Recent Strategies in the Management of Carotid Artery Disease

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I am a veteran of >2200 CAS Procedures, and passionately believe that CAS, IF performed by appropriately trained operators who use meticulous technique AND careful case selection, is an excellent procedure.
Brief Opening Thoughts....

• CAS is an excellent procedure *IF done correctly, by an experienced operator, and in appropriate patients and lesions.*

• CAS is ~ the most politically-affected procedure in our field (& at your site!)

• It is unclear whether CAS will ever be reimbursed as a standard therapy

• CAS should **only** be done by appropriately trained operators, *after* training and *and* performing other endovascular and PCI procedures independently, *and after* establishing a local reputation.
CAS Background

- CEA: excellent procedure for many patients
- Natural history of carotid disease is ~ benign for asymptomatic patients (med Rx)
- Patient’s CAS risk should be ≤ CEA risk or natural history *in that patient* (in your hands)
- **CAS is complimentary** to CEA, not competitive; choice is individualized
The Best Way to Manage Complications is to AVOID Them!
Best Ways to Avoid Complications:

- Careful PATIENT selection
- Careful LESION selection
- Patient Preparation
- METICULOUS CAS TECHNIQUE
- Know when to STOP or say NO
- You MUST exercise good judgment and restraint (always) to be a good CAS operator
My Advice to Early (and All) CAS Operators

• Scrub *or watch* as many CAS cases as you can with good operators

• Avoid difficult cases in 1\textsuperscript{st} 100 cases, & avoid bad cases for your entire career

• The more difficult a case, the more you should re-evaluate R/B of CAS (by you, or anyone)

• Increased procedural time or “factors adding up”- the more you should stop

• Personally call surgeon for bad CAS cases
The (US) Data for CAS is Supportive!

- ALL 3 US RCT’s of CEA vs. CEA show equivalence
- Real world, carefully adjudicated Registry trials in high CEA risk patients have good CAS results (50,000+)
- Proximal protection results even better
- CAS Results continue to improve
- Newer devices (TCAR, micro-mesh stents) have early promising data
Primary Endpoint ≤ 4 years
(any stroke, MI, or death within peri-procedural period plus ipsilateral stroke thereafter)

<table>
<thead>
<tr>
<th>CAS vs. CEA</th>
<th>Hazard Ratio, 95% CI</th>
<th>P-Value</th>
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</thead>
<tbody>
<tr>
<td>7.2 vs. 6.8%</td>
<td>HR = 1.11; 95% CI: 0.81-1.51</td>
<td>0.51</td>
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</tbody>
</table>

“Standard Risk” CEA Patients; Symptomatic & Asymptomatic
ACT-1 Background

RCT CEA vs CAS; Asx “Standard Risk” Patients

- Comparison of carotid artery stenting with embolic protection and carotid endarterectomy in:
  - Patients 79 years of age or younger
  - Severe carotid artery stenosis
  - Asymptomatic (i.e., had not had a stroke, transient ischemic attack, or amaurosis fugax in the 180 days before enrollment)
  - Were not considered to be at high risk for surgical complications (i.e. ‘low-risk’)

A composite of death, stroke (ipsilateral or contralateral, major or minor) or myocardial infarction during the 30 days after the procedure or ipsilateral stroke during the 365 days after the procedure.

Long-term Results of Stenting vs Endarterectomy for Carotid-Artery Stenosis

Durability: 10-Year CREST TCT Data

Primary Composite End Point

<table>
<thead>
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<th>Follow-up (yr)</th>
<th>Patients (%)</th>
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<tr>
<td>0</td>
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<tr>
<td>1</td>
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<td>2</td>
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<td>4</td>
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<table>
<thead>
<tr>
<th>No. at Risk</th>
<th>Endarterectomy</th>
<th>Stenting</th>
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<tbody>
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CAS Trials: High-Risk CEA Patients With Neurologic Adjudication

Improving Results of CAS

IDE Trials in HIGH Risk CEA Patients
Proximal Embolic Protection
### 6 Study Databases (N=2,397)

<table>
<thead>
<tr>
<th>Database #</th>
<th>Study and First Author</th>
<th>Year Published</th>
<th>Device</th>
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<tr>
<td>1</td>
<td>ERCAS Registry (Stabile et al)&lt;sup&gt;1&lt;/sup&gt;</td>
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<td>MO.MA</td>
<td>N=233</td>
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<td>2</td>
<td>ARMOUR (Ansel et al)&lt;sup&gt;2&lt;/sup&gt;</td>
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<td>N=262</td>
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<td>Single-center registry in Italy (Stabile et al)&lt;sup&gt;4&lt;/sup&gt;</td>
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<td>EMPIRE (Clair et al)&lt;sup&gt;5&lt;/sup&gt; + European Registry (Nikas et al)&lt;sup&gt;6&lt;/sup&gt;</td>
<td>2011</td>
<td>GORE FRS</td>
<td>N=475</td>
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**Meta-analysis, Bersin, Robert, et.al**

