The study's investigators and management team included study chairman Peter Barry FRCS, Royal Victoria Eye & Ear Hospital and St Vincent's University Hospital, Dublin, Ireland and study coordinator David Seal MD, FRCCOphth, Applied Vision Research Centre, City University, London. In addition, Prof George Gettrinby PhD and his team at the Department of Statistics and Modelling Science, University of Strathclyde, Glasgow, Scotland, provided the statistical design and analysis of the study, and Crawford Revie PhD, at the University of Strathclyde's department of computer and information sciences oversaw the information technology aspects of the study.

Intracameral antibiotics adopted for all intraocular procedures

Günter Grabner MD, a clinical partner in the ESCRs endophthalmitis prophylaxis study told EuroTimes that as a result of the study’s findings, he now uses intracameral injections of cefuroxime in all procedures which penetrate the eye, including cataract surgery, keratoplasty, trabeculectomy and vitrectomy procedures. “Every operation at our clinic that opens the eye gets cefuroxime, there is no good sense in not giving it to them,” said Dr Grabner, University Eye Clinic, Paracelsus Private Medical University, Salzburg, Austria.

He noted that he did not use intracameral injections of cefuroxime prior to the study because the rate of endophthalmitis was already fairly low at his centre. He attributed their previous low rate of the complication to their standard routine application of betadine to the eye for three minutes prior to surgery. “We used betadine extensively with a standard routine of three minutes. David Seal handed out stopwatches to all the centres so that they would do likewise. But I’m convinced that using cefuroxime intracamerally decreases the rate further,” he added.

Dr Grabner said that he was not surprised by the study’s finding that clear corneal incisions increase the risk of endophthalmitis. His centre was one of two centres that routinely used scleral tunnel incisions in their cataract surgery, a practice he has long advocated.

“What was nice for me was that it showed there was really a difference between doing clear corneal incisions and scleral tunnel incisions. That is something I have always pointed out to my assistants, because if you have a scleral tunnel it covers up the incision. This was shown by this study, which was again a landmark finding,” he said.

On the other hand, Dr Grabner said he still continues to use silicone IOLs. He suggested that scrupulous application of Betadine together with intracameral cefuroxime probably eliminates most of the risk associated with the lenses. He also cited a recent study by Rupert Menapace MD at the University of Vienna, which showed that, contrary to the findings of studies with a shorter follow-up, the risk for secondary cataract is much lower in the longer term with silicone IOLs than it is with other lens types.

He added that he welcomes the fact that the ESCRs has become actively involved in organising and carrying out research. “It’s wonderful that the ESCRs is not just organising congresses and meetings but also embarking on this kind of research. The way that they handled this topic and presented the findings at last year’s ESCRs Congress to an audience of 4,000 ophthalmologists was great. There’s no single country that can ignore this study,” he said.

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Rigorous study design

The study was designed to evaluate the prophylactic effect of intracameral cefuroxime with or without perioperative topical levofloxacin on postoperative endophthalmitis after cataract surgery. Secondary questions included finding a more reliable estimate of the true rate of endophthalmitis and identifying risk factors for the complication.

Patients in the study were randomised into four treatment groups. One group received vehicle drops perioperatively and no intracameral injection. The second group received placebo drops and an intracameral injection of 1.0mg of cefuroxime in 0.1ml saline at the end of surgery. The third group received levofloxacin eye drops perioperatively but no intracameral injection and the fourth group received both perioperative levofloxacin eye drops and intracameral cefuroxime. All groups received povidone iodine pre-operatively and topical levofloxacin postoperatively for six days.

The intracameral regimen in the trial is identical to that now widely adopted in Sweden, which has the lowest rate of endophthalmitis worldwide. Cefuroxime is active against the majority of bacteria implicated in endophthalmitis, including most staphylococci and streptococci, many Gram-negative organisms p. acne and the diphtheroids.

The study’s investigators collected data from the study using a multilingual database with study-specific data-entry forms. In addition to recording the prophylactic regimen used in each case, the participating surgeons entered a range of data pertaining to the surgical style of the procedure and details about the patient.

The study’s organisers had originally aimed to include 8,750 patients in each of the four treatment groups, amounting to a total study size of 35,000 patients. However, recruitment for the study, which commenced on September 15, 2003, was terminated on January 13, 2006, when the study’s monitors detected a trend in favour of intracameral antibiotics.

