Recent global evidence for TEVAR in Type B aortic dissections

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Recent global evidence for TEVAR in Type B aortic dissections

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Disclosures

• Consultant – Medtronic
• Consultant – WL Gore
Evolving Paradigm
Treating Physicians
Team
Classification System
Aortic Dissection

Classification—Stanford and DeBakey
DISSECT: A New Mnemonic-based Approach to the Categorization of Aortic Dissection

- **Duration** of dissection (symptoms)
- **Intimal Tear (Primary)** Location
- **Size** of the aorta
- **SEgmental** extent of involved aorta
- **Clinical** complications
- **Thrombosis** of aortic false lumen
Treatment Algorithm
Type B Aortic Dissection Protocol

Imaging-diagnosed Type “B” Dissection

- Admit to ICU (Cardiac or Vascular Surgery)
  - BP Control (β-block)
  - When stable, PO meds and reg floor
  - Repeat imaging in a week

- If malperfusion develops
  - Persistent pain
    - Repeat imaging
  - Admit to ICU (Cardiac or Vascular Surgery)
    - BP Control (β-block)
    - When stable, PO meds and reg floor
    - Repeat imaging

- Isolated Lower Extremity
  - Fem-fem bypass
  - Successful: To ICU
  - Unsuccessful:
    - Fenestrate
    - Open Surgery
    - Ex Lap

- Malperfusion
  - To OR
  - TEVAR – 1st Line
  - +/- Laparoscopy for ? Of mesenteric ischemia

- No Malperfusion
  - Stable CT
  - ICU and Post-op Management

Suspected Acute Aortic Syndrome

RAAA/TAA: Activate Acute Aortic Syndrome (AAS) Team
Follow RAA Protocol

STAT CTA per AAS Protocol

Imaging-diagnosed Type “A” Dissection

- Activate Acute Aortic Syndrome (AAS) Team
- Follow Type “A” Protocol

(-) CTA = w/u other cause

Rupture
- To OR
- Stable CT

ICU and Post-op Management

Persistent pain
- To OR
- Repeat imaging
Complicated Type B dissection: Accepted indication for TEVAR

Malperfusion syndrome treated with endovascular stent-graft and PETTICOAT; a) angiography of lower body malperfusion; b) reperfusion after proximal stent-graft; c) 3D CT reconstruction of acute complicated dissection with malperfusion; d) reconstructed aorta and abolished malperfusion after stent-graft and PETTICOAT.
Complicated Type B dissection: Escalating complexity I-III

Simple Stentgraft  PETTICOAT  Complex branched
Medical: Uncomplicated Type B dissection over time
Type B Aortic Dissection Protocol

Suspected Acute Aortic Syndrome

RAAA/TAA: Activate Acute Aortic Syndrome (AAS) Team Follow RAA Protocol

STAT CTA per AAS Protocol

Imaging-diagnosed Type “B” Dissection

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Malperfusion

To OR

• TEVAR – 1st Line
• +/- Laparoscopy for ? Of mesenteric ischemia

Isolated Lower Extremity

Fem-fem bypass

Successful:
• To ICU

Unsuccessful:
• Fenestrate
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Malperfusion develops

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Rupture

• To OR

Stable CT

(-) CTA = w/u other cause

Imaging-diagnosed Type “A”

Activate Acute Aortic Syndrome (AAS) Team Follow Type “A” Protocol
What is the Evidence?
Stable “Acute” ADSORB

BMT (31) vs TEVAR & BMT (30)

– 30 days
  • No complications
  • No Deaths
  • Favorable aortic remodeling

TEVAR/BMT

– Aortic dilatation:
  • TAG+BMT 11/30 (37%)
  • BMT 14/31 (45%)
INSTEAD and INSTEAD XL

Management of Uncomplicated Type B Aortic Dissection

2-Year and 5-Year Results of the Randomized Investigation of Stent Grafts in Aortic Dissection Trial

- Characterize short-term and long-term outcomes and vessel morphology of uncomplicated, TBAD patients treated with OMT vs OMT+TEVAR
- 7 European Centers
- N = 140 subjects, OMT = 68, OMT+TEVAR = 72. 2 year and 5 year follow-up
- Primary Endpoint: All-cause mortality
- Secondary Endpoints: Aorta-specific mortality and disease progression
**INSTEAD: Endpoints**

**Primary endpoint**
- All-cause mortality at 2 years

**Secondary endpoints**
- Thrombosis of False Lumen
- Degree of Aortic Expansion
- Cardiovascular morbidity
- Quality of life
- Length of ICU and hospital stay
- Crossover

Nienaber CA et al. Circulation 2009;120:2519-2528
**INSTEAD:** 2 years-outcomes after TEVAR in stable patients

