Early Experience With The Gore Endograft For Treating Lesions Of The Ascending Aorta: Advantages And Limitations

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ARISE: Gore Type A Dissection Early Feasibility Study
• The ARISE Type A EFS is the first industry sponsored FDA approved trial for endovascular repair in the ascending aorta
• Focused goal of this EFS is to assess the feasibility of endovascular repair of Type A dissections
  – Early clinical learnings will inform the evolution of the clinical treatment and design of devices for ascending dissections

ARISE: Gore Type A Dissection Early Feasibility Study
• Study Population: DeBakey Type I/II Dissection
• Approved for up to 10 patients
• Currently expanding to 6 US sites
  National Principal Investigator: Michael Reardon, MD
  Houston Methodist Hospital
  Principal Investigators:
  Memorial Hermann Heart & Vascular Institute
  Anthony Estrera, MD
  St. Luke’s Health Baylor
  Joseph Coselli, MD
  Cleveland Clinic
  Eric Roselli, MD
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  Houston Methodist Hospital
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ARISE: Gore Initial Study Device
• The Aortic Extender from the Gore Thoracic Branch Endoprosthesis System is being used to line the dissection and stabilize the entire ascending aorta, mimicking surgical repair
• The rest of the TBE system is available for distal extension to cover any distal tears in the arch and DTA that may provide flow to the ascending false lumen
• All implants to date have been isolated stent grafts in the

ARISE: Gore Type A Dissection EFS Current Status
• Trial is currently expanding from 3 to 6 sites
• Investigational device for all future implants will be the Gore Ascending Stent Graft
  – The Gore TBE Aortic Extenders will no longer be the primary study device
• New Gore Ascending Stent Graft has been designed to help mitigate some of the challenges from early EFS implants
  – Minimize number of devices required
  – Enhance conformability
  – Optimize orthogonality in the proximal ascending aorta
  – Provide staged deployment to allow for confidence in an accurate deployment in the ascending environment
ARISE: Gore Type A Dissection Early Feasibility Study Clinical Experience Overview

- Four enrollments with the TBE Aortic Extenders
  - 2 – Acute DeBakey Type I Dissections
  - 1 – Chronic DeBakey Type II Dissection
  - 1 – Acute DeBakey Type II Dissection

Gore ARISE EFS Early Clinical Experience Learnings

- Quality Imaging and Expertise
  - Fusion has huge benefit for these cases, currently used for TAVI and structural heart repairs
  - Multifaceted imaging needs:
    - Coronaries, entry tear location, arch vessels – need multiple C-Arm angles and fusion helps reduce contrast runs
    - Impossible to visualize all important structures with an angiogram in one plane

Intraprocedural Skills

- Expertise in Rapid Pacing
  - With each heart beat the proximal ascending aorta pulses up and down, making the coronary arteries a moving target
- Crossing the Aortic Valve
  - Wires and catheters needed to cross a valve in a Type A patient are not the same as for TAVI