Incidence and Impact of Reported Infectious Endophthalmitis Events Following Cataract Surgery in Pennsylvania Ambulatory Surgery Centers

By Lynette Hathaway**, MSN, RN, Shawn Kepner**, MS & Rebecca Jones**, MBA, RN
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**Corresponding author
Patient Safety Authority
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Abstract

Infectious endophthalmitis is a severe eye infection that can occur following cataract surgery. In this study, we sought to explore post-cataract infectious endophthalmitis events reported by ambulatory surgery centers (ASCs) in Pennsylvania. We queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for post-cataract endophthalmitis events that occurred between 2009 and 2018. In the 10 calendar years analyzed, we identified 174 reports of post-cataract endophthalmitis, with rates per 1000 cataract procedures ranging from 0.05 in 2009 to 0.19 in 2018. The vast majority of these events were classified as serious (93%; n = 162 of 174), reflecting harm to patients, with one resulting in enucleation (the need to remove the affected eye). Healthcare staff and all involved stakeholders should act now by identifying sources of potential perioperative contamination, adhering to evidence-based infection prevention practices, and prioritizing areas of opportunity for improvement.

Keywords: infectious endophthalmitis, eye infection, cataract surgery, postoperative endophthalmitis, healthcare-associated infection

Introduction

Endophthalmitis is a serious eye infection that can lead to permanent harm, including blindness.1 There are two types of endophthalmitis: endogenous (bloodborne), which may occur from a number of systemic risk factors that spread bacteria or fungi from the primary source of infection into the eye;2 and exogenous, which may occur after ocular trauma, following a cornel infection, or after eye surgery—particularly cataract surgery.1 Cataracts impact the vision of more than 24 million Americans age 40 and older. By age 75, approximately half of all Americans will have visibly significant cataracts.2 By the year 2050, the number of people in the United States with cataracts is expected to double from 24.2 million to about 50 million.2 Aging is the most common cause of cataracts, as the normal proteins in the lens of the eye begin to break down and cause clouding.3 As the elderly population in Pennsylvania continues to grow,11 cataract surgeries are also on the rise.11 Given that most cataract surgeries are performed in ambulatory surgery centers (ASCs) and outpatient departments it is no surprise that more than one million cataract procedures were performed in Pennsylvania ASCs between 2009 and 2018.12

Cataract surgery is one of the most common ocular surgical procedures in medicine15 and one of the most frequent surgical procedures performed by ophthalmic surgeons in the United States.13 While cataract surgery is usually successful and safe,10 it is not without risk. Infectious endophthalmitis is a rare yet significant complication of cataract surgery.4 Defined as an infection of the intraocular fluids (aqueous and/or vitreous) and cavities,1 infectious endophthalmitis is accompanied by complaints of decreased vision, eye pain, and redness in the operative eye. It typically occurs within days of surgery, but may not cause symptoms until weeks post-procedure, depending on the causative microorganism.1 A diagnosis of endophthalmitis following cataract surgery is usually based on clinical presentation thought to be related to infection, with cultures of vitreous and/or aqueous fluids.14–16 Although the exact manner of development for infectious endophthalmitis is unknown, potential sources of contamination during cataract surgery include intraocular instruments and the intraoperative suite,17 as well as unsterile solutions/material or the patient’s eyelid skin flora.18–19 Recognizing the lack of data surrounding infectious endophthalmitis in the ASC setting in Pennsylvania, we sought to identify the rate of infectious endophthalmitis events following cataract surgery reported by Pennsylvania’s ASCs, explore key aspects of the identified cases, and identify strategies to reduce the risk of this harmful complication.

Methods

We queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database for events that occurred between January 1, 2009, and December 31, 2018, to identify and analyze reports of infectious endophthalmitis following cataract surgery (“post-cataract endophthalmitis”). Key search terms included “endophthalmitis,” as well as a combination of the terms “infection” and “eye,” and “infection” and “cataract.” Our initial search yielded 349 reports which the first two authors independently reviewed and analyzed to determine whether they represented post-cataract endophthalmitis cases. We then compared our findings and resolved discrepancies through joint review and consensus. A subject matter medical expert was also consulted to confirm validity.

