TASS
TOXIC ANTERIOR SEGMENT SYNDROME

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Toxic Anterior Segment Syndrome (TASS)
Eye disease prompts Toronto cataract surgery centre to close

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CBC News

Doctors in Toronto are setting up a network to track cases of a mysterious eye disease that has shut down one of the city's busiest cataract surgery centres.

Toxic anterior segment syndrome, or TASS, causes an inflammation in the eye's interior. The disease has

Cause of eye disease never found at Montreal hospital

Last Updated: Thursday, November 30, 2006 | 15:57 PM ET
CBC News

Hospitals in Montreal and Toronto have seen a cluster of cases of a mysterious eye disease following cataract surgery.

Toxic anterior segment syndrome, or TASS, causes an inflammation in the eye's interior. The disease has appeared at about 127 eye centres across North America in the past 18 months.
FDA Statement

FOR IMMEDIATE RELEASE

Statement
February 13, 2006

FDA-Requested Recall - Cytosol Laboratories, Inc.
Product Contains Dangerous Levels of Endotoxin

The U.S. Food and Drug Administration (FDA) today delivered a letter to Cytosol Laboratories, Inc., of Braintree, Mass., to request a recall of all brands and sizes of Balanced Salt Solution (BSS) that the firm manufactures. BSS is a drug used by health professionals to irrigate a patient’s eyes, ears, nose and/or throat during a variety of surgical procedures including cataract surgery.

FDA requested the recall because product lots were found to have elevated levels of endotoxin. Endotoxins, also known as pyrogens, are substances found in certain bacteria that cause a wide variety of serious reactions such as fever, shock, changes in blood pressure and in other circulatory functions. FDA has received reports of a serious and potentially irreversible eye injury called Toxic Arterial Sepsis Syndrome (TASS) which occurs when a pyrogenic substance such

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Outbreak Investigation Principles

1. Identify and determine extent of problem
2. Establish surveillance and reporting measures
3. Review disease control measures
4. Enhance communication, planning and personnel with the goal of primary prevention
Condition termed Toxic Anterior Segment Syndrome (TASS) Monson et al. JCRS 1992

Sporadic reports of severe anterior segment inflammation following cataract surgery

October
Increasing reports of sterile Inflammation linked to BSS (Endosol)

November
Joint investigation (AMO/Cytosol) tracking cases by CDC & IORC
Endosol pulled from market
Preliminary Findings – Potential Sources

- Shortening processing time may cause sterilization issues
- No conclusive epidemiological data to suggest any one product was responsible for TASS cases.
- No single IOL type found to be associated with increased cases beyond market share differences
- Most important factor may be the cleaning and sterilization of instruments.
Baffling Disease Shuts Eye Centre
Toronto hospital halts cataract surgery
Infection can cause blindness

Puzzle of Eye Illness Grows
Expert doubts link to disease but eye surgeries remain cancelled
Causes of Inflammation after Anterior Segment Surgery

- Surgical trauma – iris manipulation, complicated surgery, etc.
- Infectious endophthalmitis
- Retained lens material
- Pre-existing uveitis
- Sterile toxic substances
Rule out Endophthalmitis

- Many of the same clinical characteristics as endophthalmitis (pain, decrease VA, corneal edema, fibrin, hypopyon)

**TASS**
- Usually occurs within 24hrs
- Limbus to limbus edema
- Vitreous usually clear
- Culture negative
TASS results when a noninfectious toxic agent enters the anterior segment during surgery and causes an inflammatory reaction.

Anything that you inject into or around the eye during surgery can be a potential cause of TASS.
TASS – Known Causes

Ophthalmic Ointments

- Consider not using them post-op
- Consider not tight patching post-op
- Consider using a suture
- If you notice ointment in the A/C → immediate washout +/- IOL exchange

(Aralikatti et al. J Cataract Refract Surg 29, 595-7)
Intraocular Lens Implants

  - 10 cases of delayed TASS with aluminum oxide polishing compound suspected as the culprit

- Potential Factors:
  - IOL design
  - IOL finish
  - Chemicals used in the polishing/sterilization/packaging process
TASS – Known Causes

Intraocular Lens Implants

- Be careful when trying new technologies
- Implant what you are comfortable with
- Learn from the experiences (and mistakes) of others
TASS – Known Causes

Water

- Outbreak of TASS in 2002 linked to the softened city water that supplied the autoclave steam generator (Hellinger et al. Infect Control Hosp Epidemiol 2006)
  - Found a sulphate impurity on the cataract instruments and in the autoclave steam
- Sterilization of instruments by autoclave steam generator should be supplied with deionized, ultrafiltered water
- Inadvertent injection of water into the AC can lead to TCED (Toxic Corneal Endothelial Destruction)
  - Never have sterile water in any syringe on the surgical table
TASS – Known Causes

Antibiotic Agents (Intracameral)

