1 Better Surgery Through Chemicals
ASCRS 2014 Boston

William G. Myers, M.D., Course Director
Sunday, April 27, 2014 1:00-2:30PM (27-203)

Intravitreal Antibiotics and Steroid for Dropless Cataract Surgery
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2 Financial Disclosure
• Consultant and Investor: Imprimis Pharmaceuticals
• Manufacturer of TriMoxi and TriMoxiVanc
• Manufacturer of lidocaine with epi and with phenylepi
• ASCRS Exhibition Booth: 1481

3 Intravitreal Antibiotics and Steroid for Dropless Cataract Surgery
Intraocular drugs during surgery:
Prophylaxis against Infection
Control Inflammation Preemptively
Greater Patient Convenience
Better Therapeutic Compliance
Less Patient and Insurance Cost
Easier Communication with Patient

4 Intravitreal Antibiotics and Steroid for Dropless Cataract Surgery
Post-Cataract Endophthalmitis: 70/10,000
Povidine (Betadine) Eye Scrub: 23/10,000
ESCRS Endophthalmitis Prophylaxis Study:
Intracameral Antibiotics: 4/10,000

Risk Factors: Prior vitrectomy, diabetes, trauma, glaucoma surgery, corneal transplant, blepharitis, dialysis, compromised
Intravitreal Antibiotics and Steroid for Dropless Cataract Surgery

Topical Antibiotics:
Prophylaxis against most common organisms
Broad spectrum coverage
Fluoroquinolones and Gram Positive Performers
Penetration varies: drug concentration in eye
Compliance issues (including accuracy)
Cost issues: generic vs trade name drugs
Treating Ocular Surface: Threat is inside eye
Vitreous is where the infection takes hold

Intravitreal Antibiotics and Steroid for Dropless Cataract Surgery

Topical Anti-Inflammatory Medications:
Inflammation is guaranteed from surgery
Greater procedures, more tissue manipulation yields greater inflammatory reaction
  Femto-Assisted Cataract Surgery (FACS)
  Phacoemulsification
  Extracapsular Cataract Extraction (ECCE)
  Add glaucoma surgery, iris issues (IFIS)

Intravitreal Antibiotics and Steroid for Dropless Cataract Surgery

Therapeutic Goal of Anti-Inflam Drugs:
  Reduced Pain
  Reduced Photosensitivity (from iritis)
  Lessens Corneal Edema
  Helps Cystoid Macular Edema (CME)
  Faster Visual Recovery

Problems: Toxicity, Discomfort, Cost, Dosing
8 Intravitreal Antibiotics and Steroid for Dropless Cataract Surgery
Compliance, Dosage Issues, Physical Limitations, Patient Psychology:
• Purchase price may be too high, unable to afford
• Insurance limitations causing phone calls and unfilled prescriptions
• Pharmacy inventories may not match prescription: delay obtaining drug (back orders)
• Fingers/hands may not be able to squeeze bottle
• Accuracy of eye drop placement into tear film: missed drop; tremors, head/neck malposition
• Patient anxiety: “Eye Drop Phobia”

9 Intravitreal Antibiotics and Steroid for Dropless Cataract Surgery
Compliance, Dosage Issues, Physical Limitations, Patient Psychology:
• Neck or posture issues: kyphosis, scoliosis, torticollis… impossible to position self
• May require family members to place drops: availability and schedule
• Basic fear of touching eyes: personally unable to place drops
• Extra drops released, not enough volume, missed dosing schedule, quickly running out of drops

10 Intravitreal Antibiotics and Steroid for Dropless Cataract Surgery
Intraocular Antibiotics for Infection Prophylaxis

Narrow Spectrum vs Broad Spectrum Antibiotics
• Ocular compatibility: critical for high safety
• Iso-osmotic and iso-tonic
• pH balanced
• Soluble medication in balanced salt solution
• Stability in formulation: long shelf life
• Ease of handling: transfer to sterile field, preparations by surgical staff for delivery

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Intraocular Antibiotics for Infection Prophylaxis

Popular Medications Injected into Eye

• Moxifloxacin *
• Vancomycin *
• ** Ceftazidime
• ** Cefuroxime

* Look for these in the TriMoxiVanc injection
** ESCRS Intracameral Prophylaxis Study

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Intraocular Antibiotics for Infection Prophylaxis

Combination drugs yield broadest spectrum:
• Different antibiotics require different pH
• Concentrations vary based on target therapy
• Binders and stabilizers critical to avoid precipitation
• Osmolarity and tonicity different for each drug

Single dose delivery would be VERY helpful

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Intraocular Antibiotics for Infection Prophylaxis

