New Findings From The SAMMPRIS RCT Comparing Intracranial Stenting To Best Medical Treatment (BMT): BMT Is Feasible And There Is A High Incidence Of In Stent Restenosis (ISR) Causing Strokes

Colin P. Derdeyn, M.D.
Krausenhoff Professor and Chair, Department of Radiology
Professor of Radiology, Neurology, and Neurological Surgery
Director, NeuroEndovascular Service

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What is Good Medical Therapy?

- Single antiplatelet agent (dual for symptomatic patients)
- Systolic BP less than 140 mm Hg
- LDL-cholesterol less than 70
- Modest physical activity
- Smoking cessation

Turan et al Circ Cardiovasc Q Outcomes 2012

Risk Factor Control and 3-yr Stroke/MI/Vasc Death

In Stent Restenosis (ISR)

Financial Disclosures

Consultant
- Penumbra, Inc (3D separator DSMB)
- Silk Road, Inc (Chair, ROADSTER DSMB)
- Microvention, Inc (Angio core lab LVIS II trial)

Equity
- Pulse, Inc (Chair, Scientific Advisory Board)

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It Can be Done: Tolerance and Compliance

% of patients meeting risk factor targets in SAMMPRIS

Turan et al Neurology 2017
• 183 of 224 randomized to the stent arm were stented and had no 30-day endpoint
• 27 (14.8%) had stroke (17) or CITS (10)
  – Adequate vascular imaging in 24
  – ISR in 16 (67%)
• 16 (8.7%) TIA over median follow up of 35 months
  – Adequate vascular imaging in 10
  – ISR in 8 (80%)

ISR Results

ISR Multivariable Results

<table>
<thead>
<tr>
<th>Variable</th>
<th>No Endpoint (n=153)</th>
<th>Symptomatic ISR (n=18)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIHSS &gt;1</td>
<td>48 (32%)</td>
<td>9 (53%)</td>
<td>0.11*</td>
</tr>
<tr>
<td>Cholesterol ≥ 148 mg/dl (median)</td>
<td>79 (52%)</td>
<td>4 (22%)</td>
<td>0.02*</td>
</tr>
<tr>
<td>LDL ≥ 90 mg/dl (median)</td>
<td>75 (49%)</td>
<td>5 (28%)</td>
<td>0.13*</td>
</tr>
<tr>
<td>JPEG review (yes)</td>
<td>64/115 (56%)</td>
<td>2/12 (17%)</td>
<td>0.07</td>
</tr>
<tr>
<td>Problems with Balloon (yes)</td>
<td>4 (33%)</td>
<td>2 (11%)</td>
<td>0.12</td>
</tr>
<tr>
<td>Pre-Angio Dn ≥ 2.9mm (median)</td>
<td>78 (47%)</td>
<td>13 (76%)</td>
<td>0.04</td>
</tr>
<tr>
<td>Max Balloon Pressure &gt; 6 atm (median)</td>
<td>47 (31%)</td>
<td>9 (50%)</td>
<td>0.12</td>
</tr>
<tr>
<td>Credentialing &gt; 6 aneurysm stents</td>
<td>66 (43%)</td>
<td>12 (66%)</td>
<td>0.08</td>
</tr>
</tbody>
</table>

P less than 0.14 included
* Similar p values when tested as a continuous variable

Symptomatic ISR

Annual rates for Symptomatic ISR (Kaplan-Meier)

<table>
<thead>
<tr>
<th>Time</th>
<th>Rate</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>7.1</td>
<td>(4.1 – 12)</td>
</tr>
<tr>
<td>2 year</td>
<td>8.9</td>
<td>(8.9 – 14)</td>
</tr>
<tr>
<td>3 year</td>
<td>11.2</td>
<td>(7.2 – 17)</td>
</tr>
</tbody>
</table>

ISR Conclusions

• Symptomatic ISR is a major barrier to the potential success of PTAS for ICAD
• 3-year risk of recurrent stroke after peri-procedural events was 10% - same rate as medical group
  – Majority (11/17, 65%) associated with ISR
• Symptomatic ISR not strongly associated with any baseline characteristics
  – Study underestimates ISR incidence
  – Relationship with risk factor reduction remains to be explored