

Anesthesia Liability

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Purpose of risk management recommendations

OMIC regularly analyzes its claims experience to determine loss prevention measures that our insured ophthalmologists can take to reduce the likelihood of professional liability lawsuits. OMIC policyholders are not required to implement risk management recommendations. Rather, physicians should use their professional judgment in determining the applicability of a given recommendation to their particular patients and practice situation. These loss prevention documents may refer to clinical care guidelines such as the American Academy of Ophthalmology's *Preferred Practice Patterns*, peer-reviewed articles, or to federal or state laws and regulations. However, our risk management recommendations do not constitute the standard of care nor do they provide legal advice. Consult an attorney if legal advice is desired or needed. Information contained here is not intended to be a modification of the terms and conditions of the OMIC professional and limited office premises liability insurance policy. Please refer to the OMIC policy for these terms and conditions.

Version 11/18/20

Retina specialist Dr. Michael Morley, anesthesiologist Dr. Karen Nanji, and I conducted a study of OMIC ophthalmic anesthesia claims from 2008 to 2018 that was published in the July 2020 issue of *Ophthalmology*.¹ Part 1 of this article presents some of the data from our study. Part 2 provides risk management recommendations and answers questions about liability for anesthesia care. OMIC hopes this information contributes to the ongoing safety of ophthalmic anesthesia.

Part 1: Data from our claims study

As we note in the *Ophthalmology* article, ophthalmic surgery typically yields good outcomes and is well tolerated by the vast majority of patients. The safety of the various anesthesia options contributes to the excellent safety profile of ophthalmic surgery. Anesthesia lawsuits are rare: only 50 plaintiffs filed lawsuits during the ten-year period of our study. Injuries from anesthesia are significant, however, and some of these can be prevented.

¹ Morley M, Menke AM, and Nanji KC. Ocular Anesthesia-Related Closed Claims from Ophthalmic Mutual Insurance Company 2008-2018. *Ophthalmology* 2020 Jul; 127(7):852-858. [https://www.aaojournal.org/article/S0161-6420\(19\)32371-1/fulltext](https://www.aaojournal.org/article/S0161-6420(19)32371-1/fulltext).

Many of the findings were expected. Cataract surgery and retina procedures were the most common type of surgeries, accounting for nearly a quarter of the cases (**Table 1**), and globe perforation was the most frequent injury (**Table 2**). Injection anesthesia, including retrobulbar, peribulbar, and local blocks, accounted for 70% of the lawsuits (**Table 3**). Ophthalmologists performed all but five of the blocks (**Table 4**), and all five of the blocks administered by anesthesia providers led to globe perforation. Six of the globe perforation lawsuits ended up settling with an average payment of \$271,000 (range \$20,000 to 585,000). Although globe perforation is a known complication of blocks, the plaintiffs had significant vision loss, and experts had a hard time explaining that perforation can occur in the absence of negligence.

Table 1. Procedure type in 50 cases

TYPE	NUMBER	PERCENTAGE OF TOTAL CASES
Cataract/IOL replacement	24	48%
Retina (Vitreotomy/scleral buckle)	12	24%
Laser	5	10%
Lid/oculofacial plastic	5	10%
Pterygium	3	6%
Strabismus	1	2%

Table 2. Injury type in 50 cases

TYPE OF INJURY	NUMBER	PERCENT OF TOTAL CASES
Globe perforation	17	34%
Death	13	26%
Retrobulbar hemorrhage	7	14%
Optic nerve injury	4	8%
Vascular occlusion, pain, movement during surgery resulting in injury	2 each, 6 total	4% each, 12% total
Numbness, diplopia, tooth loss	1 each, 3 total	2% each, 6 total

Table 3. Anesthesia type in 50 cases

TYPE	NUMBER	PERCENTAGE OF TOTAL CASES
Peribulbar	16	32%
Retrobulbar	16	32%
Local	6	12%
Topical	5	10%
General	5	10%
Unknown but not general	2	4%

Table 4. Who administered blocks (32 cases)

PROVIDER	NUMBER	PERCENTAGE OF TOTAL CASES
Ophthalmologist	27	85%
Anesthesiologist	3	9%
CRNA	2	6%

Table 5. Who administered blocks complicated by globe perforation (17 cases)

PROVIDER	NUMBER	PERCENTAGE OF TOTAL CASES
Ophthalmologist	12	70%
Anesthesiologist	3	18%
CRNA	2	12%

The main unexpected finding was that death was the second most frequent injury, accounting for 26% of the cases. All but one patient who died had preexisting, significant comorbidities (**Table 6**). Many patients undergoing ophthalmic procedure have these conditions, underscoring the importance of conducting a careful preoperative medical assessment. Two deaths were related to brainstem anesthesia. Blocks were associated with the vast majority of deaths (62%), with one occurring in the physician’s office. All patients who died had been classified ASA Physical Status III, and had procedures performed in an ASC. The site of surgery was challenged by some plaintiff and defense experts. Payments were made in 5 cases; the average was \$73,500 (range \$20,000 to \$160,000). Payments after patient deaths tend to be lower, since there are no future medical expenses.

