How to prevent cerebral embolisation during TEVAR

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

Research grant: Gore Medical
Cerebral embolization, silent cerebral infarction and neurocognitive decline after thoracic endovascular aortic repair

A.H Perera, N Rudarakanchana, L Monzon, CD Bicknell, B Moderai, O Kirmi, M Hamady, and RG Gibbs
TEVAR
N=52
Median age 69

TCD
N=42

100% HITS
Stent deployment
Contrast injection

TEVAR
N=52
Median age 69

DW-MRI
N=31

81% cerebral infarction
13% stroke
68% SCI

Neurocognitive assessment
N=17

88% Decline
6/7 domains
age>69

81% cerebral infarction
13% stroke
68% SCI

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

Zones 0/1 > Zones 3/4

Emboliisation rates

Zone 0/1: 450
Zone 2: 207 (p=0.001)
Zone 3/4: 72
Kaplan–Meier curves showing the event-free survival rate according to the aortic atheroma severity.

A atheroma grade 4-5 > grade 1-3

Emboliization 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)

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

Results presented at TCT 2015 by Dr. Nicholas Van Mieghem

The results seen with the Claret Medical system are striking.
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

Claretmedical.com
Reducing cerebral injury during TEVAR

- Physical compatibility of Sentinel CPD device and TEVAR assessed using pulsatile flow benchtop model (n=8)

- 4 aortic stent grafts tested (Bolton, Medtronic, Gore, Cook)

- No impediment to deployment of aortic stent graft or retrieval of device
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?
### 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%
7/9 (78%) 23 new lesions
Median number 1 (1-3)
Total SA=379mm²
Median SA= 6mm² (3-16)

9/12 (75%) 55 new lesions
Median number 3 (1-4)
Total SA=1534mm²
Median SA=16mm² (3-103)
MR Lesions by vascular territory

MRI lesion surface area mm²

- Anterior: Protected 37, Unprotected 197
- Posterior: Protected 339, Unprotected 1150
- Left Posterior: Protected 220, Unprotected 1087
- Right Posterior: Protected 119, Unprotected 63
- Borderzone: Protected 3, Unprotected 187

Vascular territories

Protected n=7
Unprotected n=9
Number and surface area of new MRI lesions vs solid HITS

![Graph showing the correlation between number of SOLID HITS and number and surface area of new MRI lesions.](image)

- **Number of new lesions**: $\text{rho} = 0.928$, $p = 0.01$
- **Surface area of new lesions**: $\text{mm}^2$, $\text{rho} = 0.794$, $p = 0.06$
Number of new MRI lesions vs gaseous HITS

\[
\text{rho} = 0.912, \quad p = 0.01
\]
Histopathology

10 Proximal, 9 distal filters: 95% contained debris

Median no particles: 937 (146-1687)

Median SA=2.66mm²

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

• CEPD reduced both number and size of new infarcts

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

_BUT....._

• L SCA and vertebral unprotected

• Role of gaseous emboli