@ 1 year crossover rate  14% (p=0.02)
@ 2 years crossover rate  20% (p=0.02)
Remodeling after Stentgraft

90% remodeling with TEVAR ($p \leq 0.001$) after 2 years
INSTEAD XL: Key Results

TEVAR FOR AORTIC DISSECTION PREVENTS LATE EXPANSION; ENCOURAGES AORTIC REMODELING

Cumulative Clinical Results: Year 0 through Year 5

- All-Cause Mortality: OMT n=68, TEVAR+OMT n=72
  - OMT: 19.3%
  - TEVAR+OMT: 11.1%
  - Absolute Risk Reduction: 12.4%
  - p=0.13

- Aorta-Specific Mortality: OMT n=68, TEVAR+OMT n=72
  - OMT: 19.3%
  - TEVAR+OMT: 11.1%
  - Absolute Risk Reduction: 6.9%
  - p=0.04

- Disease Progression: OMT n=68, TEVAR+OMT n=72
  - OMT: 46.1%
  - TEVAR+OMT: 27.0%
  - Absolute Risk Reduction: 19.1%
  - p=0.04
INSTEAD XL: Conclusions

- INSTEAD XL demonstrates:
  - Elective TEVAR results in favorable aortic remodeling and long-term survival
  - Reinterventions were low and clustered in first year
  - TEVAR prevents late expansion and malperfusion and encourages aortic remodeling
  - TEVAR associated with improved 5-year aortic-specific survival and delayed aortic disease progression
TEVAR better than medical mgm. in uncomplicated B dissection

Less late events after TEVAR in uncomplicated Type B in China
## Acute Dissection: 30-Day Results

### Literature Comparison

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<th>30-Day Event</th>
<th>STABLE I (Petticoat) Acute (N = 55)</th>
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Treat everyone?...or, Who is at high-risk?
New risk group: Partial false lumen thrombosis?

Two patients with a small initial false lumen diameter at the upper descending thoracic aorta showed a complete resorption of the false lumen (left) or did not show an aneurysm for approximately 3 years (middle), while another patient with a large initial false lumen diameter developed an aorta aneurysm after approximately 2.5 years (right).

New risk group: False Lumen diameter: FL > 22 mm

**New risk group:** Entry size and long-term outcome?

- Entry tear of aortic dissection visualized by 2-dimensional (left) and color-Doppler (right) TEE

- Type B dissection with an entry tear located in the proximal part of the descending aorta (arrow) by tranverse view

- Type A dissection with an entry tear in the proximal part of the residual dissection (arrow) in the upper ascending aorta by longitudinal view
New risk group: Local Inflammation, Partial FL thrombosis, rupture?

- Partial FL thrombosis
- Expanding FL
- Ongoing metabolic activity on FDG-PET
- Rupture?
BioMarkers

Serologic examination

- D-dimer, FDP, Platelets, Antithrombin III, C-Reactive protein.

- FDP ≥ 20 ug/ml
  - Associated with Aortic Growth

Usefulness of Fibrinogen/Fibrin Degradation Product to Predict Poor One-Year Outcome of Medically Treated Patients With Acute Type B Aortic Dissection

Shuichi Kitada, MD; Koichi Akatsu, MD; Yuiichi Tamori, MD; Tsuyoshi Yoshimuta, MD; Hidenori Hashimoto, MD; and Satoshi Takehisa, MD

Previous studies have indicated that medical therapy provides excellent outcomes for patients with uncomplicated Stanford type B acute aortic dissection. However, affected aortas are often compromised by aneurysmal dilatation and rupture, resulting in poor outcomes. The purpose of this study was to determine predictors of aortic events in patients with Stanford type B acute aortic dissection receiving conservative medical therapy. The study group consisted of 78 consecutive patients with Stanford type B acute aortic dissection who were admitted to the hospital within 48 hours of onset. These patients were treated medically and followed up for 1 year; aortic events were defined as rupture, recurrent dissection, aortic expansion with diameter ≥260 mm, rapid aortic expansion at a rate of ≥10 mm/yr, and the development of visceral or limb ischemia. Predictors of these events were determined using multivariate analyses. During 1-year follow-up, aortic events were observed in 13 (17%) patients, including aortic rupture in 3 (4%), aortic diameter ≥160 mm in 4 (5%), rapid expansion of the aorta in 3 (4%), the development of visceral or limb ischemia in 3 (4%). On multivariate analysis, fibrinogen/fibrin degradation product level ≥20 µg/ml (odds ratio 7.802, 95% confidence interval 1.405 to 43.335) on admission was the only independent predictor of aortic events at 1 year. In conclusion, careful monitoring is required for patients with medically treated Stanford type B acute aortic dissection associated with fibrinogen/fibrin degradation product level ≥20 µg/ml on admission. © 2008 Elsevier Inc. All rights reserved (Am J Cardiol 2008;101:1341–1344)

In the present study, we performed a retrospective analysis of patients with Stanford type B acute aortic dissection who had initially received conservative medical therapy and sought to determine the predictive factors of adverse aortic outcomes.

