A Novel Filter for Stroke Protection in TEVAR

Richard Gibbs
Imperial Vascular Unit,
St Mary’s Hospital
London UK
Disclosures

Research Funding – Gore Medical
Neurological Complications

Patterson et al JVS 2014
Stroke rate for TEVAR = 3-6%
Cerebral embolization, silent cerebral infarction and neurocognitive decline after thoracic endovascular aortic repair

A. H. Perera¹, N. Rudarakanchana², L. Monzon³, C. D. Bicknell¹, B. Modarai⁴, O. Kirmi⁵, T. Athanasiou⁷, M. Hamady¹,⁶ and R. G. Gibbs¹

¹Imperial Vascular Unit, Department of Surgery and Cancer, Imperial College and Imperial Healthcare NHS Trust, ²Department of Vascular Surgery, Royal Free Hospital, ³Department of Interventional Radiology, Guy’s and St Thomas’ NHS Foundation Trust, ⁴Academic Department of Vascular Surgery, King’s College London, British Heart Foundation Centre of Research Excellence and National Institute of Health Research Biomedical Research Centre at King’s Health Partners, St Thomas’ Hospital, Departments of ⁵Neuroradiology and ⁶Interventional Radiology, Imperial Healthcare NHS Trust, and ⁷Department of Surgery, Imperial College London, London, UK

Correspondence to: Mr C. D. Bicknell, Department of Surgery, Imperial College London, 10th Floor QEQM Building, St Mary’s Hospital, South Wharf Road, London W2 1NY, UK (e-mail: colin.bicknell@imperial.ac.uk)
TEVAR
N=52
Median age 69

TCD
N=42

100% HITS
Stent deployment
Contrast injection
PLZ + atheroma severity

DW-MRI
N=31

81% cerebral infarction
13% stroke
68% SCI

Neurocognitive assessment
N=17

88% Decline
6/7 domains age>69
Landing Zones

Zones 0/1 > Zones 3/4

Embolisation rates

<table>
<thead>
<tr>
<th>Zone</th>
<th>Value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 0/1</td>
<td>450</td>
<td>0.001</td>
</tr>
<tr>
<td>Zone 2</td>
<td>207</td>
<td></td>
</tr>
<tr>
<td>Zone 3/4</td>
<td>72</td>
<td></td>
</tr>
</tbody>
</table>
Aortic Atheroma Severity

Atheroma grade 4-5 > grade 1-3

Emboli rates

Grade 1-3
Grade 4-5

100
207

p=0.042
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

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

14 October 2015

Results presented at TCT 2015 by Dr. Nicholas Van Mieghem

WASHINGTON—(BUSINESS WIRE)—The CLEAN-TAVI endpoint by demonstrating that brain lesions detected by a serial FFR reduction in the number of lesions in the Claret Medical System are significantly lower in the MISTRAL-C arm than in the DEFLECT III arm. The results suggest that Claret Medical’s Sentinel Cerebral Protection System is an effective tool for reducing neurological events during TAVR.

Any worsening in NIHSS

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Embolic Protection</th>
<th>Events</th>
<th>Total</th>
<th>No Embolic Protection</th>
<th>Total</th>
<th>Weight</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLEAN-TAVI</td>
<td>8</td>
<td>60</td>
<td>14</td>
<td>50</td>
<td>79.3%</td>
<td>0.57 [0.26, 1.24]</td>
<td></td>
</tr>
<tr>
<td>DEFLECT III</td>
<td>2</td>
<td>42</td>
<td>3</td>
<td>35</td>
<td>15.9%</td>
<td>0.66 [0.07, 3.14]</td>
<td></td>
</tr>
<tr>
<td>MISTRAL-C</td>
<td>0</td>
<td>28</td>
<td>1</td>
<td>22</td>
<td>4.8%</td>
<td>0.26 [0.01, 6.19]</td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>120</td>
<td>107</td>
<td>0.55 [0.27, 1.09]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Test for overall effect: Z = 1.71 (P = 0.09)

MoCA Score

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Embolic Protection</th>
<th>Mean</th>
<th>SE</th>
<th>SD</th>
<th>Total</th>
<th>Mean</th>
<th>SE</th>
<th>SD</th>
<th>Total</th>
<th>Weight</th>
<th>Std. Mean Difference M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFLECT III</td>
<td>22.8</td>
<td>2</td>
<td>39</td>
<td>22</td>
<td>33</td>
<td>2</td>
<td>5.5</td>
<td>22</td>
<td>55</td>
<td>0.40 [0.07, 0.86]</td>
<td></td>
</tr>
<tr>
<td>MISTRAL-C</td>
<td>23.2</td>
<td>4.2</td>
<td>28</td>
<td>21.2</td>
<td>5.5</td>
<td>22</td>
<td>40.8%</td>
<td>0.41 [0.16, 0.97]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>67</td>
<td>55</td>
<td>100%</td>
<td>0.40 [0.04, 0.76]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Test for overall effect: Z = 2.18 (P = 0.03)

Overt stroke

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Embolic Protection</th>
<th>Events</th>
<th>Total</th>
<th>No Embolic Protection</th>
<th>Events</th>
<th>Total</th>
<th>Weight</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEFLECT III</td>
<td>2</td>
<td>46</td>
<td>2</td>
<td>39</td>
<td>71.1%</td>
<td>0.85 [0.13, 5.74]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMBOL-X</td>
<td>0</td>
<td>14</td>
<td>0</td>
<td>16</td>
<td>33.3%</td>
<td>Not estimable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MISTRAL-C</td>
<td>0</td>
<td>32</td>
<td>2</td>
<td>33</td>
<td>28.9%</td>
<td>0.21 [0.01, 4.13]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>92</td>
<td>88</td>
<td>100.0%</td>
<td>0.56 [0.11, 2.82]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Test for overall effect: Z = 0.70 (P = 0.49)
Sentinel Cerebral Protection System

