INCORPORATING GLAUCOMA CLINICAL TRIALS INTO CLINICAL DECISION MAKING
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- Associate Professor of Ophthalmology
- Medical School - Indiana University School of Medicine 2004
- Residency - Saint Louis University 2008
- Glaucoma Fellowship - Bascom Palmer Eye Institute 2009

- Director of Adult Clinical Ophthalmology
- Assistant Director of Medical Student Education
Conflict of Interest

I was an investigator (unfunded) in the OHTS3 and PTVT trials
Objectives

• Learn how to incorporate glaucoma clinical trials into everyday practice
• Analyze current glaucoma trial results and understand the main conclusions
Patient/Study Factors

– Does my patient mirror the study population
  - Do they have the same stage of glaucoma?
  - Are they similar to the patient demographics?
  - Does my patient have any circumstances that influence the decision?
  - Was the study designed to answer the question I want answered?
Comparing Studies

• Very difficult to draw good conclusions
• Study design is important
• Different standards of success

Methods
In this retrospective chart review study, we evaluated the baseline clinical characteristics and the 12-month outcomes of patients with mild to severe glaucoma who underwent implantation of two iStent inject devices with concomitant cataract surgery, at a single ophthalmology clinic. The primary outcomes included the intraocular pressure (IOP) and anti-glaucoma medication use. The secondary outcomes were complete success rate (IOP ≤ 18 mmHg without any anti-glaucoma medications) and qualified success rate (IOP ≤ 18 mmHg with or without anti-glaucoma medications). Changes in IOP and medications were evaluated using repeated measure ANOVA with significance set at p < 0.05.

Results
A total of 101 eyes of 61 patients were included with an average age of 68.5 ± 8.8 years. All eyes had moderate to severe glaucoma with the following subtypes: 56% primary open-angle, 18% primary closed-angle, 13% normal tension, 7% pseudoexfoliation, 5% pigmentary, and 1% congenital glaucoma. The preoperative IOP decreased significantly from 16.6 ± 4.0 mmHg to 14.3 ± 2.8 (p < 0.001), and the average anti-glaucoma medication use dropped by 53% at one-year follow-up (p < 0.001). Qualified and complete success rates were 90.1% and 38.6%, respectively. There were no intraoperative complications; however, eight eyes underwent secondary surgery for management of elevated IOP.
Ocular Hypertension Treatment Study

• Study Design
  – Original Study Question- “Does treatment of Ocular Hypertension prevent POAG?”
  – 1636 Patient randomized to medication versus observation
  – Baseline characteristics
    • 40-80yo, 56% Female, 70% Caucasian, 25% AA, 35% with FHx of Glaucoma, c/d 0.4, CCT 570
    • Normal 30-2 HVF, Normal ONH, IOP 24-32 in study eye (21-32 in fellow eye)
OHTS Results

– OHTS Phase 1- 44(4.4%)/104 (9.5%) patients developed glaucoma at five years in the treatment versus observation group

– OHTS Phase 2- 71/60 patients developed glaucoma in the original treatment versus observation group
Take Home Message from the OHTS

- Treatment reduced the conversion of OHTN to POAG by about 50% at 5 years. Number needed to treat was about 20.
- Treatment of high-risk individuals provides greatest benefit

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Untreated</th>
<th>Treated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Risk (&lt;6%)</td>
<td>7%</td>
<td>4%</td>
</tr>
<tr>
<td>Moderate Risk (6-13%)</td>
<td>18%</td>
<td>8%</td>
</tr>
<tr>
<td>Severe Risk (&gt;13%)</td>
<td>42%</td>
<td>19%</td>
</tr>
</tbody>
</table>

10 Year incidence of glaucoma in OHTS 2
Hot of the Presses- OHTS 3

- 46% of patients developed glaucoma (55% in African Americans)- Cumulative incidence
- 49.3% in the Observation group and 41.9% in the original treated group
- 25% of patients had visual field loss
- 3.2% had MD <-22 dB
- 8% had Tube or Trabeculectomy
- 70% were on topical medications
- Incidence increased from low, medium, or high risk tertiles from 32%, 48%, 60%
Other Messages from OHTS