Table 6. Patients who died (n = 13)

Clinical characteristics	Anesthesia type
Diabetes mellitus	All ASA PS III
Atherosclerotic cardiovascular disease	Retro/peribulbar (8)
Congestive heart failure	General (4)
Pulmonary edema	Topical with sedation (1)

Retrobulbar hemorrhage was the third most frequent complication. Four claims settled; the average payment was \$92,000 (range \$29,999 to \$200,000). Only 3 of the 7 plaintiffs with retrobulbar hemorrhage were taking anticoagulant/antiplatelet medications at the time of the surgery.

Part 2: Risk Management Recommendations

Screen for medical conditions that increase the patient’s risk of complications.

Surgery and anesthesia both have inherent risk. These risks cannot be eliminated. Rather than “clear” patients for surgery, anesthesiologists, cardiologists, and other internal medicine specialists have worked

to develop guidelines to identify the level of risk, optimize the patient's condition before surgery whenever possible, anticipate potential complications, and determine where surgery should take place. We provide detailed recommendations in our document entitled "Preoperative medical assessment."² Those pertinent to anesthesia liability are presented here.

- Screen for conditions that increase their risk for a major adverse cardiovascular event or MACE:
 - Ischemic heart disease
 - Congestive heart failure
 - Cerebrovascular disease, including transient ischemic attacks
 - Diabetes mellitus treated with insulin
 - Renal disease
- Ask about conditions that increase the potential for bleeding, especially if you are planning on using a block for anesthesia:
 - Hemophilia
 - Hypertension
 - Anticoagulant or antiplatelet medications
 - Discuss any changes to these medications with the physician who prescribed them.
 - Obtain informed consent for continuing or discontinuing these medications (our sample consent form is available at <https://www.omic.com/anticoagulant-consent/>).
- Screen for conditions that could impair the patient's ability to breathe well while recumbent:
 - COPD
 - Obesity
 - Sleep apnea
- Refer patients with conditions that put them at higher risk during surgery and anesthesia to their primary care physician or cardiologist.
 - Indicate the proposed surgical procedure, type of anesthesia, and planned site. Ask the physician to share any concerns about these.
 - Ask about the need for preoperative tests such as coagulation studies, ECGs, and chest x-rays.
 - Explain your plan to continue/discontinue anticoagulant or antiplatelet therapy, and get input on any planned changes to the patient's medications.

Discuss your choice of anesthesia/sedation with the patient.

Each type of anesthesia or sedation has different risks. For example, the risk of hemorrhage is increased when anesthesia blocks are administered to patients with poorly-controlled hypertension, hemophilia, and those taking anticoagulant/antiplatelet medications. The need for general anesthesia, especially during prolonged vitreoretinal procedures, may increase the risk for patients with diabetes and cardiovascular or respiratory conditions.

² Menke AM. Preoperative Medical Assessment; <https://www.omic.com/preoperative-medical-assessment/>. Accessed 11/13/20.

Explain the type of anesthesia/sedation you prefer and why you feel this is the best option for the patient. If the patient is referred to another physician for the preoperative medical assessment, clarify what type of anesthesia/sedation is planned, and ask the physician to comment on it. If you will be administering the block, obtain informed consent for it. OMIC's sample consent forms for surgical procedures include a section on the risk of anesthesia and sedation.

Determine what role if any you play in anesthesia care

While hospitals usually have anesthesiologists on site, many ambulatory surgery centers (ASCs) do not. Instead, anesthesia care is provided by Certified Registered Nurse Anesthetists (CRNAs). State nursing practice acts clarify the CRNA's scope of practice, and what if any type of supervision by a physician is required. If physician supervision is required, and there are no anesthesiologists on site or available by phone, ophthalmologists may be deemed the supervising physician during surgery. This supervision may be needed, for example, to comply with billing regulations issued by the Centers for Medicare and Medicaid Services (CMS).

OMIC has analyzed the liability risk for ophthalmologists when anesthesiologists or CRNAs provide care.³ Physicians may be held vicariously (or indirectly) liable for the actions of employees. When physicians supervise CRNAs who are not their employees, however, they are not necessarily liable for the CRNA's actions. Courts generally focus on the amount of control the physician exercises over the provider—whether the anesthesia provider is a CRNA or an anesthesiologist. Ophthalmologists generally ask for a specific type of anesthesia or sedation (e.g., retrobulbar with monitored anesthesia care). They do not provide any guidance on the particular medications or dosages used. In many ASCs, ophthalmologists are asked to sign anesthesia orders, evaluations, or records. While plaintiff attorneys might argue that the ophthalmologist's signature on these forms is proof of control, they will need further evidence that the physician directed the actions of the anesthesiologist or CRNA to win their case.

