

Patient Harm in Cataract Surgery: A Series of Adverse Events in Massachusetts

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Massachusetts state agencies received reports of 37 adverse events (AEs) involving cataract surgery from 2011 to 2015. Fifteen were anesthesia related, including 5 wrong eye blocks, 3 cases of hemodynamic instability, 2 retrobulbar hematoma/hemorrhages, and 5 globe perforations resulting in permanent loss of vision. While Massachusetts' reported AEs likely underrepresent the true number of AEs that occur during cataract surgery, they do offer useful signal data to indicate the types of patient harm occurring during these procedures. (*Anesth Analg* 2018;126:1548–50)

Cataract surgery is widely regarded as one of the safest operations. Still, errors occur at multiple points in the process, and in rare cases, result in permanent harm. While >3.5 million cataract operations are performed annually in the United States,¹ the literature on errors and adverse events (AEs) during cataract surgery is sparse.^{1–3} A series of AEs reported to the state of Massachusetts provides the opportunity to better understand when and how anesthesia-related patient harm may occur during cataract surgery. Hospitals and ambulatory surgery centers (ASCs) in Massachusetts are required to report serious reportable events (SREs) to the Department of Public Health (DPH), and major incidents to the Quality and Patient Safety Division (QPSD) at the Board of Registration in Medicine. SREs are defined as clearly identifiable and measurable events that result in serious adverse patient outcomes and are reasonably preventable.⁴ Major incidents involve serious patient harm that may or may not be preventable.

In 2014, a facility reported 5 cases of permanent vision loss due to globe perforation during eye blocks performed for cataract surgery by an anesthesiologist in 1 day.⁵ Many additional AEs related to cataract surgery were reported to the state in recent years, including anesthesia administered to the wrong eye, wrong lens insertion, and wrong side surgery. The purpose of this article is to describe the series of anesthesia-related AEs that occurred during cataract surgery in Massachusetts from 2011 to 2015.

METHODS

We reviewed deidentified descriptions of all AEs involving cataract surgery that were submitted to the Massachusetts

DPH and QPSD between January 1, 2011, and December 31, 2015. These reports included AEs throughout the cataract surgery process, including preoperative patient assessment, anesthesia administration, surgery, and follow-up. External data sources supplemented the AE reports, including malpractice claim data from the Anesthesia Quality Institute's Anesthesia Closed Claims Project (Seattle, WA) database, containing over 10,000 summaries of claims against anesthesiologists from medical liability insurers; the malpractice insurer CRICO's (Boston, MA) Comparative Benchmarking System, a database of over 300,000 medical malpractice cases; and event reports from the Anesthesia Quality Institute's (Schaumburg, IL) Anesthesia Incident Reporting System, a national database of AEs voluntarily reported by anesthesiologists, and National Anesthesia Clinical Outcomes Registry (NACOR), a database of case-level administrative and clinical information from participating facilities. While facilities report both the presence and absence of specific AEs to NACOR, different facilities report on different AEs. We restricted our analysis to AEs with at least 60 participating facilities (the top quartile of AEs) to increase the reliability of our analyses. Results are presented as counts with percentages. Analyses were conducted in Microsoft Excel 2010 (Redmond, WA) and SAS 9.4 (Cary, NC).

RESULTS

State agencies in Massachusetts received reports of 37 AEs involving cataract surgery from 2011 to 2015, as shown in the Table. Wrong intraocular lens (N = 15, 41%) involved selecting a lens intended for a different patient, and was the most frequent AE, followed by complications from needle-based eye blocks (N = 10, 27%), which included 5 globe perforations (SREs) and 5 non-SRE major incidents, such as retrobulbar hematoma. Other AEs included wrong side eye blocks (N = 3, 14%), suspected toxic anterior segment syndrome (N = 3, 8%), retained object/tissue (N = 2, 5%), wrong patient surgery (N = 1, 3%), and wrong side surgery (N = 1, 3%).

Of the 37 AEs, 29 (78.4%) were SREs reported by 19 Massachusetts facilities from 2011 to 2015. Sixteen of these SREs were reported after ASCs began mandatory reporting in 2014, 6 (37.5%) by 6 hospitals and their associated outpatient centers, and 10 (62.5%) by 5 independent ASCs. Thirteen SREs were reported by 8 additional hospitals from