At that point, among the 8,244 patients in the two groups that did not receive intracameral cefuroxime there were 23 (0.28 per cent) presumed cases of endophthalmitis, 16 (0.15 per cent) of which were proven. By comparison, among the 7,997 patients in the two groups that did receive intracameral cefuroxime there were only five (0.06 per cent) presumed cases, three (0.038 per cent) of which were proven.

In their discussion of the study’s findings, the authors note that their findings are in agreement with those of a Swedish retrospective uncontrolled study of 151,874 cataract operations with administration of intracameral cefuroxime, in which the incidence of endophthalmitis was only 0.053 per cent.

“The results presented here indicate that with the prophylactic use of intracameral cefuroxime, the incidence rate can be reduced to a level below 0.08 per cent”

Study Authors

“The results presented here indicate that with the prophylactic use of intracameral cefuroxime, the incidence rate can be reduced to a level below 0.08 per cent,” the study’s authors pointed out.

The rate of endophthalmitis among those who did not receive intracameral cefuroxime was higher than that reported in other studies, but in those studies patients received other forms of prophylaxis, which may have conferred some benefit, they added.

As regards the risk factors for endophthalmitis identified in the study, the authors noted that the finding of a significantly increased risk in patients who underwent procedures with clear corneal incisions is also supported by previous studies. However, they noted that only two out of the 24 clinics participating in the study used a scleral tunnel incision. It is therefore theoretically possible that there was a hospital or centre effect.

The finding of an increased risk of endophthalmitis with silicone IOLs is supported by some studies but contradicted...
by others. For example, one study showed that implantation of silicone IOls increased the rates of culture positive endophthalmitis by eight times. However, a group of Swedish investigators found that in their first assessment silicone IOls actually decreased endophthalmitis, but three years later could find no significant correlations between endophthalmitis and the type of IOl material used.

“One theory as to why silicone IOls might pose an increased risk has to do with the hydrophobic nature of the material. However, in the present study the use of hydrophobic acrylic IOls was not associated with an increased incidence of the complication compared to hydrophilic acrylic IOls.

“The explanation is likely more subtle, involving an understanding of how differing biofilms are formed based on the surface properties of varying types of IOls,” the study’s authors surmised.

“The results clearly show that endophthalmitis is a multi-factorial problem with associations to risk factors that depend on the attributes of the patient, the clinician, the antibiotic treatment, the surgical procedure, and the IOL materials used.”

Study Authors

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Endophthalmitis prophylaxis protocol enthusiastically adopted in Italy

Roberto Bellucci MD, Ospedale Borgo Trento, Verona, a clinical partner in the ESCRS endophthalmitis prophylaxis study told EuroTimes that the use of intracameral cefuroxime has already been widely adopted by cataract surgeons in Italy.

“This study was well appreciated in Italy and it changed the habits of the majority of surgeons. It’s a leading study and has changed the way endophthalmitis is prevented in Italy,” he said.

He noted that prior to the study he had not used intracameral antibiotics. His approach to endophthalmitis prophylaxis involved including a small amount of vancomycin in the BSS used in cataract surgery. While his rate of endophthalmitis was already quite low before the study, he said he noticed a reduced amount of subclinical infections when using the cefuroxime intracameral regimen.

“I’m happy with cefuroxime. Of course, it’s a rather old antibiotic but its advantage is its safety to the endothelium. It might be that other drugs could be tried and used, but it is my opinion that cefuroxime is here to stay for the next four to five years. After that we may move to another drug of the same safety but improved activity.”

Another practice his centre has adopted from the study is to wash the conjunctival sac with povidone iodine before surgery, which prior to the endophthalmitis study they had not performed in every case.

Dr Bellucci noted that he continues to use clear corneal incisions because of his centre’s low rate of endophthalmitis prior to the study. However, he said that it was possible that, in light of the study’s findings, he and his associates may move to making very limited conjunctival incisions. He added that he will continue to use silicone IOls but always with injectors, preferably pre-loaded.

He also said that he has now extended his indications for intracameral cefuroxime to a wide variety of intracocular procedures.

“As cefuroxime is safe for the corneal endothelium, it is also safe for retina and glaucoma surgery, in phakic lens implants and now even for posterior segment surgery,” he said.

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