Rapid Fire MIGS A Modern Solution to a Complex Problem

Course Description: Minimally (or Micro-) Invasive Glaucoma Surgeries, or MIGS, are an increasingly popular treatment modality in the management of glaucoma. This rapid fire talk with familiarize the audience with four common MIGS procedures, including evidence-based information on their efficacy.

Course Objectives:

1) Understand what defines a glaucoma procedure as MIGS

2) To gain knowledge on the specifics of each of the following four MIGS procedures: GATT, iStent, CyPass, and Xen. This will include the ideal patients, the surgical procedure steps, and post-operative complications.

3) To familiarize optometrists with the efficacy of the MIGS procedures using evidence-based medicine.

MIGS Rapid Fire Outline

1\textsuperscript{st} talk: Goniotomy, Lisa Young, OD, FAAO

1. Introduction

2. Glaucoma Surgery Utilization Graph: Figure 1. Glaucoma surgery utilization
   Source: Medicare Part B paid claims data 1994-2014

3. MIGS
   a. Common goal of glaucoma treatment is to lower IOP
   b. Avoid serious complications of traditional surgery
      i. Trabeculectomy
      ii. GDD

4. General explanation of MIGS
   a. Benefit
      i. Less Invasive approach
      ii. Preserves conjunctival tissue
   b. Patient selection
      i. Early/Mild glaucoma
ii. Target IOP high teens
c. Contraindications

5. Definitions
   a. Ab-interno vs. Ab-externo

6. Approach Options
   a. Increasing trabecular outflow
      i. Goniotomy based
      ii. Stent based: iStent
   b. Suprachoroidal shunts
      i. Cypass micro-stent
   c. Subconjunctival filtration
      i. Xen

7. Goniotomy Based Procedures
   a. Trabectome: first MIGS, approved in 2012
      i. Procedure (Photo/Video)
         1. Ab-interno trabeculotomy uses high frequency electrocautery to ablate TM and inner wall of Schlemm’s canal Outcomes
      ii. Data
         1. Vold, 6 month data
            a. Pre-op IOP 17 mmHg or less
               i. IOP reduction 7%
               ii. 35% reduction in glaucoma medications
            b. Pre-op IOP 30 mmHg or greater
               i. IOP reduction up to 48% IOP reduction
               ii. 25% reduction in glaucoma medications
   b. Gonioscopy-assisted transilluminated trabeculotomy (GATT)
      i. Procedure (Photo/Video)
         1. Ab-interno approach uses a flexible microcatheter (iTrack®250A, Ellex) to enter and open Schlemm’s canal
      ii. Data
         1. Grover et al, 6 month data
a. IOP decrease 7.7 mmHg
b. Average decrease of 0.9 glaucoma medications
c. Kahook Dual Blade
   i. Procedure (Photo/video)
      1. The instrument is designed to excise a strip of TM and Schlemm's canal outer wall
   ii. Data
      1. Abdullah et al, 6 month data
         a. IOP reduction 5.8 mmHg
         b. 59% have reduction of at least one glaucoma medication
d. Goniotomy Risks
   i. Hyphema: Immediate post-op and delayed
   ii. IOP spike
   iii. Iridodialysis
   iv. Corneal endothelial defect

2nd talk: iStent, Anthony DeWilde, OD, FAAO

I. iStent
   a. MIGS procedure that is combined with cataract extraction
   b. Ab-Interno
      i. Idea is to bypass trabecular meshwork with small stent placed at time of cataract extraction
      ii. Benefit is lowering IOP without Ab-Externo procedure that can induce scarring and introduce major complications (i.e. hypotony, endophthalmitis)
   c. Discuss technique (photo)
   d. Spiegel et al – prospective case series – iStent combined with CE
      i. Post-op IOP 17 mmHg
      ii. Medication reduced from 1.6 to 0.4
   e. Samuelson et al – prospective randomized controlled
i. CE with iStent versus CE alone
ii. Treatment reduced IOP by 8 +/- 4 mmHg vs 9 +/- 4 mmHg for control
iii. Reduction in medication in treatment group by 1.4

f. Craven – randomized controlled trial
   i. CE with iStent vs CE alone
   ii. Treatment reduced IOP by 8 mmHg vs 7 mmHg in control
   iii. Reduction in medication in treatment group b 1.3

g. Some small trials and case series looking at multiple stents. Does not appear to add much benefit to 1 stent. Does not appear to add risk either.

h. Risks
   i. Transient hyphema
   ii. If shallow A/C
      1. Iris root tears
      2. Corneal endothelial damage
   iii. Most complications are like those with cataract extraction alone

i. Clinical experience

j. iStent inject
   i. Benefits of 2 stents
   ii. Video of procedure
   iii. Not many trials at this time
   iv. FDA approval 6/2018

k. Discuss future products
   i. iStent SA
   ii. iStent Supra

3rd talk: Cypass, Brett Bence, OD, FAAO

A. Ab-interno insertion of a stent into the supraciliary space
   a. Suprachoroidal/uveoscleral aqueous outflow
      i. AC, ciliary muscle bundles, suprachoroidal space, sclera
ii. Outflow efficacy is age-dependent (indirect measurement)

