DEBATE
NOT SO: TRANSFEMORAL ACCESS SHOULD BE THE FIRST OPTION FOR MOST CAS PROCEDURES IN MOST LOW RISK AND MANY HIGH RISK PATIENTS: WHY IT IS BETTER THAN TCAR!

G. Biamino

Disclosure

- Speaker name:
- I have the following potential conflicts of interest to report:
  - Consulting
  - Employment in industry
  - Stockholder of a healthcare company
  - Owner of a healthcare company
  - Other(s)
- I do not have any potential conflict of interest

The first great message of this Debate

REVOLUTIONARY NEWS

TCAR - Surgically Inspired CEA-like Neuroprotection

UNFAIR, BECAUSE TCAR TENDS TO SUGGEST THE EXCLUSION OF INTERVENTIONALISTS FROM CAS PROCEDURES IS THIS A CORRECT SCIENTIFIC APPROACH ?? I DOUBT IT!!!

Transcervical Carotid Artery Revascularization

- 1-2cm Incision
- Local anesthesia
- Flow reversal circuit: carotid artery to femoral vein

Courtesy of Brian Delfubertos

RATIONALE FOR TransCarotid Artery Revascularization (TCAR)

- MAIN Assertion is Advancing Guide wires and catheters through the calcified aortic arch is one of the REALLY ??? OF TRANSFEMORAL PERI-PROCEDURAL STROKES
NO SCIENTIFIC DATA!!

- As Cardiologist and Interventional Angiologist, it is not congruent to me to follow this hypothesis!
- In fact, every day around the world many thousand diagnostic or interventional procedures are performed in the coronary field passing the aortic arch at least 3x per intervention.
- Cerebral embolic complications are an absolute rarity!!!!

Anatomical considerations to TCAR (Prof. G. Torsello, Münster)

1. Percutaneous approach to CCA can be risky due to nerve damage
2. Failed bleeding control is an important complication in the neck
3. Cut down of the CCA for 1-2 is impossible in our patient with “westfalian” neck
4. If I expose the ACC, then I expose also the ICA and make a CEA

Surgical, Anatomical considerations to TCAR (K. Deloose, Belgium)

1. The incision you have to make on the CCA for a comfortable purse string suture is almost as big as the incision for an eversion endarterectomy
2. With the current system, you would be uncomfortable
3. ENDO IS ENDO and......
4. OPEN IS OPEN!!
5. compared to MOMA
6. No plans to implement TCAR in Dendermonde

TCAR Scientific data NOT RUBUST,YET

Safety and feasibility of a novel transfemoral access neuroprotection system for carotid artery stenting in the PROOF Study
Laslo Pinter, MD, Marc Ribis, MD, Christopher Luft, MD, Barton Lane, MD, Tracy Roberts, MT (ASCP), Tony Y. Chiu, MD, and Ralph H. Jakenbach, MD, PhD, Düsseldorf, Germany; Barcelona, Spain; and Los Angeles, Palo Alto, Sunnyvale, and San Francisco, CA (J Vasc Surg 2011;54:1317-23) – N= 44

Results of the ROADSTER multicenter trial of transcatheter stenting with dynamic flow reversal
Christopher J. Kwolek, MD; Michael R. Jaff, DO; Ignacio J. Saavedra, MD; L. Nelson Hopkins, MD; Robert M. Shah, MD; Todd M. Hanover, MD; Sumaira Macdonald, MD; and Richard P. Cambria, MD, Boston, Mass; Toledo, Spain; Cleveland, Ohio; and Cleveland, OH, Sunnyvale, CA, and Michigan (J Vasc Surg 2015;62:3227-35)

Technical aspects of transcatheter artery revascularization using the ENROUTE transcatheter neuroprotection and stent system
Mahmoud B. Malaeb, MD, MPH; Jose Leal, MD; Vikram Kashyap, MD; Richard Paul Cambria, MD; Christopher J. Kwolek, MD; and Enrique Criado, MD, Reilly, Md; Cleveland, Ohio; Sunnyvale, CA, and Midland, Mich (J Vasc Surg 2017;65:316-20)
2018

Transcarotid artery revascularization versus transfemoral carotid artery stenting in the Society for Vascular Surgery Vascular Quality Initiative

Mahmoud B. Malas, MB, MD, MHS,a Hanaa Dakour-Aridi, MD,a Grace J. Wang, MD,b Vikram S. Kashyap, MD,Reghu L. Maiti,MD, d Michael E. Tomsick, MD,e David J. Feinberg, MD, f and Marc L. Schermerhorn, MD,g Baltimore, Md; Philadelphia, Pa; Cleveland, Ohio; Indianapolis, Ind; Portland, Me; Lebanon, NH; and Boston, Mass

Most Patients Are Eligible for Transcarotid Revascularization

Despite 1st Anatomic Restrictions, Patric Liang, et al. Beth Israel Deaconess Medical Center, Boston, Mass

Abstracts e109 Journal of Vascular Surgery Volume 68, Number 4

Courtesy Prof H.H. Eckstein, Munich

ROADSTER: Outcomes by Symptom Status

Symptomatic Patients – Per Protocol

ROADSTER 1 ROADSTER 2
n=46 n=122
Stroke/Death/MI 4 2.2% 1 0.8%
MI 2 1.3% 0 0.0%
Death 3 1.0% 0 0.0%

Symptomatic Patients – Per Protocol

ROADSTER 2 n=348
n=157
Stroke/Death/MI 4 2.5% 6 1.7%
MI 2 1.3% 3 0.9%
Death 1 0.6% 1 0.3%

TCAR Scientific data

• Not robust data yet !!!!!