Methods

From December 2000 to January 2006, a total of 383 patients with acute aortic dissection (138 with Stanford type A and 243 with Stanford type B) were admitted to the Cardiology Department of the National Cardiovascular Center (Suita, Japan). Of these 383 consecutive patients, 78 patients were admitted within 48 hours of the onset of type B aortic dissection and treated with conservative medical therapy. Patients who were judged at initial presentation as candidates for emergent aortic surgery or endovascular intervention; those who had previous episodes of aortic dissection, aortic surgery, and/or endovascular intervention; those with Marfan’s syndrome; and those with uncontrolled systemic diseases including malignancy, were excluded.

The diagnosis of Stanford type B acute aortic dissection was confirmed by computed tomographic scanning or magnetic resonance imaging performed at the time of admission. Follow-up computed tomographic scanning or magnetic resonance imaging was routinely performed at the prescribed intervals (i.e., at 1 and 2 weeks and 1, 3, 6, and 12 months thereafter). During the acute phase, all patients were initially treated with anti-platelet therapy if there were no indications for surgical treatment, such as aortic rupture, diameter of the descending aorta ≥260 mm, malperfusion of the thoracoabdominal aorta, and pseudoaneurysm formation with uncontrollable hypertension. All patients who survived the acute phase with medical therapy were followed up at the outpatient clinic, and data on disease history, physical examination, and routine blood testing were collected. The patients were also followed up with computed tomographic scanning or magnetic resonance imaging as described previously.

To determine the predictors of aortic events, baseline clinical characteristics such as smoking habit; co-morbidities including hypertension, diabetes mellitus, and hyperlipidemia; the patency of the false lumen; the diameter of the dissected aorta; the presence of true aortic aneurysm; and routine admission laboratory tests including platelet count, C-reactive protein (CRP), fibrinogen/fibrin degradation product level ≥20 µg/ml on admission were analyzed.
Risk profiles of Type B aortic dissection (update 2013)

Classic Criteria for complicated type B dissection:

- Total aortic diameter ≥ 5.5 mm
  
  Elefteriade 2002, Ann Thoracic Surgery

- Malperfusion Syndromes
  
  Nienaber 2011, JVS

- Impending rupture (extraaortic blood)
  
  Davies 2002, Annals of thoracic surgery

- Early false lumen expansion
  
  Song 2007, JACC

Recent Criteria…

- Partial false lumen thrombosis
  
  Tsai T, NEJM 2007

- Focal FDG-uptake (inflammation)
  
  Sakalihasan N, p.c.

- Ongoing episodes of pain
  
  Trimarchi S, Circ 2010

- Intractable hypertension
  
  Evangelista A, Circ 2012

- Large entry size (> 15 mm)
  
  IRAD, Circ 2010

What is left as uncomplicated dissection?
Rethinking TEVAR for Dissection

Long-term follow-up of INSTEAD-XL and IRAD in type B aortic dissection reveals:

- Uncomplicated type B dissection is a misnomer, is not stable and medical management is not safe
- Isolation of the false lumen leads to remodeling to avoid new (late) acute scenarios
- Successful remodeling (usually completed after 2 years) ensures longterm stability
- Preemptive TEVAR in type B dissection sets the stage for remodeling and will become a therapeutic option for all candidates with a reasonable life expectancy
## Treatment of aortic dissection

<table>
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<th>Class</th>
<th>Level</th>
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<td>In all patients with AD, medical therapy including pain relief and blood pressure control is recommended.</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>In patients with type A AD, urgent surgery is recommended.</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>In patients with acute type A AD and organ malperfusion, a hybrid approach (i.e. ascending aorta and/or arch replacement associated with any percutaneous aortic or branch artery procedure) should be considered.</td>
<td>Ila</td>
<td>B</td>
</tr>
<tr>
<td>In uncomplicated type-B AD, medical therapy should always be recommended.</td>
<td>I</td>
<td>C</td>
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<td>In uncomplicated type-B AD, TEVAR should be considered.</td>
<td>Ila</td>
<td>B</td>
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<td>In complicated type-B AD, TEVAR is recommended.</td>
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Conclusions

• Global evidence is evolving

• TEVAR data supports survival advantage
  – as long as you can minimize the risk with early intervention

• High-risk groups are being better defined
Uncomplicated Type B dissection: does it exist?
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