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

DWMRI new lesions in 73-84%
◆ Neurocognitive decline
◆ Premature dementia

Multiple lesions in majority
MAJOR BARRIER FOR MOVING TO LOW RISK PATIENTS

Claret Sentinel Cerebral Protection System

• 6 French
• Radial access
• 140 micron pores
• BCA and LCCA
• Filtration
• CE marked
• Commercialized OUS
• IDE trial
**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)

**Edwards Embrella Embolic Deflector**
- Nitinol frame
- Polyurethane membrane
- 100 μ 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)**
- Average Volume (cc)
- Lesions/Subject
- p = 0.000...
- Data from CP-001
Secondary Endpoint Analysis – TCD

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


- 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

- 9 French
- Femoral access
- Remains tethered
- Stabilizer bars
- Deflection
- CE marked
- DEFLECT III Trial
- Decreased lesion number and volume
- RCT planned

CONCLUSIONS

- Stroke is a barrier to expanding the indication for TAVR
- Stroke etiology is multifactorial
- EPDs are effective at reducing the number and volume of lesions seen on DWMRI
- Clinical stroke impact less clear
- Further study with larger trials is necessary