

Ophthalmic Risk Management Digest

OMIC DIGEST

Endophthalmitis and TASS: Claims Results and Lessons

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Uncomplicated cataract surgery was performed on an elderly woman. At the end of the procedure, the ophthalmologist was informed by the nurse that the sterilization indicator on the instruments had not changed. It was feared that the instruments had been washed but not sterilized. The physician and ASC medical director decided not to inform the patient of the potential problem, opting instead to increase the frequency of topical antibiotics. No signs of infection were noted at the first postoperative visit, but two days later, endophthalmitis developed. Ten days after surgery, the two physicians informed the patient and her family that the same strain of pseudomonas aeruginosa had grown in the eye and the ultrasonic bath water at the ASC, leading them to conclude that problems with sterilization were the likely cause of her endophthalmitis and phthisical eye. The patient's lawsuit was settled on behalf of the ASC for \$650,000.

Poor outcomes such as this make infectious endophthalmitis one of the most feared complications of ophthalmic surgery. Recently, a type of inflammatory response known as TASS, or Toxic Anterior Segment Syndrome, has garnered attention and prompted calls to OMIC's Risk Management Hotline. While not all adverse events can be prevented, there is much ophthalmologists can do to reduce the incidence of endophthalmitis and TASS. In its review of OMIC's claims experience and the lessons learned from it, this article offers risk management guidance on more effective prevention, recognition, and response to these sight-threatening conditions.

Since OMIC's inception in 1987, endophthalmitis has accounted for 6% of claims frequency (150 claims out of 2,559 total) and 5% of claims severity (\$3,345,964 in paid indemnity out of \$63,191,199 total). Of these 150 cases, 25 remain open; of the 125 closed cases, only 8 were taken to trial, and in all but one, the jury returned a defense verdict. A poll of the jury after the sole plaintiff verdict of \$735,000 revealed that the award was in response to the defendant group's practice of

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MESSAGE FROM THE CHAIRMAN



Since 1997, OMIC has put considerable effort into forming strategic alliances ("cooperative ventures") with state and subspecialty societies and ophthalmic special interest groups. Under the terms of these alliances, OMIC agreed to provide an annual jointly sponsored risk

management seminar or audioconference to the society's membership. OMIC insureds who were members of a cooperative venture society received a 10% risk management discount on their OMIC premium if they participated in one of these jointly sponsored programs. This discount was 5% more than the standard risk management premium discount available to all OMIC insureds who participate in an OMIC-sponsored program.

These cooperative venture alliances benefited both parties. They allowed OMIC to solidify its relationship with key states and subspecialty groups and provided opportunities for face-to-face contact with OMIC insureds. The cooperative venture societies benefited because their annual meetings were often better attended when an OMIC-sponsored seminar was scheduled.

In 2003, OMIC began to examine the cost-effectiveness of continuing the cooperative venture

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locking up medical records on weekends, thus preventing access to key patient information needed to assess the plaintiff's condition. Since the practice's name did not appear on the jury's form, a settlement on its behalf was effected for the amount of the verdict, and the plaintiff award against the ophthalmologist was vacated.

More than three-quarters (78%) of OMIC's endophthalmitis cases have closed without an indemnity payment. The percentage of cases that have settled (22%) and the median settlement amount (\$75,000) are comparable to OMIC's overall data. Despite the severity of the outcome for the patient, endophthalmitis settlements have ranged from \$9,000 to \$735,000 compared to a low of \$500 and a high of \$1.8 million for all settlements. Reflecting the relative novelty of TASS, allegations in all but 3 of the 150 claims involve an infectious rather than an inflammatory process.

Given the estimated 2 million cataract procedures performed annually in the United States, one might anticipate that cataract surgery would account for 61% of all endophthalmitis cases. Surprisingly, however, only 23% of cataract-related endophthalmitis cases resulted in an indemnity payment.

During the informed consent process for cataract surgery, ophthalmologists routinely disclose this rare complication, and most actively try to prevent its occurrence by treating preexisting conditions such as blepharitis, preparing the eye with povidone iodine, and administering antibiotics. Assuming cataract surgery was indicated in the first place and the endophthalmitis was promptly recognized and treated, experts view this complication as a tragic maloccurrence rather than malpractice. On the other hand, cases of endophthalmitis resulting from trauma are rare (5%), but they result in settlement 57% of the time. Clearly, ophthalmologists who do not administer antibiotics and/or carefully monitor the eye for signs of endophthalmitis after trauma are not supported by defense or plaintiff experts.

Analysis of Risk Issues

It is helpful to analyze the risk issues associated with substandard care by dividing them into four categories. "Clinical" issues include debates in the ophthalmic community on the standard of care and the natural history of the disease or condition. "Systems" issues involve complicated processes of care, such as medications (research, manufacture, distribution, ordering, etc.), equipment, and follow-up and telephone screening

methods. Finally, the acts, omissions, and decisions of individual physicians and patients also impact care outcomes. Table 2 indicates the type and frequency of risk issues in OMIC's endophthalmitis and TASS cases.