Inclusion Criteria

Reports meeting the following inclusion criteria were classified as post-cataract endophthalmitis events:

1. The precipitating procedure was identified as a cataract surgery.
2. The report reflected a clear diagnosis using the term “endophthalmitis” (n=120).

Exclusions

Excluded events consisted of unconfirmed diagnoses of endophthalmitis, diagnoses of endophthalmitis or other postoperative infection with no surgery identified or not related to a cataract procedure, reported sterile endophthalmitis or toxic anterior segment syndrome (TASS) with or without identified surgical procedures, postoperative complications following a cataract procedure not identified as endophthalmitis, postponed or cancelled procedures, and other unrelated events (e.g., break in sterile technique, drug recall, policy not followed).

Results

Rate

We identified 174 reports of post-cataract endophthalmitis over a 10-year period between 2009 and 2018. We then obtained current procedure terminology (CPT) codes from the Pennsylvania Health Care Cost Containment Council (PHCCC) to calculate the rate of post-cataract endophthalmitis events reported by Pennsylvania ASCs each year during the study period. As seen in Figure 1, rates ranged from 0.05 to 0.19 per 1000 cataract procedures. In the 10 calendar years analyzed, we noted what could be an increase in rates of post-cataract endophthalmitis events, however the increase was not statistically significant (P = 0.2530 > 0.05).

Age/Gender

Patient age was approximately symmetric about the mean value of 73 years with a skewness statistic of -0.18 (N = 174). The median and mode were also 73. As seen in Figure 2, a very small number of reports were related to patients younger than 50 years of age. Of the 174 events identified, females accounted for 53.45% of the reports, which is not significantly different than the estimated PA population comprised of 51.06% females (P = 0.5286 > 0.05).

Harm Score

The vast majority (93%; n = 162 of 174) of post-cataract endophthalmitis events were reported as Serious Events, reflecting harm to patients. Most were reported under harm score “E,” indicating temporary harm that required treatment or intervention. Based on the information provided four of the events resulted in permanent harm, one of which required enucleation (the need to remove the affected eye). See Table 1.

*PA-PSRS is a secure, web-based system through which Pennsylvania hospitals, ambulatory surgical facilities, abortion facilities, and birthing centers submit reports of patient safety–related incidents and serious events in accordance with mandatory reporting laws outlined in the Medical Care Availability and Reduction of Error (MCARE) Act (Act 13 of 2002). All reports submitted through PA-PSRS are confidential, and no information about individual facilities or providers is made public.
The Pennsylvania Health Care Cost Containment Council (PHC4) is an independent state agency responsible for addressing the problem of escalating health costs, ensuring the quality of healthcare, and increasing access to healthcare for all citizens regardless of ability to pay. PHC4 has provided data to this entity in an effort to further PHC4’s mission of educating the public and containing healthcare costs in Pennsylvania. PHC4, its agents, and staff, have made no representation, guarantee, or warranty, express or implied, that the data—financial, patient, payor, and physician-specific information—provided to this entity, are error-free, or that the use of the data will avoid differences of opinion or interpretation. This analysis was not prepared by PHC4. This analysis was done by the authors. PHC4, its agents and staff, bear no responsibility or liability for the results of the analysis, which are solely the opinion of this entity.

A “Serious Event” is an event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional healthcare services to the patient.

