Stent Grafts in Aortic Dissection

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SCOPE OF TALK

- Aortic dissection—demographics and natural history
- Treatment options
- Endovascular Outcomes
- Future studies and treatment
Acute Aortic Syndromes

- Aortic dissection
- Intramural hematoma (IMH)
- Penetrating atherosclerotic ulcer
- Focal aortic tear - contained rupture
- Traumatic aortic transection
- Rapidly expanding aneurysm / impending rupture

Intra-mural blood "dissection"
Suspected Acute Aortic Syndrome
MDCT in 373 Emergency Evaluations
(Hayter RG, Radiology 2006; 238:841-852)

* 365 patients (male 56%; women: 44%)
* Mean age: 61 years (range 21 to 96)
* 67 (18%) positive for AAS (n=112)
  * 23 (34%) acute aortic dissections; A=13 (19%), B=10 (15%)
  * 14 (21%) acute aortic IMH; A=1 (2%), B=13 (19%)
  * 20 (30%) acute penetrating ulcer; A=3 (5%), B=17 (25%)
  * 44 (67%) new or enlarging aortic aneurysms
  * 11 (17%) acute aortic ruptures
* Overall hospital mortality: 6% (4/67); A=2; B=2; 3/4 ruptured
Aortic Dissection

• 20 - 30 cases per million people per year
• 9,000 U.S. cases annually
• 21% of patients with acute dissection die before hospital admission

• Life-threatening condition
  • Early mortality 1-2% per hour
  • Survival is improved with prompt therapy
Mortality for Type B Dissection

* Hospital mortality of medical therapy (80 to 85% of total): 3 to 18% (12.5%)

* Hospital mortality of surgical therapy (15 to 20% of total): 25 to 60% (35%)

* 5, and 10-year mortality of medical group:
  * 18 - 27% and 31 - 60%

* 5, and 10-year mortality of matched U.S. population cohort:
  * 4% and 22%
Classification of Aortic Dissection: Based on Involvement of the Ascending Aorta

DeBakey
I
II
III

Stanford
A
62%
B
38%
Specific Complications of Acute Aortic Dissection
Impact Presentation

- Rupture into pericardium
- Acute MI 2%
- Aortic insufficiency 32%
- Mesenteric ischemia 5%
- Lower extremity ischemia 3%
- Stroke 5%
- BP differential 15%
- Paraplegia <1%
- Renal ischemia 5-8%

International Registry of Acute Aortic Dissection (IRAD)
Aortic Dissection:
30-Day Mortality by Type and Management

Cumulative Mortality (%)

Days of Follow-up

Overall
A - surgical
B - surgical
A - medical
B - medical

International Registry of Acute Aortic Dissection (IRAD)
Cumulative Mortality of Untreated Acute Aortic Dissection
Evolution of Endovascular Techniques to Manage Dissection

- Fenestration
  - Equalize true false lumen pressure to re-perfuse viscera
  - Did nothing for preventing aneurysms

- Bare stents in TL

- Stent-graft coverage of entry tear
  - Distal stents below entry tear to encourage FL thrombosis
  - Covered stents into branches to exclude FL
Who to Treat With Stent Graft

- Historically medical management for type B
  - 15-20% of patients go to surgery with life-threatening complications
  - 12 to 14% medical mortality

- Many of the acute dissections managed with bypass or fenestration can now be managed with stent grafts

- The late beneficiaries of stent graft would also include those requiring emergent or elective surgery post-discharge (5 to 7% at 6 mos; 18 to 25% at 4-5 years) or those treated medically who rupture post-discharge (12%)
75 Y/O Woman With 15lb. Weight Loss Over Three Weeks
True Lumen Collapse And Ischemic Left Kidney
Arch Aortogram Pre Stent-graft
Post Stent-Graft Placement
True Lumen Post Stent-Graft
Post Right Renal Stent
Pre Discharge Studies
Pre Discharge Studies
Comparison Studies
74-year-old Man With Acute Back Pain And Shock
74-year-old Man With Acute Back Pain And Shock
Initial Aortogram
Stent Graft Placement
Follow-up @ 5 weeks
Follow-up @ 5 weeks
50-year-old Man with Acute Type B; ICU Medical Management Initially
4 Hours Later, Ischemic Legs, Decreasing Renal Function
TX2 Graft and Bare Z-Stent Extension for Dissection
CT Immediately After TX2 Placed
Renal Function Normal; Legs Asymptomatic
Flow Through Bare Stent Skirt into Aortic FL via Fenestration @ Left Renal
3 Months Post Procedure, LRA Stent Placement via Aortic TL
CT Post Renal Intervention with Resultant FL Thrombosis
False Lumen Fate After Stent-Graft Placement (Acute)