Intracameral Injection vs Intravitreal Placement

- Anterior Chamber Volume Turnover: Washout Rate
  - Two hours max retention in anterior chamber (250 μl at 2.5 μl/min)
- Trabecular Meshwork: outflow altered by drug
- Corneal Endothelium: drug concentration and toxicity
  - Direct exposure to highest concentration limits ABX options
- Intravitreal Depot: Bound into protein matrix
- Drug retention and release gradually
- Transparent nature of ABX combination: not visualized

Intravitreal Antibiotics and Steroid for Dropless Cataract Surgery

Intraocular Antibiotics for Infection Prophylaxis

Multiple studies: 100,000+ procedures
- Lower incidence of endophthalmitis with intraocular injection compared to topical eye drops
- Well tolerated intraocular delivery: no toxicity
- Efficiently delivered intraoperatively: various methods
- ESCRS Endophthalmitis Study: 4/10,000 infections
- Not reimbursable by insurance or Medicare

Intravitreal Antibiotics and Steroid for Dropless Cataract Surgery

Intraocular Medications to Reduce Inflammation

- Intraocular Steroids in Solution and Suspension
  - Dexamethasone
    - Soluble steroid in clear solution: minimum floaters
    - Short acting: clears intraocular space within four hours
    - Preservative Free is expensive (Single Dose Vials)
• Not reimbursed by Medicare or insurance

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Intraocular Medications to Reduce Inflammation

• Intraocular Steroids in Solution and Suspension
  • Triamcinolone acetonide
    • Suspension in buffered preservative free solution
    • Small particulate size required to transfer through cannula
    • Long acting drug: several weeks of immunosuppression
    • Suspends easily into vitreous
    • Reimbursed by insurance companies and Medicare (J3300)

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Intraocular Medications & Proactive Control:
Intracameral Injection vs Intravitreal Placement
• Anterior Chamber Placement of Steroid
  • Anterior chamber particulate creates pseudo-hypopyon
  • Particulate clogs trabecular meshwork: IOP spikes

• Intra-Vitreal Placement: Trans-Zonular Injection
  • 27ga or 30ga Cannula: Very tiny particulate size
  • Vitreous holds particulate for slow release
  • Floaters seen: 80% POD1, 20% POW1
  • High safety, no zonular damage, easy to learn, quick delivery

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Intravitreal Medications: Proactive Control
Combination Antibiotic and Steroid into one injection
• TriMoxi and TriMoxiVanc
  • Highly efficient delivery into the vitreous
  • Inexpensive compared to pharmacy drugs (SDV)
  • Produced by Compounding Pharmacy
    • FDA Manufacturing Protocols: GMP
    • Highly Regulated: Highest Safety with Accredited Facility
    • Reimbursable by Medicare and Commercial Insurance
    • Nationally available 2Q2014: Marketing campaign starting
    • Learn more at ASCRS Boston: Booth 1481

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20 Intravitreal Antibiotics and Steroid for Dropless Cataract Surgery

  Intravitreal TriMoxi and TriMoxiVanc:
  Statistics: Endophthalmitis Rates and Inflamm Control
  • 3% to 7% require supplemental topical steroids:
    • My office 2013 Study: 4.7% (n=738)
    • PF1% or FML 0.1% generic option (BID or TID x days)
    • ~1 out of 15 patient have break through inflammation
    • Usually 10-14 days postop, typical symptoms, quick to respond to topical
    • No IOP elevation with <4mg triamcinolone
    • Endophthalmitis rate <0.005%, 10x lower than topical
    • One infection in >20,000 cataract procedures
    • CME rate (OCT): 1.8% in healthy eyes with cataract
      • Compared to 5.79% (2010 Study by Dr Law)
      • NSAIDs not used unless clinically significant edema noted

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Intravitreal Surgery

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ESCRS Endophthalmitis Study:
   Intracameral Antibiotics: 4/10,000
Intravitreal ABX/Steroid Inject: 0.5/10,000
TriMoxi and TriMoxiVanc

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24 Intravitreal Antibiotics and Steroid for Dropless Cataract Surgery
Patients Benefiting from Dropless Cataract Surgery
   • Severe kyphosis without physical ability to instill eye drop
   • Mentally retarded with cataract: combative and uncooperative
   • Nursing home patients: saves nursing time
   • Severe rheumatoid arthritis: unable to squeeze eye drop bottles
   • Impoverish patients without insurance, $$ or access to samples
   • Unrecognized patients with “Eye Drop Phobia”
   • Healthy individuals seeking a more convenient alternative
   • Every one of my patients seeking intraocular surgery

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