• Risk Stratification with IOP is important in making treatment decisions.
• CCT “rediscovered” as a risk factor
• Cataract Extraction is a good IOP lowering surgery (at least for a few years)
• Important to confirm VF defects
• Glaucoma specialists are “really bad” at picking up disc hemorrhages
  — And disc hemorrhages are important
Selective Laser Trabeculoplasty versus eye drops for the first line treatment of ocular hypertension and glaucoma: LiGHT Trial

• 718 Eyes Randomized to medications versus selective laser trabeculoplasty

• Patient Inclusion Criteria
  – 18 years or older
  – OAG or OHTN
  – MD in better eye of > -12, and worse eye >-15
  – Excluded patient who had undergone intraocular surgery except CE >1 year prior

• Patient Demographics
  – Age 63yo
  – 77% OAG (17% Moderate or Severe), 23% OHTN
  – 70% Caucasian, 20% Black, 7% Asian
  – 55% Male
  – IOP-24 mm Hg
  – 6% pseudophakia
Treatment and Control

- 74% of patients in laser group only had one SLT
- Medication burden was significantly reduced in SLT group
- Both groups had >93% at target at 3 years
- Disease Progression was lower in the SLT group (3.8% versus 5.8%)
- Patient in eye drop group was more likely to have glaucoma surgery
Clinical Endpoints and visits

- VA, IOP and Visual Field were maintained in both groups at 3 years.
- Excluding the 2-week SLT visit, visit number were similar in both groups.
LiGHT Trial Adverse Events

- Ocular and Systemic events were similar between the two groups and generally transient and self limited.
Survival of Repeat SLT (Red) compared to initial SLT (Blue)
LiGHT take home points

• Patients should be offered Laser Trabeculoplasty as a primary therapy
• Patients with severe disease were less likely to be controlled in both the medication and laser groups
• Consider Repeat of SLT even if no prolonged effect from the first laser
• Laser Trabeculoplasty is a cost-effective alternative to drops
• Maybe do not need follow-up before 1 month
Zhongshan Angle Closure Prevention trial: ZAP Trial

- 889 Patient Single Site Prospective trial in which one eye received LPI and other eye did not
- 6-year trial
- Patient Inclusion Criteria
  - 50-70 yo
  - Primary Angle Closure Suspect (PACS) with >180 of appositional closure without OHTN (<22), synechiae or glaucomatous optic neuropathy
- Exclusion Criteria
  - >15 mm Hg rise in IOP with dilation or dark room provocation test

![Flowchart showing patient flow and outcomes](image_url)
Comparison of eyes

- Mild Hyperopia
- AL - 22.49
- c/d 0.4
Kaplan-Meier plot of endpoints

- 3 End Points
  - IOP >24 X2
  - > 1 clock hour PAS
  - AACG attack
Reach Primary Endpoint

- Incidence per 1000 eye years
  - IOP- 0.66 vs 1.11
  - PAS- 3.31 vs 6.64
  - AAC- 0.22 vs 1.11
Comparing eyes that did and did not reach endpoint

<table>
<thead>
<tr>
<th></th>
<th>Eyes that did reach endpoint, n=553</th>
<th>Eyes that did not reach endpoint, n=1723</th>
<th>Hazard ratio (95% CI)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Univariate model</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Randomly assigned to laser peripheral iridotomy</td>
<td>34.5%</td>
<td>50.5%</td>
<td>0.53 (0.30-0.92)</td>
<td>0.024</td>
</tr>
<tr>
<td><strong>Multivariate models</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, years (per 1 year older)</td>
<td>60.9% (54-76)</td>
<td>59.25 (4.97)</td>
<td>1.07 (1.01-1.13)</td>
<td>0.015</td>
</tr>
<tr>
<td>Female (vs male)</td>
<td>81.8%</td>
<td>82.9%</td>
<td>1.11 (0.55-2.24)</td>
<td>0.765</td>
</tr>
<tr>
<td>Randomly assigned to laser peripheral iridotomy (vs control)</td>
<td>34.5%</td>
<td>50.5%</td>
<td>0.52 (0.30-0.91)</td>
<td>0.023</td>
</tr>
<tr>
<td>Baseline intraocular pressure, mm Hg (per 1 mm Hg increase)</td>
<td>15.76 (3.02)</td>
<td>15.06 (2.83)</td>
<td>1.09 (0.99-1.19)</td>
<td>0.075</td>
</tr>
<tr>
<td>Total angle width, score (per 1 score higher)</td>
<td>4.80 (2.37)</td>
<td>5.36 (2.38)</td>
<td>0.91 (0.82-1.02)</td>
<td>0.098</td>
</tr>
<tr>
<td>Limbal anterior chamber depth1, % (per 10% higher)</td>
<td>18.64 (8.41)</td>
<td>22.28 (7.57)</td>
<td>0.49 (0.34-0.71)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Central anterior chamber depth1, mm (per 1 mm deeper)</td>
<td>2.47 (0.24)</td>
<td>2.55 (0.22)</td>
<td>0.21 (0.06-0.72)</td>
<td>0.013</td>
</tr>
<tr>
<td>Lens thickness1, mm (per 1 mm thicker)</td>
<td>4.95 (0.37)</td>
<td>4.87 (0.32)</td>
<td>1.57 (0.65-3.79)</td>
<td>0.318</td>
</tr>
<tr>
<td>Dark room prone provocative test, mm Hg (per 1 mm Hg increase)</td>
<td>3.76 (3.39)</td>
<td>4.27 (2.97)</td>
<td>0.94 (0.86-1.03)</td>
<td>0.399</td>
</tr>
</tbody>
</table>