- **Obliterated:** FL diameter $< 5 \text{mm}$
- **Decreased:** FL diameter decreased $> 5 \text{mm}$
- **Increased:** FL diameter increased $> 5 \text{mm}$

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<thead>
<tr>
<th></th>
<th>Oblit.</th>
<th>Decr.</th>
<th>No Δ</th>
<th>Incr.</th>
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<tbody>
<tr>
<td><strong>Acute B (n=32)</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 month</td>
<td>14%</td>
<td>53%</td>
<td>30%</td>
<td>3%</td>
</tr>
<tr>
<td>6 months</td>
<td>56%</td>
<td>28%</td>
<td>16%</td>
<td>0</td>
</tr>
<tr>
<td>1 year</td>
<td>67%</td>
<td>21%</td>
<td>12%</td>
<td>0</td>
</tr>
<tr>
<td>2 years</td>
<td>76%</td>
<td>18%</td>
<td>6%</td>
<td>0</td>
</tr>
<tr>
<td>3 years</td>
<td>82%</td>
<td>18%</td>
<td>0</td>
<td>0</td>
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</table>

*Kusagawa H, CIRCULATION. 2005; 11:2951 - 2957*
One Year Survival of Type B Dissection with SG

2. Fattori R. et al. (TTR); JTCS 2006; 132:332-9.
3. Tsai T. et al. (IRAD); Circulation 2006 (in press)
INSTEAD study: INvestigation of STEnt Grafts in Patients with type B Aortic Dissection

- Prospective randomized clinical study (PI: Nienaber)
- 136 patients, 11 European clinical sites (Austria, Germany, France, and Italy),
- **Purpose:** Assess role of endografts in uncomplicated patients with chronic type B dissection (occurring 2-52 weeks before randomization)
- **Objective:** Compare 1-year outcome for patients treated for aortic dissection with an endograft (Medtronic Talent Thoracic Stent Graft System) in addition to antihypertensive treatment to patients managed medically with antihypertensive treatment only
INSTEAD study: Investigation of Stent Grafts in Patients with type B Aortic Dissection

- Began in 2002
- Patient enrollment completed in February 2005
- Follow-up at 3, 12, and 24 months
- Primary endpoint: All-cause mortality
- Secondary endpoints:
  - Conversion to stent and/or surgery
  - Induced thrombosis of the false lumen
  - Quality of Life
  - Length of ICU/hospital stay
# Dissection Related Symptoms

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<tr>
<th></th>
<th>Stent-Graft N= 70</th>
<th>Medication N= 66</th>
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<tbody>
<tr>
<td><strong>At diagnosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Asymptomatic</strong></td>
<td>2/70 (3%)</td>
<td>6/66 (9%)</td>
</tr>
<tr>
<td><strong>Back Pain (only)</strong></td>
<td>56/70 (80%)</td>
<td>50/66 (76%)</td>
</tr>
<tr>
<td><strong>Side branch occlusion (only)</strong></td>
<td>5/70 (7%)</td>
<td>0/66 (0%)</td>
</tr>
<tr>
<td><strong>Back Pain &amp; Side branch occlusion</strong></td>
<td>7/70 (10%)</td>
<td>10/66 (15%)</td>
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<tr>
<td><strong>Mean time between Diagnosis &amp; Randomization (Days)</strong></td>
<td>57.3</td>
<td>83.3</td>
</tr>
<tr>
<td><strong>Range (Days)</strong></td>
<td>4 - 393</td>
<td>7 - 562</td>
</tr>
<tr>
<td><strong>At randomization</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Asymptomatic</strong></td>
<td>56/70 (80%)</td>
<td>56/66 (85%)</td>
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<tr>
<td><strong>Back Pain (only)</strong></td>
<td>12/70 (17%)</td>
<td>6/66 (9%)</td>
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<tr>
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<td>2/70 (3%)</td>
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<td>0/70 (0%)</td>
<td>2/66 (3%)</td>
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### INSTEAD: All-Cause Mortality