Amid ongoing debate of evidence-based guidelines for prevention of

TABLE 2
INCIDENCE OF RISK ISSUES
IN ENDOPTHALMITIS AND
TASS CASES

CLINICAL	4
Antibiotics	
• Route	
• Timing	
SYSTEMS	32
Telephone care (16)	
• After-hours (12)	
• Staff (4)	
Sterilization (6)	
• Not done (2)	
• Ultrasound bath contaminated	
• Cracked irrigation bottle	
• Saline flush contaminated	
• Donor tissue not cultured	
Equipment malfunction (3)	
Product liability (2)	
Medical records (1)	
PHYSICIAN	57
Diagnostic process (18)	
• Diagnosis did not account for symptoms	
• Exam elements	
Documentation (7)	
• Missing	
• Late	
• Altered	
Surgery not indicated or contraindicated (6)	
Treatment (6)	
Follow-up interval (5)	
Referral delay (5)	
Informed consent and disclosure (4)	
Coordination of care with PCP (3)	
Supervision of OD (2)	
Discharge instructions (1)	
PATIENT	5
• Noncompliance	

TABLE 1
ENDOPTHALMITIS CLAIMS BY SPECIALTY

SPECIALTY	TOTAL CLOSED CLAIMS	CLOSED WITHOUT INDEMNITY	CLOSED WITH INDEMNITY	SETTLEMENT RANGE	MEDIAN SETTLEMENT
Cataract	77	59	18	\$9,000 – 735,000	\$75,000
Retina	23	19	4	\$58,000 – 101,476	\$75,000
Cornea	14	13	1	\$300,000	
Trauma	7	3	4	\$24,999 – 248,000	\$31,000
Glaucoma	2	2	0		
Endogenous	1	0	1	\$15,000	
Uveitis	1	1	0		

endophthalmitis, it is noteworthy that antibiotic administration was not a key issue in any case; nor was patient noncompliance a significant factor. Ophthalmologists have a leadership role to play in addressing the many systems issues that adversely impact care outcomes. In their capacity as users, surgical directors, board members, and owners, they can review equipment maintenance and infection control measures in hospitals and ASCs, focusing particular attention on issues such as flash sterilization, re-use of single-use items, and the ordering, preparation, and use of ophthalmic products, devices, and medications.

Screening Patient Complaints

The two primary issues in OMIC's endophthalmitis cases—telephone care and the diagnostic process—indicate the need to carefully screen patients who present with ophthalmic complaints, especially postoperatively, and to educate them about which symptoms to report. Each of these identified risks is squarely within physician control and thus can be modified. This issue's **Closed Claim Study** illustrates the perils of inadequate screening and failed coordination of care; the **Risk Management Hotline** advises physicians on how to disclose and investigate sterilization problems or clusters of cases, and prevent TASS. "Telephone Screening of Ophthalmic Problems" provides screening protocols and contact forms for both staff and physicians taking after-hours calls and can be found at www.omic.com.

"A Witty (WIT-D) Approach to Avoiding Mistakes" proposes an easy-to-remember and effective strategy for improving the diagnostic process. Establish a prioritized differential diagnosis in order to rule out the **worst** case scenario; determine the **information** you need to obtain during the history and examination, or through studies, to rule that in or out; **tell** the

patient and other health care providers to ensure that you are notified of all signs and symptoms that could help establish the diagnosis and determine the treatment plan; and **document** your decision-making process and follow-up plan.

Endophthalmitis or TASS?

Failure to rule out endophthalmitis has resulted in harm to patients and significant liability exposure for OMIC policyholders. Emerging research indicates that the ophthalmologist should also include inflammatory reactions such as TASS in the differential diagnosis. Indeed, mistaking one for the other could lead not only to a delay in treatment but may worsen the outcome.

Table 3 summarizes some of the

distinguishing features. Although this table may be helpful, it can still be difficult or impossible at times to distinguish between endophthalmitis and TASS. For more information see, "Endophthalmitis and TASS: Prevention, Diagnosis, Investigation, Response" at www.omic.com.

1. Carolyn Buppert, "A Witty (WIT-D) Approach to Avoiding Mistakes," *Gold Sheet* 4(6), 2002. See "Risk Management Issues in Failure to Diagnose Cases: A Focus on Traumatic Eye Injuries."
2. Table compiled from information in Mamalis, Nick et al. "Review/Update: Toxic Anterior Segment Syndrome." *J Cataract Refract Surg* Vol 32, February 2006:324-333; Ronge, Laura J. "Toxic Anterior Segment Syndrome: Why Sterile Isn't Clean Enough." *EyeNet*, November/December 2002:17-18; and Davis, Brandon L, and Mamalis, Nick. "Averting TASS: Analyzing the Cause of Sterile Postoperative Endophthalmitis Provides Valuable Clues for its Prevention." *Cataract & Refractive Surgery Today*, February 2003:25-27.

	TASS	ENDOPHTHALMITIS
Cause	Noninfectious reaction to toxic agent present in: BSS solution Antibiotic injection Endotoxin Residue	Bacterial, fungal, or viral infection
Onset	12-24 hours	4-7 days
Signs/ Symptoms * distinguishing feature	Blurry vision Pain: none, or mild to moderate Corneal edema: diffuse, limbus to limbus* Pupil: dilated, irregular, nonreactive* Increased IOP* Anterior chamber: mild to severe reaction with cells, flare, hypopyon, fibrin Signs and symptoms are limited to anterior chamber* Gram stain and culture negative	Decreased VA Pain (25% have no pain) Lid swelling with edema Conjunctival injection Hyperemia Anterior chamber: marked inflammatory response with hypopyon Vitreous involvement Inflammation in entire ocular cavity*
Treatment	Rule out infection Culture anterior chamber Intensive corticosteroids Monitor IOP closely for signs of damage to trabecular meshwork and side effects of steroids Watch closely over next few hours for signs of bacterial infection	Culture anterior chamber and vitreous Intravitreal and topical antibiotics Vitrectomy