Review Article

Recommendations for an expert team investigating a case of cluster endophthalmitis

Shachi R Desai, Purvi R Bhagat[1], Dipali Parmar[2]

Occurrence of postoperative cluster endophthalmitis is a nightmare for the operating surgeon, the involved hospital, and the patients. Due to its multifactorial etiology, surveillance of such an event is extremely important to identify the causative factor and to prevent recurrences in future. For surveillance, a team of ophthalmologists and microbiologists is often appointed by the local health department, and it is imperative that this team investigates thoroughly, reports appropriately safeguarding the interests of all, and also suggests remedial measures for future. Much literature is available on postoperative endophthalmitis and sterilization and disinfection protocols, but to the best of our knowledge, there is none to guide the surveillance team regarding the conduct of the entire process of investigation in the case of such unfortunate incidents. Through this article, we have made an attempt to formulate recommendations for expert teams investigating cases of postoperative cluster endophthalmitis.

Key words: Cluster endophthalmitis, disinfection protocols, sterilization protocols, surveillance

Access this article online

Website: www.ijo.in

DOI: 10.4103/ijo.IJO_804_17

Quick Response Code:

Postoperative endophthalmitis is a rare but visually devastating complication and can occur after any intraocular procedure. With advances in surgical technique, instrumentation, and perioperative aseptic measures, the incidence of postoperative endophthalmitis has significantly decreased in the past two decades. Cataract surgery is one of the commonest intraocular surgery performed, and around 90% postoperative endophthalmitis occurs following cataract surgery.[1] In literature, the incidence of postoperative endophthalmitis ranges from 0.02% to 0.8% across the world.[2-5] Cluster endophthalmitis is a nightmare for surgeons, hospitals, and undoubtedly for the patients. A clear definition of cluster endophthalmitis yet does not exist. In a study published by Malhotra *et al*., it is defined as five or more cases of endophthalmitis occurring on a particular day in a single operating room in one center.[6] Several studies of cluster endophthalmitis have been reported in India following cataract surgeries and intravitreal injections.[6-8] Cluster endophthalmitis cases are generally exogenous in origin and are described in association with various solutions/fluids used during surgery such as internal fluid pathways of phacoemulsifier, irrigating solutions, viscoelastic substances, intracameral injections, and with drops/drug solutions used in perioperative period.[9-11] They can also occur due to breach in the sterilization or aseptic protocols. Loss of sight in one eye has a profound impact on the patient's life, their social well-being, and possibly their profession. Being a potentially vision-threatening condition, the occurrence of endophthalmitis is a dreaded situation for any ophthalmic surgeon. Such complications occurring in clusters attract a lot of media attention, and irrespective of the doctors' or hospital's previous reputation, the incident is portrayed in negative lights and remains a blemish on them.

Surveillance of such incidences should be a part of the management algorithm to find the causative factor and to prevent such outbreaks from recurring in future.[12] Often, when a red alert is issued, a team of ophthalmologists and microbiologists is appointed by the State Government Health authorities for investigating the incidences occurred in a government or nongovernment organization.[12] It is imperative that this team investigates thoroughly, possibly identifies the cause, and recommends required changes in the perioperative protocols of the concerned hospital. There are innumerable reports mentioning sterilization and disinfection protocols,[13-17] clinical presentations, and visual outcomes of cluster endophthalmitis across the world.[8,11,18,19] Unfortunately, very few studies have mentioned in detail about the investigative approach for such tragic events.