**Table 1: Harm Score in Reports of Post-Cataract Endophthalmitis Events (N= 174)**

| Harm Score | Description |
|------------|-------------|
| D          | An event occurred that required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm. |
| E          | An event occurred that contributed to or resulted in temporary harm and required treatment or intervention. |
| F          | An event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization. |
| G          | An event occurred that contributed to or resulted in permanent harm. |

**Table 2: Pathogens Identified in Reports of Post-Cataract Endophthalmitis Events (n = 37)**

| Pathogen Description                        | Frequency |
|---------------------------------------------|-----------|
| Coagulase-negative staphylococci            | 16        |
| | (including *Staphylococcus lugdunensis*)   |           |
| Staphylococcus species (including methicillin-resistant *Staphylococcus aureus/MRSA*) | 10        |
| Streptococcus species (including beta, pneumococcus and viridans) | 6         |
| Gram-positive cocci                          | 2         |
| Candida species (fungal)                    | 2         |
| Polymicrobial                               | 1         |
| Streptococcus and Staphylococcus             |           |

**Figure 1: Rate of Reports of Post-Cataract Endophthalmitis Events by Year**

**Figure 2: Frequency by Age Group in Reports of Post-Cataract Endophthalmitis Events (N = 174)**

**Figure 3: Regional Distribution in Reports of Post-Cataract Endophthalmitis Events (N = 174)**

**Figure 4: Symptoms Identified in Reports of Post-Cataract Endophthalmitis Events (n = 82)**

*Some reports identified more than one symptom
+Other includes tearing, foreign body sensation, headache, photophobia, swelling, purulent drainage, cobwebs
Regional Distribution

After controlling for a few outlier facilities, we determined the distribution of reports across the six regions of Pennsylvania was close to what was expected given the general distribution of acute care events in PA-PSRS. Figure 3 displays the regional distribution of the 174 reported events.

Symptoms

Almost half (47%; n = 82 of 174) of the post-cataract endophthalmitis events report included details regarding patient symptoms. Consistent with other studies of postoperative endophthalmitis,2,4-6,16 of the reports that included one or more symptoms, decreased/blurry vision (73%; n = 60 of 82) and pain (49%; n = 40 of 82) were noted most frequently. Other symptoms included floaters or spots, redness, and acute loss of vision. Figure 4 illustrates the frequency of symptoms identified in the post-cataract endophthalmitis events. We also analyzed the most frequently reported symptom (decreased/blurry vision and pain) in relation to age and gender, but did not identify any relevant associations. The other symptom categories had too few positive indications to include in the analysis.

Pathogens

Only 32% (n = 55 of 174) of the post-cataract endophthalmitis events included information about a culture or the pathogen involved. Of the events that contained this detail, one-third (33%; n = 18 of 55) reflected negative results. The other two-thirds (67%; n = 37 of 55) reported positive cultures, with 95% (n = 35 of 37) involving gram-positive pathogens. This is consistent with other literature, which suggests that most cases of post-cataract endophthalmitis are caused by gram-positive bacteria.2,5,20,22 Table 2 displays additional detail regarding the pathogens identified in these 37 cases.

Postoperative Days From Surgery to Diagnosis

Nearly half (46%; n = 80 of 174) of the event narratives contained information regarding the number of postoperative days from cataract surgery to diagnosis of endophthalmitis or infection. Days ranged from post-op Day 1 to post-op Day 28. Post-op Day 4 was noted most frequently (19%; n = 15 of 80). Figure 5 illustrates the range of postoperative days from surgery to diagnosis. Given that more than half of the reports did not include sufficient information to determine the number of postoperative days from surgery to diagnosis, we were unable to evaluate any possible associations between the time of surgery and diagnosis of post-cataract endophthalmitis or other factors analyzed.