- Percutaneous device via brachial artery
- 6 Fr compatible sheath, 0.014 guide wire
- 140\text{um} diameter pore filters in brachiocephalic and left common carotid
Pilot Study: Cerebral Protection during TEVAR

- 10 patients
- Inclusion criteria: PLZ 2,3,4
- Innominate diameter: 9-15mm
- L carotid diameter: 6.5-10mm

- Procedural TCD
- Pre + post op MRI
- Cognitive function
- Recovered embolic debris – histopathological analysis
TCD: what are the emboli?

- C TAG
  - 0.025-0.04mls

- Valiant
  - 0.1-0.3mls

Inci et al, SAGE open med 2016
TCD: Solid vs gaseous emboli
• Protected n=10
  • Mean Age 68yrs (46-85)
  • Male n= 7 F =3
  • Elective 30% Emergency 70%
  • Stent graft
    – Gore c-Tag n=10

• Pathology
  – TAA n=5
  – Acute aortic syndrome n=5

• Procedure
  – TEVAR n= 6
  – TEVAR C/S BYPASS n= 3
  – TEVAR C/C % C/S BYPASS n=1

• Landing zones 2 (40%) 3 (60%)
• Atheroma grade
  – 1&2 n=7
  – 3&4 n=3

• Unprotected n=12
  • Mean age 61yrs (28-81)
  • Male n= 8 F=4
  • Elective 75% Emergency 25%
  • Stent Graft
    – Gore c –Tag n=4
    – Medtronic n=4
    – Bolton n=3
    – COOK n=1

• Pathology
  – TAA n=2
  – Acute aortic syndrome n=5
  – Coarctation & transection aorta n=5

• Procedure
  – TEVAR n= 6
  – TEVAR C/S BYPASS n= 6

• Landing zones 2 (70%) 3 (30%)
• Atheroma grade
  – 1&2 n=5
  – 3&4 n=6
  – 5 n-1
Pilot Study: Reducing cerebral injury during TEVAR

<table>
<thead>
<tr>
<th></th>
<th>Procedure Median (IQR)</th>
<th>CEPD Median (IQR)</th>
<th>Addition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time (mins)</td>
<td>149 (125.5-191.5)</td>
<td>6.59 (4.6-16)</td>
<td>6.59 mins</td>
</tr>
<tr>
<td>Contrast (mls)</td>
<td>93 (76.3-108.8)</td>
<td>22.5 (20-32.5)</td>
<td>23mls</td>
</tr>
<tr>
<td>Radiation DAP (mGy.cm²)</td>
<td>58600 (41667-183303)</td>
<td>1824 (1235-3392)</td>
<td>2.2%</td>
</tr>
<tr>
<td>Fluoroscopy time (mins)</td>
<td>12.4 (10.4-14.9)</td>
<td>3.3 (2.4-3.9)</td>
<td>3.3mins</td>
</tr>
</tbody>
</table>

- 90% success rate
- No device associated complications or stroke
TCD: Procedural embolization

**solid emboli :**15 (IQR 144-16)
gaseous emboli 369 (IQR 214-459)

**Maximum proportion of SOLID HITS**
- Wire & pigtail: 13% solid
- Stent deployment: 11%
**Protected**

7/9 (78%) 23 new lesions  
Median number 1 (1-3)  
Total SA=379\(\text{mm}^2\)  
Median SA= 6\(\text{mm}^2\) (3-16)

**Unprotected**

9/12 (75%) 55 new lesions  
Median number 3 (1-4)  
Total SA=1534\(\text{mm}^2\)  
Median SA=16\(\text{mm}^2\) (3-103)
MR Lesions by vascular territory

<table>
<thead>
<tr>
<th>Vascular territories</th>
<th>Protected n=7</th>
<th>Unprotected n=9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior</td>
<td>37</td>
<td>197</td>
</tr>
<tr>
<td>Posterior</td>
<td>339</td>
<td>1150</td>
</tr>
<tr>
<td>Left Posterior</td>
<td>220</td>
<td>1087</td>
</tr>
<tr>
<td>Right posterior</td>
<td>119</td>
<td>63</td>
</tr>
<tr>
<td>Borderzone</td>
<td>3</td>
<td>187</td>
</tr>
</tbody>
</table>
Number and surface area of new MRI lesions vs solid HITS

![Graph showing correlation between number of new lesions and number of solid HITS.](image-url)

- **Rho**: 0.928
- **P-value**: 0.01

- **Rho**: 0.794
- **P-value**: 0.06
Number of new MRI lesions vs gaseous HITS

\[ \rho = 0.912 \]
\[ p = 0.01 \]
Histopathology

10 Proximal, 9 distal filters: 95% contained debris

Median no particles: 937 (146-1687)

Median SA=2.66mm$^2$

acute thrombus (95%)
arterial wall (63%)
foreign material (32%).
Conclusions

• Embolic showering causes stroke and SCI

• The more proximal the landing zone and the more diseased the aorta - the greater the risk

• SCI is not silent
Conclusions

• Median number of particles captured in filters = 937 (146-1687)

• CEPD reduced both number and size of new infarcts

_BUT….._

• L SCA and vertebral unprotected

• Role of gaseous emboli