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Table. Cataract Surgery Adverse Events Reported to Massachusetts Agencies, 2011–2015

| AE Type | 2015, N (%) | 2014, N (%) | 2013, N (%) | 2012, N (%) | 2011, N (%) | Total, N (% of Subcategory/% of Total 37 Events) |
|--|----------------|----------------|----------------|----------------|----------------|--|
| SREs reported to the Department of Public Health ^a | | | | | | |
| Wrong lens implanted | 3 (60) | 4 (36) | 4 (100) | 2 (33) | 2 (67) | 15 (52/41) |
| Wrong eye anesthetized | 1 (20) | 2 (18) | 0 (0) | 1 (17) | 1 (33) | 5 (17/14) |
| Nerve block causing loss of vision | 0 (0) | 5 (45) | 0 (0) | 0 (0) | 0 (0) | 5 (17/14) |
| Retained object/tissue | 0 (0) | 0 (0) | 0 (0) | 2 (33) | 0 (0) | 2 (7/5) |
| Surgery on wrong patient | 1 (20) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | 1 (3/3) |
| Surgery on wrong eye | 0 (0) | 0 (0) | 0 (0) | 1 (17) | 0 (0) | 1 (3/3) |
| Subtotal (SREs) | 5 (100) | 11 (100) | 4 (100) | 6 (100) | 3 (100) | 29 (100/78) |
| % of all surgical SREs ^b | 6.9 | 13.3 | 4.8 | 8.0 | 4.8 | 7.7 |
| Major incidents (non-SRE) reported to the QPSD at the Board of Registration in Medicine ^c | | | | | | |
| Toxic anterior segment syndrome | 3 (50) | 0 (0) | 0 (0) | ... | ... | 3 (38/8) |
| Retrobulbar hematoma/hemorrhage | 2 (33) | 0 (0) | 0 (0) | ... | ... | 2 (25/5) |
| Hemodynamic instability | 1 (17) | 0 (0) | 2 (100) | ... | ... | 3 (38/8) |
| Subtotal (reports to QPSD) | 6 (100) | 0 (0) | 2 (100) | ... | ... | 8 (100/22) |
| Total | 11 (100) | 11 (100) | 6 (100) | 6 (100) | 3 (100) | 37 (100) |
| AEs reported to DPH and QPSD | | | | | | |

Abbreviations: AE, adverse event; DPH, Department of Public Health; SRE, serious reportable event; QPSD, Quality and Patient Safety Division.

^aThe number of SREs involving cataract surgery reported to the Massachusetts DPH from 2011 to 2015. Summarized by the Betsy Lehman Center. Percentages for annual totals are rounded to the nearest whole number.

^bCataract surgery–related events as a percentage of total SREs categorized as category 1 (“surgical or invasive procedure”) on National Quality Forum–endorsed list of SREs.

^cThe number of major incidents (non-SRE) related to cataract surgery submitted to the QPSD at the Board of Registration in Medicine in Massachusetts from 2013 to 2015. Review and analysis conducted by QPSD for the Betsy Lehman Center.

2011 to 2013. Cataract surgery–related AEs represented 7.7% of all surgical events reported annually to the Massachusetts DPH from 2011 to 2015.

Five SREs involved permanent vision loss due to globe perforation during blocks administered by 1 anesthesiologist in a single day. According to the SRE reports, 3 of these patients experienced probable retinal perforation and central retinal artery occlusion, and 2 experienced vitreous hemorrhage, with possible retinal break/perforation. Two mechanisms could have led to vision loss in these cases: (1) restriction of blood flow through the central retinal artery due to pressure exerted on the artery by blood or local anesthetic volume and (2) direct needle trauma to the retina. If restricted blood flow is quickly recognized and treated, the risk of permanent vision loss is greatly reduced. However, in these 5 cases, the facility reported that the patients did not experience pain, and the injuries were not realized until the patients were seen by the ophthalmologist in follow-up 1–3 days after surgery. Neither the ophthalmologist nor anesthesiologist noted any unusual findings at the time of surgery. The patients' axial lengths ranged from 23.16 to 26.77 mm. Two of the patients had axial lengths longer than 25 mm, which may be an independent risk factor for globe perforation.⁶ The SRE reports noted that the anesthesiologist used a 25-gauge, 5/8 inch long needle for all 5 blocks, and a similar anesthetic for each, involving 1–2 mg of midazolam and 50–100 µg of fentanyl for intravenous sedation, followed by 6 mL of a 2%–3.3% lidocaine solution with epinephrine 1:200,000 to 1:333,000 and hyaluronidase 7.5 units/mL, which was administered inferolateral to the eye as a single injection. While all 5 SRE reports noted that the surgeon requested a peribulbar block, 1 report noted elsewhere that the needle was retrobulbar. The Figure shows proper needle placement for eye blocks.