B. Stents
   a. CyPass® Micro-stent (Alcon, July 2016)
   b. iStent SUPRA® (Glaukos, in trials)
   c. MINject™ (iSTAR, in trials)

C. Ideal candidate
   a. Planned cataract surgery
   b. Mild to moderate glaucoma
   c. One or more topical glaucoma medications
   d. Dry eye; poorly tolerant of topical hypotensive medications
   e. Damage to trabecular meshwork and/or Schlemm’s canal

D. Video presentation

E. COMPASS trial
   a. Two-year COMPASS trial, 24 centers
   b. Mean IOT reduction of stent vs. control: 7.4 vs. 5.4
   c. Medication reduction 2° to stent: 1.4 to 0.2
   d. Medication reduction for controls: 1.3 to 0.7

F. Benefits
   a. Initial: less complications as an ab-interno
   b. Conjunctival sparing if future ab-externo filtering surgery
   c. Reduction in meds, perhaps less variability in IOT than with meds

G. Complications and adverse events; short and long term safety
   a. Loss of best corrected vision
   b. Iritis
   c. Corneal edema
   d. Hyphema
   e. Hypotony
   f. Loss of effect, additional treatment
   g. Stent obstruction, movement
   h. Endo cell loss

H. Alcon voluntarily removes CyPass
   a. 5-year XT study results – effectiveness, ECL
   b. Retention ring exposure as risk factor

I. Take away points - supraciliary shunts
   a. Initial: rapid IOT drop, proximal end patency
   b. Retention ring exposure: stent-to-cornea relationship
   c. Watch for elevation of IOT after 2-3 months
   d. Endo cell count
   e. The future? Feasibility of other supraciliary shunts

4th talk: Xen 45 Gel Stent, Sarah Dougherty Wood, OD, FAAO

1. Intro
   a. Purpose: Create a non-physiologic route to increase outflow to ultimately lower IOP in glaucoma patients
   b. Approved by FDA 11-2016
   c. Size (picture relative to baerveldt)- designed to have some flow resistance through a cylindrical tube to minimize hypotony-
- 45um in diameter
- 6mm in length
d. Composition: porcine gelatin with glutaraldehyde. Highly biocompatible and resistant to neovascularization and fibrotic proliferation. Hydrates on contact with water and conforms to tissue which reduced risk of erosion.
e. Hand-held pre-loaded Injector- 27g with beveled needle tip

2. How it works
   a. MOA- subconjunctival filtration: shunts aqueous from the anterior chamber to the subconjunctival space for filtration. Requires no conjunctival or scleral incision
   b. Procedure steps (including video):
      - Topical anesthesia
      - Inferotemporal clear corneal incision (2mm)- ab interno approach
      - Side port is made to inject viscoelastic into AC
      - Goniolens used to view angle
      - Needle goes across AC to opposite side where sharp tip is inserted at TM or slightly anterior and advanced through sclera to exit 2.5-3mm posterior to limbus into subconjunctival space
      - Stent is deployed and needle retracted
      - Irrigation in anterior chamber done to insure proper location, flow and bleb formation
      - MMC in subconjunctival space with small needle
c. Pictures of placement in the eye
      - Gonioscopy view
      - Anterior segment OCT image
      - View from slit lamp of conjunctiva
d. post-operative care:
      - glaucoma drops are stopped on the day of surgery and only added prn
      - use AB for 4 weeks as prophylaxis and steroids for at least 4 weeks
      - needling if bleb is flat or fibrotic

3. Ideal candidate
   a. Range of glaucoma severity- even in refractory glaucoma (grover et al)
b. Open angle glaucoma, closed angle and other types have not really been studied yet

4. Trials
   - 75.4% had >20% reduction in IOP
   - Mean drop= 9.1mmHg
   - 149 eyes with OAG
   - Xen + cataract surgery: 2/3, Xen alone 1/3
   - At one year, 57.5% of xen alone and 64.2% of xen/phaco had IOP <18mmHg
   - Results: Xen as a stand alone procedure or combined with cataract surgery is safe and had sustained IOP reduction at one year

   - 13 eyes with POAG
   - Mean drop in IOP at 12 months was 23% with a drop in number of medications from 1.9 +/- 1 to 0.3 +/-0.49. (p=0.003)
   - 4 eyes needed needling, 2 had transient hypotony, 1 required repositioning, 2 required further surgical intervention, no loss of acuity in any patient

   - 185 xen versus 169 trab
   - Retrospective cohort study
   - 43% xen vs 31% trab underwent needling
   - 22/xen vs 30/trab had complications- most transient
   - Summary: no detectable difference in failure or safety between the two (although the study was underpowered for safety)

5. Advantages
a. Less invasive than trabs/tubes
b. Can be combined with cataract surgery or stand-alone (cataract extraction done first followed by Xen)

c. Spares the conjunctiva so other procedures such as a trab can be done later, as needed
d. Easy to insert
e. complications are typically mild to moderate with minimal long-term consequences

6. Complications
   a. Needling
   b. Non-persistent loss of best-corrected visual acuity
   c. Transient hypotony
   d. exposure or malpositioning of the implant
   e. long-term safety not known due to recent introduction of this device

7. Clinical experience/case

8. Cost/insurance coverage (if time)