Furthermore, to the best of our knowledge, no literature exists to guide the investigating teams regarding the conduct of the entire process; the samples to be sought for microbiological analysis; managing the media, patients, and relatives effectively; and preparing the report. Through this article, we

Vitreo-retina surgeon, The Eye Centre, Bodakdev, [1]Glaucoma Clinic, M & J Western Regional Institute of Ophthalmology, [2]Cornea Clinic, M & J Western Regional Institute of Ophthalmology, Ahmedabad, Gujarat, India

Correspondence to: Dr. Shachi Rohan Desai, The Eye Centre, 204, Sigma II Complex, Above SBI Bank, Sunrise Park Road, Opp Himalaya Mall, Bodakdev, Ahmedabad - 380 052, Gujarat, India. E-mail: drshachidesai@gmail.com

Manuscript received: 05.10.17; Revision accepted: 27.03.18

Cite this article as: Desai SR, Bhagat PR, Parmar D. Recommendations for an expert team investigating a case of cluster endophthalmitis. Indian J Ophthalmol 2018;66:1074-8.

have made this first attempt to formulate recommendations for expert teams investigating cases of postoperative cluster endophthalmitis.

Recommendations for the Investigating Team after an Outbreak of Postoperative Cluster Endophthalmitis

1. Before the visit to the hospital, the team members should gather as much information as possible about the affected patients, their ongoing treatment, their recent clinical condition, the operating surgeon, and the hospital where the patients were operated. If the patients have been referred or transferred to other centers, one should gather similar information from the treating ophthalmologists
2. Media involvement and communication is to be expected, and as a part of the investigative team, one has to be prepared to deal with them with wisdom and patience. It is advisable to select one person from the team to be the spokesperson to maintain uniformity and avoid conflicts in answers.

   Following are a few tips:
   - Be polite and keep calm: Losing temper can make matters worse.
   - At the same time, be confident: Do not get carried away by the pressure or by the emotions. It is essential to keep a balanced attitude.
   - Answer general questions, for example, how many patients are affected? What treatment is going on? etc.
   - Avoid answering questions about which one is unsure, for example, visual outcome of patients, their prognosis, etc.
   - Avoid questions with very specific answers, for example, what have you come to know from today's assessment? In how many days will the report be submitted?
   - Do not answer leading questions, for example, will the patients completely recover? Who is responsible for the incident?
   - Do not totally avoid responding or talking to the media persons because it is also important that they are given proper scientific information to avoid misrepresentation.
   - Talk less and answer to the point.
   - The investigative team may inform the media that reports are confidential and shall be revealed only to the higher authorities.
3. Visit to the hospital where the surgeries were done, and cluster endophthalmitis occurred should be planned as early as possible. The team should carry with them necessary documents/checklists required for the assessment. Inform the concerned persons (hospital staff, local health officials, and hospital administrators) about your visit so that all the concerned staff is available to provide adequate information and documents for analysis.

Check for Immediate Measures that were Taken by the Operating Surgeon and the Hospital Authority at Site

1. On suspicion of postoperative cluster endophthalmitis, whether all the patients operated on the day were contacted immediately and called for examination.
2. Whether, on confirmation of cluster endophthalmitis, all the concerned authorities, i.e., head of the department, director, or superintendent of the Institute or Hospital, Commissioner of Health and Health Secretary for the state, were informed.
3. Once cluster endophthalmitis was confirmed, whether all future planned intraocular surgeries were postponed till further clearance.[12]
4. Whether prompt and effective decisions were taken for management of the affected patients.
5. Enquire about the treatment given to the patients in the initial 24–48 h and whether a vitreoretinal surgeon was called for further management. Inquire whether affected patients were given intravitreal broad-spectrum antibiotics after a vitreous tap/biopsy, about the results of vitreous tap/biopsy culture, and whether antibiotics were modified according to the culture reports.
   In case of nonavailability of a vitreoretinal surgeon, whether the patients were transferred to a higher and appropriately equipped center for further management.
6. Counseling of affected patients and their relatives is very essential. They should be explained and counseled about their condition, possible factors responsible, ongoing treatment, and possible outcomes. The same should have been well documented on the case sheets. The patients and their relatives should be kept aware of all progress and plans of management.
7. All residual materials, fluids, drugs, and devices used for the surgeries should have been noted, isolated, and kept for analysis. In cases of discarded items, material of the same batch should have been identified.
8. The operation theater (OT) should be sealed till further notice from higher authorities.[12]
9. Details of patients' demography; their ocular condition; treatment and advice provided; and preoperative, operative, and postoperative notes including surgical items used should have been documented carefully and precisely.

