

Patient Safety Tip of the Week

December 5, 2017

Massachusetts Initiative on Cataract Surgery

Cataract surgery is generally considered to be one of the safest surgical procedures. We have, however, identified problems related to cataract surgery over the years (see the full list at the end of today's column). A year ago we discussed the findings of a report from Massachusetts' Betsy Lehman Center for Patient Safety regarding patient safety issues in cataract surgery (see our May 17, 2016 Patient Safety Tip of the Week "[Patient Safety Issues in Cataract Surgery](#)").

Now two reports have been published regarding the adverse events (AE's) in cataract surgery from the Betsy Lehman Center study, with a focus on the anesthesia-related issues ([Roberto 2017](#), [Nanji 2017](#)).

The first report ([Roberto 2017](#)) described the reports of 37 AE's reported to state agencies in Massachusetts involving cataract surgery from 2011 to 2015. Wrong intraocular lens (N = 15, 41%) involved selecting a lens intended for a different patient, and was the most frequent AE. We've discussed this issue in several of our prior columns.

Next most frequent were complications from needle-based eye blocks (N = 10, 27%), which included 5 globe perforations (serious reportable events or SRE's) and 5 non-SRE major incidents, such as retrobulbar hematoma. There were also 3 cases of wrong side eye blocks and one case of wrong side surgery. Other AE's included retained object/tissue (2 cases) and 3 cases of suspected toxic anterior segment syndrome. The authors discuss possible mechanisms for the permanent visual loss related to the needle-based blocks. The authors also queried the Anesthesia Incident Reporting System, the CRICO Comparative Benchmarking System, and the Anesthesia Closed Claims Database and identified other adverse events. They conclude that there is likely underreporting of adverse events in all these data sources but that the types of injuries identified should be a signal for investigation into ways to avoid these adverse events. In particular, they note that reporting from ASC's (ambulatory surgery centers) has been less robust than from hospitals. That is a concern since there has been a massive shift in cataract surgery from hospital-based outpatient surgery to ASC's ([Stagg 2017](#)).

The companion paper ([Nanji 2017](#)) delved into details of the Massachusetts cases with adverse events and a panel of experts identified 2 principal categories of contributing factors: systems failures and choice of anesthesia technique. Systems failures included inadequate safety protocols (48.7% of contributing factors), communication challenges (18.4%), insufficient provider training (17.1%), and lack of standardization (15.8%).

Choice of anesthesia technique involved the increased relative risk of needle-based eye blocks.

Among the **inadequate safety protocols** they identified inadequate timeout protocols (40.5%) and poor adherence to time-outs (37.8%) as major contributing factors. Failure to include a second provider in the time out, incomplete time outs, and time outs separated in time from the procedure were specific deviations noted. Improper lens storage was cited in 13.5% of incidents and failure to use at least 2 independent sources of lens verification was also identified as a contributing factor. One facility reported that they bring lenses for all scheduled patients into the operating room at the start of the day.

The authors also identified high case volumes and time pressures as significant contributing factors. These often led to workarounds for time outs, complacency with time outs, and distractions by concurrent activities leading to lack of active participation in time outs. They also mention the literature notes changes in surgical schedules may contribute.

All these are very familiar to us. Over 20 years ago we investigated our first case of wrong lens implantation. A high number of cases were scheduled at an ASC for one ophthalmologist, who brought into the OR all his outpatient records for patients scheduled that day plus all the lenses expected to be used that day. When one patient complained he had wanted to be first case of the day, staff changed the OR schedule and inserted that patient earlier than originally scheduled. As a result, two consecutive patients each received the wrong lens implants before the situation was recognized. That was the case that led us to develop a comprehensive time out process that served as a template for New York State's first time out policy and eventually Joint Commission's Universal Protocol.

Having multiple patient records in the room and having multiple lenses in the room simply increased the odds of mistakes considerably. Verification of the correct lens (using primary source verification) also needs to be a formal part of the time out process. Because cataract surgery typically is done on an ambulatory basis, some factors come into play. There is typically no "hospital" medical record with details available and much of the vital information is in the physician office notes, which have not become part of the facility medical records. Failure to ensure that a history & physical are in the chart prior to the start of the case also is a missed opportunity to identify discrepancies that may lead to wrong patient or wrong eye or wrong lens events.

