Managing an outbreak of postoperative endophthalmitis

Introduction

This chapter describes a systematic approach to managing an outbreak of endophthalmitis following cataract surgery, but many of the general principles would apply equally well to other potentially repeating complications of surgery such as postoperative corneal decompensation. Endophthalmitis is one of the most serious and feared complications of cataract surgery, and although the incidence is low the morbidity is significant and return of sight is uncertain. The BOSU study estimated the incidence in the UK to be 0.14% i.e. approximately one case per 700 cataract extractions, and the visual acuity outcome for one third of the patients was worse than 6/60, and was better than 6/60 in two thirds of cases (1). Even a single case of endophthalmitis is challenging and stressful to treat. Much more so is a series of cases. Healthcare associated infection (HAI) is an area of great concern in all specialties including ophthalmology. This chapter is basically a suggested 'aide de memoire' for procedures to be followed in an outbreak of endophthalmitis.

In general terms, action comprises:

- Prompt and effective treatment of endophthalmitis cases.
- Reporting to the appropriate authorities.
- Analysis of the cause.
- Introduction of improved procedures to reduce future risk.
- Continuous audit of complications and regular monitoring of procedures.

Definition: outbreak or not?

Endophthalmitis may be defined for practical purposes as post-surgical inflammation requiring vitreous biopsy and intravitreal antibiotics, as not all cases will be culture proven.

How many cases comprise an outbreak? This is a difficult question to answer. In a sense this may be the wrong question because what we really want to be alert to is the possibility that infection has arisen from a preventable and recurring fault in the process of cataract surgery. For example one recent outbreak was identified by a slight increase in incidence over a three month period, highlighting the importance of morbidity reporting and careful audit. Just two cases with a common organism should trigger a search for batch contamination, but in the absence of incriminatory microbiology, what incidence of endophthalmitis should provoke a response? This question has generated much debate. Perhaps a graded response provides a sensible balance between complacency and overkill. Using the binomial theorem, and assuming a 1 in 700 risk of endophthalmitis (as reported in the BOSU study), there is an approximately 1 in 20 chance of two cases occurring within 270 cases; and a similar chance of three cases occurring in 630 cataract

operations, although strict adherence to these figures in attempting to identify a significantly increased incidence would cause many false alarms countrywide.

The following is proposed:

- One case: Immediately informally review the case, ideally with a colleague, to identify possible causative factors and ensure that theatre procedures and preventative measures are robust. Alert other consultant colleagues in the unit, e.g. by email. Report the case at the next audit meeting.
- Two cases in 270 or three cases in 630 or four in 1000: 'Amber alert.' Ask the microbiology department to fully subtype any organisms grown from the second and subsequent cases (and also the first if the cultures have not yet been discarded). The ophthalmology department should urgently review all likely relevant factors following the action plan below.
- Two cases in 50 or three in 300 or four in 500. 'Red alert.' As above, but in addition give serious consideration to a temporary closure of theatre(s), for reasons of patient safety, until investigation is complete and any changes made.

Note: These figures are intended as a guide for endophthalmitis following *cataract* surgery only, assuming an expected incidence of 1 in 700.

John Sparrow has developed another approach based on Monte-Carlo simulation models in order to examine the likelihood of clusters of cases occurring by chance to help recognize an outbreak. The reader is referred to the figures in his article (2).

Still not sure?

Consider also the following:

- Resume day two or day three follow-up if this is not normally undertaken
- Verify that patients are fully aware of postoperative danger symptoms.
- Ensure all reasonable preventative measures are taken.
- Cease bilateral simultaneous cataract surgery where performed.
- Ensure case reporting procedures are robust.
- Ask neighbouring units if they also have noticed an increased incidence of endophthalmitis.

Causation

Essentially there must be a source or a reservoir of the infecting organism, and there must be a means of transmission into the patient's eye.

Most cases of postoperative endophthalmitis are caused by patients' own bacterial flora (3,4). Standard procedures should aim to limit the risk from this source e.g. by isolating the lid margins with a non-permeable drape, and by using preoperative 5% povidone iodine in the conjunctival sac (5). Alternatively, the source of infection may be exogenous: for example cases may result from contaminated instruments, intraocular solutions or

implants either due to manufacturing problems, faulty sterilization, poor operating technique or theatre environment. Such cases may include fungal endophthalmitis.

Prevention

The low incidence of endophthalmitis makes it difficult to assess accurately the efficacy of preventative measures. Many studies either have low statistical power in assessing the influence of a change in procedure on the incidence of postoperative endophthalmitis, or measure surrogate outcomes such as change in conjuctival flora or aqueous bacterial counts. One literature review identified only preoperative povidone iodine as 'moderately important to clinical outcome' and other measures including preoperative topical antibiotics, preoperative saline irrigation, lash trimming, antibiotics in irrigating solutions and postoperative subconjunctival antibiotics were 'possibly relevant but not definitely related to clinical outcome' being based on weak and conflicting evidence (6). Certainly preoperative use of povidone iodine has become widely accepted as essential in non-allergic patients. More recently the ESCRS study of prophylaxis of postoperative endophthalmitis after cataract surgery has shown a benefit of intracameral cefuroxime in reducing the rate of endophthalmitis, although it should be noted that the rate in control patients was higher than other studies and in the absence of a ready prepared and diluted product the risk of dosing errors needs consideration (7). A detailed analysis of the efficacy and hazards of prophylaxis is beyond the scope of this chapter but suggestions for prevention follow: some widely accepted, and some controversial.