Steps to be followed on Site by the Investigative Team

Thorough examination of the affected patients

- If the affected patients are being treated at the site, they should be examined first with a sympathetic approach. The relatives should also be counseled if they are present.
- A brief history of the patients should be taken, and copies of case papers should be collected.
- Patients' details should be recorded including name, age, sex, address, contact number, their preoperative findings (especially for any features of systemic/local infection, systemic illness, and immune-compromised status), and postoperative findings.
- Detailed examination including vision, slit-lamp examination, and fundus examination should be done.
- Ultrasonography should be done in cases where fundus details are not visible.
- Patient's built, nourishment, hygiene, and general systemic condition should be inspected and noted.
- Details of treatment given should be noted. Treatment given should be assessed on the basis of its promptness and its resemblance with the standard protocol.

Inquiry and record of all operative details

Complete operative details of all the affected patients should be noted with special mention of the following points:

1. Date on which the patients were operated.
2. Sequence in which the patients were operated.
3. Number, names, and sequence of the operating surgeons.
4. Operative technique used for all the patients.
5. Whether operated on single or different tables.
6. Whether operated with single or different microscopes.
7. Details of the phacoemulsifier or any other machine used during surgery.
8. Date when the phacotubings were last replaced/changed.
9. Details of cleaning method for the phacomachine: Who cleans the machine? When is it done? How is it done? The concerned staff maybe asked to describe the technique. Demonstration may also be asked for if required, but only after collection of microbiological samples from the machine.
10. Details of all the surgical and pharmaceutical materials used in each patient.
11. Operative time for each patient.
12. Number of personnel in OT on that specific day, any change of shifts during operative hours, any newly appointed/replacement staff on a particular day.
13. Movement in OT during surgery and reasons.

Gather all information about the hospital, ophthalmic department, and ophthalmic staff

- Hospital details should be recorded including its date of establishment, number of departments/specialties in the hospital, total number and types of ophthalmic staff, and nature and quantity of ophthalmic work done.
- All details of ophthalmic staff should be recorded: number of visiting/operating surgeons, OT assistants, paramedical staff; their names, brief address, qualification details, and surgical/training experience.
- Overall health of the staff members should be inquired for and assessed.
- Ask about the duration for which the ophthalmology department works/OT functions in a day.
- Details of different kinds of surgeries performed in the ophthalmic OT, number of major and minor surgeries per month, and average number of surgeries performed in a day.

Assessment of complete ophthalmic setup and its surroundings

The date and time of removal of OT seal should be documented before proceeding for the inspection of the OT.

Photographs and/or videos should be taken where possible for future record and reference while preparing the report.

Assessment should be done for all of the following:

