Embolic Protection for TEVAR/TAVR: Does it work?

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Disclosure
- Consultant to Endologix
- Consultant to Shape Medical
- Founder, Embrella Cardiovascular, Inc
- Founder, StemPlant, LLC

<table>
<thead>
<tr>
<th>TAVR and stroke</th>
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<tbody>
<tr>
<td>Transcatheter Aortic-Valve Implantation — At What Price?</td>
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<td>In 2006, Kemberle et al. described transvenous placement of a pulmonary-side prosthesis and speculated that similar technology might be used to other cardiac valves, including the aortic position. Two years later, the first transcatheter insertion of an aortic-side prosthesis was performed by Cohrs et al. Transcatheter aortic-valve patients who are eligible for transcatheter insertion and may decrease vascular injury. But the increased risk of stroke associated with transcatheter replacements, as compared with surgical replacements, is a special concern. Brin and colleagues report a 5.3% risk of stroke or transient ischemic attack within 30 days after</td>
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<th>TAVR and stroke</th>
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<tr>
<td>Clinical Stroke:</td>
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<td>- 3.8% and 5% (PARTNER A and B)</td>
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<td>- 2.3% and 3.9% (US CoreValve High Risk Study)</td>
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<td>- Associated with post-dilation, AF</td>
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<td>- No improvement despite newer generation devices</td>
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<tr>
<td>- DWMRI new lesions in 73-84%</td>
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<td>- Neurocognitive decline</td>
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<td>- Premature dementia</td>
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<td>Multiple lesions in majority</td>
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<td>MAJOR BARRIER FOR MOVING TO LOW RISK PATIENTS</td>
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<tr>
<th>Patient Concerns re Stroke</th>
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<td>Procedural stroke is a significant concern for TAVR patients</td>
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<td>Audience Response from Cardioprotection Session at ACC 2014</td>
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<td>Question 1: What is the biggest concern for your patients undergoing TAVR?</td>
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<td>1. Having general anesthesia: 30%</td>
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<td>2. Risk of death: 30%</td>
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<td>3. Needing additional procedures: 10%</td>
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<td>Question 2: Is CPS necessary during TAVR?</td>
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<tr>
<td>1. No: 70%</td>
</tr>
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<td>2. Yes, in selected patients: 30%</td>
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<tr>
<th>Claret Sentinel Cerebral Protection System</th>
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<td><img src="image_url" alt="Image" /></td>
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Claret Sentinel Cerebral Protection System

- 6 French
- Radial access
- 140 micron pores
- BCA and LCCA
- Filtration
- Only FDA approved device

CLEAN-TAVI trial

- N=100
- Randomized 1:1
- Medtronic Core Valve
- DWMRI and NIHSS
- Debris in filter 88%
- Stroke rate 28%
- Decreased number of lesions (60%)
- Decreased volume of lesions (53%)
- Decreased ataxia (9% vs 24% control)
- IDE trial planned (N=284, 15 sites)


Sentinel Device

Significant Stroke and Mortality Reduction with Embolic Protection


Sentinel IDE trial

- N=363 TAVR
- Randomized 2:1 (protected:control)
- DWMRI and NIHSS
- Debris in filter 99%
- Stroke rate 5.6% vs 9.1%; P = 0.25NS
- MACE 7.3% vs 9.9%; P = 0.41NS
- New lesion volume 102.8 mm$^3$ vs 178.0 mm$^3$; P = 0.33NS


Edwards Embrella Embolic Deflector

- Nitinol frame
- Polyurethane membrane
- 100μm pores
- Deflection
- 6 French
- Radial access
- CE marked
- Commercialized OUS

Seeger et al. J Am Coll Cardiol Intv 2017;10:2297–303
CE Mark Trial

Types of Procedures

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<tr>
<th>Procedure</th>
<th>Count</th>
<th>Edwards %</th>
<th>CoreValve %</th>
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<tr>
<td>BAV</td>
<td>2</td>
<td>63%</td>
<td>37%</td>
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<tr>
<td>TAVI</td>
<td>27</td>
<td>17/27</td>
<td>10/27</td>
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Average Procedure Time*, minutes ± SD = 120 ± 1.2
Average Embrella Dwell Time*, minutes ± SD = 39 ± 0.6

Procedural Safety – CP-001 Data

- 100% Procedural Safety – 0 device related AE’s/SAE’s
- No strokes
- Successful deployment and coverage of brachiocephalic and LCCA (100% Passed)
- No interference with catheters (100% Passed)
- Successful retrieval (100% Passed)

DW MRI Results: Volume (cc)

- Embrella Control
  - Average Volume (cc) Lesions/Subject: 5.91 (±17.32)
  - Lesions/Subject: 0.538 (±0.33)
  - p = 0.000...

Secondary Endpoint Analysis – TCD

- Significantly fewer hits than control group (p = 0.001)
- 91.6% of HITS were during TAVI procedure

PROTAVI-C Pilot

- 42 TAVR with EPD, 12 Control
- 100% technical success
- No peri-procedure strokes
- 80% follow-up (test), 50% follow-up (control)
- Higher TCD HITS in test group
- DWMRI:
  - 100% of subjects had lesions
  - Smaller volume/lesion with EPD
  - Less total volume with EPD
  - All lesions gone by 30 days!
- High drop-out rate and low strength MRI

Keystone Heart TriGuard

- 42 TAVR with EPD, 12 Control
- 100% technical success
- No peri-procedure strokes
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  - 100% of subjects had lesions
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  - Less total volume with EPD
  - All lesions gone by 30 days!
- High drop-out rate and low strength MRI
Keystone Heart TriGuard

- 9 French
- Femoral access
- Remains tethered
- Stabilizer bars
- Deflection
- CE marked
- DEFLECT III Trial
- Decreased lesion number and volume
- RCT (REFLECT) in progress

CONCLUSIONS

- Stroke is a major concern of patients and clinicians
- Stroke etiology is multifactorial
- EPDs are effective at reducing the number and volume of lesions seen on DWMRI
- Reduction in clinical stroke likely
- Further study with larger trials is necessary