Dissected Aorta Repair Through Stent Implantation (DARTS) Trial: AMDS Arch Remodeling Hybrid Graft

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On behalf of the DARTS Investigators
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
Acute DeBakey I aortic dissection is a life-threatening condition that requires emergent surgery to save the patient’s life.

Emergent hemiarch repair is the standard-of-care and it successfully addresses the primary entry tear by resection, however, with several limitations:

- Residual false lumen (FL) remains in the distal aorta
- Threat of visceral and peripheral malperfusion
- Creation of an anastomotic entry tear, allowing for antegrade pulsatile flow and pressurization of FL

Leads to significant negative aortic remodelling, often requiring secondary aortic interventions.
Anastomotic Entry Tear after STD Repair
This report summarizes the international results of the DARTS trial with the Ascyrus Medical Dissection Stent (AMDS) in patients with an acute DeBakey I aortic dissection.

- Novel, partially covered aortic arch hybrid graft implanted antegrade during deep hypothermic circulatory arrest (DHCA) to promote full true lumen (TL) expansion and aortic remodelling.

- Developed as an adjunct to standard surgical repair and designed to improve malperfusion and promote positive remodelling of the aortic arch and distal dissected aorta.
AMDS Mode of Action

- **Proximal Seal Zone:** secure closure of anastomotic entry tear.
- **Distal Zone:**
  - Malperfusion management
  - Additional distal remodeling
  - True lumen expansion

- **Treatment Zone:** Aortic arch remodeling
Enrollment

**Inclusion Criteria**
- Patients 18-80 years
- Acute DeBakey I aortic dissection or intramural hematoma within 14-days

**Exclusion Criteria**
- Stroke within 30-days
- Extreme hemodynamic compromise requiring CPR
- Marfan, Loeys-Dietz, or Ehlers-Danlos syndrome
- Proximal descending thoracic aortic aneurysm >45mm
Primary Safety End-Points

• All-cause mortality
• Neurologic dysfunction
• Aortic injury associated with device implantation
• Aortic arch branch vessel patency
• Device related reintervention
• Serious adverse events
Effectiveness Outcomes

Positive aortic remodeling
- FL obliteration
- FL thrombosis
- Stable or decreased total aortic diameter (±5mm)
- Stable or increased TL size (±5mm)
- Stable or decreased FL size (±5mm)

Malperfusion management
From March 2017 to April 2018, a total of **24 patients** presented with acute DeBakey I aortic dissections and underwent emergent surgical repair with AMDS implantation.

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y)</td>
<td>64 +/- 13</td>
</tr>
<tr>
<td>Female Gender</td>
<td>38% (9/24)</td>
</tr>
<tr>
<td>Malperfusion</td>
<td>58.3% (14/24)</td>
</tr>
<tr>
<td>Reoperation</td>
<td>8.3% (2/24)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>75% (18/24)</td>
</tr>
<tr>
<td>Prior Stroke</td>
<td>12.5% (3/24)</td>
</tr>
<tr>
<td>COPD</td>
<td>12.5% (3/24)</td>
</tr>
<tr>
<td>Chronic Renal Failure</td>
<td>12.5% (3/24)</td>
</tr>
</tbody>
</table>
# Procedure and Hospital Course

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful Device Deployment</td>
<td>100% (24/24)</td>
</tr>
<tr>
<td>Total Arch Replacement</td>
<td>8.3% (2/24)</td>
</tr>
<tr>
<td>Mean DHCA Duration (min)</td>
<td>34.7 +/- 12</td>
</tr>
<tr>
<td>Mean Cerebral Perfusion Duration (min)</td>
<td>30.1 +/- 10</td>
</tr>
<tr>
<td>Mean AMDS Implantation Time (min)</td>
<td>2.9</td>
</tr>
<tr>
<td>Mean ICU length-of-stay (days)</td>
<td>10.6 +/- 13</td>
</tr>
<tr>
<td>Mean hospital length-of-stay (days)</td>
<td>20.8 +/- 25</td>
</tr>
<tr>
<td>Blood transfusion required</td>
<td>87.5% (21/24)</td>
</tr>
<tr>
<td>Mean number of units transfused within 24-hours</td>
<td>4.3 +/- 1.2</td>
</tr>
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</table>
# Mortality and SAEs

<table>
<thead>
<tr>
<th>Category</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-day mortality</td>
<td>8.3%</td>
</tr>
<tr>
<td>Neurologic deficit</td>
<td>12.5%</td>
</tr>
<tr>
<td>Aortic injury from device implantation</td>
<td>0%</td>
</tr>
<tr>
<td>Stent fracture/failure of structural integrity</td>
<td>0%</td>
</tr>
<tr>
<td>Distal stent induced new entry tear</td>
<td>0%</td>
</tr>
<tr>
<td>Aortic arch branch vessel patency</td>
<td>100%</td>
</tr>
<tr>
<td>Device related reintervention</td>
<td>0%</td>
</tr>
<tr>
<td>Acute renal failure (Cr increase &gt;2x BL)</td>
<td>37.5%</td>
</tr>
<tr>
<td>Dialysis</td>
<td>12.5%</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>20.8%</td>
</tr>
<tr>
<td>Mechanical circulatory support</td>
<td>4.2%</td>
</tr>
</tbody>
</table>
During mean follow-up of 279 ± 96-days, 20 (83.3%) patients had at least 1 post-operative CT scan. Two patients excluded due to early death without post-operative CT scan.

Positive remodeling ± complete or partial thrombosis of the aortic arch occurred in all (100%) of cases.
- Full FL obliteration or complete FL thrombosis in 14 (70%).

Positive remodeling ± complete or partial thrombosis of the proximal descending thoracic aorta in 19 (95%) of cases.
- Full FL obliteration or complete FL thrombosis in 15 (75%).
Aortic Remodeling

PRE-OP

POST-OP
Detected pre-operatively in **58.3% (n=14)** with **31 vessel malperusions** identified
90.3% (n=28) resolved after AMDS implantation without an additional procedure

Three patients (12.5%) had clinical evidence of paralysis
All had complete resolution of paralysis at discharge

Four patients required disease-related secondary procedures
- Left renal artery stenting for distal malperfusion
- Left common carotid artery stenting for de-novo dissection
- SMA stenting for static malperfusion
- Left common carotid interposition graft, left subclavian covered stent and coiling of the FL due to expansion of the proximal DTA
Malperfusion Management

Nearly Occluded Common Carotid Arteries

Patent Common Carotid Arteries

PRE-OP

POST-OP
Malperfusion Management

PRE-OP

POST-OP
Conclusion

- The AMDS is a safe, feasible and reproducible adjunct to current standard-of-care repair in acute type A aortic dissection.

- Induces positive remodeling of the aortic arch in the majority of patients without increasing surgical time or operative risk.

- Allows one-stage management of malperfusion involving major and vital aortic branches.

- Ongoing follow-up will provide additional insight into the long-term effects of the AMDS on overall aortic remodelling and patient outcomes.