Analysis performed by Harvard Clinical Research Institute (Boston, MA)
Overall 30-day Event Rates

- Composite MACCE to 30 days post-procedure: 2.25%
- Stroke: 1.71%
- Mortality: 0.40%
- Myocardial infarction: 0.02%
- Intolerance: Device Use Interruption+: 0.63%
- Intolerance: Alternate Device Use++: 0.35%
Real World CAS Registries

*High Risk CEA Pt’s; ALL get NIHSS*

- CHOICE - over 18,000 pt’s
- SAPPHIRE WW - over 21,000 pt’s
- CAPTURE 2 - > 6,500 patients
- CANOPY (1500+ post-CREST “Real World”)

*All satisfy AHA guideline outcomes in high risk CEA patients*
Summary of CAS Trials

- CAS results continue to improve
- In North American RCT’s, IDE, and Large Prospective Registry Trials, CAS c/w CEA:
  - Has less MI’s, CNI’s, and LOS
  - No difference in major strokes
  - Equal efficacy in preventing strokes
  - $\geq$ Equal Long term patency
  - More minor strokes early, with no neurologic difference at 30 days and beyond (better recent results)
“Newer” Developments in CAS

(~SLOW Recent Developments; Reimbursement & Politics)

- Distal embolic protection (1\textsuperscript{st} gen→ newer generation)
- Proximal embolic protection
- Combined proximal & distal embolic protection
- TCAR (CAS w/ flow reversal w/ surgical pCCA access)
- New stent designs (micro-mesh)
Carotid Stenting with Distal Embolic Protection

Guide catheter
Wiring RICA lesion with 0.014” wire

“Filter Basket” distal EPD deployed
Pre-dilation with 4 X 30 balloon

Self-expanding carotid stent deployed
Post-dilation within stent

Removing dEPD after angio w/ TIMI 3 flow
Proximal Embolic Protection
Proximal Embolic Protection
Case: Severe TIA’s; HIGH Risk CEA Patient

RICA OK; R→L collaterals

Severe LICA w/ Sx’s
Baseline left cerebral angios
ECA balloon inflated
Wiring with 0.014” wire in *protected* fashion
Protected PTA before stent

Stent after pre-dilation
Aspirate B4 balloons down

Post-dilation within stent
Final LICA angios

Final Left cerebral angios
Silk Road “Hybrid CAS”

- Direct surgical access to Prox. CCA
  - Avoids manipulation in arch & CCA’s
  - Less risk of CNI, less invasive
  - General or local anesthesia

- CAS via sheath in CCA w/ flow reversal
  - Blood filtered and returned via venous sheath

- Roadster 1 Trial: Outstanding results (* Interesting CMS)
  141 high CEA risk patients; stroke/ death 30 days 1.4%
Challenging CAS at a High Volume Center

- 75 yo female w/ CAD and EF 20-25%
- 60+ pack year tobacco/COPD
- R Hemispheric stroke Thanksgiving
- CTA 80% RICA; 95% LICA
- Seen after rehab, also 3 L hemispheric TIA’s
- CTA with severe tortuosity RCCA
RICA and tortuous R CCA
Severe LICA stenosis
Wiring LICA after proximal protection

Deploying distal embolic protection basket
Pre-dilatation w/ 4 X 30 NC

Deploying 10X8X30 Xact stent
Post-dilatation w/ 5 X 20 NC PTA
Nav6 dEPD out with proximal protection
Final LICA and left cerebral angios
Symptomatic RICA, severe RCCA tortuosity

Silk Road; direct pCCA Access; flow reversal
Wiring RICA w/ flow reversal

Pre-dilatation w/ 4X30 NC PTA
Deploying 10 X 30 Precise stent

Post – dilatation w/ 5X20 NC PTA
Final RICA and right cerebral angios
Micromesh Stents
Causes of Late Embolization

Many CAS strokes occur after CAS within 24 hours

Plaque protrusion may lead to late events.

Debris
Arterial Wall
Stent Struts

Prof. Dr. Klaus Mathias, TCT 2013
Roadsaver – dual layer micromesh Carotid stent

- Braided Nitinol carotid stent with a built-in Nitinol micromesh for sustained embolic protection
Cell Size Comparisons

Rocksaver  Wallstent  Precise  Acculink

XACT  Protégé  Crystallo (ends)  Crystallo (middle)
B: 3D Optimal Frequency Domain Imaging - No plaque prolapse; good apposition

C: OCT - Some plaque prolapse thru stent, NOT thru micro-mesh

D: OCT 3D reconstruction - no plaque prolapse
Wiring lesion
Deploying distal EPD
Pre-dilate 4X30

Deploying MM stent
Post-dilate 5X20

Final angio
Final cerebral angios

lateral

AP Towne’s
Conclusions

- CAS is an excellent procedure when performed by experienced operators utilizing meticulous technique in well-selected patients and lesions.

- Newer technologies may further improve CAS outcomes, *but do not* replace good CAS technique and judgment.
Thank You for Your Attention!