All values are mean (SD) unless stated otherwise. Multivariable Cox proportional hazards models include laser peripheral iridotomy, age, gender, baseline intraocular pressure, and variables of interest. *Total angle width was calculated by the sum of Shafer grading of all four quadrants (range from 0 to 16, larger number indicates wider angle). **Limbal anterior chamber depth was evaluated by modified van Herick grading. ***Central anterior chamber depth and lens thickness were measured by ultrasound A-scan.

Table 3: Baseline ocular biometrics and gonioscopic factors associated with endpoint at 72 months
# Complications

<table>
<thead>
<tr>
<th></th>
<th>Laser peripheral iridotomy (n=889)</th>
<th>Control (n=889)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Immediately after laser peripheral iridotomy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Localised hyphema, n (%)</td>
<td>257 (29%)</td>
<td></td>
</tr>
<tr>
<td>Localised corneal burn, n (%)</td>
<td>1 (&lt;1%)</td>
<td></td>
</tr>
<tr>
<td>Intraocular pressure ≥30 mm Hg, n (%)</td>
<td>6 (&lt;1%)</td>
<td></td>
</tr>
<tr>
<td><strong>72 months after laser peripheral iridotomy</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corneal endothelium (cells per mm²), mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endothelial cell density</td>
<td>2470.51 (308.32)</td>
<td>2484.59 (306.21)</td>
</tr>
<tr>
<td>Change in endothelial cell density from baseline</td>
<td>-107.95 (152.24)</td>
<td>-93.20 (134.23)</td>
</tr>
<tr>
<td>Cataract Lens Opacity Classification System III, mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nuclear opalescence</td>
<td>2.87 (0.78)</td>
<td>2.79 (0.69)</td>
</tr>
<tr>
<td>Nuclear colour</td>
<td>2.92 (0.79)</td>
<td>2.84 (0.71)</td>
</tr>
<tr>
<td>Cortical</td>
<td>0.78 (1.13)</td>
<td>0.81 (1.13)</td>
</tr>
<tr>
<td>Posterior subcapsular cataract</td>
<td>0.05 (0.41)</td>
<td>0.05 (0.40)</td>
</tr>
</tbody>
</table>

Endothelial cell density was measured by specular microscopy.
Follow-up

• Angles deepened with LPI and became more shallow in control group
• Vision and IOP stayed similar in both groups

