral antibiotics were used routinely by 66% of surgeons overall, most commonly in Sweden and Spain (100% and 95% respectively), and least frequently in Germany and the Netherlands (36% and 40%, respectively). Twenty-nine percent of surgeons stated that they did not use intracameral antibiotic during surgery, whereas 5% reported using intracameral antibiotics only in specific patient groups, most frequently in those with diabetes (22%), those considered at risk of infection (22%), or those with a history of eye infection (18%). Of the surgeons who used intracameral antibiotics either routinely or in particular patient groups, 77% reported that the antibiotic injection was prepared by operating nurses. In the remainder, the injection was prepared by an internal pharmacy (20%), an external provider (9%), or by the surgeon (7%). Although branded cefuroxime was used by most surgeons (66%) for intracameral injection, 35% were already using the recently licenced product (Aprokam); the remainder continued to prepare intracameral injection by dilution of injectable brands. The remainder used predominantly generic cefuroxime (Figure 2).

Of the surgeons who used dilute, off-label antibiotics for intracameral injection, 4% reported issues,

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**Table 3. Route of administration of antibiotics administered in the operating room in cataract surgery.**

<table>
<thead>
<tr>
<th>Antibiotic</th>
<th>Overall Use</th>
<th>Intracameral</th>
<th>Eyedrops</th>
<th>Ointment</th>
<th>Sub-conjunctival</th>
<th>Irrigation Fluid</th>
<th>Intravenous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefuroxime</td>
<td>42%</td>
<td>93%</td>
<td>1%</td>
<td>3%</td>
<td>2%</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Gentamycin</td>
<td>11%</td>
<td>10%</td>
<td>9%</td>
<td>20%</td>
<td>19%</td>
<td>41%</td>
<td>2%</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>8%</td>
<td>31%</td>
<td></td>
<td></td>
<td></td>
<td>69%</td>
<td></td>
</tr>
<tr>
<td>Levofloxacin</td>
<td>7%</td>
<td>83%</td>
<td>2%</td>
<td></td>
<td></td>
<td>15%</td>
<td></td>
</tr>
<tr>
<td>Tobramycin/dexamethasone</td>
<td>4%</td>
<td>6%</td>
<td>91%</td>
<td></td>
<td></td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>Tobramycin</td>
<td>4%</td>
<td>4%</td>
<td>41%</td>
<td>27%</td>
<td>1%</td>
<td>26%</td>
<td>1%</td>
</tr>
<tr>
<td>Moxifloxacin</td>
<td>3%</td>
<td>17%</td>
<td>79%</td>
<td></td>
<td></td>
<td>4%</td>
<td></td>
</tr>
<tr>
<td>Ofloxacin</td>
<td>2%</td>
<td>99%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1%</td>
</tr>
<tr>
<td>Chloramphenicol</td>
<td>1%</td>
<td>56%</td>
<td>44%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
predominantly dilution errors (73%). Of the few surgeons who had issues, the reported consequences were epithelial wound-healing disorders and inflammation in equal number.

Product Use After the Patient Leaves the Operating Room

The use of antibiotics and anti-inflammatory products is summarized in the right-hand panel of Figure 1.

Antibiotics Antibiotics (not including fixed combination with other agents) were prescribed in 44% of surgeries, 93% in eyedrops, 8% orally, and 3% as ointment. A variety of drugs were used topically, but tobramycin, ofloxacin, levofloxacin, chloramphenicol, moxifloxacin, and azithromycin together accounted for 68% of all surgeries when topical antibiotics were used (22%, 22%, 12%, 11% and 10% and 7%, respectively). Azithromycin, gentamicin, ciprofloxacin, amoxicillin, and other antibiotics were all below 10%. Antibiotic treatment was typically commenced on the day of surgery or the day after. Antibiotics prescribed after surgery were predominantly eyedrops to be administered 3 to 5 times daily. For those given orally (8%), ofloxacin, amoxicillin, and cefuroxime were most frequently used (34%, 34%, and 16% respectively).

