Hypotony as an Adverse Outcome of Minimally Invasive Glaucoma Surgery

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Disclosure Statement

- Dr. Skuta serves on the Claims Committee and the Finance Committee of the Ophthalmic Mutual Insurance Company (OMIC).
- He has no other financial disclosures.
- He has served as an investigator for the Collaborative Normal Tension Glaucoma Study, the Advanced Glaucoma Intervention Study, the Collaborative Initial Glaucoma Treatment Study, and the Tube versus Trabeculectomy Study.
- He also has served on the Data and Safety Monitoring Committee for the Ocular Hypertension Treatment Study.
Definition of Hypotony

- Some would define hypotony as intraocular pressure (IOP) below set level (e.g., < 6 mmHg).
- In two textbooks, Pederson defined “statistical hypotony” as IOP < 6.5 mmHg (more than 3 standard deviations below mean).
- Others, including Pederson, would define “clinically significant hypotony” as IOP below which eye does not function normally.
- Fannin, Schiffman, and Budenz (Ophthalmology, 2003) defined hypotony as IOP ≤ 5 mmHg.
- Tube versus Trabeculectomy (TVT) Study: IOP ≤ 5 mmHg on two consecutive visits after 3 months.
Manifestations of Hypotony

- Corneal folds, edema, and astigmatism
- Shallow or flat anterior chamber
- Peripheral anterior synechiae
- Cataract
- Choroidal effusion and suprachoroidal hemorrhage
- Hypotony maculopathy:
  - Decreased visual acuity
  - Optic nerve and retinal edema/cystoid macular edema
  - Macular folds
- Some eyes with “statistical hypotony” experience none of the above
- Some eyes without “statistical hypotony” experience some or all of the above
Courtesy of Paul Palmberg, MD, PhD
Risk Factors for Hypotony Maculopathy

- 228 eyes of 228 patients from BPEI with hypotony
- 81 eyes with hypotony maculopathy; 147 control eyes with hypotony alone
- Risk factors for hypotony maculopathy: young age, male gender, and myopia
- History of diabetes and choroidal effusion were associated with decreased risk for hypotony maculopathy

Fannin, Schiffman, Budenz, Ophthalmology, 2003
# Risk Factors for Hypotony Maculopathy

<table>
<thead>
<tr>
<th></th>
<th>Hyp/Mac</th>
<th>Hyp</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>81</td>
<td>147</td>
<td></td>
</tr>
<tr>
<td>Mean age (y)</td>
<td>50.5</td>
<td>70.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Male</td>
<td>54.3%</td>
<td>33.6%</td>
<td>0.004</td>
</tr>
<tr>
<td>Ref error (D)</td>
<td>-3.02</td>
<td>-0.61</td>
<td>0.003</td>
</tr>
<tr>
<td>Choroidals</td>
<td>21%</td>
<td>52.4%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Fannin et al, Ophthalmology, 2003
TREATMENT OUTCOMES IN THE TUBE VERSUS TRABECULECTOMY (TVT) STUDY AFTER FIVE YEARS OF FOLLOW-UP

Steven J. Gedde, M.D.
Bascom Palmer Eye Institute
## Treatment Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Tube Group (n = 73)</th>
<th>Trabeculectomy Group (n = 84)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure</td>
<td>24 (33%)</td>
<td>42 (50%)</td>
<td>0.034</td>
</tr>
<tr>
<td>Success</td>
<td>49 (67%)</td>
<td>42 (50%)</td>
<td>0.034</td>
</tr>
<tr>
<td>Qualified</td>
<td>31 (42%)</td>
<td>18 (21%)</td>
<td></td>
</tr>
<tr>
<td>Complete</td>
<td>18 (25%)</td>
<td>24 (29%)</td>
<td>0.58</td>
</tr>
</tbody>
</table>
## Reasons for Treatment Failure

<table>
<thead>
<tr>
<th>Reason</th>
<th>Tube Group (n = 24)</th>
<th>Trabeculectomy Group (n = 42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate IOP control</td>
<td>20 (83%)</td>
<td>28 (67%)</td>
</tr>
<tr>
<td>Persistent hypotony</td>
<td>3 (13%)</td>
<td>13 (31%)</td>
</tr>
<tr>
<td>Loss of LP vision</td>
<td>1 (4%)</td>
<td>1 (2%)</td>
</tr>
</tbody>
</table>

\( P = 0.43 \) for the difference in distribution of reasons for treatment failure
Collaborative Initial Glaucoma Treatment Study (CIGTS)
Collaborative Initial Glaucoma Treatment Study

- Hypotony not systematically defined or recorded as postoperative complication on post-trabeculectomy follow-up form
- Of 465 trabeculectomies performed in study, 4 eyes (0.9%) were described by investigators under “Other Problems” as having “hypotony” or “prolonged low IOP.”
Trabecular Micro-Bypass Stents
Intracanalicular MicroStent (Hydrus)
Trabecular Micro-Bypass Stent (iStent)

- Randomized controlled clinical trial in which 111 patients underwent iStent with cataract surgery and 122 underwent cataract surgery alone.

- One eye (group not specified) experienced transient hypotony at 5 – 7 hours that resolved by 1 day postoperatively.

Samuelson et al, Ophthalmology, 2011
Ab-Interno Suprachoroidal Stents
iStent Supra

From RA Hill et al, Surgical Innovations in Glaucoma, 2014
Suprachoroidal Micro-Stent (CyPass)

- Prospective case series in which 184 patients underwent cataract surgery and placement of suprachoroidal micro-stent
- Most common complication was transient early hypotony (IOP < 6 mmHg, 25 eyes, 13.8%)
- Hypotony resolved in all but 1 case by 1 month and all cases by 6 months

Hoeh et al, JCRS, 2013
Suprachoroidal Micro-Stent (CyPass)

- Transient hypotony was attributed to micro-stent placement and creation of cyclodialysis cleft
- Particularly in early postoperative course, cleft may extend beyond implant’s external diameter

Hoeh et al, JCRS, 2013
Subconjunctival-Based Transscleral Filtration Devices
AqueSys XEN Gel Stent

- Soft, collagen-based gelatin implant injected into subconjunctival space by ab interno approach through clear corneal incision
- No peer-reviewed publications to date

 Courtesy Steven R. Sarkisian, Jr., MD
InnFocus Microshunt

- Filtering device made from polymer called poly(styrene-block-isobutylene-block-styrene) and placed by ab externo approach
- Procedure involves creation of fornix-based conjunctival flap and use of intraoperative mitomycin
- No peer-reviewed publications to date

From InnFocusInc.com
AqueSys XEN Gel Stent and InnFocus Microshunt

- Both involve diversion of aqueous to subconjunctival space and creation of filtering bleb
- InnFocus Microshunt accompanied by use of intraoperative mitomycin
- Both devices attempt to control flow and minimize hypotony by applying Poiseuille’s Law of laminar flow to create tube that is sufficiently long and narrow
- As filtering procedures, will be important to determine incidence of transient and long-term hypotony and any impact on vision
Summary and Conclusions

- Would be helpful and appropriate to establish consistent definition of hypotony.
- Documentation of transient and longer term hypotony may be particularly relevant for minimally invasive surgical procedures that involve placement of device into suprachoroidal space or subconjunctival filtration.
- Very important to document visual impact, if any, and differentiate postoperative “statistical hypotony” from “clinically significant hypotony”.