<table>
<thead>
<tr>
<th>Presenting visual acuity, logarithm of the minimum angle of resolution</th>
<th>Laser peripheral iridotomy</th>
<th>Control</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (n=889)</td>
<td>0.19 (0.17)</td>
<td>0.19 (0.17)</td>
<td>0.908</td>
</tr>
<tr>
<td>6 months (n=863)</td>
<td>0.15 (0.15)</td>
<td>0.16 (0.16)</td>
<td>0.016</td>
</tr>
<tr>
<td>18 months (n=836)</td>
<td>0.18 (0.16)</td>
<td>0.19 (0.17)</td>
<td>0.017</td>
</tr>
<tr>
<td>36 months (n=778)</td>
<td>0.21 (0.18)</td>
<td>0.22 (0.18)</td>
<td>0.093</td>
</tr>
<tr>
<td>54 months (n=695)</td>
<td>0.24 (0.18)</td>
<td>0.25 (0.19)</td>
<td>0.244</td>
</tr>
<tr>
<td>72 months (n=628)</td>
<td>0.29 (0.21)</td>
<td>0.28 (0.20)</td>
<td>0.121</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intraocular pressure, mm Hg</th>
<th>Laser peripheral iridotomy</th>
<th>Control</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (n=889)</td>
<td>15.07 (2.85)</td>
<td>15.09 (2.83)</td>
<td>0.673</td>
</tr>
<tr>
<td>6 months (n=863)</td>
<td>15.89 (2.66)</td>
<td>15.64 (2.64)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>18 months (n=837)</td>
<td>14.99 (2.71)</td>
<td>14.81 (2.79)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>36 months (n=777)</td>
<td>15.05 (2.35)</td>
<td>14.86 (2.37)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>54 months (n=695)</td>
<td>15.76 (2.38)</td>
<td>15.59 (2.33)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>72 months (n=628)</td>
<td>15.26 (2.47)</td>
<td>15.09 (2.44)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total angle width, score*</th>
<th>Laser peripheral iridotomy</th>
<th>Control</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (n=889)</td>
<td>5.33 (2.37)</td>
<td>5.34 (2.40)</td>
<td>0.858</td>
</tr>
<tr>
<td>6 months (n=863)</td>
<td>10.29 (2.82)</td>
<td>4.91 (2.42)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>18 months (n=837)</td>
<td>9.57 (2.85)</td>
<td>4.53 (2.22)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>36 months (n=777)</td>
<td>11.47 (3.38)</td>
<td>4.74 (3.99)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>54 months (n=695)</td>
<td>9.78 (3.59)</td>
<td>3.69 (2.60)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>72 months (n=628)</td>
<td>9.62 (3.41)</td>
<td>3.93 (3.09)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Limbal anterior chamber depth, %†</th>
<th>Laser peripheral iridotomy</th>
<th>Control</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline (n=889)</td>
<td>22.17 (7.46)</td>
<td>22.35 (7.78)</td>
<td>0.917</td>
</tr>
<tr>
<td>6 months (n=863)</td>
<td>38.33 (16.31)</td>
<td>20.10 (8.15)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>18 months (n=837)</td>
<td>42.19 (20.75)</td>
<td>19.10 (9.80)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>36 months (n=777)</td>
<td>38.90 (17.21)</td>
<td>19.05 (9.00)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>54 months (n=695)</td>
<td>33.16 (14.90)</td>
<td>16.71 (9.46)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>72 months (n=628)</td>
<td>31.85 (13.59)</td>
<td>17.01 (10.39)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*Total angle width was calculated by the sum of Shaffer grading of all four quadrants (range from 0 to 16; larger number indicates wider angle). †Limbal anterior chamber depth was evaluated by modified van Herick grading.
My take home points from ZAP

• **You** probably do too many peripheral iridotomies
• Patient population probably do not match ours
• Is 6 years long enough to look for necessity of PI?
• Have to consider in relation for timing of cataract extraction
• Have to look at each patient and talk with patients regarding R/B/A
Effectiveness of Early Lens Extraction for the treatment of Primary Angle Glaucoma: EAGLE Study

- 419 Eyes Randomized to Clear Lens Extraction versus Laser Peripheral Iridotomy
- Patient Inclusion Criteria
  - 50 years or older
  - No visually significant Cataract
  - Primary Angle Closure with IOP >30 or Primary Angle Closure Glaucoma
  - Excluded Symptomatic Cataract, past LPI or AACG
- Patient Demographics
  - Age 67 yo
  - 31% Chinese
  - 58% Women
  - IOP 30
  - Axial Length 22.6mm
  - Refraction- +1.4
  - MD of VF- -3.3 dB
EAGLE Results

- At 3Y, Eyes with Clear Lens Extraction had
  - Less Medication
  - Less likely to have glaucoma surgery
  - Better Quality of Life

