

TASS RESOURCES

Background

Toxic anterior segment syndrome (TASS) is a noninfectious inflammatory disease with symptoms and signs that mimic infection. A variety of factors that may cause TASS have been described and outbreaks may occur in a cluster at a specific surgical center. Inadequate or inappropriate cleaning of surgical instruments has been implicated as a factor in TASS outbreaks. Recommendations for cleaning and sterilizing intraocular surgical instruments have been prepared by the American Society of Cataract and Refractive Surgery and the American Society of Ophthalmic Registered Nurses.

Another factor has been a high level of endotoxins. The Food and Drug Administration (FDA) has been involved in the investigations of ophthalmic medical products related to TASS outbreaks.

Increased Reporting Efforts to the FDA

Analysis of TASS-related reports reveal significant underreporting and delayed reporting to FDA. In order for FDA's investigation to have the ability to minimize the next outbreak, it is important that reports of TASS potentially associated with ophthalmic products are submitted promptly. Currently, voluntary reporting takes place under MedWatch, a program created in 1993 to encourage voluntary reporting by all interested parties. MedWatch allows health care professionals and consumers to report serious problems that they suspect are associated with the medical devices they prescribe, dispense, or use.

The Academy, therefore, urges ophthalmologists to report adverse events to the FDA through the MedWatch program. (The FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise by checking a box on the form.)

Instructions for Reporting to FDA

To ensure that the necessary information related to TASS cases associated with ophthalmic products are appropriately captured, reporters are being instructed to provide the following information (if available) on the MedWatch reporting form

<http://www.fda.gov/medwatch/report/hcp.htm>

- Write "TASS" in the event description under B5 of the MedWatch form and provide details of the adverse event.

- The manufacturer, trade names and lot numbers of any ophthalmic product (e.g., IOL, irrigating solution, viscoelastic, etc.) that is suspected to have caused TASS. If the suspected ophthalmic product is a drug, e.g., an irrigating solution, it should be included under “D. associated with ophthalmic products are submitted promptly. Voluntary reporting to FDA of device –related Suspect Product(s)” on the Med Watch form. If the suspected ophthalmic product is a device, e.g., a viscoelastic or an IOL, it should be included under “E. Suspect Medical Device” on the Med Watch form.
- The manufacturer and trade names of other ophthalmic products used during the surgical procedure (e.g., irrigation/aspiration tips, inserters, IOL cartridges, etc...) and the manufacturer and trade names of any anti-inflammatory agents used pre-operatively, operatively, or post-operatively. These should be included under “F. Other (Concomitant) Medical Products” on the Med Watch form.
- The results of any cultures taken.
- Any discoloration or abnormalities observed with products (e.g., clear product is discolored, potential contamination from the syringe coating, etc...)
- Summary conclusions of any internal investigation by the institution into the cause of the TASS case.
- Whether single use products were reused.

Educational Resources

Cataract in the Adult Eye, October 2011

<http://one.aao.org/CE/PracticeGuidelines/PPP.aspx>

Toxic Anterior Segment Syndrome from the Academy Practicing Ophthalmologists Curriculum, February 2011

<http://one.aao.org/CE/MOC/POC.aspx>

TASS Task Force, February 2008

<http://aao.org/publications/eyenet/200802/cataract.cfm>

Noninfectious endophthalmitis, Q4, 2007

<http://one.aao.org/cc/News/CurrentInsight/Abstract.aspx?cid=31e0dd40-6d36-41e3-955d-762e2e27cc94>

TASS Outbreak: Lessons Learned, February 2007

<http://www.aao.org/publications/eyenet/200702/cataract.cfm>

Toxic Anterior Segment Syndrome After Cataract Surgery -- Maine, 2006

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5625a2.htm>

Risk Management Resources from OMIC:

Endophthalmitis and TASS: Prevention, Diagnosis, Investigation, Response

http://www.omic.com/resources/risk_man/forms.cfm

*Endophthalmitis and TASS; Claims Results and Lessons
Sterilization Breakdowns in Endophthalmitis, TASS, Spring 2006*

http://www.omic.com/new/digest/Digest_spring06.pdf

Cleaning and Disinfection

American Society of Cataract and Refractive Surgery and the American Society of Ophthalmic Registered Nurses. Special Report: Recommended Practices for Cleaning and Sterilizing Intraocular Surgical Instruments

http://www.asorn.org/alerts/200708ASCRSPPracticeCS_IO-SurgEquip.pdf

American Academy of Ophthalmology Practicing Ophthalmologists Curriculum

Toxic anterior segment syndrome (TASS)

I. Describe the approach to establishing the diagnosis

A. Describe the etiology of this disease

1. Potential intraoperative sources for toxic substances that may result in TASS
 - a. Irrigating solutions and ophthalmic viscosurgical devices (OVDs)
 - i. Incomplete chemical composition
 - ii. Incorrect pH (<6.5 or >8.5)
 - iii. Incorrect osmolality (<200 mOsm or >400 mOsm)
 - iv. Preservatives or additives(e.g., antibiotics, diluting medications)
 - b. Ophthalmic instrument contaminants
 - i. Detergent residues (ultrasonic, soaps, enzymatic cleaners)
 - ii. Bacterial lipopolysaccharides or other endotoxin residue
 - iii. Metal ion residue (copper and iron)
 - iv. Denatured OVD
 - c. Ocular medications
 - i. Incorrect drug concentration
 - ii. Incorrect pH (<6.5 or > 8.5)
 - iii. Incorrect osmolality (<200 mOsm or >400 mOsm)
 - iv. Vehicle with wrong pH or osmolality
 - v. Preservative in medication solution (e.g., epinephrine)

