Cerebral Embolic Protection in Thoracic Aortic Stent-grafting

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- No relevant financial relationship reported
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- **Speakers Bureau:** Bolton Medical; Hansen Medical; Gore & Associates
- **Consultant/Advisory Board:** Bolton Medical; Hansen Medical; Gore & Associates
Silent Brain Infarcts and Cognitive Decline

**BACKGROUND**
Silent brain infarcts are regularly detected using diffusion-weighted imaging (DWI) in healthy elderly individuals, and are associated with dementia and cognitive decline.

- **63** - 68% of people over 65 have silent brain infarcts.
- **SCI ‘silent brain infarcts’, dementia, stroke, depression**
  
- **Cerebral embolisation – principle risk factor** for clinical stroke. Silent brain infarcts – predictor of progressive cognitive decline.
SCI, stroke and neurocognitive decline
St Mary’s experience…

- Silent cerebral infarction after TEVAR: a neuroimaging study
  - N=19, 63% SCI rate

- Perera et al (submitted for publication), prospective observational study:
  - N=52, 81% cerebral infarction, 68% SCI rate,
  - 13% overt stroke
Neuro-psychometric testing demonstrates a worrying cognitive decline……

TEVAR
N=52
Median age 69

TCD
N=42

100%

DW-MRI
N=31

68%

SCI

88%
Decline 6/7 domains age>69

Neurocognitive assessment
N=17

100%

HITS

68%

SCI

88%
Decline 6/7 domains age>69

Maximum HITS
Stent deployment
62 (IQR 35–192)
Contrast injection
62 (IQR 22–163)

Median infarct volume
164 mm²
IQR (108.64–1328.30 mm²)

• REY auditory verbal test, verbal learning and memory
• Trail A – visual search and motor
• Trail B – mental flexibility & switching
• Grooved pegboard – fine motor skills
• COWA – executive function
Sentinel Cerebral Embolic Protection System
SPCS; Claret Medical, CA, USA

- Percutaneous device through brachial artery
- 6 Fr compatible sheath, 0.014 guide wire
- 140 μm diameter pore filters in brachiocephalic and left common carotid
MISTRAL-C Trial Shows Neurocognitive Benefit of Sentinel Cerebral Protection System during TAVR

Results presented at TCT 2015 by Dr. Nicholas Van Mieghem

Data showed that unprotected patients had worse cognitive function compared to patients treated with the Claret Medical Cerebral Protection System as assessed using the Mini Mental State Examination.

Results from the multi-center, randomized 2-center, single-blind, parallel-group, 1:1 trial being reported in an oral presentation today at the 33rd Transcatheter Cardiovascular Therapeutics (TCT) meeting by Principal Investigator Dr. Nicholas van Mieghem of the Thoraxcenter, Erasmus Medical Center, Rotterdam, showed that the MISTRAL-C study showed the use of the Claret Medical System reduced the number and volume of brain lesions detected by magnetic resonance imaging (MRI) post-TAVR.

MISTRAL-C showed a 52 percent reduction in new brain lesions two days post-procedure as assessed by MRI in the Claret Medical group compared to standard of care. In addition, 65 percent of the patients in the Claret Medical group had no new brain lesions compared to 39 percent in the control group.

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 53 percent reduction in the total volume of new brain lesions and a 69 percent reduction in the number of new brain lesions two days after the procedure. The results were reported today by Professor Axel Linke, MD in a Late Breaking Clinical Trial session at the 26th Transcatheter Cardiovascular Therapeutics (TCT) meeting, the annual scientific symposium of the Cardiovascular Research Foundation.

“The 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 NIHSS (National Institute of Health Stroke Scale) trained specialist, demonstrating that prospective assessment pre-
Cerebral Embolic Protection in TEVAR
A Pilot Study

- SPCS successfully deployed and retrieved with all commercially available grafts: c-Tag GORE, Medtronic, COOK, Bolton on pulsatile flow model testing N=8

- CEPD deployment & retrieval time (mins): 16 9 8 2

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age</th>
<th>Gender</th>
<th>CTA grade of arch</th>
<th>Pathology</th>
<th>Proximal landing zone</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></td>
<td></td>
<td></td>
<td>No of lesions</td>
<td>Volume of lesions mm²</td>
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<td>79</td>
<td>F</td>
<td>2</td>
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</table>
MRI lesions

FEMALE 1

MALE 2

25.3mm²

15.2mm²
Debris captured in Proximal filters (n=4)

- Any debris: 100%
- Acute thrombus*: 100%
- Organizing thrombus: 25%
- Valve Tissue: 0%
- Arterial Wall: 0%
- Calcification: 0%
- Foreign material: 0%

*Acute thrombus was always found in combination with other materials

Debris captured in Distal filters (n=4)

- Any debris: 100%
- Acute thrombus*: 100%
- Organizing thrombus: 75%
- Valve Tissue: 25%
- Arterial Wall: 75%
- Calcification: 75%
- Foreign material: 0%
RCT Planned
(INTerCEPT: INTERvention with Cerebral Embolic Protection in Tevar)

- After completion of pilot trial N=30
- Proceed to RCT double-blinded
  - (1) TEVAR (2) TEVAR + CEPD
  - Primary endpoint: Volume of SCI post-op DW MRI
  - Secondary endpoints:
    - 30 day stroke
    - No of SCIs
    - Neurocognitive score 6 weeks, 6 months
    - 30 day mortality
Conclusion

- Encouraging results with initial experience with embolic protection device in TEVAR

- 2/4 patients NO new lesions. Smaller volume lesions post CEPD

- RCT to ascertain true benefit
Acknowledgments

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Thank you

Any Questions?