ROADSTER Trial 12-month Outcomes

High Surgical Risk Pivotal Group, ITT (n=131) Pivotal Group, PP (n=136)

S/D/MI* 5 3.5% 4 2.9%
Major Stroke 0 0% 2 1.5%
Minor Stroke 2 1.4% 1 0.7%
Death 2 1.5% 2 1.5%
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Stroke & Death 4 2.8% 3 2.2%
Cranial Nerve Injury (CNI) 1 0.7% 1 0.7%
CNI Unresolved at 6 Mos 0 0% 0 0%

Transcervical Carotid Artery Revascularization

TCAR

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NOT ROBUST YET

From the Society for Vascular Surgery ARTICLE IN PRESS

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Unadjusted Outcomes

<table>
<thead>
<tr>
<th></th>
<th>TCAR</th>
<th>CEA</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke/Death</td>
<td>1.6%</td>
<td>1.4%</td>
<td>.33</td>
</tr>
<tr>
<td>Stroke/Death/MI</td>
<td>2.5%</td>
<td>1.9%</td>
<td>.16</td>
</tr>
<tr>
<td>Stroke</td>
<td>1.4%</td>
<td>1.3%</td>
<td>.68</td>
</tr>
<tr>
<td>Ipsilateral stroke</td>
<td>1.2%</td>
<td>0.9%</td>
<td>.33</td>
</tr>
<tr>
<td>TIA</td>
<td>0.9%</td>
<td>0.5%</td>
<td>.11</td>
</tr>
<tr>
<td>In-hospital Death</td>
<td>0.3%</td>
<td>0.3%</td>
<td>.88</td>
</tr>
<tr>
<td>30-day Death</td>
<td>0.9%</td>
<td>0.4%</td>
<td>.06</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>1.1%</td>
<td>0.6%</td>
<td>.11</td>
</tr>
</tbody>
</table>

57,942 patients needed per group to detect a 0.2% difference in stroke/death

Limitations

- No randomization between treatment options
- Comparison are difficult with studies evaluating 30-day event rates
- 33% strokes and 53% deaths after CEA occur after discharge (Fokkema et al.)
- Only 30-day mortality available through linkage with Social Security Death Index

Conclusions

- Despite higher medical risk in patients undergoing TCAR, major adverse events were similar between TCAR and CEA
- TCAR had shorter OR time, lower cranial nerve injury and postoperative hypertension
- Long term follow-up pending

Montevergine Registry on PEC protected CAS

- From July 2004 to March 2009
- 1300 patients underwent CAS using PEC
- All patients had a >80%, if asymptomatic, and >60%, if symptomatic, diameter stenosis of the internal carotid artery, measured according to the NASCET criteria
- The only exclusion criteria were the presence of critical stenosis of the ipsilateral common carotid artery and/or the occlusion of the ipsilateral external carotid artery
- Patients received a detailed clinical assessment one hour, twenty four hours and 30 days

Clinica Montevergine-VME-VMC Registry

<table>
<thead>
<tr>
<th></th>
<th>Frequency (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death and Stroke</td>
<td></td>
</tr>
<tr>
<td>IP</td>
<td>0.0% (0)</td>
</tr>
<tr>
<td>PP</td>
<td>2.02% (4)</td>
</tr>
<tr>
<td>30 Day</td>
<td>0.5% (1)</td>
</tr>
<tr>
<td>Total</td>
<td>2.52% (5)</td>
</tr>
</tbody>
</table>

Cumulative results at 30 days (MACCE = 1.3 %) No AMI!
**Results 1° Endpoint**

![Graph showing results 1° endpoint](image)

**30d Results (ITT & Full Population)**

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>ITT (n=220)</th>
<th>ITT + Roll-in (n=257)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Stroke</td>
<td>0.9%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>2.7%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Death</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>MI</td>
<td>0.0%</td>
<td>0.9%</td>
</tr>
<tr>
<td>Stroke</td>
<td>0.8%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Death</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>MACCE</td>
<td>1.4%</td>
<td>2.7%</td>
</tr>
</tbody>
</table>

**30d Results by Symptoms and Age (ITT)**

<table>
<thead>
<tr>
<th>Symptom / Age</th>
<th>ALL</th>
<th>Asymptomatics</th>
<th>Symptomatics</th>
<th>Age &gt;75</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Stroke</td>
<td>2.2%</td>
<td>2.7%</td>
<td>3.2%</td>
<td>3.7%</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>2.7%</td>
<td>2.7%</td>
<td>2.3%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Death</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>MI</td>
<td>0.0%</td>
<td>0.8%</td>
<td>0.8%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Stroke</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Death</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