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### Table 1: EAGLE Results

<table>
<thead>
<tr>
<th>Patient-reported NLI (n=106)</th>
<th>Laser/peripheral iridotomy (n=25)</th>
<th>Difference in change between groups (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>205, 68-4 (12-4)</td>
<td>205, 68-4 (12-4)</td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>182, 86-4 (10-4)</td>
<td>196, 86-3 (12-3)</td>
<td></td>
</tr>
<tr>
<td>12 months</td>
<td>188, 107 (8-8)</td>
<td>188, 107 (8-8)</td>
<td></td>
</tr>
<tr>
<td>24 months</td>
<td>172, 90.9 (10-4)</td>
<td>182, 90.9 (10-4)</td>
<td></td>
</tr>
<tr>
<td>36 months</td>
<td>185, 96.1 (12-3)</td>
<td>185, 96.1 (12-3)</td>
<td></td>
</tr>
<tr>
<td>36 months vs baseline</td>
<td>-</td>
<td>-</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

### Table 2: Glaucoma Utility Index

| Baseline          | 190, 0.895 (0.015)               | 190, 0.895 (0.015)                           |         |
| 6 months          | 182, 0.890 (0.017)               | 182, 0.890 (0.017)                           |         |
| 12 months         | 184, 0.897 (0.013)               | 182, 0.897 (0.013)                           |         |
| 24 months         | 177, 0.893 (0.017)               | 182, 0.893 (0.017)                           |         |
| 36 months         | 180, 0.899 (0.012)               | 180, 0.899 (0.012)                           |         |
| 36 months vs baseline | -                              | -                                           | <0.0001 |

### Medications (eye drops)

| Baseline          | 205, 1.0 (1-1)                   | 205, 1.0 (1-1)                               |         |
| 6 months          | 192, 0.64 (0-7)                  | 200, 0.6 (0-6)                               |         |
| 12 months         | 186, 0.4 (0-6)                  | 193, 0.4 (0-6)                               |         |
| 24 months         | 177, 0.4 (0-6)                  | 180, 0.4 (0-6)                               |         |
| 36 months         | 178, 0.4 (0-6)                  | 181, 0.4 (0-6)                               |         |
| 36 months vs baseline | -                              | -                                           | <0.0001 |

### Medications (eye drops) at 36 months

| 0                | 5 (25-64%)                      | 45 (31-39%)                                 |         |
| 1                | 3 (15-6%)                       | 62 (38-86%)                                 |         |
| 2                | 1 (5-7%)                        | 65 (21-84%)                                 |         |
| 3                | 1 (5-6%)                        | 19 (9-98%)                                  |         |
| 6                | 1 (5-6%)                        | 4 (9-98%)                                   |         |
| Missing           | 30 (14-48%)                    | 30 (14-48%)                                 |         |

### Additional glaucoma surgery

- Lens extraction: 0
- Trabeculoplasty: 1 (100%) of 1
- iStent: 0
- Ahmed valve: 0

### Angle closure at 36 months

- 0-4 mm: 64 (31-234)
- 4-8 mm: 17 (7-46)
- Missing: 3 (6-46)

### SYNCHRONAL ANGLE CLOSURE AT 36 MONTHS

- 0-4 mm: 76 (89-45)
- 4-8 mm: 7 (9-46)
- Missing: 12 (13-58)

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**EUGENE AND MARILYN GLICK EYE INSTITUTE**

**INDIANA UNIVERSITY**

School of Medicine
Complications in EAGLE Trial

- Complication rates were similar between two groups
Take Home Points from the EAGLE Trial

• Cataract Extraction can greatly improve intraocular pressure in patients with PAC and PACG
• Medication burden is less after Cataract Surgery compared with LPI
• Insurers and physicians have to adapt to considering Clear Lens Extraction as a treatment for a potentially blinding disease
Quick Question

• A 50 yo with neovascular glaucoma presents on maximum tolerated medical therapy with an IOP of 40 and a vision of 20/80. What is the most appropriate surgical therapy?
  – Trabeculectomy with mitomycin C
  – Baerveldt glaucoma drainage device
  – XEN implantation
  – Ahmed glaucoma drainage device
Ahmed Baerveldt Comparison (ABC)/Ahmed versus Baerveldt (AVB) Trial

• 514 Eyes Randomized to Ahmed FP7 versus Baerveldt 350mm tube shunt

• Patient Inclusion Criteria
  – 18 or older
  – IOP uncontrolled

• Patient Demographics
  – Age 65 yo
  – IOP 32 on 3.3 meds
  – 60% Caucasian, 19% African American
  – 50% of patient had POAG, 29% NVG, 9% Uveitis, 7% CACG
IOP in Pooled ABC/AVB Trial
Kaplan Meier Survival
Medication Usage in the ABC/AVB
Take Home Points from Trial