In a few states, CRNAs may not order the medications they administer during anesthesia. If there is no anesthesiologist present at the surgery center, the ASC may require the surgeon to order these medications. This kind of supervision does increase the liability exposure for ophthalmologists, who have little to no current competency in sedation or anesthesia other than blocks. If your ASC asks you to write anesthesia orders, contact your practice attorney for advice. You may need to perform surgery at a different location.

Similarly, CMS Conditions of Participation stipulate that only a physician may perform the mandatory anesthesia and procedure risk assessment immediately prior to surgery.⁴ Ophthalmologists who do

³ Carol Poindexter, JD, and Kimberly Wittchow, JD, "Anesthesia and Sedation Risks and Precautions," *OMIC Digest* Summer/Fall 2004. Available at <https://www.omic.com/anesthesia-and-sedation-risks-and-precautions/>.

⁴ State Operations Manual Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals Table of Contents (Rev. 200, 02-21-20); accessed 10/29/20. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf.

not have current competency in performing history and physical examinations may not feel they can conduct the APRA. You may need to perform surgery at a different location.

Promote patient safety and limit your liability exposure by taking these actions:

- Communicate any pertinent information (e.g., long or wide eye, staphyloma, ocular or medical comorbidities) both orally and by including it in the preoperative orders.
- Offer moderate (“conscious”) sedation in an office setting **only** if an anesthesia provider is present (i.e., an anesthesiologist or certified registered nurse anesthetist).⁵
 - Patients receiving moderate sedation risk slipping into deep sedation, where the ability to maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate.⁶
 - Most ophthalmic personnel lack the skill, training, and licensure to monitor and rescue patients receiving moderate sedation. Moreover, office surgical suites are rarely adequately equipped to monitor and rescue these patients.
 - If moderate (“conscious”) sedation is administered, the office must have appropriate emergency and monitoring equipment.
- Be prepared to manage complications from blocks.
 - OMIC has settled lawsuits related to the administration of local and retrobulbar blocks in the ASC and office.⁷
 - Patients have experienced globe perforations, hemorrhage, and death from brainstem anesthesia.
 - Be prepared to perform procedures such as lateral canthotomy and CPR with bag mask respirations.
 - Consider early referral to ophthalmic sub-specialists for ocular complications, and urgent referral to a hospital for other anesthesia complications.

RESOURCES

- **OMIC documents**
 - Preoperative medical assessment: <https://www.omic.com/preoperative-medical-assessment/>.
 - Office-based surgery for adults: <https://www.omic.com/office-based-surgery-for-adults-recommendations/>.
 - Sample consent form for anticoagulant/antiplatelet medications: <https://www.omic.com/anticoagulant-consent/>
- **American Society of Anesthesiologists** (all accessed on 10/26/20) www.asahq.org

⁵ Menke AM. Office-based Surgery for Adults. <https://www.omic.com/office-based-surgery-for-adults-recommendations/>. Accessed 11/16/20.

⁶ ASA Continuum of Depth of Sedation: <https://www.asahq.org/standards-and-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedationanalgesia>

⁷ Morley M, Menke AM, Nanji KC. Ocular Anesthesia-Related Closed Claims from Ophthalmic Mutual Insurance Company 2008 to 2018. *Ophthalmology*; 2020; 127: 852-858. [https://www.aaojournal.org/article/S0161-6420\(19\)32371-1/fulltext](https://www.aaojournal.org/article/S0161-6420(19)32371-1/fulltext); accessed 10/30/20.

- ASA Physical Status Classification System: www.asahq.org/clinical/physicalstatus.htm.
- Continuum of Depth of Sedation: <https://www.asahq.org/standards-and-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedationanalgesia>
- Office-Based Anesthesia Guidelines: <https://www.asahq.org/standards-and-guidelines/guidelines-for-office-based-anesthesia>.
- Basic standards for anesthesia care:
 - Pre-Anesthesia Care: <https://www.asahq.org/standards-and-guidelines/basic-standards-for-preanesthesia-care>
 - Basic Anesthesia Monitoring: <https://www.asahq.org/standards-and-guidelines/standards-for-basic-anesthetic-monitoring>
 - Post-Anesthesia Care: <https://www.asahq.org/standards-and-guidelines/standards-for-postanesthesia-care>
- Documentation: <https://www.asahq.org/standards-and-guidelines/statement-on-documentation-of-anesthesia-care>
- Statement on Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists: <https://www.asahq.org/standards-and-guidelines/statement-of-granting-privileges-for-administration-of-moderate-sedation-to-practitioners>
- **American Heart Association** (accessed 10/30/20): www.americanheart.org
 - BLS for Healthcare Providers <https://cpr.heart.org/en/cpr-courses-and-kits/healthcare-professional/basic-life-support-bls-training>
 - AED Implementation Guide: <https://cpr.heart.org/en/training-programs/aed-implementation>.

OMIC policyholders who have additional questions or concerns are invited to call OMIC's confidential Risk Management Hotline at (800) 562-6642, option 4, or email us at riskmanagement@omic.com.