**Detection of new cerebral lesions (NL) after CAS using DW-MRI**

- PROOF Silk Road TCAR n=56
  - DW-MRI : 18% NL
- PROOF Silk Road TCAR n=56
  - DW-MRI in only 10 of 56

- DEVERSE STUDY MoMa n=127
  - (out of 1267 CAS procedures with complete angiography)
  - DW-MRI : 26% NL

**Proximal Protection meta-analysis**

*(K. Hacker et al. CC 2012)*

![Graph showing proximal protection meta-analysis](image)

The incidence of stroke was 1.71%

**THE GREAT SOLUTION ??**

**RoadSaver® All Comers Italian Registry**

- First results on 150 Patients -

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>30 days (n=150)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACCE (MI, stroke, death)</td>
<td>0</td>
</tr>
<tr>
<td>MI</td>
<td>0</td>
</tr>
<tr>
<td>Stroke</td>
<td>0</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
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</table>

**Post-procedural phase**

- The majority of strokes occur post-procedure (+/- 70%)

**Capture trial (3500 patients)**

- Timing of strokes

**Disadvantages of TCAR Procedure**

1. Issues related to initial access
   - Short working distance from access to lesion
   - Access site dissections
2. Body habitus concerns and anatomic constraints
3. Ergonomics of current stent systems
4. Interpretation of reversed-flow angiograms
5. Optimal training requirements not clearly established
6. Limitations for non-surgeon interventionalists

*Courtesy of A. Cremonesi*

*Courtesy of Brian DeRubertis*
GAPS IN CLINICAL EVIDENCE FOR CAS IN 2018

• NO data considering the ability of the interventionalist to produce a complication-free result.

Patient Tailored Transfemoral CAS:
Physician training requirements

<table>
<thead>
<tr>
<th>Addressing challenges</th>
<th>CAS experience (no.)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;100</td>
</tr>
<tr>
<td>Aortic arch:</td>
<td>II and III</td>
</tr>
<tr>
<td>Lesion anatomy:</td>
<td>angled</td>
</tr>
<tr>
<td>Vessel anatomy:</td>
<td>severely tortuous</td>
</tr>
<tr>
<td>Lesion characteristics:</td>
<td>angled, severely calcified, high grade, sub-occlusive</td>
</tr>
<tr>
<td>Plaque composition:</td>
<td>dis-homogeneous, soft, ulcerated</td>
</tr>
</tbody>
</table>

(Courtesy A. Cremonesi 2010)

Causes of Transfemoral Peri-procedural Stroke

Advancing catheters through aortic arch
18% non-Ipsilateral stroke rate was observed in the CAPTURE Study


Causes of Transfemoral Peri-procedural Stroke

• Traditional Transfemoral CAS requires 3 steps that create embolic risk
  1. Advancing catheters through aortic arch
  2. Navigating the lesion before neuroprotection established
  3. Inadequate neuroprotection from misaligned filters and inadequate manual aspiration of emboli
Carotid Artery Disease 2017
• 115,000 US Procedures
• 90+% CEA

30 Day Stroke (ITT)
ROADSTER 30 Day All Stroke Per Protocol 0.7%
The devastating consequence of a procedure intended to prevent stroke is...
stroke
Causes of Transfemoral Peri-procedural Stroke

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  1. Advancing catheters through aortic arch
     - 18% Non-Ipsilateral stroke rate in CAPTURE Study
  2. Navigating the lesion before neuroprotection established
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Crossing the aortic arch

Crossing the lesion


Diseased Aortic Arch

Misaligned Filter

TCAR - Surgically Inspired CEA-like Neuroprotection

Continuous high rate of flow reversal to remove micro and macro debris throughout intervention

Direct Carotid Access

CCA Clamp or Loop Control

The proof is in the filter

THE PROOF IS IN THE FILTER
Macro & Micro emboli in ENROUTE® NPS FILTERS

Dedicated TCAR Tool Set with TransCarotid Indication

ENROUTE® Transcarotid Neuroprotection & Stent System

Blood flow is reversed from the common carotid artery

Working channel for interventional devices

Blood flow is returned to femoral vein

ENROUTE® Transcarotid Stent System (5/mm)

Dynamic Flow Controller & Integrated 200µ Filter
Hi / Low / Off

Blood flow is returned to common carotid artery

THE PROOF IS IN THE FILTER
Macro & Micro emboli in ENROUTE® NPS FILTERS

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Less Invasive & Patient Friendly Procedure

CEA vs. TCAR

Reduced rate of cranial nerve injury
CREST – 2.1% unresolved at 6mths
ROADSTER – 0% unresolved at 6mths

Reduced rate of cranial nerve injury
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Local anesthesia can improve recovery time

Cosmetic result of a less invasive procedure
Smaller scar in a less obvious location than with surgery