1. Location of ophthalmology department if it is a multispecialty hospital.
2. Location of ophthalmic OT – Is it shared with any other specialty? Does it have a common door with other specialty OT? Is there any toilet in close vicinity?
3. Location of changing room and its distance from OT.
4. Location of scrub area – does the passage to scrub area pass through the OT?
5. The distance between preoperative area and ward from the OT and condition of the passage in between.
6. Type of water used for scrubbing – running tap/reverse osmosis/stored water. If overhead tank water is used, then the condition of tank should be checked, and its schedule and method of cleaning should be inquired for.
7. The scrub technique – duration, use of soap bar/liquid, use of betadine or any antiseptic solution – should be asked for
8. Presence of clock in scrub area.
9. Details of separate septic OT or the place where septic procedures are performed.
10. Number of operating tables in the OT.
11. Number of microscopes in the OT.
12. All the walls, windows, floorings, and doors and all hinges. Any crevices, holes, or gaps should be identified.
13. Details about the air conditioner (AC) – number, type (split/window/central), last service date, and its record.
14. High-efficiency particulate air filters.
15. Number of trolleys/racks/cupboards in the OT and their overall condition.
16. Number of cataract sets; whether same or different sets used for different surgeries; cleaning methods of instruments between two surgeries. Instruments should be inspected for rusting and defects.
17. Change of phacotubings between patients should be inquired for.
18. For irrigating fluids, drugs, and viscoelastic substances, inquiry should be made regarding the use of multi-dose bottles and vials for multiple patients.
19. Whether the surgical supplies are manufactured and provided by trusted and reputed firms should be confirmed. Expiry date must be checked for all supplies.
20. Solutions, drugs, and viscoelastics must be inspected against bright light for any suspended particles.
21. Inquiry should be made about the practice of change of gloves or use of antiseptic solution between two patients.
22. Number of Formalin chambers in OT, number of tablets in one formalin chamber, frequency of change of tablets, and its record.
23. Use of Savlon and cheatle forceps should be noted along with its records – Savlon company name, how the solution is prepared, who prepares the solution, and how frequently is the solution changed.
24. Details of autoclave machine – location, closeness to OT, passage from autoclave area to OT, number of machines, type (horizontal or vertical), model, year of purchase, number of drums kept in one cycle, and last repair/service date.
25. Pressure indicator in the autoclave.
26. Autoclave register with indicator strips.
27. Hot air oven and ultrasonic cleaner.
28. OT cleaning/washing and daily mopping – technique, materials used, and schedule. Check all the records.
29. Fumigation of OT – technique, materials used, and schedule. All records should be verified.
30. Inquiry should be done about culture swab analysis from the OT – places from where swabs are taken, frequency, and place where swabs are sent for analysis.
31. Linens – cleaning and sterilization details and records.
32. Biomedical waste disposal systems and relevant documentation.

Assessment of various perioperative protocols

Ask for hospital protocols: preoperative, operative, and postoperative.

Preoperative protocol should include patient preparation, surgeon/nurse preparation, and OT preparation.

Information regarding patient preparation protocol should specifically include the following:

1. Whether sac syringing is done preoperatively.
2. Lid conditions such as meibomian gland dysfunction, style, or blepharitis are ruled out or treated.
3. Whether contact procedures such as tonometry and axial length measurement are done on the day of surgery.
4. Whether patient's general hygiene is checked.
5. Patient preparation in ward – bath, hairwash, shaving/trimming of beard and mustache, handwash.
6. Patient preparation in preoperative room – instillation of antibiotic/Betadine drops.
7. Cleaning of lid and the surrounding skin with betadine.
8. Protocol for peribulbar block/topical anesthesia.
9. Protocol of informed written consent especially in high-risk cases.

Surgeon preparation protocol should include protocol for both the operating surgeon and the assistant nursing staff.

OT preparation protocol should include OT cleaning, fumigation, autoclaving details, OT preparation, and phacoemulsification machine preparation.

Collection of swabs for culture analysis

The appointed microbiologist(s) in the surveillance team should be instructed to collect swabs from the following places. All samples should be accurately labeled, dated, and signed.

List of places from where swabs should be collected [Table 1].[16,17]

- Samples should also be collected from used bottles (remaining solutions) and also from unused/packed bottles of same and another batch.
- The drugs/dyes/solutions commonly used during cataract surgery and to be considered for sampling are antiseptic solutions, chlorhexidine solution, povidone-iodine (10%, 5%) drops and solution, irrigating solutions, viscoelastics, pilocarpine, gentamicin, bupivacaine, hyaluronidase, lignocaine, adrenaline, topical antibiotic drops and ointments, cycloplegics, steroid drops, and ointment.

Trade name, company name, batch number, and expiry date for all should be recorded.

All the samples collected should be sent to the microbiology laboratory of the authorized hospital.

