FEASIBILITY OF ENDOVASCULAR AORTIC ARCH REPAIR AFTER HEMIARCH REPLACEMENT FOR ACUTE TYPE A AORTIC DISSECTION

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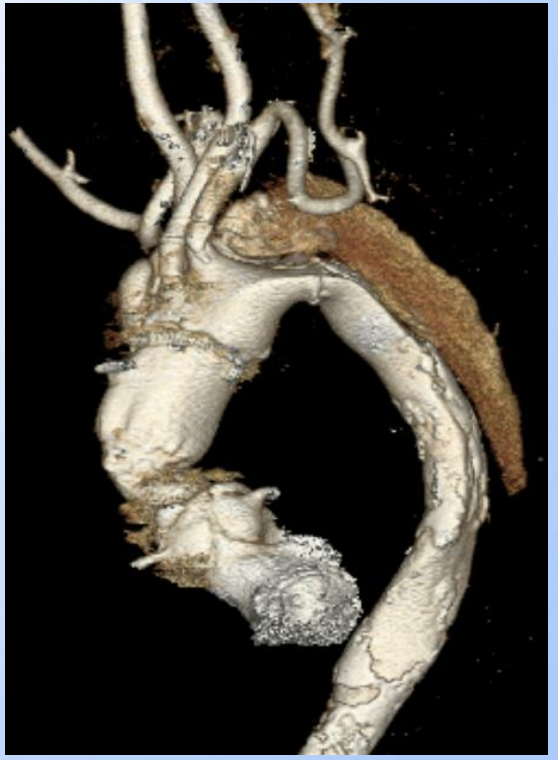
Background / Study Objective

- Branched arch endografts provide a novel treatment strategy for patients with aneurysmal degeneration of residual DeBakey type I dissection after initial ascending aortic replacement

- We assessed the treatment feasibility of three investigational arch branch endografts for patients who have undergone hemiarch replacement for an acute type A dissection



Review of Institutional database of patients with Acute type A Aortic dissection with intent to identify 50 consecutive patients suitable for imaging review

Patients

Excluded:
- Debakey II dissections
- No Postoperative CT scan
- Extensive (> hemiarch) aortic replacement

71 patients identified with:
- Residual Debakey I dissection
- underwent a hemiarch replacement
- had a postoperative CTA with contrast available for review

71 patients were screened to identify 50 patients that met device study inclusion criteria

Excluded per IFU (n=21):
- Extension of dissection into the innominate artery (n=13)
- Mechanical Aortic Valve (n=7)
- Connective tissue Disorder (n=1)

Final Study Cohort: 50 CT scans reviewed for anatomic suitability for branch TEVAR

Methods I

- CT scans of the 50 patients in the final study cohort were analyzed for suitability for treatment with:
  1. **Cook Medical Zenith Arch Branched Device** (IDE Study)
  2. **Gore TAG Thoracic Branch Endoprosthesis** (clinical trial)
  3. **Terumo Relay Dual Branch Device** (clinical trial)

Cook Medical

Zenith Arch Branched Device

W.L. Gore & Associates

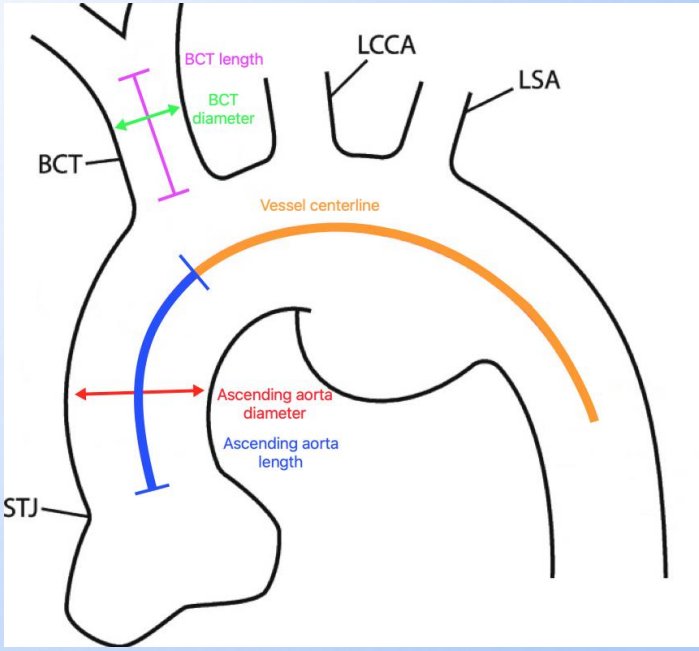
TAG Thoracic Branch Endoprosthesis

Terumo Aortic

Relay Plus Double-Branched Device

Methods II

- Proximal landing zone anatomy i.e. ascending aortic (AA) and great vessel (GV) landing zones, were evaluated on postoperative CTAs
- Suitability of distal landing zone in the descending aorta was not evaluated
- Measurements were conducted using 3D imaging software and compared against the manufacturer recommended sizing criteria (IFU) for each of the three devices
- Criteria for potential exclusion for the use of each endograft was identified for each patient



Methods III

- Reasons for exclusion were divided into:
  - **Patient factors** (non-modifiable at the initial hemiarch operation): BCT diameter, BCT length, dissection into BCT, and connective tissue disorder.
    - ➢ Endovascular treatment for these patients will require new device design, or additional treatment considerations
  - **Technical factors** (modifiable at initial operation): Mechanical valve placement, Ascending aortic graft diameter and length
    - ➢ These patients could potentially be candidates for endovascular repair with appropriate planning at the initial operation

Results 1

- Of patients that met inclusion criteria, **42 (84%) patients could be treated by at least one of the three devices, while 8 patients (16%) were excluded from all three devices** and would not be candidates for endovascular repair
  - 16 (32%) patients were candidates for all three devices
  - Additional 8 (16%) patients were candidates for two devices

Reason for Patient Exclusion from Individual Branched Arch Endograft based on landing zone anatomy on postoperative CT (n=50)			
	Cook	Gore	Terumo
Ascending aortic (neck) diameter too big or small	5 (10%)	4 (8%)	12 (24%)
Inadequate ascending aortic length	15 (30%)	4 (8%)	19 (38%)
Brachiocephalic trunk diameter too big or small	0	7 (14%)	1 (2%)
Inadequate Brachiocephalic trunk length	0	10 (20%)	8 (16%)
Left common carotid artery too small	0	0	1 (2%)

Results 2

- Overall non-candidacy rates for all screened pts (n=71) were 40 (56.3%) for Cook, 39 (54.9%) for Gore, and 52 (73.2%) for Terumo

Patient vs. Technical factors for exclusion for endovascular treatment		
	Patient related factors (non-modifiable)	Technical factors (Modifiable)
Cook	14 (19.7%)	26 (36.6%)
Gore	28 (39.4%)	15 (21.1%)
Terumo	24 (33.8%)	31 (43.7%)

Technical (modifiable) factors were the reason for 21 - 44% of patients being excluded from endovascular treatment

Conclusion

- Despite the availability of multiple branched endovascular devices, a significant number of pts may be unsuitable for subsequent endoarch repair
- Both patient-related factors and technical factors contributed to pts being excluded; awareness of anatomic inclusion criteria for arch endografts and modification of surgical technique for creation of a suitable landing zone at initial operation may increase likelihood of subsequent endovascular repair
- These data may inform changes in device design to accommodate a more variable patient anatomy
- In patients with unsuitable branch vessel anatomy on preoperative CT scan, a more extensive arch reconstruction may be considered to facilitate subsequent endovascular repair.