Cataract surgery, almost exclusively outpatient, can have a serious complication if instruments retain a chemical residue after cleaning. It is known as TASS, for toxic anterior segment syndrome.

Ophthalmologists say it is rare, but there are no consistent data to indicate when, where, and how often TASS occurs.

The Food and Drug Administration (FDA) hopes to change that and perhaps develop protocols that will lead to elimination of TASS with a reporting and tracking program.

A pilot test was due to begin in February 2012, to last for 3 months, and to lead to development of a permanent physician registry to record TASS occurrences.

**New detection methods**

The FDA estimates 3 million cataract surgeries take place each year and expects that number to increase as the population ages. The American Academy of Ophthalmology (AAO), which is collaborating on the project, estimates 1.8 million of those procedures are paid for by Medicare.

Outcomes Sciences Inc, a firm specializing in data registries, will develop the database and reporting criteria with help from AAO. The Centers for Disease Control and Prevention (CDC) will collect and transport samples of TASS-affected tissue to the FDA for analysis.

What is making the program possible at this time, according to the FDA, is that the agency’s Center for Devices and Radiological Health (CDRH) has developed new methods for detecting contaminants that remain on the delicate instruments used in eye surgery.

In addition to finding better ways of avoiding contamination, the CDRH hopes to determine how devices may be responsible for TASS incidents and to share that information with manufacturers to improve instrument safety.

“Information collected by the program will lead to the earlier investigation of national TASS outbreaks and determination of whether a medical device is the source of the outbreak,” explains Mavina Eydelman, MD, of the CDRH’s device evaluation office in a news release.

**How prevalent is TASS?**

The first goal is to establish how prevalent TASS is, especially in its more serious form, which can harm vision.

“The problem is that TASS is very rare, and we don’t know what the actual incidence is,” says Flora Lum, MD, who is consulting on database development for AAO. She is executive director of the AAO’s Hoskins Center for Quality Eye Care in San Francisco.

“Our people are developing the registry to develop a truer estimate of how often it occurs.”
Building the database
AAO is considering what information to ask for and recruiting surgeons to participate. AAO has not yet decided on a final reporting method for the registry. One possibility is the online Ophthalmic Patient Outcomes Database, which physicians already use to report data for the Centers for Medicare and Medicaid Services (CMS) Physician Quality Reporting System.

For the pilot, Dr Lum is asking surgeons to report on a web-based registry managed by Outcome Sciences. They are asked to report symptoms they have noted as well as products and devices used, such as the type of intraocular lens (IOL).

Questions will be refined following analysis of the pilot results, Dr Lum says. The final database will be open to all ophthalmologists, she says, but participation in the reporting is voluntary.

Cleaning is critical
The term “TASS” was coined by researchers at the University of Utah, where ophthalmology professor Nick Mamalis, MD, has been studying inflammation following ocular surgery. A task force he led after a 2006 outbreak found the most common cause was inadequate cleaning and sterilization of instruments.

Working with the American Society of Cataract and Refractive Surgery (ASCRS), the task force developed guidelines for processing instruments and a website for reporting TASS cases.

A smaller outbreak the previous year was blamed on a different cause: contaminated fluids used in the surgery. A recall of a batch of balanced salt solution (BSS) ended that incident.

In 2010, Dr Mamalis analyzed the TASS cases reported during the previous 3 years. Based on reports by 70 surgery centers, there were 909 cases of TASS out of 50,000 cataract surgeries, a rate of 1.8%. Dr Mamalis and his colleagues then made 54 visits to additional centers. They identified 367 cases out of 140,000 surgeries in the previous 3 years, a rate of 0.3%. The most common causes discovered were:

- inadequate flushing of phaco and irrigation/aspiration instruments
- remnants of enzymatic cleaners from inadequate rinsing
- reuse of cannulas and other devices, whether meant to be single use or reusable
- failure to properly clean ultrasonic baths after each use
- poor instrument maintenance
- presence of preservatives in medications used in the eye.

Dr Mamalis published his findings in the July 2010 Journal of Cataract and Refractive Surgery. “The updated report highlights that cleaning and sterilizing ophthalmic instruments remains a critical factor in TASS cases,” he wrote. In addition, medications injected in the eye must be free of preservatives. “This is especially important in terms of the epinephrine added to the BSS solution during surgery,” he added.

A near miss
A rare and likely under-reported condition like TASS makes it difficult to find accounts of actual cases. However, a pair of physicians found one that was narrowly prevented and were concerned enough to educate themselves about the behind-the-scenes instrument cleaning process.

According to Alex Cohen, MD, PhD, and Thomas Oetting, MD, MS, who posted their account on the University of Iowa Hospitals and Clinics website, they were present during a cataract procedure when the surgeon picked up a syringe filled with BSS to hydrate the wound.
He depressed the plunger to force out air bubbles and waited to see a clear drop of BSS. Instead, the authors recall, “blue-colored fluid came out.” It was trypan blue dye remaining from a previous surgery, though the syringe had been cleaned and sterilized. Because the surgeon noticed in time, the patient received a different dose and recovered normally. “However,” the authors note, “this event seemed like a close call and could have very easily resulted in TASS.”

Had the patient been exposed to an irritant, the patient might have developed blurry vision, eye irritation, anterior segment inflammation, corneal edema, and other symptoms indicating inflammation. Because the procedure is outpatient, OR staff would not be aware of this, but the patient would be expected to inform the surgeon.

The diagnosis of TASS, according to Drs Cohen and Oetting, would be based on the following observations:

• The gram stain and culture are negative.
• The inflammation is limited to the anterior chamber.
• The condition improves with steroids.

Treatment varies depending on the severity. “Some cases are self-limited and don’t need treatment at all,” Dr Lum notes. “Others might require anti-inflammatory treatments such as corticosteroids.”

While finding and reporting TASS are the responsibility of surgeons, evidence so far points to the importance of thoroughly cleaning instruments, the task of OR and central processing staff. Dr Lum recommends using, until further notice, the 2007 ASCRS guidelines, available at www.ascrs.org.

—Paula DeJohn

References