The remaining 8 AEs were non-SRE major incidents that were reported to QPSD from 2013 to 2015, including 3 cases

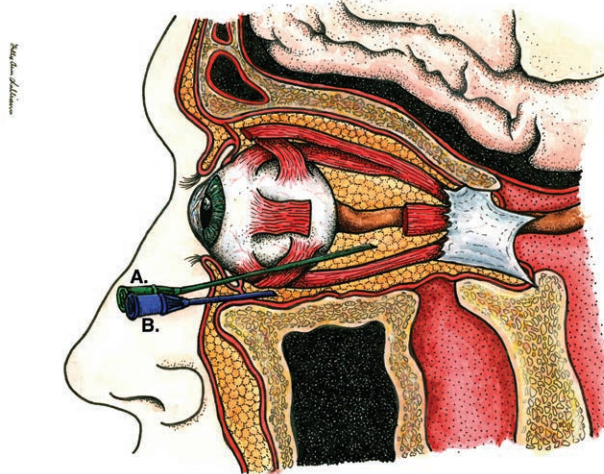


Figure. Injection position for (A) retrobulbar block and (B) peribulbar block. Illustration by Holly Sullivan.

of suspected toxic anterior segment syndrome and 5 complications from needle-based blocks. Of the block-related major incidents, 3 involved peribulbar blocks (1 retrobulbar hemorrhage and 2 episodes of bradycardia/hypotension) and 2 involved retrobulbar blocks (1 retrobulbar hematoma and 1 tachycardia/hypertension/unresponsive state).

Data from other sources document similar anesthesia-related AEs to those in the Massachusetts-mandated AE reports. A query of Anesthesia Incident Reporting System cases between April 2011 and July 2015 using search terms ophthalmology, cataract, retrobulbar, and peribulbar produced 3 cases, 2 of which involved permanent harm after retrobulbar block: 1 globe perforation leading to loss of vision; and 1 case of prolonged intensive care unit admission due to

hypotension, with neurologic sequelae. An analysis of AEs reported to NACOR involving 61,450 cataract procedures performed from January 2014 to May 2015 yielded an AE rate of 1.17 per 100 procedures, with AEs ranging in severity from nausea/vomiting and hypotension to cardiac arrest.

An analysis by CRICO of its Comparative Benchmarking System identified 174 malpractice claims from 2010 to 2014 involving lens and cataract procedures. Ten of these listed anesthesiology as the primary responsible service and cited factors such as inadequate patient assessment, poor communication between providers, and improper choice of anesthetic. An analysis by the Anesthesia Closed Claims Database found 74 claims associated with cataract surgery that occurred from 1990 to 2013, with 21 (28%) of them occurring from 2000 to 2013.⁷ Of the 49 (66%) claims involving anesthesiologist-performed blocks, 41 (84%) were associated with globe perforations; the remaining claims included events involving wrong side blocks and patients moving during the procedure.

DISCUSSION

Preventable AEs occur during relatively safe procedures like cataract surgery, and more can be done to reduce their frequency. Our accompanying narrative review discusses contributing factors to these AEs and recommendations for preventing them.⁸ These results are supported by data from other states' mandated reporting systems. For example, from July 2004 to June 2015, the Pennsylvania Patient Safety Authority received reports of 84 wrong lens errors and 19 wrong side blocks during 1,633,039 cataract surgeries,⁹ with an incidence of 51.4 wrong lens errors and 11.6 wrong side blocks per 1 million cataract procedures. Additional block-related complications included 24 cases of retrobulbar hemorrhage and 3 cases of respiratory arrest related to retrobulbar blocks reported from June 2004 to March 2007.¹⁰

Our data have limitations. First, our sample of 37 AEs likely understates the actual number of cataract surgery-related AEs occurring in Massachusetts. There is evidence of underreporting in both voluntary^{11,12} and mandatory¹³ incident reporting systems. This may be particularly true for ASCs in Massachusetts, among which only an average of 5 (8.4%) facilities per year report an SRE.¹⁴ Given that cataract surgery is primarily performed in ambulatory settings, underreporting of SREs associated with the procedure may be even more pronounced. Second, malpractice claims fail to include cases that did not proceed to litigation,¹⁵ which risks underrepresenting temporary harm that may be more common but correctable, such as wrong eye blocks. Finally, we are unable to verify whether any instances of duplicate reporting exists across our different registry and claims sources.

Considering these limitations, the number of reported cataract surgery-related AEs likely understates the true incidence of harm associated with the procedure. Rather than rely on Massachusetts' AE reporting as a measure of incidence for cataract surgery-related harm, these event reports may be best used as signal data to indicate the types of harm events occurring during cataract surgery and strategies for

prevention. These data warrant further investigation and concerted efforts toward safety improvement for >26 million Americans affected by cataracts today.¹ ■■

DISCLOSURES

Name: Sarah A. Roberto, MPP.

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