Nanji and colleagues also identified **communication issues** as the second major contributing factor. Many involved staff miscommunication during lens time outs but others were miscommunications with patients (a cited example was when the wrong patient responded when the nurse called for the next patient). But written communication breakdowns were also an issue, often related to poor handwriting. And, as we so often see in serious incident investigations, failure of staff to speak up and hesitancy to voice concerns in high-turnover rooms was involved in 28.6% of the communications challenges identified.

The third most common contributing factor identified was **insufficient training**. Inadequate orientation and training and use of temporary staff or locum tenens staff contributed in some cases. Inadequate training on the administration of eye blocks was cited as a factor in the 5 cases of globe perforation in the Massachusetts series. The authors note that less than one fourth of anesthesiology residency programs offer ophthalmic anesthesia training.

The fourth contributing category identified was **lack of standardization** across and even within facilities. Things that have not been standardized across sites include: lens ordering forms, site marking techniques, and even variations in lens packaging.

Choice of anesthesia technique was a major focus of the Nanji paper. Over 40% of the adverse events in the Massachusetts series involved eye blocks. They note that none of the AEs involved topical anesthesia, sub-Tenon's block, or general anesthesia. Importantly, the anesthesiologist with 5 reported globe perforations was a contracted provider working his second day at the facility. His privileges had been granted based upon information provided by a credentialing service. The expert panel suspected that inadequate credentialing and insufficient orientation to unfamiliar equipment and lack of knowledge/experience or improper technique contributed as well as the inherent risks associated with the type of anesthesia used. The Nanji paper goes into detail about the types of anesthesia technique (including an appendix describing each in detail) and the great variation with which each is used across facilities and providers.

The panel identified **6 key strategies** to help prevent AE's in cataract surgery:

1. Perform a separate time-out immediately before administering a block, involving active verification by at least 2 team members and the patient, when possible
2. Adopt a standardized, facility-wide policy for marking the operative eye that involves the same unambiguous and enduring mechanism used by all providers within the facility
3. Strengthen credentialing and orientation processes for new, contracted, and locum tenens anesthesia staff, including clear internal assessment criteria and standardized questions to be evaluated by qualified staff; and adequate onboarding that reviews elements such as a facility's work flow, site-marking policy, and time-out procedures
4. Observe the initial blocks of any anesthesia provider who is new to a facility, and require that they have adequate and documented training, both didactic and clinical, on proper technique, management of complications, and identification of high-risk patients
5. Use the least invasive form of anesthesia that is appropriate for the patient and case, considering the patient's preferences and comorbidities, the planned procedure, and potential complications
6. Stay current on evidence-based practices for minimizing the risk of harm from anesthesia, and avoid relying on personal experience to assess the relative safety of techniques

To these we would add our own further recommendations (these and others are described in our May 17, 2016 Patient Safety Tip of the Week “[Patient Safety Issues in Cataract Surgery](#)”):

- Don't allow multiple charts in the room
- Don't allow multiple lenses in the room
- Don't allow handwritten lens orders
- Your time outs need full participation and undivided attention of all participants
- All primary source documents must be available in the room prior to start of a procedure (and the H&P must be visible for all to see, not simply “dictated”)
- Minimize last-minute schedule changes and, if a change is absolutely necessary, make sure that all involved parties are fully aware of that change and its implications
- Use checklists! (for case scheduling, pre-op huddle, anesthesia block, time outs, and post-op debriefings)

The two papers resulting from Massachusetts' Betsy Lehman Center for Patient Safety investigation are important contributions to our understanding of factors contributing to adverse events in cataract surgery. While cataract surgery remains one of the safest procedures done today, the findings indicate we can do more to make it even safer.

Some of our previous patient safety columns involving ophthalmology issues:

June 5, 2007	“ Patient Safety in Ambulatory Surgery ”
March 11, 2008	“ Lessons from Ophthalmology ”
June 8, 2010	“ Surgical Safety Checklist for Cataract Surgery ”
June 2012	“ Tailored Timeouts for Ophthalmologists ”
May 20, 2014	“ Ophthalmology: Blue Dye Mixup ”
September 2014	“ Another Blue Dye Eye Mixup ”
May 17, 2016	“ Patient Safety Issues in Cataract Surgery ”

References:

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Stagg BC, Talwar N, Mattox C, et al. Trends in Use of Ambulatory Surgery Centers for Cataract Surgery in the United States, 2001-2014. *JAMA Ophthalmol* 2017; Published online November 22, 2017

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