Documents to be collected

All the following documents/records/registers should be photocopied and preferably be signed and dated by the involved surgeon or hospital administrator(s):

1. Surgical notes
2. Cases of patients
3. Autoclave register
4. Fumigation record
5. Mopping/OT cleaning record
6. List of places from where the culture swabs have been taken
7. Phacotubing change record
8. AC service record

Table 1: List of places from where swabs should be collected

	Places/sites	Remark
1	OT tables	
2	Footstep	
3	Lights/lamp(s)	
4	Drum stand	
5	All drums	From the insides of the drum as well
6	Air conditioner	
7	Microscope and its handles and knobs	
10	Surgeon's table(s)/chair(s)	
11	Phacomachine and its foot paddle	
12	Phacotubings and phacoprobe	
13	Trolley(s)	
14	Formalin chamber	
15	Patient head ring	
16	Washbasin and soap dish	
17	IV stand and IV set	
18	Syringes 2cc, 5cc, 10 cc	
19	Hydrocannulas and needles	
20	Floor and walls	
21	Tap and tap water	From OT and preoperative room
22	Gloves	
23	Disposable blades - sideport, crescent, keratome	
24	IOLs	All details of IOL (batch number, type of IOL, trade name, company name, manufacture, and expiry date should be recorded)

OT: Operation theater, IOLs: Intraocular lenses

Preparation of report

All details collected from the site should be analyzed minutely by the entire team.

A preliminary report should be submitted to the concerned health authorities as soon as possible after the visit. It should briefly mention about the visit, condition of patients, their treatment, hospital details, doctors' details, investigations carried out, and materials and samples gathered for analysis from the site.

The final report should be submitted only after microbiological reports of all the samples are collected, and all the information and documents are completely procured and assessed thoroughly. All the gathered relevant information should be mentioned in complete detail in the final report. The report should be written neutrally without evidence of any bias or prejudice toward the doctor/hospital. It may not be possible to have a flawless OT setup at all places. At the same time, certain protocols have to be followed essentially and cannot be overlooked. The possible factor(s) responsible for the cluster endophthalmitis maybe mentioned if they are strongly

evident from the investigation. Other flaws and fallacies in the setup maybe pointed out carefully. Recommendations may be provided for change or improvement. Possible remedial measures to prevent such outbreaks in future should also be preferably suggested in the report.

Conclusion

Occurrence of cluster intraocular infections after surgery is unfortunate for patients, doctors, and institutes/hospitals, but it needs to be remembered that postoperative endophthalmitis is a multifactorial event. The factors involved maybe perioperative protocols, sterilization protocols, aseptic precautions, patient hygiene and immunity, and quality of materials and drugs used in the perioperative period. Therefore, even after utmost precautions, it is not possible to create an absolute microorganism-free environment.