Discussion

This study is, to our knowledge, the first to evaluate both the rates of and key details regarding post-cataract endophthalmitis events based on patient safety reports by ASCs. In the 10 calendar years analyzed, we noted what could be an increase in the rate of reported post-cataract endophthalmitis, however the increase was not statistically significant (P = 0.2530 > 0.05). Our findings, including common symptoms and pathogens most often involved in cases of post-cataract endophthalmitis, were generally consistent with those identified in the literature.3,5,6,13,21,22 Our findings revealed varying degrees of patient harm, with most cases requiring additional ophthalmology specialist consults, intracocular antibiotic injections, or vitreous procedures, all of which add to the patient’s direct medical costs.3,21

Toxic Anterior Segment Syndrome

It can be challenging to accurately diagnose a patient who presents with acute inflammation of the operative eye following cataract surgery. Postoperative noninfectious endophthalmitis, sometimes described as toxic anterior segment inflammation, is a sterile anterior segment inflammation reported with symptoms similar to infectious endophthalmitis. Diagnosing TASS against postoperative infectious endophthalmitis can be difficult;23-25 given the potential damage that can result from bacterial endophthalmitis, most cases of inflammation following cataract surgery are viewed as infectious endophthalmitis until otherwise confirmed.24,26 Noninfectious reactions in the operative eye following cataract surgery may also be referred to as postoperative anterior segment inflammation, sterile endophthalmitis, and noninfectious endophthalmitis.3

Risk Factors Associated With Post-Cataract Endophthalmitis

Infectious endophthalmitis is a rare but real risk of cataract surgery. Some of the most common factors that increase the risk include advanced age, impaired immune system secondary to systemic diseases, intraocular exposure to the patient’s own ocular flora, septic periocular conditions, intraoperative posterior capsular break, and wound leak.27,28 Other risk factors cited that may contribute to the development of healthcare-associated post-cataract endophthalmitis include surgical face masks not worn during surgery, breaks in sterility, conjunctival disinfection without povidone-iodine, and not placing a patch or eye shield after surgery.29-31

Risk Reduction Strategies

Ophthalmologists may use a combination of antisepsics and antibiotics as measures to prevent post-cataract complications. There is general agreement in the preoperative use of povidone-iodine in the conjunctival cul-de-sac.27 however, there is no general consensus as to the type and route of antibiotic treatment nor the use of intraocular injection after an uncomplicated cataract procedure.27,28 While intracameral antibiotic therapy has been associated with a reduction in acute endophthalmitis,6,27 the potential complications associated with prophylactic antibiotics—including toxicity—should be considered.27,29,30 Currently there is no Food and Drug Administration-approved product available for intracameral therapy,29 providers will need to weigh the risk and benefits of therapy.29 As new research in the management and treatment of post-cataract endophthalmitis emerges, physicians should remain current to better guide their treatment options.

Surgical personnel’s awareness of potential sources of contamination that may enter the eye during cataract surgery is imperative in the prevention of post-cataract endophthalmitis.31 Healthcare-associated infections may be avoided by observing the practices recommended by the American Academy of Ophthalmology, the Association of periOperative Registered Nurses, the American Society of Cataract and Refractive Surgery, and the American Society of Ophthalmic Registered Nurses. Basic infection prevention measures include hand hygiene, standard precautions, and adherence to disinfection and sterilization protocols.23-25

Table 3 provides perioperative risk reduction strategies aimed specifically at reducing sources of contamination.

Limitations

This article is based on cases of post-cataract endophthalmitis reported to the PA-PSRS database by Pennsylvania ASCs and does not quantify post-cataract endophthalmitis rates across the entire state of Pennsylvania. Despite mandatory reporting laws, this data is subject to the limitations of self-reporting and the complexities of the reporting system and structure. Thus, our ability to substantiate the diagnosis of post-cataract endophthalmitis was limited by the incompleteness and variability of the reporting system.
Preoperative risk reduction strategies

- Adhere to proper disinfection and manufacturer recommended sterilization protocols.
- Prepare medication just prior to the procedure. Do not draw up multiple patients’ medications for the day.
- Never store or carry medications in personal clothing or pockets.

