Will transcarotid approaches for CAS be a game changer even without any specialized devices and why?

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BACKGROUND

Transfemoral CAS with filters failed to compete with CEA mainly for symptomatic or patients > 75Y because of increased TIA’s rate.

CREST (30 days all stroke rates): 6.9% Vs 3.1% p=0.035

It makes sense to abandon transfemoral CAS for elderly or symptomatic patients.

Transfemoral CAS can be maintained for asymptomatic younger patients with a healthy Aortic arch.

Transcarotid CAS could be a game changer for elderly, symptomatic or any validated HRP

Faggioli (EJVS 2007)

- Technical failure
- Neurological complications

Kastrup (JVS 2003)

I. Avoid Arch navigation
(1% risk in shaggy aorta)
- Cervical Access

Factors to reduce TIA’s and stroke

3 components play a major role:

I. Cervical access (avoid arch navigation)

Combined to:

II. Flow interuption or reversion
(avoid antegrade flow embolisation)

III. Mesh covered stents
(avoid post procedure embolisation)

No disclosure

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Redefining HRP for Surgery

- NRP (normal risk patients) Stroke rate:
  - SVS vascular registry for Symptomatic (Sx) 5.4%; Asymptomatic (Asx) 1.6%.
  - CREST results: Sx: 4.5%; Asx: 2.2%

- HRP:
  - EBM validation VSGNE (vascular group study of New England), JVS oct 2015
  - 3096 CEA in 20 centers (2003-2011) for HRP (sapphire criteria) MAE= 14.2%

4 validated independent Significant Risk Factors associated with adverse event:
  - Age, CHF, DM, COPD
  - SAPPHIRE study: 2 other risk factors not validated by VSGE but unwarranting for CEA based on common sense:
    - hostile neck, high lesions on the ICA

They are validated HRP Candidates for CAS by cervical access
II. Avoid antegrade flow emboli
- no flow technique: distal occlusion (Percusurge + Export Catheter)
Theron, Bergeron, Amor, Henry, Wooley:
J Endovasc Ther. 2002; 9(4): 2.2%

Optional: ischemic preconditioning (Filaerus Vascular 2000)

- reverse flow technique (MOMA, PAES...)
Bersin (Catheter Cardiovasc Interv 2011):
6 US and EU trials submitted to Harvard research analysis
S/D RATE: 2.7%

III. Avoid Post operative emboli
favor Mesh covered stents

Results from cervical access with reverse flow
- Non specialized devices (First attempts)

<table>
<thead>
<tr>
<th>Study</th>
<th># Patients</th>
<th>Death (30 days)</th>
<th>Major Stroke (30 days)</th>
<th>Minor Stroke (30 days)</th>
<th>S/D Rate</th>
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</thead>
<tbody>
<tr>
<td>Chang 2004</td>
<td>21</td>
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<tr>
<td>Lin 2005</td>
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<td>0</td>
<td>2</td>
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<tr>
<td>Forgha 2010</td>
<td>46</td>
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<td>0</td>
<td>1</td>
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<tr>
<td>Lead 2010</td>
<td>35</td>
<td>0</td>
<td>0</td>
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<td>0</td>
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<tr>
<td>TOTAL</td>
<td>318</td>
<td>0</td>
<td>0.6%</td>
<td>1.6%</td>
<td>2.2%</td>
</tr>
</tbody>
</table>

Other Cervical access data
- Meta analysis on CAS by cervical access:
545 pts (47% cutdown) 1996-2010
S/D rate: 2.2% ; Strokes: 1.6%
(instead of 3.5% EVA3S, 7.5% SPACE and 4.1% CREST)

- Personal experience: 1992-2012: Among 461 CAS over ~ 2000 Carotid reconstructions
245 selected pts treated by CAS on direct percutaneous access: S/D rate: 0.8%
(1 hyperperfusion 54; 1 monocular blindness; 2 TIA’s)


- Cervical Reverse flow studies with specialized devices
  PROOF study (75 pts, 0% MAE, 6.5% DW-MRI)
  TESLA registry (58 pts, 0% MAE)
  ROADSTER trial (136 pts, 2.2%)
Anticipated S/D rate for CAS by cervical access around 2%

Cervical access: Micro-Emboli Measurement
Palombo (EVS 2010)
New MRI lesions by cervical access: 14% Vs femoral: 3.7%

PROOF Study
DW-MRI Studies - Silk Road’s CEA-Like Outcomes

<table>
<thead>
<tr>
<th>Study</th>
<th>Procedure</th>
<th>Embolic Protection</th>
<th>Patients</th>
<th>% of New DWI Lesions</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICOS</td>
<td>CEA</td>
<td>Clamp, buckled</td>
<td>107</td>
<td>17%</td>
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<tr>
<td>PROOF</td>
<td>Silk Road</td>
<td>Transcranial Access, no Flow Reversal</td>
<td>$6</td>
<td>16.3%</td>
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<tr>
<td>PROOF</td>
<td>Transcranial CAS</td>
<td>Proximal occlusion, MAFASE</td>
<td>31</td>
<td>45%</td>
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<tr>
<td>ICOS</td>
<td>Transcranial CAS</td>
<td>Distal filter</td>
<td>51</td>
<td>73%</td>
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<tr>
<td>PROOF</td>
<td>Transcranial CAS</td>
<td>Distal filter (Embo Shield)</td>
<td>31</td>
<td>87%</td>
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</tbody>
</table>

1. van der Steen AJ et al. CEA: 13% DW-MRI new white matter lesions
2. Student’s t-test at 0.05 significance level
   (c) 2011 Silkroad Medical, Inc.
Cervical access advantages

- No Arch crossing neither manipulation
- No risk of contralateral or posterior stroke
- Quick procedure
- Lower dose of heparine and contrast
- No risk of cranial nerve injury
- Simplified stenting: straight and short path from the carotid access enables to accommodate carotid tortuositites or angulated take off of ICA
- Safe access thanks to US guided puncture and use of closing device
- Can be associated Advantageously to antegrade flow interruption

CONCLUSION

Transcarotid approach for CAS will be a game changer for surgeons who desire a less invasive and safe procedure with excellent long term outcomes.

Cardiologist will not change for a cervical approach but should limit transfemoral CAS to ASX patients < 75Y

The use of specialized devices is not mandatory but helps to secure the procedure