Preventive measures ***should*** include:

- Treatment of patients with blepharitis, conjunctivitis and nasolacrimal infections prior to surgery.
- Povidone iodine solution 5% instilled into the conjunctival sac prior to surgery.
- Perfect draping technique to isolate the lid margins and lashes from the surgical field avoiding contamination of the surgical gloves and instruments in the process. This is easier if the skin 'prep' has dried prior to draping.
- Non-touch technique as far as possible, avoiding touching the functional end of instruments.
- Rigorous theatre procedures including thorough hand washing, respect for preparation and sterile areas and minimization of unnecessary theatre traffic.
- Ensure theatres and the hospital sterilizing unit comply with appropriate guidelines. Ensure instruments do not dry before being cleaned. (see chapter on 'Theatres' in this book). Avoid using bench-top sterilizing units.
- Follow manufacturers' guidelines regarding single use of instruments.
- Ensure all equipment, intraocular lenses, viscoelastics and solutions are from a reliable source.
- Resist cost-cutting if safety may be jeopardized.
- Reject instruments which show signs of poor cleaning such as debris or deposits. Do not clear blocked instrument lumens e.g. of an irrigation-aspiration cannula during the procedure as sterility may then be uncertain.
- Consider intracameral cefuroxime at the end of the procedure.
- Any other procedure which after the preparation of this guide is shown to be effective with good statistical support.

Preventive measures ***may*** include (more controversially):

- Wear facemasks in theatre, especially scrub nurses and surgeons.
- Preoperative topical antibiotics.
- Preoperative saline irrigation.
- Injecting lens implants rather than folding them with forceps, in order to reduce the possibility of contact with the lid margin. Reject lens implants which have inadvertently contacted the lid margins.
- Antibiotics in irrigating solutions (consider risk of dilution error causing retinal toxicity and emergence of resistant organisms).
- Intra-operative heparin.
- Wash lens implants with BSS prior to implantation.
- Postoperative sub-conjunctival antibiotic injections.

Suggested plan of action

- Treat promptly and vigorously all endophthalmitis cases.
- Involve the hospital consultant microbiologist and hospital infection team at an early stage.
- Alert the lead clinician, clinical director and the medical director and submit a patient safety incident form in line with local reporting procedures. In due course this should trigger a report to the National Patient Safety Agency (NPSA) and the Commission for Healthcare Audit and Inspection (CHAI) (8).
- Consider reporting to the hospital clinical governance team.
- Give serious consideration to cessation of all intraocular surgery in the interests of patient safety whilst investigating the cause.
- Ensure colleagues are aware to ensure identification and reporting of further cases.
- Keep detailed records of all action taken.
- Document patient/surgical risk factors such as vitreous loss, blepharitis, nasolacrimal disease, immunosuppression, duration of surgery.
- Try to identify common hospital factors such as draping and surgical technique, antibacterial prophylaxis, surgeon, nursing staff and other personnel, theatres, solutions, viscoelastics, intraocular lenses, disposable and non-disposable equipment, which autoclave used, and any changes in procedure or environment which may coincide with the outbreak. Microbiology may reveal a common organism or subtype. Track batch numbers of solutions, disposables and lenses. Consider microbiological culture of solutions or viscoelastics. Where appropriate, consider taking nasal and skin swabs from theatre personnel including surgeons. Note on which day of the week, which position on the list and at what time of day patients were operated.
- Assess efficacy of cleaning and sterilization processes. Arrange for professional assessment of the hospital sterilizing service. Be alert to signs of failure of this process such as damaged or debris laden instruments, and blocked lumens.
- Confirm that the theatre environment is to a sufficiently high standard with regard to cleanliness, air-flow and ergonomics. Repeat plate tests and airborne particulate matter test as appropriate in consultation with the infection control team.
- Check theatre records to identify cases from other specialties or potentially ‘dirty’ cases which may have been operated in adjacent sessions.

- Assess that all equipment and disposables are functional and used according to manufacturers instructions. Confirm single use where instruments are so designated. Ensure correct procedures are followed for cleaning and sterilization especially of phaco hand pieces.
- Check that reasonable preventive measures are utilized with consideration of the above list.
- A statistical approach may be necessary, comparing precise procedures, solutions, disposables, lenses and involved personnel between endophthalmitis and non-endophthalmitis cases in order to pinpoint a possible cause (9). Other statistical methods have been utilized to confirm and investigate an outbreak (10). Furthermore, an analytical technique new to medicine but widely used in the food industry known as Hazard Analysis Critical Control Points (HACCP) and which was originally developed by a group including NASA to ensure sterility of food used on space missions, may be used to identify key points in the healthcare process to target corrective action and monitoring (11).

Clinical governance and incident reporting

- Postoperative endophthalmitis cases should be reported to the hospital risk management team.
- Audit meetings should include a regular complications and morbidity slot which should consider any cases of endophthalmitis.
- Electronic patient records supporting the cataract data set should eventually facilitate continuous audit and surveillance, and identify even a small rise in endophthalmitis cases or other complications which might not otherwise be evident.
- Report, if appropriate, to the Medicines and Healthcare products Regulatory Agency any problems with drugs or devices (12).
- Report, where appropriate, to the National Patient Safety Agency either via local hospital risk management systems or directly (8).
- Where significant patient numbers are involved consider reporting to the Department of Health (via the Director of Public Health), local GPs and the local Press.

Summary

The discovery or suspicion of an outbreak of endophthalmitis should prompt a rapid, systematic and open investigation to identify and eradicate the cause. Patient safety should be paramount and this may involve temporary cessation of intraocular surgery.

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