Embolic Protection for TEVAR/TAVR: Does it work?

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Disclosure

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TAVR and stroke

Clinical Stroke:
- 3.8% and 5% (PARTNER A and B)
- 2.3% and 3.9% (US CoreValve High Risk Study)
- Associated with post-dilation, AF
- No improvement despite newer generation devices

DWMRI new lesions in 73-84%
- Neurocognitive decline
- Premature dementia
- Multiple lesions in majority
MAJOR BARRIER FOR MOVING TO LOW RISK PATIENTS

Patient Concerns re Stroke

Procedural stroke is a significant concern for TAVR patients

Audience Response from Cardiac Protection Session at ACC 2016

Question #1: What is the biggest concern for your patients undergoing TAVR?
1. Having general anesthesia
2. Risk of death
3. Refusing stroke
4. Other

Question #2: Is CPS necessary during TAVR?
1. No, never
2. May consider some patients
3. Yes, in selected patients

Claret Sentinel Cerebral Protection System
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 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


Sentinel Device

**Significant Stroke and Mortality Reduction with Embolic Protection**

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

Edwards Embrella Embolic Deflector

- Nitinol frame
- Polyurethane membrane
- 100$\mu$m pores
- Deflection
- 6 French
- Radial access
- CE marked
- Commercialized OUS
CE Mark Trial

Types of Procedures

- 2 BAV
- 27 TAVI

63% Edwards – 17/27
37% CoreValve – 10/27

Average Procedure Time*, minutes + SD = 120 + 1.2
Average Embrella Dwell Time*, minutes + SD = 39 + 0.6

*Data from CP-001

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)

<table>
<thead>
<tr>
<th>Lesions/Subject</th>
<th>Average Volume (cc)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embrella</td>
<td>0.538 (+/- 0.33)</td>
</tr>
<tr>
<td>Control</td>
<td>5.91 (+/- 17.32)</td>
</tr>
</tbody>
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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
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