To be an investigator in such incidences is not an easy task. With all the sympathy for the patients affected and empathy for the doctors, the expert is supposed to work with neutrality and maturity. To be a part of such an investigative team is also a matter of immense responsibility because on the prepared report lies the trust and faith of the patients, the future career of the surgeon involved, and the reputation of the hospital. This is also a task for which one does not receive any formal training during the residential or professional years. When assigned such responsibility, each one of us relies on the experience of others for guidance. This article, therefore, aims to act as a guiding tool for investigative experts to make their mammoth tasks relatively simpler to conduct.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Verbraeken H. Treatment of postoperative endophthalmitis. Ophthalmologica 1995;209:165-71.
2. Lundström M, Wejde G, Stenevi U, Thorburn W, Montan P. Endophthalmitis after cataract surgery: A nationwide prospective study evaluating incidence in relation to incision type and location. Ophthalmology 2007;114:866-70.
3. Endophthalmitis Study Group, European Society of Cataract & Refractive Surgeons. Prophylaxis of postoperative endophthalmitis following cataract surgery: Results of the ESCRS multicenter study and identification of risk factors. J Cataract Refract Surg 2007;33:978-88.
4. Yao K, Zhu Y, Zhu Z, Wu J, Liu Y, Lu Y, *et al.* The incidence of postoperative endophthalmitis after cataract surgery in China: A multicenter investigation of 2006-2011. Br J Ophthalmol 2013;97:1312-7.
5. Cao H, Zhang L, Li L, Lo S. Risk factors for acute endophthalmitis following cataract surgery: A systematic review and meta-analysis. PLoS One 2013;8:e71731.
6. Malhotra S, Mandal P, Patanker G, Agrawal D. Clinical profile and visual outcome in cluster endophthalmitis following cataract surgery in central India. Indian J Ophthalmol 2008;56:157-8.
7. Ramappa M, Majji AB, Murthy SI, Balne PK, Nalamada S, Garudadri C, *et al.* An outbreak of acute post-cataract surgery *Pseudomonas* sp. endophthalmitis caused by contaminated hydrophilic intraocular lens solution. Ophthalmology 2012;119:564-70.
8. Khan P, Khan L, Mondal P. Cluster endophthalmitis following multiple intravitreal bevacizumab injections from a single use vial. Indian J Ophthalmol 2016;64:694-6.
9. Zaluski S, Clayman HM, Karsenti G, Bourzeix S, Tournemire A, Faliu B, *et al. Pseudomonas aeruginosa* endophthalmitis caused by contamination of the internal fluid pathways of a phacoemulsifier. J Cataract Refract Surg 1999;25:540-5.
10. Swaddiwudhipong W, Tangkitchot T, Silarug N. An outbreak of *Pseudomonas aeruginosa* postoperative endophthalmitis caused by contaminated intraocular irrigating solution. Trans R Soc Trop Med Hyg 1995;89:288.
11. Lalitha P, Sengupta S, Ravindran RD, Sharma S, Joseph J, Ambiya V, *et al.* A literature review and update on the incidence and microbiology spectrum of postcataract surgery endophthalmitis over past two decades in India. Indian J Ophthalmol 2017;65:673-7.
12. Verma L, Gupta S, Tewari HK, Talwar D, Gupta A. Cluster endophthalmitis. DOS Times 2008;14:31-3.
13. AIOS Guidelines to Prevent Intraocular Infection; 2009. Available from: http://www.aios.org/guidelinesendoph.pdf. [Last accessed on 2018 Feb 19].
14. Barry P, Cordovés L, Gardner S. ESCRS Guidelines for Prevention and Treatment of Endophthalmitis Following Cataract Surgery: Data, dilemmas and Conclusions; 2013.
15. The Royal College of Ophthalmologists' Quality and Safety group. Managing an outbreak of postoperative endophthalmitis. Ophthalmic Services Guidance; July 2016.1-12.Available from: https://www.rcophth.ac.uk/wp-content/uploads/2016/07/Managing-an-outbreak-of-postoperative-endophthalmitis.pdf. [Last accessed on 2018 Mar 24].
16. Guidelines for the Management of Cataract in India. Vision 20-20: Right to Sight Publication; October, 2011. Available from: https://www.sightsaversindia.in/wp-content/uploads/2014/06/16480_Cataract_Manual_VISION2020.pdf. [Last accessed on 2018 Mar 24].
17. National Program for Control of Blindness. Guidelines for Preoperative, Operative and Postoperative Precautions for Intra Ocular Eye Surgery. National Program for Control of Blindness. Available from: http://www.npcb.nic.in/writereaddata/mainlinkfile/File325.pdf. [Last accessed on 2018 Feb 19].
18. Akçakaya AA, Sargin F, Erbil HH, Yazici S, Yaylali SA, Mesçi C, *et al.* A cluster of acute-onset postoperative endophthalmitis over a 1-month period: Investigation of an outbreak caused by uncommon species. Br J Ophthalmol 2011;95:481-4.
19. Bastola P. An experience of management of cluster endophthalmitis in Western hilly rural region of Nepal: A descriptive, interventional study. J Chitwan Med Coll 2017;5:10-9.