- d. Intraocular lenses
 - i. Polishing compounds
 - ii. Cleaning and sterilizing compounds (e.g., chlorhexidine gluconate)
 - e. Skin cleaners containing chlorhexidine gluconate
 - B. Define the relevant aspects of epidemiology of the disease
 - 1. Patients undergoing cataract or anterior segment surgery often representing an endemic outbreak at a specific surgical center
 - C. List the pertinent elements of the history
 - 1. Typically occurs in the first 12-24 hours (vs 2-7 days for bacterial endophthalmitis)
 - 2. Almost always limited to anterior segment
 - 3. Improves with topical steroids
 - 4. Commonly presents with diffuse corneal edema
 - 5. Blurry vision, eye pain, eye redness, photophobia
 - D. Describe pertinent clinical features
 - 1. Intraoperative and postoperative corneal appearance after a toxic substance has been injected into the anterior chamber
 - a. Intraoperatively
 - i. No effect or
 - ii. Ground glass like haze at endothelial level
 - b. Postoperatively
 - i. Folds in Descemet's membrane
 - ii. Corneal edema (limbus to limbus)
 - iii. Variable intraocular pressure (IOP) elevation due to trabecular meshwork damage
 - iv. Iris damage possible pupil dysfunction
 - v. Cystoid macular edema
 - vi. Sterile anterior segment inflammation with possible hypopyon
 - vii. Fibrin formation in anterior chamber or on intraocular lens (IOL) or iris
 - viii. Relative lack of vitreous cell or inflammation compared to anterior chamber
 - 2. Compare and contrast the appearance of corneal edema from mechanical trauma and that from a toxic agent
 - a. Mechanical trauma typically involves the central cornea but spares the periphery
 - b. Toxic agent involves both the central and the peripheral cornea

II. List the differential diagnosis

- A. Causes of post operative corneal edema
 - 1. Mechanical trauma
 - 2. Toxic agent/substance

3. Pre-existing endothelial compromise, e.g., Fuchs endothelial dystrophy
 4. Excessive use of ultrasound energy
 5. Descemet's detachment
- B. Infectious endophthalmitis
- C. Uveitis flare-up

III. Describe patient management in terms of treatment and follow-up

- A. Intraoperative and postoperative management for corneal damage from a toxic agent (Main treatment of TASS centers on prevention)
1. Intraoperative (Immediate recognition of toxic agent)
 - a. Irrigate anterior chamber with balanced salt solution plus (BSS+) to wash out all the toxic agent
 - b. Refill anterior chamber at conclusion of procedure with BSS+
 - c. Subconjunctival corticosteroid injection
 2. Postoperatively managing from slight to progressively more severe inflammatory reaction
 - a. Consider culture to rule out infection
 - b. Main stay is frequent topical corticosteroid drops (prednisolone acetate 1%)
 - c. Lower IOP with aqueous suppressants drops if elevated
 - i. IOP can be lowered even if within normal range if corneal edema present to lower pressure gradient endothelial cells have to work against (avoid prostaglandin analogues)
 - d. Sub-Tenon's injection of corticosteroid if needed to control inflammation
 - e. Intravitreal corticosteroid injection if needed to control inflammation
 - f. Systemic corticosteroids if needed to control inflammation
 - i. Prednisone –rapid taper
 - ii. Side effects
 - g. Penetrating keratoplasty or endothelial keratoplasty may be required to restore vision if corneal edema is not reversible
 - h. Gonioscopic evaluation for peripheral anterior synechia (PAS)
 - i. Specular or confocal microscopy for endothelial evaluation

IV. List the complications of treatment, their prevention and management

- A. Topical, sub-Tenon corticosteroids include ocular hypertension, and with intracameral or intraocular injections the risk of infectious endophthalmitis

1. Monitor IOP during and after treatment
- B. Review of protocol for cleaning and sterilizing ophthalmic instruments
- C. Review of protocol for ordering medications and preparing medications
- D. Reusable instruments should be kept to a minimum and should be cleaned with sterile, deionized water

V. Describe disease-related complications

- A. Loss of vision
- B. Endothelial cell loss to bullous keratopathy
- C. Secondary glaucoma due to PAS and trabecular meshwork damage
- D. Iris damage with fixed, dilated pupil
- E. Cystoid macular edema

VI. Describe appropriate patient instructions

- A. Close frequent visits in the immediate postoperative period
 1. Monitor inflammation, IOP, corneal edema, vision
- B. Long-term evaluation of cornea, IOP and vision

Additional Resources

1. AAO, Cataract Surgery and Intraocular Lenses, 2nd edition, 2001, p.60.
2. AAO, Basic and Clinical Science Course. Section 11: Lens and Cataract, 2010-2011.
3. Toxic Anterior Segment Syndrome Review/Update Mamalis N, Edelhauser HF, Dawson DG, Chew J, LeBoyer RM, Werner L. J Cataract Refract Surg 2006; 32:324-333.

Approvals

American Academy of Ophthalmology, Quality of Care Secretariat, February 2008; updated December 2011, March 2012

©2012 American Academy of Ophthalmology®
P.O. Box 7424 / San Francisco, CA 94120-7424 / 415.561.8500