Not So: Why TEVAR Should Only Be Performed Selectively On Patients With Uncomplicated Acute TBADs

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Professor and Chair, Division of Vascular Surgery
University of Pittsburgh School of Medicine

No Financial Compensation or Conflicts
Aortic Advisory Board: Medtronic/WL Gore
National PI for the TAMBE early Feasibility trial
National PI for the US IDE InCraft study

Why TEVAR Should be Performed on ALL Acute TBAD Patients (Including Totally Uncomplicated Patients)

Acute Type B Aortic Dissection
Everyone gets Aggressive Medical Rx

Complicated or Early Complications
Late Complications Mostly Aneurysms
No Complications

Intervention TEVAR preferred
Intervention Aortic Replacement Preferred
Prophylactic TEVAR All vs Selective

LT FU: Intervention needed in only 26% after 6m and It is Predictable!

254 Patients with mean FU of 6.8 years
- Early Intervention < 6 months 12%
- Late Intervention > 6 months 26%

All late interventions were performed for aneurysmal degeneration. A variety of readily available features can predict the need for eventual operative intervention... these parameters can guide the desirability of early TEVAR.

Why TEVAR for ALL is not Appropriate
- Not ALL Patients need TEVAR
- Not ALL Patients benefit from TEVAR
- Not ALL Patients are anatomically suitable for TEVAR
- TEVAR has its own Complications: type A stroke /SINE…
- Remodeling is common with TEVAR but not complete
- Mortality rate is almost as high as Medical Treatment
- Reintervention rate is almost as high as Medical Treatment
- New strategies daily to improve results of TEVAR: FLIRT, Petticoat, Knickerbocker, Candy Cane…
- Cost is Substantially Increased
- Selective targeted treatment obviates many of these issues

Disclosures
Not All Patients Need Prophylactic TEVAR
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


Not All Patients Benefit from Prophylactic TEVAR


Emory from 2000-2016
- TEVAR in 80 patients for complications
- 318 Uncomplicated TBAD Patients
- No Need for Late Interventions: 172 (55%)
- Late Interventions: 27% TEVAR  22% Open
- Stroke risk in TEVAR 7.5%

Complications of TEVAR related to Anatomy!

J Vasc Surg 2018;68:1314-23

264 patients
- Mortality 1.5%
- Morbidity 9%
- Landing zone <40 mm. Risk of retrograde dissection 18%
- Coverage of Subclavian increases Adverse Events

Many TBAD Anatomies NOT Suitable for TEVAR

New Anatomic Severity Scoring System
- 27% Hi score >23  62% Reintervention at 1 year (KM)
- 73% Lo Score <23  0% Reintervention at 1 year (KM)
Reintervention NOT that different from OMT

<table>
<thead>
<tr>
<th>Outcomes of Thoracic Endovascular Aortic Repair for Acute Type B Dissection in Patients With Intractable Pain or Refractory Hypertension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lisa Laquinta, MD, Salvatore T. Scali, MD, Thomas M. Bevacqua, MD, MS, Paul Kubilis, MD, Adam W. Rieck, MD, Kristina O'Farrell, MD, Thomas S. Heuser, MD, PhD, Richard J. Fattori, MD</td>
</tr>
<tr>
<td>101 Uncomplicated dissections</td>
</tr>
<tr>
<td>Reintervention with TEVAR</td>
</tr>
<tr>
<td>Intervention with OMT</td>
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<tr>
<td>Retrograde dissection 4%</td>
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Substantial Additional Costs for TEVAR

<table>
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<tr>
<th>Favorable impact of thoracic endovascular aortic repair on survival of patients with acute uncomplicated type B aortic dissection</th>
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<tbody>
<tr>
<td>James C. Lambrinidis, MD, MPH, 1, 2 Sahar M. Stanislav, MD, 1, 2 Yariv J. Babak, MD, MPH, 1 Robert T. Lancaster, MD, MPH, 1, 2, 3 Mohammad T. Choudhury, MD, MPH 4, 5, 6, 7 Richard P. Carver, MD, 1, 2, 8 and Vennela I. Reddy, MD, MPH, 1, 2, 3, 9 Boston, Mass and New York, NY</td>
</tr>
<tr>
<td>State Review</td>
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<tr>
<td>Costs of Medical Treatment</td>
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<tr>
<td>Costs of TEVAR</td>
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<tr>
<td>Excess costs of TEVAR</td>
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<tr>
<td>Nationwide additional costs of TEVAR for ALL UTBAD</td>
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<tr>
<td>$676,602,000</td>
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<td>A waste of 400,000,000 over a selective policy</td>
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Mortality and Dilatation NOT that different from OMT

