Preventing strokes in TEVAR: What factors should be considered?

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Disclosure

Speaker name:

........................................M Hamady..........................................................

I have the following potential conflicts of interest to report:

- Consulting
  - Gore/ Medtronic/Bolton Medical/BSC

- Education grants
  - Gore
CVA events in TEVAR
Acute dissection

• Stroke risk in TEVAR TAA is 2-9% (pooled 4.1%) *

• Stroke in TEVAR AAD 0-12% (pooled 3.9%)***

* Patterson BO, et al JVS 2014
*** Moulakakis K Ann Cardiothorac Surg 2014
R Allmen Eur J Vasc End Surg 2016
‘Silent’ cerebral infarction in TEVAR

Pre TEVAR DWI

Post TEVAR DWI (asymptomatic patient!)
CVA events in TEVAR
Acute dissection

• Silent infarcts are seen in up to 63-68% cases***

• Silent infarcts are predictor of stroke, dementia, depression and neurocognitive decline

Kalhert et al, Ann Thorac Surg 2014 ***
Perera et al (In Press)
Cerebral Ischemic Lesions on Diffusion-Weighted Imaging Are Associated With Neurocognitive Decline After Cardiac Surgery
P. Alan Barber, Sylvia Hach, Lynette J. Tippett, Linda Ross, Alan F. Merry and Paget Miles

Stroke. 2008;39:1427-1433; originally published online March 6, 2008;
doi: 10.1161/STROKEAHA.107.502989
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Association of MRI Markers of Vascular Brain Injury With Incident Stroke, Mild Cognitive Impairment, Dementia, and Mortality: The Framingham Offspring Study
Stéphanie Debette, Alexa Beiser, Charles DeCarli, Rhoda Au, Jayandra J. Himuli, Margaret Kelly-Hayes, Jose R. Romero, Carlos S. Kase, Philip A. Wolf and Sudha Seshadri

Stroke. 2010;41:600-606; originally published online February 18, 2010;
doi: 10.1161/STROKEAHA.109.570044
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Prospective observation study

- TEVAR
  - N=52
  - Median age 69

- TCD
  - N=42

- DW-MRI
  - N=31

- Neurocognitive assessment
  - N=17

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Embolicization rate/ procedure steps

Embolicization/ atheroma grade

P; 0.019
Zone 0 and 1: median 446 (IQR 211-1786)
Zone 2: median 207 (IQR 102-271)
Zone 3 and 4: median 84 (IQR 33-184)
p=0.008

Type of pathology
p=0.856
Causes of stroke and source of embolisation

- Multifactorial
  - Embolic (atherosclerotic)
  - Embolic (air?)
  - Hypoperfusion
Risk factors for stroke

- Shaggy aorta
- Proximal landing zone
- LSCA coverage
- Previous stroke
- Blood loss >800mls
- Prolonged procedure
- IHD
- Female sex

Amarenco P et al N Eng Med J1994 *
Feezor R et al J Endovasc Ther 2007 **
LSCA coverage

- 25 series of LSCA covered vs uncovered *
  - Stroke 7.4% (covered)[1177 pts]
  - vs 4% (zone 3 & 4)[2,661 pts]
- 20 series looking at stroke distribution
  - 25% posterior circulation vs 75% anterior or diffuse
- Posterior circulation stroke
  - Higher mortality (33% vs 0%)
  - Lower recovery rate (17% vs 75%)

How can we reduce cerebral infarction?

- High dose statins
- Anti-platelet agents
- Anti-coagulation
Prevention methods

• Technical
  – Appropriate procedure planning
  – Minimize wire manipulation
  – Careful preparation of hardware and connections
  – Minimize unnecessary manipulation
  – Heparin and flushing
  – Device profile
  – Balloon!

• Patient selection
  – ‘Shaggy aorta’
  – Dominant vertebral
  – L SCA perfusion
Prevention methods

- Revascularization of LSCA
  - Carotid subclavian bypass
  - Branch devices
- Cerebral filters
- CO2
- New device structure/packaging?
LSCA re-vascularisation

• VS guidelines to re-vascularize LSCA
• The exact role and benefits to be determined
• Systematic review of 2594 pts +
  – Stroke without LSCA coverage 3.1% (95% CI 1-6.5)
  – Stroke with revascularisation 5.3% vs 8%
  – Conclusion: Stroke probably increases post LSCA
  – coverage, particularly in those without revascularisation

+ R Allmen et al Eur J Vasc Endovasc Surg 2016
LSCA re-vascularisation

- Systematic review of 1161 pts*
  - Stroke with revascularisation 5.8%
  - Stroke without revascularisation 7.8%
  - No significantly lower risk $p=0.1$
  - No difference in perioperative mortality 6.5% vs 7.2%
  - Moderate heterogeneity of studies

- No established relation between stroke/mortality and bypass technique**

* Hajibandeh et al. J Endovasc Ther 2016
** Zamor K J Am Coll Surg 2015
Sentinel cerebral embolic protection system

- Percutaneous device through brachial artery
- 6 Fr compatible sheath, 0.014 guide wire
- $140_{\mu m}$ diameter pore filters in brachiocephalic and left common carotid

Claretmedical.com
Experience of SPCS in TAVI

MISTRAL-C Trial Shows Neurocognitive Benefit of Sentinel Cerebral Protection System during TAVR

Results presented at TCT 2015 by Dr. Nicholas van Mieghem

Data show that unprotected percutaneous transcatheter aortic valve replacement (TAVR) was associated with increased neurocognitive impairment when compared to patients undergoing protected TAVR with the Claret Medical Cerebral Protection System (CPS). The CPS allows for real-time cerebral blood flow monitoring, which can be assessed using the Mini Mental State Examination (MMSE). The results revealed a 32.5% improvement in MMSE scores for patients who underwent protected versus unprotected TAVR.

