Most Acute Uncomplicated TBADs Need To Be Treated
By TEVAR: The INSTEAD RCT Proves It:
We Do Not Need Further RCTs

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- Atricure, Bard, Neomend, Edwards (not relevant)

Uncomplicated Type B Dissection
ACC/AHA Evidence Guidelines:
Class II: Conflicting evidence or a divergence of opinion about the usefulness/efficacy of performing the procedure/thrapy.
Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

"In patients with uncomplicated acute Type B aortic dissection, (medical management) constitutes a benchmark that will be difficult to surpass, or even to match, by [interventional] treatment."

Patients with uncomplicated acute type B dissection should be treated with medical therapy. At present, there is no evidence of advantage with TEVAR or open surgery.

ESC Guidelines 2014
TEVAR in Complicated and "uncomplicated" TBAD is backed up by Guidelines...

Current recommendations...

Management of Descending Thoracic Aorta Disease: Evolving Treatment Paradigms in the TEVAR Era

The ESC guidelines are evidence of a recent, dramatic change in the management of descending thoracic aortic disease marked by the steady adoption of endovascular repair in standard of care. When repair is indicated, TEVAR is almost universally recommended instead of open repair. The ESC guidelines also clearly state that the "surgical approach has no place in these guidelines."

Importantly, the advantages of open surgical repair are emphasized in certain instances. For chronic TBAD with persistent symptoms or aneurysmal degeneration, open repair is recommended in patients with appropriate surgical risk. Chyung et al. have demonstrated this approach to be safe and effective and should be considered as an alternative to TEVAR in patients with chronic TBAD.

In patients with uncomplicated acute Type B aortic dissection, medical management constitutes a benchmark that will be difficult to surpass, or even to match, by interventional treatment. At present, there is no evidence of advantage with TEVAR or open surgery.
Survival pattern of Aortic Dissection

Group A included 2340 patients (25.74%) treated surgically for type A AD
Group B included 1144 patients (12.58%) treated endo/surgically for type B AD
Group C included 5608 patients (61.68%) with any type of AD treated with medical therapy only.

Poor Natural History – even for completely uncomplicated patients!
- Hospital mortality 8.8%
- uncorrected 1.2-3%
- 3-year-survival: 77%
- 5 & 10-year survival: 82%, 69%

Uncomplicated TBAD…

Medical Management

Rationale of TEVAR for all TBAD
- Prevent Rupture
- Alleviate Malperfusion
- Alleviate Pain
- Re-route the blood to TL
- Obliterate FL
- Aneurysm in 28% of pts
- Obviate early/late re-operation!
- Reverse Aortic Remodeling
Feasibility of reverse remodeling

Distribution of intimomedial tears in patients with type B aortic dissection


Endovascular classification based on location of intimomedial tears

Type 1 and 2 had 97% reverse remodeling!


ATBAD:
Pre & Post TEVAR Angiogram

So what is the evidence?

Virtue, INSTEAD, MGH, Chinese registry, many smaller series, INSTEAD XL!

Thoracic aortic dissection – INSTEAD

Randomized Comparison of Strategies for Type B Aortic Dissection

The Investigation of Stent-grafts in Aortic Dissection (INSTEAD) Trial

- Multicenter randomized in Europe
- 70 Medical vs. 66 TEVAR
- Uncomplicated Type B
- 2-52 weeks prior to randomization (subacute and chronic)
INSTEAD: 2 yrs outcomes after TEVAR in uncomplicated patients

- 1 year crossover rate 14% (p=0.02)
- 2 years crossover rate 20% (p=0.02)

INSTEAD XL
Management of Uncomplicated Type B Aortic Dissection
Long-term Results of the Randomized Investigation of Stent Grafts in Aortic Dissection Trial

- Characterize 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. 5 year follow-up
- Primary Endpoint: All-cause mortality at 5 years
- Secondary Endpoints: Aorta-specific mortality and disease progression

INSTEAD XL: Key Results

- TEVAR for Aortic Dissection
  Prevents late expansion; encourages aortic remodeling

INSTEAD XL: Landmark Analysis

INSTEAD XL results

- European prospective randomized multicenter trial follow-up 2-5 yrs
- Best medical management vs TEVAR
- All-cause mortality 11.1% vs 19.3%
- Aortic-related mortality 6.9% vs 19.3%
- Elective TEVAR superior to medical therapy in uncomplicated type B aortic dissection

INSTEAD XL conclusions

- 70% of Type B aortic dissections are uncomplicated
- Uncomplicated TBAD patients traditionally treated with OMT only
- OMT only carries a 30% 5 year mortality rate
- 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
**ADSORB trial**
- Prospective randomized European multicenter study in Acute type B uncomplicated aortic Dissection evaluating Stent-graft placement OR Best medical treatment alone.
- 270 pts, 30 centers
- 3-year follow-up
- Principal investigator: Dr. Jan Brunkwall, University of Cologne

**Conclusion**
- We have enough data from INSTEAD XL and other studies to offer TEVAR to uncomplicated TBAD.
- Further data is welcome but not needed
- Further data is unlikely and expensive to come by!
- We like Dr. Mussa, but…
- The contrarian view of my opponent is unreasonable

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**late advantage consistently supported by RCT and registries**

<table>
<thead>
<tr>
<th>RCT</th>
<th>REGISTER</th>
<th>RCT</th>
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<tbody>
<tr>
<td>INSTEAD-XL (n=140)</td>
<td>Chinese registry (n=133)</td>
<td>ADSORB (n=61)</td>
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On aggregate, all data are consistent!

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**late advantage also supported by MGH Cohort study**

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**Epiphany:**
We have enough data from INSTEAD and other studies to offer TEVAR to uncomplicated TBAD. Further data is welcome but not needed. Further data is unlikely and expensive to come by! We like Dr. Mussa, but… The contrarian view of my opponent is unreasonable. Epiphany: Eventually every TBAD will be treated with TEVAR!