We Still Need More Evidence Before We Treat Most Uncomplicated Acute/Subacute TBAD Patients With TEVAR

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TEVAR
The solution to all aortic problems?

Let us list what we still do not know About TEVAR for UNCOMPLICATED TBAD

Acute UNCOMPLICATED Type B Dissection
Medical Management is safe acutely

Updated IRAD Data
Mortality in 550 Patients with Type B Dissection

Acute UNCOMPLICATED Type B Dissection
Medical Management is safe acutely

Disclosures
No Financial Compensation
Consultant
WL Gore: Scientific Advisory Board, PI TAMBE
Cordis: PI for Incraft IDE
Medtronic: PI for Endurant IDE, Advisory Board

Research Grants in Aortic Field
WL Gore, Cook, Cordis, Medtronic, Boston Scientific, Bolton, Lombard, Endologix, Trivascular

Acute UNCOMPLICATED Type B Dissection
Medical Management is safe acutely

Outcomes of Patients With Acute Type B (DeBakey III) Aortic Dissection A 13-Year, Single-Center Experience

UT Houston
442 patients 255 Uncomplicated

Mortality of Uncomplicated Dissection
Medical Management 2%

Circulation 2015;132:748-754
Proposed Goals

- Improve Late Survival / Aortic Related Survival
- Prevent Late Complications (Aneurysms)
- Late aortic Interventions

So How much do we know about these late events which was started by the INSTEAD XL study?

- How high is the rate of Late complications?
- Is it high enough to justify prophylactic TEVAR?
- Is it similar in all patients?

Why even consider TEVAR for Uncomplicated Dissection?

Randomized Comparison of Strategies for Type B Aortic Dissection

The INVESTigation of STEnts in Aortic Dissection (INSTEAD) Trial

Christopher A. Nienaber, MD, PhD, Hervé Rassmuss, MD, PhD, Heinric Eggenhuis, MB, Stephan Kuehle, MD, Berndt Fuster, MD, PhD, Tim C. Roberts, MD, Onderur Keath, PhD

Frank Schiesser, MD, PhD, Marius Cocovici, MD, PhD, Tito Alvanaki, MD, Barbara Zipter, MD

Louis Labropoulos, MD, PhD, Vicente Inza, MD, PhD

579 Uncomplicated Chronic Dissection pts evaluated
140 Patients randomized >2 weeks after sx

At 2 years
Mortality was better with Medical Rx
Remodeling was better with TEVAR

Circulation 2009; 120:2519-28

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Short of hard endpoints
Aortic Remodeling with TEVAR

- Used as a surrogate for healing and long term stability

Aortic Related Mortality of Medical Rx from Randomization

- 20% @ 6 years

Retrograde type A Conversion: 1-4%

57 Y/O with Acute Complicated Type B Dissection

Will Require Open Surgical Conversion!!

Courtesy of M. Dake MD
Aortic Related Mortality of Medical Rx from Randomization ~20% @ 6 years

Late Follow up of The INSTEAD Trial
68 Patients Intent to treat by Medical Rx
66 Patients followed per protocol
14 late interventions by 5 years
26.7% Late Aortic Interventions

Combined KM Aortic mortality Conversions Interventions Access revisions Peripheral int.


Criticism of The INSTEAD Trial
- Underpowered
- Chronic study. Most patients entered late
- OMT TEVAR
  Days after Dissection 45 (20–252) 39 (18–252)
  Large mean size of aorta at entry 43.5 ± 9.3 mm
  Long term FU was not planned. Retrospective. No indication in Manuscript how it was done?
  Unusual “Landmark” statistical analysis
  Death within 1 hour of a symptom classified as Aortic related. 4/11 deaths after 2 years
  Protection of TEVAR missed early complications

IRAD: International Multicenter Prospective Registry
The IRAD Classification System for Characterizing Survival after Acute Dissection

<table>
<thead>
<tr>
<th>440 Medically Treated Type B Dissection</th>
<th>N</th>
<th>30 days Mortality</th>
<th>1 year Deaths</th>
<th>False Lumen Patent</th>
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<tr>
<td>In Hospital Mortality 40 patients (9.1%)</td>
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<tr>
<td>Stroke 1 (2.9%)</td>
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<td>Tamponade 1 (2.9%)</td>
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<td>Visceral Ischemia 7 (20.0%)</td>
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<tr>
<td>Rupture 20 (57.1%)</td>
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<tr>
<td>Other 6 (17.1%)</td>
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Endovascular Repair of Acute Uncomplicated Aortic Type B Dissection Promotes Aortic Remodeling: 1 Year Results of the ADSORB Trial
- Initial goal of 150 patients not reached
- 61 highly selected patients randomized <14 days

- L. Subclavian covered partially or completely: 64%
- 3 Crossovers BMT to TAG 2 withdrawals from TAG
- 2 failures in BMT by 1 year: malperfusion and aneurysm
- FL increased in size in BMT but decreased in TAG
Acute UNCOMPLICATED Type B Dissection
We do not know **WHEN** to treat with TEVAR

- Early <14 days (Acute) as advocated by ADSORB to protect against early death?
- Subacute to avoid retrograde dissection as suggested by MOTHER registry and PENN?
- Late (Chronic) as suggested by INSTEAD?

**Or Wait for Indication?**

**Many Patients Simply Heal their Dissection**

**MW 51 year old woman Oct 2004**

Oct 20 04 / 37 mm

Nov 10 04 / 30 mm

Jun 18 05 / 28 mm

May 1 06 / 26 mm

**Other Patients Remain Completely Stable**

**PW 63 year old man. March 2010**

Type B dissection Uncomplicated

**PW: 28 Months later. July 2012**

Completely Unchanged

No dilatation Anywhere

**Uncomplicated type B can be stable for a long time**

**PY (53 F) CTA for PE**

12/2/2006

37x41 mm

2/4/2013

6.3 years

37x41 mm

Can we predict who is at higher risk of expansion or late complications?

Yes
But unfortunately not very accurately and...there are way too many predictors

- Size of Aorta
- Size of False Lumen
- Use of Calcium Channel Blockers
- Gender
- Age
- Marfan's
- Location of Entry Tear on curvature of Aorta
- Size of Entry tears
- Re-entry Tears
- Ulcer like projections

Predictors of late aortic events after Stanford type B acute aortic dissection

- 117 patients. Cox Regression
- Maximal diameter > 40 mm Most Predictive of later Aortic Dissection Related Events. $P = .003$
- Ulcer like projections also Highly Predictive. 5 year event free rate 36%. $P = .016$

CONCLUSION

WE STILL NEED MORE EVIDENCE BEFORE WE RECOMMEND TEVAR TO MOST PATIENTS WITH ACUTE UNCOMPLICATED TYPE B DISSECTION