TCAR Is A Game Changer For CAS And Should Replace Transfemoral CAS Procedures

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Disclosure
Consultant

PRESIDENTIAL ADDRESS

From the Society for Vascular Surgery

The endovascular revolution stopped at the carotid bifurcation . . . or did it?

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Distal Filter Protected Transfemoral CAS: “A failed experiment”

Legacy FDA approval trials showed dismal results

30-Day MAE Rate (S/D/MI) in HSR Patients

What’s the reason?
1. Do we have better technology? MAYBE
2. Did we do a better job selecting patients? DEFINITELY

TF-CAS Results Did Improve Over Time

SVS - 2012
STAY TUNED ~
CAS LIKELY TO GET BETTER
We need to advance the technology to serve **ALL** of our patients

- Proximal Protection
- Proximal Protection with Flow Reversal
- Alternative Access

My worthy opponent thought so too. A bit better but not great.

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*Proximal Endovascular Occlusion for Carotid Artery Stenting*

*Results From a Prospective Registry of 1,300 Patients*

*Eugene Stabile, MD, PhD, Luigi Salvarani, MD, Giovanni Sorichetti, MD, Tullio Traversi, MD, Walter Guerriero, MD, Massimo Monaco, MD, Grigoris Popovas, MD, Angelo Coppo, MD, Vittorio Antonio, MD, Linda Cora, MD, Giovanni Dalla Pera, MD, Angelo Antico, MD, Andrea Fandino, MD, Andrea Gatti, MD, Paolo Robino, MD*

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**30 Day MAE (S/D/MI): 1.4%**

- >50% of patients were normal risk
- <10% of patients were age > 80 years
- <30% were Symptomatic
- Experience (<50 cases) was a predictor of poor outcomes

**MO.MA Proximal Balloon Occlusion System**

*(requires ECA occlusion to prevent antegrade ECA to ICA flow)*

**ENROUTE Transcarotid Neuroprotection System**

*(large bore, low resistance extracorporeal tubing reverses flow in both ECA and ICA)*

**FLOW STAGNATION ≠ HIGH FLOW REVERSAL**

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Furthermore, the authors acknowledged the following:

"Embolic signals were detected during insertion and removal of the Proximal Endovascular Occlusion device."

This lead one prominent cardiologist to comment on this study: "...a rough correlation exists between quantitative embolic signals and the risk of neuro-embolic events, making embolic signals a reasonable surrogate marker for embolic events related to CAS." (C. White JACC 2010)

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Our Prime Suspect: The Aortic Arch

*Schmidt et al. JACC 2004*
You MUST Avoid the Arch!

- Proximal Protection
- Proximal Protection with Flow Reversal
- Alternative Access

<0.5% of patients screened in ROADSTER 1 were excluded for unfavorable anatomy at the access site (3/705).

Proximal Balloon Occlusion vs. TCAR:
>2x the rate of ipsilateral new white lesions

<table>
<thead>
<tr>
<th>Study</th>
<th>Procedure</th>
<th>Embolic Protection</th>
<th>Patients</th>
<th>% w/ New DWI Lesion</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICSS^2</td>
<td>CEA</td>
<td>Clamp, backbleed</td>
<td>107</td>
<td>17%</td>
</tr>
<tr>
<td>PROOF^3</td>
<td>Silk Road</td>
<td>Transcranial Access, w/ Flow Reversal</td>
<td>56</td>
<td>18%</td>
</tr>
<tr>
<td>PROOF^1</td>
<td>Transfemoral CAS</td>
<td>Proximal occlusion (MoMA)</td>
<td>31</td>
<td>45%</td>
</tr>
<tr>
<td>ICSS^2</td>
<td>Transfemoral CAS</td>
<td>Distal filter (various)</td>
<td>51</td>
<td>73%</td>
</tr>
<tr>
<td>PROOF^1</td>
<td>Transfemoral CAS</td>
<td>Distal filter (EmboShield)</td>
<td>31</td>
<td>87%</td>
</tr>
</tbody>
</table>

Results of the ROADSTER multicenter trial of transcranial stenting with dynamic flow reversal

Christopher J. Kovach, MD, Michael R. Litt, MD, J. Ignacio Lee, MD, LN, Nelson Hopkins, MD, Ranjith M. Mathew, MD, Toshio Mackay, MD, Sumanta Banerjee, MD, and Richard F. Campeau, MD, Saint Luke’s Medical Center, Kansas City, KS; University of Virginia, Charlottesville, VA; and University of California, San Francisco, CA.

