Value of LSA branch devices in clinical practice – Early experience with the Valiant Mona LSA device

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Disclosure

Speaker name:

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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, conical-shaped cuff for BSG
  - RO visualization proximal and distal
- 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
  - LSA cannulation wire
- Pre-cannulated LSA cuff
- Tip capture for precise MSG delivery
Valiant MonaLSA Device

Main Stent Graft Deployment

Good wire separation
Valiant MonaLSA Device

Branch Stent Graft Deployment

Retrograde angiogram for BSG positioning
Valiant MonaLSA Device
Completion angiogram
Valiant MonaLSA Device

Post-op 3D CTA and Extracted device
Valiant MonaLSA Device

Sequential 3D CTAs
Valiant MonaLSA Device

Sequential Overlays
Valiant Mona LSA Early Feasibility Trial

1-Year Outcomes
Baseline Demographics and Clinical Characteristics

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

Aneurysm Morphology

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

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

- Treatment Success: 100%
  - Technical Success: 100%

Composite Safety Endpoints through 1-Year

- All-Cause Mortality: 0 patients
- Aneurysm-Related Mortality: 0 patients
- Stroke: 3 patients, all within 30d
  - Minor, non-disabling neurological events
  - All regained full functional status; all still alive
- Paraplegia: 0 patients
- Left Arm/Hand Ischemia: 0 patients

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 at the 30 day visit.
Key Secondary Endpoints through 1-Year

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

- 100% Stent Graft Integrity and Patency
- No kinking, twisting, separation, migration, fracture or occlusion of Main or Branch Stent Grafts
- Endoleaks at 12 month visit: 1 Type II and 1 Type III
  - Junctional Type III between MSG/BSG since discharge. TAA stable. Continuing to monitor.
Early Feasibility 1-Year Summary

• The Valiant Mona LSA stent graft system has performed as planned through 1-year follow-up

• Patients will continue to be followed through 5 years

Valiant Mona LSA Feasibility Study – currently enrolling

• 7 sites in the US and 24 additional patients
  First patient in: April 2015

• 10 patients enrolled to date
CT Slice Parameters
Slice increment 0.4 mm (z)
Slice thickness 0.5 mm (z)
Pixel size 0.518 mm (x,y)

Valiant MonaLSA Device
Case planning

00034-001-J-D; 50 Yr, Male, Pre Op Scan May 8, 2015

RAO:  2.0
CRAN: 8.0

Pan view for LSA takeoff: RAO 2°, CRAN 8°
Best angle to view the LSA ostium

Pan view for arch: LAO 3°, CRAN 8°
Best angle to view the landing zone between the LCC and LSA
Obtainable barrel view for LSA takeoff: RAO 50°, CAUD 1°
Valiant MonaLSA Device

Summary

The Valiant Mona LSA Device is a valuable addition to zone 2 TEVAR
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