Early Clinical Results with the Valiant Mona LSA Branch Stent-Graft

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Disclosure

Speaker name: Frank R. Arko III, MD

I have the following potential conflicts of interest to report:

- Consulting
  - Employment in industry
  - Stockholder of a healthcare company
  - Owner of a healthcare company
  - Other(s)

- I do not have any potential conflict of interest
Valiant Mona LSA: Device Overview

Main Stent Graft (MSG)
- Flexible cuff “volcano” for BSG
- Diameters: 30 – 46mm
- Nominal length: 15cm

Branch Stent Graft (BSG)
- Nitinol helical stent with high radial force
- PE material with proximal flare
- Diameters: 10, 12, 14mm
- Length: 40mm
Valiant Mona LSA: Delivery System

**Delivery System**

- Two wire system
  - Main/primary aortic tracking wire
  - Pre-cannulated LSA cuff wire
- Tip capture for precise MSG delivery
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Valiant Mona LSA Clinical Experience
Trial Patient 1: 81 y/o female, DTA 5.7cm

- **Measurements**
  - Proximal Seal zone
    - Between LSA and LCC: 35.7mm
    - Beginning of Proximal Neck: 37.5mm
  - Distal Seal zone: 41.6mm
  - LSA: 8.0 - 9.0mm

- **Planned Treatment with:**
  - 46mm MSG (15cm length)
  - 10mm BSG (4cm length)
  - 46mm Distal Extension to diaphragm
Pre-Op 3D CT
Pre and Post Angios

Distal device placed first
1 Month Follow Up
1 Year Post-Op 3D CT
Emergent Patient: 84 y/o female, TAA in Arch

- Considerable arch thrombus
- Conservatively managed for 2 years post-diagnosis
- Presented symptomatically with worsening upper back/scapular pain
- CTA indicated rapidly expanding TAA with asymmetric expansion of anterior wall
- Bovine Arch with patent LSA
- Marginal access (7.0 – 7.4 mm)
3D Reconstruction
Proximal Target Landing Zone

Diameter – 40mm

Length – 13.5mm
Deployment of 46 x 150 Valiant Mona LSA
Placement of LSA Branch

Positioning of 10x40 LSA Branch Graft

Ballooning of 10x40 LSA Branch Graft
Final Angiogram
Post-op Patency and Exclusion

LSA Branch Patent

Complete Exclusion
Post-Op 3-D Fly-Through
Valiant Mona LSA Early Feasibility Trial

Acute Clinical Outcomes
Valiant Mona LSA Early Feasibility Trial

- Prospective, non-randomized, 3-center, pre-market clinical study
- 9 patients (7 US, 2 OUS)
- Goal:
  - Validate procedure
  - Assess acute safety and performance
  - Collect imaging data to augment current understanding

Principle Investigators:

- Eric E. Roselli, MD
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  Cleveland, OH, USA

- Frank R. Arko III, MD
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  Charlotte, NC, USA

- Matt Thompson, MD
  St. George’s Institute
  London, UK
Baseline Demographics and Clinical Characteristics

- 9 patients in total, 7 US and 2 UK
- Mean Age: 73 years (63-87)
- 67% female

Aneurysm Morphology
- Fusiform
- Saccular

Comorbidities
- Hypertension: 8
- Hyperlipidemia: 7
- Arrhythmia*: 5
- COPD: 4
- Cancer: 4
- TIA: 2

*All subjects presented with Cardiac Disease

- Mean Maximum Aneurysm Diameter: 53.7 mm (42-76)
- Mean LSA Diameter: Ostium – 10.3mm (8-13), Distal – 9.6mm (8-10)
Procedural Characteristics

- 100% successful delivery and deployment of MSGs and BSGs
- Duration of procedure: 125 min. (60-227)
- General anesthesia used in all 9 cases

**Main Stent Graft Access**
- Perc: 2
- Surgical: 7

**Main Stent Graft Access**
- Axillary: 2
- Brachial: 7

- 7 patients received distal Valiant device to extend coverage
- Mean hospital procedure stay: 5.9 days (5-8)
Primary Endpoints through 30-day Visit

- Treatment Success\(^1\): 100%
  - Technical Success: 100%

- Composite Safety Endpoints
  - Aneurysm-Related Mortality: 0 patients
  - Stroke: 3 patients
    - Minor, non-disabling neurological events
    - All subjects regained full functional status
  - Paraplegia: 0 patients
  - Left Arm/Hand Ischemia: 0 patients

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\(^1\) Treatment success is defined as technical success, which is the successful delivery and deployment of the stent graft and successful exclusion of the aneurysm while maintaining patency of the MSG and BSG.
Key Secondary Endpoints through 30-day Visit

- Secondary Endovascular Procedures: 0 patients
- Conversion to Surgical Procedure: 0 patients
- Surgical Revasc of the LSA: 0 patients
- Paraparesis: 0 patients
- Rupture: 0 patients

- Stent Graft Integrity: 100%
- Stent Graft Patency: 100%
- No technical issues with Main or Branch stent grafts
- Endoleaks at 30-day visit: 1 Type II and 1 Undetermined
Summary of Principle Findings through 30-days

- Primary effectiveness objective achieved at 30 days
  - 100% Treatment Success, 100% Technical Success
- No deaths, major strokes, paraplegia or left arm/hand ischemia
- No evidence device migration, infolding or fractures
- 100% stent graft integrity and patency
Conclusions

• The Valiant Mona LSA stent graft system has performed as planned in the short term

• Patients will continue to be followed through 5 years

• Expansion of Feasibility Trial planned for 2015:
  • 7 sites
  • Up to 24 additional patients
Thank You

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