<table>
<thead>
<tr>
<th>Mortality</th>
<th>Medical Treatment</th>
<th>Stent-Graft</th>
<th>P-value</th>
<th>Odds Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death at 12 months</td>
<td>2/66 (3%)</td>
<td>7/70 (10%)</td>
<td>NS</td>
<td>0.28</td>
<td>0.03 - 1.57</td>
</tr>
<tr>
<td>30-day Mortality (from randomization)</td>
<td>0/66 (0%)</td>
<td>1/70 (1.5%)</td>
<td>NS</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>30-day Mortality (from Stent-Graft implant)</td>
<td>0/66 (0%)</td>
<td>4/70 (5.7%)</td>
<td>NS</td>
<td>-</td>
<td>-</td>
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For uncomplicated type B dissection a primary strategy of tailored anti-hypertensive medical treatment and serial imaging is justified, with deferred stent-graft implantation as an option for patients failing to respond to medical management.
HIGH RISK TYPE B DISSECTIONS
IMPORTANCE OF INITIAL FL SIZE


- n = 100 consecutive; 49 type B
- 53 with CT beyond 2 years (mean 31 mos); 28% with aneurysm (> 60mm)
- overall aortic diameter not an independent predictor of expansion
- FL diameter ≥ 22 mm highly predictive
  - Aneurysm formation: 42% vs 5% (p<0.001)
  - Increased mortality: 12% vs 5% (p=0.09)
94 yo male with acute chest pain
DSA prior to stent graft
Stent graft deployment
CTA 3 months later
Stent Graft Revision
Acute Type B Dissection

- 64 year old man with DM, CVA, CAD, CRI
- Worsening renal function (Cr 2.0 mg/dl on admission and rose to 2.4 on day #2)
- Left leg claudication
- Sub-acute dissection found arising just distal to left subclavian artery
True Lumen Narrowing at Renal
Treatment Options

- Medical Management
- Operative Fenestration/bypass
- Percutaneous Fenestration
- Thoracic Endograft
  - Improves flow in true lumen
  - Reduces risk of late aneurysm development
Pre-Procedure Planning

- CTA/MRA of chest-pelvis
- Device selection
- Access planning

- CTA/MRA neck
- ASVD/dissection
- Vertebral artery dominance

Dominant right vertebral
Left vertebral patent
True Lumen Injection

True lumen compressed but supplies Celiac, SMA, and right renal artery
Device Advanced to Arch
Stent Did Not Open Completely

- Dissection too rigid to expand
- Device malfunction
- Device in false lumen

TAG 31 x 15 deployed
Endograft in False Lumen

- True lumen occluded proximally
- We confirmed distal end was in true lumen
- Wire (and device) passed from true lumen into false lumen and then back into true lumen at level of left subclavian artery

Wire re-entered true lumen here

Wire passed into false lumen here
Second Device Advanced Through Fenestration
34 x 15 TAG added proximally which covers subclavian artery
True Lumen Improved
Perfusion of Both Lumens
14 mm x 60 mm EV3 Protégé placed in left common iliac artery
Device in true lumen

True lumen enlarged distal to stent
True Lumen Enlarged At Level Of Right Renal Artery
6 Month Follow-up

- Walking 2 miles daily with no claudication
- Creatinine has improved to 1.6 mg/dl
- Initially had left arm claudication but it has nearly resolved
Conclusions

- Superior outcomes to medical plus surgical management in Type B dissection with complications
- Endograft technology is technically possible in most type B dissection cases
- As this technology undergoes refinement, a high risk sub-group of “stable” type B patients will be better defined-where endograft intervention is indicated