In addition, a fixed combination of steroid/antibiotic was used in 43% of cases and nonsteroidal anti-inflammatory-antibiotic agent in 5% of cases, predominantly topically.

There was a considerable degree of variation in the use of antibiotics between countries (Figure 3); in the United Kingdom, 89% of patients were prescribed antibiotics after surgery and 70% of these patients received chloramphenicol, an antibiotic that was used infrequently, if at all, in other countries. In Sweden, the Netherlands, and Belgium, antibiotics (as single agents, not including fixed combinations with anti-inflammatory drugs) were used in less than one fifth of surgeries (13.1% 17%, and 18.7% respectively). There appeared to be little obvious pattern in the choice of antibiotic; although tobramycin was most frequently used, it was not used at all in Germany and only rarely in the United Kingdom. Ofloxacin, the second most common choice overall, was the most popular antibiotic in Germany, Italy, Poland, and the Netherlands but was not used at all in Spain or Sweden and only occasionally in Belgium.

Anti-inflammatory Drugs Anti-inflammatory drugs were widely used postoperatively (95% overall either administered alone or in fixed combinations with an antibiotic), and, of these, steroid/antibiotic combinations were most commonly used (47%), typically as eyedrops (94%). In 62% of cases receiving antibiotics, a duration of more than 2 weeks was used and 44% of treatments were tapered. NSAIDs were also commonly used (40%), again most frequently as eyedrops (95%) and usually with a duration of more than 2 weeks (71%). Steroids were given in 34% of cases, 95% as eyedrops. NSAID/antibiotic combinations were used less frequently (5%). Anti-inflammatory medication was generally started on the day of surgery or the day after and was usually continued for more than 2 weeks. Fixed combinations...
of antibiotic and anti-inflammatory drugs were very infrequently used in Sweden (0.6%).

**Guidelines**

Most commonly, surgeons reported following local hospital guidelines (41% overall), although scientific society and national guidelines were also considered important (32% for each), but European guidelines less so (13%). Only 8% of respondents reported that they did not follow any guidelines.

There were considerable national differences in the adoption of guidelines. (Figure 4)

**DISCUSSION**

The present study provides a baseline for an annual series of updates of the European Observatory on Cataract Surgery, ahead of anticipated updated ESCRs guidelines and the more widespread introduction of licensed intracameral cefuroxime.

Considerable variation is evident in most variables examined in this study; with the exception of the near universal adoption of phacoemulsification, almost every aspect of cataract surgery, from the technique and placement of the main incision to the choice of postoperative antibiotic prophylaxis, appears to be the subject of considerable diversity. However, it is in the main topic of this study, prophylaxis against IPOE, that such variability in national practice is most evident. Before arrival at the operating room, the use of antibiotics (both oral and topical) ranged between 4% and 80%, ocular antiseptic between 5% and 60%, eyelid hygiene between 1% and 58%, and skin hygiene between 4% and 69%. Similar heterogeneity was observed in the choice of oral and topical antibiotics used before arrival at the operating room and those used in the operating room, although (with the exception of Sweden) a consistent preference for povidone iodine as ocular antiseptic was evident.

For a procedure as common as cataract surgery, such wide variation in practice patterns might appear surprising. However, the national differences probably reflect a surgical procedure in the process of change, particularly in the context of efforts to reduce IPOE as well as the reliance on local rather than international guidelines evident in this study. The widespread use of antisepsis and antibiotic use reported during and after cataract removal clearly attests to a considerable emphasis on IPOE prophylaxis. However, despite IPOE being the most unwelcome complication of cataract surgery, there appears to be little consensus, at least among the sample polled in this survey regarding the optimal methodology for prevention of IPOE.