Intraoperative risk reduction strategies

- Use povidone-iodine in the conjunctival cul-de-sac.
- Drape the patient’s eyelid and lashes precisely to prevent the patient’s skin flora from contaminating the field.
- Facemasks should be worn by the surgeon and scrubbed personnel. Facemasks should be cleaned between patients. Microorganisms can live in the environment.
- Prior to administering ophthalmic drops, carefully remove the top of the bottle and place it in a clean, protected area. If the inside of the bottle top becomes contaminated, discard it immediately.
- The eye drop tip must never come in contact with the patient’s eyelid, eyelashes, or surface of the eye.
- Surgical instruments and handpieces may be placed in a sterile water bath immediately after use to avoid drying of debris until cleaning takes place. Instrument cleaning involves the removal of soil and debris before the disinfection and sterilization process.
- All cleaned instruments must be thoroughly rinsed and dried prior to disinfection and sterilization.

Postoperative risk reduction strategies

- Customize discharge instructions and remind patients not to wear eye makeup until the surgeon approves.
- Evaluate patient comprehension regarding discharge instructions, including wearing the postoperative eye shield as directed, avoiding eye rubbing, and following postoperative eye drop regimen.
- Consider education and return-demonstration in properly instilling eye drops.

Environmental risk reduction strategies

- Clean the surgical environment between patients. Microorganisms can live in the environment on an uncleaned surface for hours to months, depending on the organism and contamination present.
- Regular maintenance of the ventilation filter system is recommended in the surgical suite to avoid potential environmental sources of contamination.
33. Niydurupola N, Austbury N. Endophthalmitis: Controlling Infection Before and After Cataract Surgery. Community Eye Health. 2008;21(65):9-10. Epub 2008/05/28. PubMed PMID: 18504468; PubMed Central PMCID: PMCPMC2377381.

34. Directors ABo. American Society of Ophthalmic Registered Nurses. Recommended Practice for Registered Nurses – Use of Multi-dose Medications. 2013 (San Francisco, CA: American Society of Ophthalmic Registered Nurses).

35. Standards of Practice for the Decontamination of Surgical Instruments. Association of Surgical Technologists. 2009.

36. Verma L, Chakravarti, A. Prevention and Management of Postoperative Endophthalmitis: A Case-Based Approach. Indian Journal of Ophthalmology. 2017;65(12):1396-402.

About the Authors

Lynette Hathaway is an infection prevention analyst for the Patient Safety Authority, where she assists with the improvement of patient safety by initiating, developing, implementing, and monitoring new and existing infection prevention initiatives throughout Pennsylvania. Her diverse nursing experience includes cardiovascular and medical-surgical nursing, gastroenterology, utilization review, long-term care, nursing education, and infection prevention and control. Prior to joining the PSA, Hathaway was manager of Infection Prevention and Control at a 156-bed acute care facility. She is board-certified in infection control and epidemiology, and an active member of the Three Rivers Chapter of the Association for Professionals in Infection Control and Epidemiology.

Shawn Kepner is a data analyst for the Patient Safety Authority, providing actionable insights using data science techniques, working with staff to focus resources and research for maximum benefit to patient safety, and helping assess the quality and validity of statistical methodologies for research and publications. Before joining the PSA, Kepner was a contractor with the Pennsylvania Department of Health, where he served as the data manager for a new community health initiative. His prior positions include decision support consultant and manager of informatics for Novitas Solutions, bureau director for program support with the Pennsylvania Department of Public Welfare (DPW), and program manager with Xerox Corporation. He also has been an adjunct mathematics instructor at Harrisburg Area Community College and a presenter on statistics to the DPW’s Leadership Development Institute.

Rebecca Jones (rebejones@pa.gov) is director of Data Science and Research at the Patient Safety Authority, where she also founded and serves as director of the Center of Excellence for Improving Diagnosis. Her previous roles at the PSA include director of Innovation and Strategic Partnerships, and regional patient safety liaison. Before joining the PSA, Jones served in various roles leading patient safety efforts and proactively managing risk in healthcare organizations. She currently is chair of the Practice Committee of the Society to Improve Diagnosis in Medicine and serves on the Advisory Committee of the Coalition to Improve Diagnosis.

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