Total Endovascular Aortic Arch Repairs with the Relay 2-Branched Endograft: the US Experience

Advantages and Limitations

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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

Progress to Date and Current Status

• IDE approved March 2, 2017
• 4 U.S. institutions and 10 U.S. subjects
  • Cleveland Clinic, Mass General, U Penn, Wash U
• January 10, 2019 Increase to 30 subjects and 10 sites
• Twelve subjects treated
  • ➔ full feasibility study

Patients
n = 12
• Mean age 68.4 years (50, 87)
• Coronary Disease 5 (42%)
• COPD 4 (33%)
• Hx Neurologic Disease 5 (42%)
• HTN 11 (92%)
• Hypercholesterolemia 8 (67%)
• Smoking 9 (75%)
• Renal Insufficiency 5 (42%)

Aortic Details
• Aneurysm 11 (92%)
  Max Thoracic Diameter 61.2 (13%) R
• Proximal end of disease:
  Zone 2 7 (64%)
  Zone 3 4 (36%)
• PAU 1 (8%)
• Mean Ascending Diameter 36.0mm, ran

ADVANTAGE: Pre-Curved Catheter, Controlled delivery, No Bare Stent

LIMITATION: Not Applied to More Proximal Disease
**ADVANTAGE: Broad Sizing Catalog**

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<th>Proximal Diameter</th>
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**Procedural Details**

- Technical Success: 12 (100%)
- Neuromonitoring: 12 (100%)
  - EEG: 3 (25%)
  - Cerebral Oximetry: 3 (25%)
  - EEG + Cerebral Oximetry: 6 (50%)
- Procedure Time, mean: 381 min
- Total Implant Time, mean: 90 min
- Post-procedure Time in ICU, mean: 87.0 hours
- Post-procedure Time in Hospital, mean: 8.6 days

**ADVANTAGE: Ease of Use**

**Outcomes**

- Death:
  - Acute: 2 (17%), day 11 & 34
  - Late: 1 (8%), day 246
- Stroke:
  - All: 6 (50%)
  - Disabling: 1 (8%)
- Paralysis: 1 (8%)
- MI: 1 (8%)
- Respiratory Failure: 1 (8%)
- Aortic Dissection: 1 (8%)

**LIMITATION: Arch Disease is High Risk Population – esp Aneurysm**

**Grafts Often Short**
Sometimes Really Short

Sometimes Ridiculously Short

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### Imaging Follow-up

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<th></th>
<th>30 Days</th>
<th>6 mos</th>
<th>12 mos</th>
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<td>Subjects w/ Adequate Imaging</td>
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<td>Loss of Patency – Main Body</td>
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Average: 191 days (SD ± 150)

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ADVANTAGE: Fatigue Tested for Long Durability