The seriousness of IPOE makes it is reasonable to take measures above and beyond strict antiseptic procedures to avoid it. The history of intracameral cefuroxime commenced in Sweden, where preliminary studies showed it to be effective in reducing the incidence of IPOE. A subsequent large, prospective,
randomized international study showed a convincing clinical benefit. In Sweden, as evidenced in the current study, the use of intracameral cefuroxime is almost universal. In the present study, intracameral cefuroxime was used routinely in two thirds of cataract removal procedures, although national differences were significant; in Sweden and Spain, almost all procedures used intracameral cefuroxime, whereas in Germany and Holland it was used in less than half the procedures. Only 29% of surgeons did not use intracameral cefuroxime at all, the remaining 5% reserving it for patients at particular risk or those who had a history of eye infection, diabetic patients, and others considered to be at particular risk.

At present, only a single formulation of intracameral cefuroxime is licensed (Aprokam/Aprok/Prokam, Laboratoires Théa, Clermont Ferrand, France) Europe-wide, but even this was not universally available at the time of this study. Not surprisingly, the use of the licensed product was more common in those countries where it has been available for the longest time. Preparation of intracameral cefuroxime by dilution of branded or generic parenteral formulations is also used by some surgeons in countries where the licensed formulation is available, presumably as parenteral cefuroxime is considered cheaper than the licensed alternative, although the possible consequences of dilution errors and the cost of preparation are not taken into account.

Preparing a solution of cefuroxime suitable for intracameral injection from powder designed to be used for parenteral systemic administration requires a number of sequential steps that increase the risk of dilution errors as well as the possibility of contamination, although in the present study, respondents seemed relatively unconcerned about such issues. A strong preference for the availability of commercially prepared cefuroxime preparations specifically designed for the intracameral route has been voiced in other contexts. The relative unavailability of a specific registered formulation is believed to be responsible, at least in part, for the slow adoption of intracameral cefuroxime into clinical practice. Moreover, the accuracy of dilutions can depend on the exact protocol used, and the single-use nature of the commercial preparation helps further reduce the risk of microbial contamination. In a previous phone survey, 77% of 250 ESCRs members interviewed said they always or usually use intracameral antibiotics in their cataract surgery procedures. The most frequently cited reasons for not using cefuroxime or other intracameral antibiotics was the lack of an approved commercial preparation and related anxieties regarding the risk of dilution errors and contamination. More than 90% of respondents said they would use cefuroxime if an approved single-unit-dose product were commercially available.

Sweden presents somewhat of a special case in that the use of intracameral cefuroxime during cataract surgery is very widespread, which seems to have effects on the other decisions in IPOE prophylaxis: use of preoperative antibiotics is considerably lower than in other countries (7.3% versus a group mean of 42%);
chlorhexidine was preferred over povidone iodine for intra-surgical skin disinfection; eyelid hygiene was practiced far less frequently than in most countries; intracameral cefuroxime was, in 90% of cases, administered as the registered preparation rather than diluted from generic parenteral cefuroxime; and finally, Sweden had the lowest rate of post-surgical antibiotic prescription. It is also evident that a closer consensus on procedure exists among Swedish ophthalmic surgeons than among their colleagues in other countries, despite the absence of any formal national guidelines in Sweden.

The results of the European Observatory on Cataract Surgery 2014 and its subsequent iterations are anticipated with interest to determine how national and international practice alters with changes to ESCRIS guidelines and more widespread availability of registered formulation of intracameral cefuroxime.

WHAT WAS KNOWN

- A variety of means exist for the prophylaxis of IPOE during cataract surgery.
- Recent studies indicate that the use of intracameral cefuroxime significantly reduces the risk of IPOE associated with cataract surgery.

WHAT THIS PAPER ADDS

- There was a very large degree of national heterogeneity in the use of intracameral cefuroxime.
- Most intracameral cefuroxime was prepared locally from preparations intended for parenteral use.
- This study provides a baseline to monitor changes in the adoption of intracameral cefuroxime as a specific intracameral formulation becomes more available.

REFERENCES