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<th>Metaanalysis: TEVAR vs OMT for uncomplicated TBAD</th>
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<td>Thoracic endovascular repair versus medical management for acute uncomplicated type B aortic dissection</td>
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<td>Tanya H. Ercolani, MD, 1, 2 Joel Green, MD, 1, 2 Ashraf S. Al-Dali, MD, 1, 2 Christopher Wibbels, MD, 1, 2 Max Pali, MD, 1, 2 Ebrahim Mahdavi, MD, 1, 2 Roselle Fattori, MD, 1, 2 Jeffrey A. Goldstein, MD, 1, 2 Nadish Gunawardena, MD, 1, 2 William A. Gogel, MD, 1, 2 Deepak L. Patel, MD, MPH, 1, 2</td>
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**AORTIC DILATION**

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>TEVAR</th>
<th>OMT</th>
<th>Total</th>
<th>Weight</th>
<th>N, Number in %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>15</td>
<td>10</td>
<td>25</td>
<td>11.0%</td>
<td>4,060 (3.97)</td>
</tr>
<tr>
<td>Fattori</td>
<td>5</td>
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<td>10</td>
<td>5.4%</td>
<td>480 (0.47)</td>
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<td>Overall</td>
<td>6</td>
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<td>12</td>
<td>14.2%</td>
<td>1,920 (1.86)</td>
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<td>Fattori</td>
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<td>6</td>
<td>12</td>
<td>15.3%</td>
<td>1,920 (1.86)</td>
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<tr>
<td>Total (95% CI)</td>
<td>12</td>
<td>9</td>
<td>21</td>
<td>180.0%</td>
<td>5,940 (5.76)</td>
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Dilatation NOT that different from OMT

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<th>Aneurysmal degeneration of type B aortic dissections after thoracic endovascular aortic repair: A systematic review</th>
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<td>Marta A. Rueda, DO, Karin Meyermann, MD, and Joseph V. Lombardi, MD, Camarillo, CA</td>
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**Systematic Review: 17 studies**

**Thoracic Aortic Growth in 7-84% of Patients**

**Abdominal Aortic Growth in 10-54% of Patients**

**TEVAR for TBAD does not prevent Aneurysmal Degeneration of the Thoracic or Abdominal Aorta**

Aortic Remodeling with TEVAR

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<th>Used as a surrogate for healing and long term stability</th>
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<td>False Lumen Thrombosis + Decreased Pressure leads to return of Aorta to its normal shape: “Remodeling”</td>
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Remodeling usually Limited to Covered Area

<table>
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<th>VM 77 year old Woman</th>
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<tr>
<td>2/5/2018</td>
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<tr>
<td>53 mm</td>
</tr>
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</table>
Even complete remodeling is not protective from late complications

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

Yes

But unfortunately not very accurately because we lack good prospective natural history studies in the rush to Rx everyone with TEVAR!

Hi Risk Predictors

- Size of Aorta: >4.0 or 4.5
- Size of False Lumen: 2.2 cm
- Location of Entry Tear on curvature of Aorta
- Size of Entry tears
- Use of Calcium Channel Blockers
- Gender
- Age
- Marfan’s
- Re-entry Tears
- Ulcer like projections

Hi Risk Predictors

- 100 Dissection patients
- False lumen diameter >22 mm predicted late aneurysm formation
  - Sensitivity 100%
  - Specificity 76%
- Other predictors
  - Marfan’s Syndrome
  - Aortic Diameter

Illustrative case: PS 55 M

False Lumen Diameter 24.4 mm (>22)

Unfavorable predictor

✓ No abdominal pain
✓ Good urine output
✓ Good femoral pulses

Medical Therapy
SUMMARY

- TEVAR for uncomplicated TBAD should be selective to optimize risk / benefit ratio
- We need a good predictive model to assess risk based on multiple factors
- We should cool down the unbridled enthusiasm to insert a stent graft into everyone