Update on Experience with the Valiant MONA LSA Single Branched TEVAR Device (From Medtronic) to Treat Lesions Involving the Aortic Arch

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Disclosures
Abbott Speaker, Investigator
Cook Speaker, Investigator
Cryolife Consultant, Investigator
Edwards Consultant, Speaker
Gore Consultant, Investigator
LivaNova Consultant, Investigator
Medtronic Speaker, Investigator
Terumo Aortic Speaker, Investigator

Investigational use of devices discussed

Multi-Segment Aortic Disease

- Descending + Distal Arch
  - Proximal Arch + Proximal Descending
  - Proximal Arch + Thoracoabdominal
- / - Dissection

17-43% of patients undergoing TEVAR have planned coverage of LSA


LSA Coverage without revascularization most important predictor of stroke
Spinal cord ischemia 4%
Arm ischemia 6%
Death 6%

TEVAR Options for the LSA

- Cover → Emergencies
- Bypass / Transpose → Current Standard
- Endovascular Revascularization
  - In Situ / In Vitro Fenestration Off-Label
  - Parallel Grafting Off-Label
  - Branched Grafts Investigational

Valiant Mona LSA Stent Graft System

Diameter
30-46mm
Length
15cm
Valiant Mona LSA Delivery

- Flexible cuff “volcano” on main body
- Two wire system
  - Main system wire
  - LSA branch thru & thru wire
- Pre-cannulated cuff
- Tip capture

LSA Thoracic Branch Stent Graft

- Nitinol helical stent / polyester fabric
- Proximal flare
- 10, 12 and 14 mm diameters
- 40 mm length
- 15 Fr profile, femoral access

Early Feasibility Study Completed

- 9 subjects were treated at 3 sites
- Prospective, non-randomized, pre-market
- Goals:
  - Validate procedure in humans
  - Assess safety and performance acutely and 30 days
  - Collect imaging data to augment current understanding

Case Demonstration

69 y/o female, DTA 55mm

- Measurements
  - Proximal sealing zone
  - Diameter Between LSA and LCC: 27.2mm
  - Length: 21.0mm
  - Distal landing zone: 31.7mm
  - LSA Diameter: 6.6 – 9.9mm
- Planned Treatment with:
  - 34mm MSG (15cm length)
  - 12mm BSG (4cm length)
  - 34 and 36mm Distal Extension to celiac a.

Pre-Operative CT
Access
Rt femoral and Lt brachial

Delivery and Deployment

Delivery and Deployment

Delivery and Deployment

Delivery and Deployment

Completion Angiogram
Follow-up 3D CTA

Procedural Characteristics

- 100% successful delivery and deployment
- Duration of procedure: 125 min. (60-227)
- General anesthesia used in all 9 cases
- 7 patients received distal extension Valiant device
- Mean length of stay: 5.9 days (5-8)

Summary of Outcomes from EFS

- Primary effectiveness objective achieved
- 100% Treatment and Technical Success
- No deaths, no major (only minor) strokes, no paraplegia and no left arm/hand ischemia
- No device migration, infolding or fractures
- 100% stent graft integrity and patency

Feasibility Trial Actively Enrolling

- 7 sites; Up to 35 additional patients
- Patients will be followed through 5 years
- Patient selection is critical predictor of outcome
  - Including dissections
  - Branch vessel and dz relationships challenging
  - Compassionate / Emergency use available
- Looking forward to Pivotal Next