CLEAN-TAVI Trial Shows Claret Medical Cerebral Protection System Dramatically Reduces Brain Lesions and Neurological Events Following Transcatheter Aortic Valve Replacement (TAVR)

Clinical Trial is First to Definitively Demonstrate That Removing Embolic Debris from Cerebral Circulation Can Significantly Shield the Brain

TCT 2014

WASHINGTON—BUSINESS WIRE)—Claret Medical™, Inc., today announced that the CLEAN-TAVI Trial met its primary endpoint by demonstrating that the company’s cerebral protection system significantly reduced the quantity and volume of brain lesions detected by a serial review of magnetic resonance imaging (MRI) following transcatheter aortic valve replacement (TAVR). The trial results showed a 59 percent reduction in the total volume of new brain lesions and a 60 percent reduction in the number of new brain lesions two days after the procedure. The results were reported today by Professor Axel Linke, MD, at a Late Breaking Clinical Trial session at the 28th Transcatheter Cardiovascular Therapeutics (TCT) meeting, the annual scientific symposium of the Cardiovascular Research Foundation.

“Results seen with the Claret Medical system are striking”

At two days post-TAVR in the “Intent to Treat” analysis, a neurological deficit was observed in 28 percent of all control patients when evaluated by a NIH-SSS (National Institute of Health Stroke Scale) trained specialist, demonstrating that prospective assessment pre-planed methods to prevent and detect neurological complications without concomitant embolic protection.
Pilot Study: Reducing cerebral injury during TEVAR
### Pilot Study SCPS: Results

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age</th>
<th>Gender</th>
<th>CTA grade of arch</th>
<th>Pathology</th>
<th>Post-op 3T DW-MRI (DAY2-5)</th>
<th>TCD HITS</th>
<th>Neurocognitive assessment</th>
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<tr>
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<td>No of lesions</td>
<td>Surface area of lesions (mm²)</td>
<td>Device manipulation &amp; deployment</td>
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Median surface area infarction 8mm vs 164mm

11.2mm$^2$ vs 6.3mm$^2$
Histopathology

Total no particles: 5681
Mean 473: range (25 - 1676)
9.8% ≥ 150um max diameter
Debris captured in 100% of filters

*Acute thrombus was always found in combination with other materials

Debris captured in Proximal filters (n=5)

Debris captured in Distal filters (n=5)

Histopathology
CO2 flushing

Abstract

Purpose: To describe the technique of carbon dioxide (CO₂) flushing of thoracic stent-grafts to reduce the risk of cerebral air embolism. Technique: To remove room air, thoracic stent-grafts were preoperatively flushed 2 minutes with carbon dioxide from a cylinder connected to the flushing chamber of the capture valves of Z-sleeve custom-made endografts, this was followed by the standard saline flush. Thirty-six patients undergoing thoracic endovascular aortic repairs (TEVAR) involving the ascending aorta and the aortic arch received CO₂ flushed Z-sleeve endografts. One patient with a highly calcified arch experienced a minor stroke. Conclusion: Arterial air embolism is a potentially underestimated problem of aortic endografting, especially in the proximal segments of the aorta. CO₂ flushing may have the potential to reduce air embolization during TEVAR.

Abstract

Purpose: To investigate the amount of gas released from Z-sleeve thoracic stent-grafts using standard saline flushing vs the carbon dioxide flushing technique. Method: In an experimental bench setting, 30 thoracic stent-grafts were separated into 2 groups of 15 endografts. One group was flushed with 60 mL saline and the other group was flushed with carbon dioxide for 5 minutes followed by 60 mL saline. All grafts were deployed into a water-filled container with a curved plastic pipe; the deployment was recorded and released gas was measured using a calibrated setup. Results: Gas was released from all grafts in both study groups during endograft deployment. The average amount of released gas per graft was significantly lower in the study group with carbon dioxide flushing (0.79 ± 0.51 mL, p<0.005). Conclusion: Thoracic endografts release significant amounts of air during deployment if flushed according to the instructions for use. Application of carbon dioxide for the flushing of thoracic stent-grafts prior to standard saline flush significantly reduces the amount of gas released during deployment. The additional use of carbon dioxide should be considered as a standard flush technique for aortic stent-grafts, especially in those implanted in proximal aortic segments, to reduce the risk of air embolism and stroke.
Conclusion

- TEVAR is associated with significant risk of stroke and silent infarcts
- Stroke prevention needs multifaceted approach
- Encouraging results with initial experience with embolic protection device in TEVAR
- Further work is needed to establish the evidence and role
Preventing strokes in TEVAR: What factors should be considered?

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