• Baerveldt implants had a
  – Higher likelihood of success
  – Lower intraocular pressure
  – Lower Medication burden
  – Higher incidence of complications and hypotony

• In Neovascular Glaucoma, Baerveldt had a higher risk for No Light Perception Vision
Tube Versus Trabeculectomy (TVT) Trial

- 212 Eyes Randomized to Trabeculectomy versus Baerveldt 350mm tube shunt
- Patient Inclusion Criteria
  - 18-85 yo
  - Prior CE and/or Trabeculectomy
  - IOP between 18-40
- Patient Demographics
  - Age 71 yo
  - IOP 25 on 3 meds
  - 45% Caucasian, 39% African American, 14% Hispanic
  - 81% of patient had POAG
5 Year Results of the TVT
Survival Curve of the TVT
Take home messages from the TVT

- Trabeculectomy was more likely to fail at 5 years
- Trabeculectomy had a greater chance for reoperation (29% versus 9%) and hypotony (31% versus 13%)
- Tube Shunt Surgery has a lower risk of serious complications
- Trabeculectomy achieves lower pressure with similar medication usage
- Perhaps Trabeculectomy had a higher risk of failure since 55% had undergone prior Trabeculectomy
Quick Question

• A 65 year old surgical naïve patient presents with progressive severe glaucoma despite SLT x 2 on maximal tolerated medical therapy with an IOP of 18. What is the most appropriate surgical therapy?
  – Trabeculectomy with Mitomycin C
  – Baeveldt Glaucoma Drainage Implant
  – iStent inject
  – Ahmed Glaucoma Drainage Implant
Primary Tube versus Trabeculectomy (PTVT) Trial

- 242 Eyes Randomized to Trabeculectomy versus Baerveldt 350mm tube shunt
- Patient Inclusion Criteria
  - 18-85 yo
  - No Prior Intraocular Surgery
  - IOP between 18-40
- Patient Demographics
  - Age 61 yo
  - IOP 24 on 3 meds
  - 40% Caucasian, 48% African American, 6% Hispanic, 6% Asian
  - 90% of patient had POAG
3 Year Results of PTVT Trial
3-Year Survival Curve of the PTVT

<table>
<thead>
<tr>
<th>Follow-up (Months)</th>
<th>Tube Group</th>
<th>Trabeculectomy Group</th>
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<tr>
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My take home points from the PTVT

• At 3 years, Tube shunt surgeries have a
  - greater risk of failure (37% versus 28%)
  - higher IOP (14 versus 12 mm Hg)
  - higher rate of reoperation (37% versus 27%)
  - greater need for medication (2 versus 1)
  - lower postoperative complications (34% versus 48%)

• Post Hoc comment
  • Tube Shunts performed poorly at low starting IOP
A Prospective Randomized Trial comparing Hydrus and iStent microinvasive glaucoma surgery implants for standalone treatment for Open-Angle Glaucoma- COMPARE Study

- 152 Eyes Randomized to Hydrus versus two iStent
- Patient Inclusion Criteria
  - 45-84 yo
  - Open Angle Glaucoma- allowed PXF, PDG
  - IOP between 23-39 (post washout)
- Patient Demographics
  - Age 67 yo
  - Female 56%
  - IOP 19 on 2.6 meds
  - 64% European, 3% African, 18% Hispanic, 15% Asian
  - 94% of patient had POAG
  - MD- -6.2 dB
  - 64% Phakic
Intraocular Pressure and Medication Use

A. Intraocular Pressure

B. Medications

Postoperative Day

Hydrus - 2 iStents

Mean Count

0.6 p<0.001

1.1

0.8 p<0.001

1.5

1.7

1.0

p<0.001
Safety

- Both Hydrus and iStent had excellent safety profiles
Take Home Conclusions from COMPARE Trial

- Both offer good iop lowering effect with a reduction in patient medication burden, with Hydrus achieving lower intraocular pressure with less medication
- iStent studied is ”older” generation
- Both surgeries with excellent safety profiles
Tips in Analyzing Clinical Trials and Incorporating Results into our practices

- Try to match patients with clinical scenario when trying to assess recommendations to patient
- Realize studies all come with limitations as to protocol variations
- Study Results are dependent on Study Populations
- Surgeon expertise and experience which may dictate superior results