A Surgeon’s View of the Silk Road System of Cervical Access and Reversal of Flow for CAS

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Disclosure Statement of Financial Interest
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship Company
Grant/Research Support Toshiba, Medtronic, Microvention
Consulting Fees/Honoraria Claret, Boston Scientific, Claret, Medina, Ostial, Apama, Ocular
Intellectual Property Rights Toshiba, Medtronic, Microvention
Company Ownership/Founder None
Intellectual Property Rights None
Other Financial Benefit None

Surgeon’s Perspective
CEA is Eating CAS’s Lunch…Why??
Higher Stroke Rate!!…Why is that??

Two Big Reasons:
1. We ignore the Aortic Arch
2. Inadequate Embolic Protection

Endovascular
Klaus…How would you handle this??

CASE SUMMARY

Patient Demographics
Age: 74 yrs
Gender: Male

Risk Factors
• Smoker
• Hyperlipidemia
• Hypertension
• Anti-cardiolipin antibody pos
• COPD
• PVD
• CAD
• CVA

Past Medical History
Previous Interventions:
Bilateral CEA (R 2013, L 2008);
R Iliac stent 5/15
Medications: Coumadin (held), Plavix, Aspirin, Atravastatin, Amlodipine

Clinical Presentation
Symptom Status: L Amnios of x 3-4 months
Doppler increasing serial ultras, L 461/102 with internal hyperplasia
CTA: 70% L ostial stenosis; 80-90% L CCA stenosis

CASE IMAGING: CTA (ostial and bifurcation stenosis)
Angiogram: Type II arch; L CCA ostial stenosis 70-80% with tortuosity; L Distal CCA 80-90% stenosis

As Dx catheter placed in the left CCA, TIA left visual loss and right UE numbness

How about this one???

• 74 year old woman
• 40 pack-year tobacco history
• TIA characterized by aphasia and R hemiparesis
• Completely resolved on presentation
  NIHSS 0
  CT Normal

Symptomatic L ICA stenosis

• L CAS
• ASA/Plavix Load
• Cook Shuttle, VTK, 0.038
• EPI Filter device
• Wallstent
• Aviator Post-Dilation Balloon
Post-Procedure

- Immediately Dysarthric with L facial and LUE weakness
- Angio L ICA and cranial unremarkable
- Review R ICA… normal
- ?? VBI symptoms

Post-Procedure

- Loaded with integrillin and 24 hour gtt instituted
- Immediate CTP and CTA negative.
- Pt improved over several hours

Post-Op Day 4 - A new event

- On ASA/Plavix.
- Sudden L facial and LUE weakness, confusion and slurred speech
- CTP: R posterior frontal increased TTP

MRI: Acute embolic ischemia

What's going on??

Lets get a CTA of the Arch
Discharge

- Somewhat improved on discharge.
- Mild facial and LUE weakness/apraxia/confusion.
- D/C Home with OP rehab.

Lessons

- Always look at the Arch
- Don’t take chances with
  - Difficult access ...esp in elderly
  - Arch disease

Strokes During CAS

CAS... 3 steps that cause strokes
1. Aortic Arch Disease
   - 18% contralateral stroke rate in CAPTURE Study
2. Crossing lesion without EP
3. Incompetent Filters
4. Proximal EP without flow arrest


Diseased Aortic Arch

<table>
<thead>
<tr>
<th>4.1%</th>
<th>6.9%</th>
<th>2.3%</th>
<th>3.1%</th>
<th>0.0%</th>
<th>1.0%</th>
<th>2.0%</th>
<th>3.0%</th>
<th>4.0%</th>
<th>5.0%</th>
<th>6.0%</th>
<th>7.0%</th>
<th>8.0%</th>
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</thead>
<tbody>
<tr>
<td>30-Day All Stroke (1)</td>
<td>30-Day All Stroke &gt; 75yrs (2)</td>
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CAS Loses!!
Double the Stroke Rate
CREST – 30-Day All Stroke Rates

**ROADSTER Study Outcomes**

Intention to Treat & Per Protocol Groups

<table>
<thead>
<tr>
<th>Event</th>
<th>ITT N=141</th>
<th>PP N=136</th>
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</thead>
<tbody>
<tr>
<td>S/D/MI*</td>
<td>5 (3.5%)</td>
<td>4 (2.9%)</td>
</tr>
<tr>
<td>Major Stroke</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>2 (1.4%)</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td>Death</td>
<td>2 (1.4%)</td>
<td>2 (1.5%)</td>
</tr>
<tr>
<td>MI</td>
<td>1 (0.7%)</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td>Stroke &amp; Death</td>
<td>4 (2.8%)</td>
<td>3 (2.2%)</td>
</tr>
<tr>
<td>Cranial Nerve Injury (CNI)</td>
<td>1 (0.7%)</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td>CNI Unresolved at 6 Months</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

*Hierarchical Per Protocol excludes major protocol deviations
All FDA-approved carotid stent systems were used per site preference (Acculink, Xact, Precise, Protégé, Wallstent)

**ROADSTER Study**

Subgroup Outcomes

<table>
<thead>
<tr>
<th>Event</th>
<th>ITT N=66 (47%)</th>
<th>PP N=36 (26%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S/D/MI</td>
<td>3 (4.5%)</td>
<td>1 (2.8%)</td>
</tr>
<tr>
<td>Major Stroke</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Death</td>
<td>2.8%</td>
<td>2.8%</td>
</tr>
<tr>
<td>MI</td>
<td>1.5%</td>
<td>0%</td>
</tr>
<tr>
<td>Stroke &amp; Death</td>
<td>3.0%</td>
<td>2.8%</td>
</tr>
<tr>
<td>Strokes in Women</td>
<td>0%</td>
<td>0%</td>
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</table>

**Why Such Great Results?**

- No strokes from Arch Disease/Manipulation
- Complete Embolic Protection
- Flow is Reversed

**Silk Road Wins Hands Down!**

- Procedure is simple!
- The patient is the beneficiary
- Results beat CEA as well as CAS (Trans Fem)
- And BTW it will become a percutaneous procedure

**Innovation**

The Future of Medicine...and Neurosurgery

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Gates Vascular Institute

**VEITH Symposium**

Connecting the Vascular Community

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