Objective. To report on the ROADSTER multicenter trial of transcranial stenting with dynamic flow reversal (FCR).

Methods. Between November 2011 and July 2016, 307 patients were enrolled in 17 centers. A prospective, nonrandomized, single-arm, multi-center registry of patients with symptomatic or asymptomatic carotid disease and high surgical risk was undertaken. Baseline data was prospectively collected in a single-site registry. The PROOF study compared previous FCR with back-bleed with a more dynamic FCR technique resulting in a lower risk of embolic complications. All patients received a carotid stent during FCR. The lowest periprocedural stroke risk ever reported for a carotid stent trial!

The lowest periprocedural stroke risk ever reported for a Carotid Stent Trial!

TCAR Demonstrates TCD Embolization Rates Comparable to CEA^1

- CEA vs TCAR vs TF-CAS
- Patients monitored w/ TC Doppler during 3 procedural phases:
  - Pre-protection
  - Before clamping, filter deployed, or reverse flow established
  - Protection
  - Until clamp removed, filter retrieved, or antegrade flow restored
  - Post-protection
  - After clamp/filter removed, or normal flow established

ROADSTER Study Outcomes in High Surgical Risk Patients

Intention to Treat & Per Protocol Groups

<table>
<thead>
<tr>
<th>High Surgical Risk</th>
<th>Pivotal Group, ITT (N=141)</th>
<th>Pivotal Group, PP (N=136)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Stroke</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>2%</td>
<td>1.5%</td>
</tr>
<tr>
<td>Death</td>
<td>2%</td>
<td>1.5%</td>
</tr>
<tr>
<td>Stroke &amp; Death</td>
<td>4%</td>
<td>3.2%</td>
</tr>
</tbody>
</table>

Multi-center, independently adjudicated results

Things finally got a bit better...

But is it the technology or patient selection?
ROADSTER 1 Study Outcomes
Not contraindicated in "at risk" sub-groups

<table>
<thead>
<tr>
<th>High Surgical Risk</th>
<th>Age ≥ 75</th>
<th>SYMPTOMATIC</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>SI/MI</td>
<td>6.8%</td>
<td>2.3%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Major Stroke</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>1.1%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Death</td>
<td>2.2%</td>
<td>2.3%</td>
<td>1.7%</td>
</tr>
<tr>
<td>MI</td>
<td>3.3%</td>
<td>0.0%</td>
<td>2.2%</td>
</tr>
<tr>
<td>Stroke &amp; All Death</td>
<td>3.3%</td>
<td>2.3%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Stroke &amp; Cardiovascular or Neurological Death</td>
<td>1.1%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

From our host...

Outcomes with TCAR continue to show promise in broader use
ROADSTER 2 Post-Approval Study
Clinical Outcomes in the FDA Analysis Population
(Multi-center, independently adjudicated)

<table>
<thead>
<tr>
<th>ROADSTER Pivotal</th>
<th>ROADSTER Combined</th>
<th>ROADSTER 2 n=136</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke/Death/MI</td>
<td>4.9%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>1.4%</td>
<td>1.0%</td>
</tr>
<tr>
<td>MI</td>
<td>1.4%</td>
<td>1.5%</td>
</tr>
<tr>
<td>Stroke/Death</td>
<td>2.2%</td>
<td>1.5%</td>
</tr>
</tbody>
</table>

At 42 sites with >70% new TCAR operators

Conclusion
• TCAR is the technical evolution of CAS
  Avoid the Arch High Flow Reversal
  Proven Superior Neuroprotection
  • TF-CAS RIP!