- Prophylaxis against endophthalmitis
  - Toxicity can occur with improper administration of these antibiotics due to concentration error, preservatives or the solution they are mixed with
- If using intracameral antibiotics, make sure you know exactly how much you are injecting, with what mixture
- Make sure the hospital pharmacy or supplier do not make any changes to the drug without your knowledge
Retained OVD in reusable intraocular instrument
- Cannulas, I/A tips, phaco tips (Kim et al., J Cataract Refract Surg 13, 537-42)
- When washed and sterilized → residue may remain in instrument’s lumen + combine with detergent residue → TASS
- Avoid reusable cannulas (OVD, BSS) whenever possible
- Immediately after case, flush reusable instrument with sterile deionized water (through both ports)
Enzymatic Cleaners

- Used in cleaning process to remove inorganic and organic debris from reusable instruments.
- Enzymes and other active ingredients may form residues on the inside or outside of these instruments, esp. when there is retained OVD.
- Enzymes and other active ingredients are deactivated when exposed to > 140°C (284°F),
  - Most sterilizers only reach 270°F – 273°F.
- Reusable narrow lumen intraocular instruments,
  - Risk of injecting denatured OVD + detergent residue into A/C.
Some of the earliest cases called “sterile hypopyon” endophthalmitis were linked to detergents. Studies have shown *in vitro* detergents toxic effects to the corneal endothelium. Heat stable endotoxin:
- Water baths, ultrasonic baths, and autoclaves that can harbor gram- organisms
- Remain enzymatically active

Oxidized metal deposits:
- Outbreak of copper and zinc impurities on the sterilized cataract surgical instruments from a plasma gas sterilizer (Duffy et al. *Arch Ophthalmol* 118, 1167-76)
Hotel Dieu Hospital – Central Services

- Recent introduction non-enzyme based detergent formulations for cleaning medical devices Accel Wash by Virox

- Approached central processing in person – informed of switch in Oct 2006 due to processing worker with allergy to EDTA

- Previously in use at KGH with no adverse reports
Enzymatic detergents widely used for the cleaning of medical devices because they help remove proteins, lipids, and carbohydrates.

Hydrogen peroxide acts as an oxidant whose hydroxyl free radicals kill microorganisms by attacking essential cell components.

TASS – Prevention

Detergents/Sterilization

- Limit reusable equipment
- Discard old instrumentation
- Immediately before and after cleaning with detergents → flush instruments with sterile deionized water
- Water baths and water reservoirs should be frequently changed to limit endotoxins
- Limit enzymatic detergents
Intracameral Anesthesia

- Kadonosono et al. *J Cataract Refract Surg* 24; 1377-81
  - Preservative-free lidocaine 2% can damage rabbit corneal endothelium
  - No damage at lower concentrations
- Anderson et al. *AJO* 127; 393-402
  - Preservative-free bupivicaine 0.5% caused more corneal edema and thickening in rabbits than lidocaine 1%
- Use a small volume (0.1 cc) of preservative-free lidocaine 1%
  - Wash it out immediately with cataract surgery
TASS – Known Causes

Preservatives
- Benalkonium chloride (BAK) is one of the most commonly used ophthalmic preservatives and is one of the most toxic too
  - Concentrations used in topical meds are toxic if they find their way into the eye
- Intracameral epinephrine 1:1000
  - Preserved with sodium bisulfite 0.1%
- Be aware what solutions you are injecting into an eye
- Ban non-preservative-free BSS from the hospital pharmacy
- Use preservative-free medications whenever possible
TASS – Known Causes

Mixtures

Miochol
Miostat
Trypan blue
Indocyanine green

Always mix with preservative free BSS (NOT WATER)
TASS – Known Causes

**pH**

- Most ocular structures will tolerate a pH between 6.5-8.5
- Outside this range → disruption of junctional complexes in the corneal endothelium → edema
- **Endosol extra™ (AMO)**
Unfortunately, despite a full and thorough investigation, most of the time, no one cause can be identified.
Treatment - TASS

1. Prevention
2. Rule out endophthalmitis
3. Communication
4. Medication
5. Surgical
Prevention – how?

- Communicate with the entire surgical team as to what is appropriate for use in the eye
  - Physicians, surgical nurses, CPD technicians, residents, pharmacists, surgical supply representatives, etc.
- Limit the use of reusable instruments such as cannulas, tubing, etc.
- Limit enzymatic detergents
- Wash and sterilize ophthalmic instruments alone (no GI/GU instrument trays)
- Use sterile de-ionized ultrafiltered water
- Use only preservative-free medications
Treatment - TASS

Rule out endophthalmitis
Treatment - TASS

Communication
If you have a case/cluster of TASS

Alert your surgical team/hospital immediately
Treatment - TASS

Medication

- Once infection is ruled out
  - Topical corticosteroids
  - IOP lowering medications
  - Close follow-up
Treatment - TASS

Surgical

- PKP
- Trabeculectomy or seton
THANK YOU