When and how to perform TEVAR: evidence based insights

Santi Trimarchi, MD, PhD

Associate Professor of Vascular Surgery, University of Milan
Head, Unit of Vascular Surgery
Fondazione IRCCS Cà Granda - Ospedale Maggiore Policlinico, Milan
**Disclosures**

**Grants:** Gore WL, Medtronic inc.

**Consultant and Speaker:** Gore WL, Medtronic inc.
Indications for TEVAR

Editor’s Choice — Management of Descending Thoracic Aorta Diseases

Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS)

TAA Repair if:

- TAA > 5.5 cm if TEVAR technically possible

**Indications for TEVAR: Aneurysm**

<table>
<thead>
<tr>
<th>Recommendation 46a</th>
<th>Class</th>
<th>Level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>In fit and unfit patients with favourable anatomy, endovascular repair may be considered for descending thoracic aorta aneurysms between 56 and 59 mm diameter</td>
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</tr>
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</table>

**Editor’s Choice — Management of Descending Thoracic Aorta Diseases**

*Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS)*

Indications for TEVAR: Ruptured TAA

<table>
<thead>
<tr>
<th>Recommendation 23</th>
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<td>In patients with ruptured descending thoracic aortic aneurysm, endovascular repair should be the first treatment option when the anatomy is appropriate</td>
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</tr>
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<tbody>
<tr>
<td>I</td>
<td>B</td>
</tr>
</tbody>
</table>

TAA Rupture

- Urgent repair
- **TEVAR preferred**
- consider LSA revascularization prior to LSA coverage (LIMA-LAD CABG; single LVA)
**Indications for TEVAR: Traumatic Aortic Rupture**

<table>
<thead>
<tr>
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<td>In patients with traumatic thoracic aorta injury and suitable anatomy, endovascular repair should be performed as the first option.</td>
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<td>C</td>
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**TAI Traumatic Aortic Injury**
- Free Rupture or Large peri-aortic hematoma
- Urgent repair
- TEVAR preferred

_Eur J Vasc Endovasc Surg (2017) 53, 4–52_

**Editor’s Choice — Management of Descending Thoracic Aorta Diseases**

_Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS)_


Complicated PAU

- Urgent repair
- TEVAR recommended

Eur J Vasc Endovasc Surg (2017) 53, 4–52

**Editor’s Choice — Management of Descending Thoracic Aorta Diseases**

*Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS)*


Indications for TEVAR: IMH

Complicated IMH

- Urgent repair
- **TEVAR recommended**
Indications for TEVAR: Complicated TBAD

<table>
<thead>
<tr>
<th>Recommendation 16</th>
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</thead>
<tbody>
<tr>
<td>In patients with complicated acute type B aortic dissection, endovascular repair with thoracic endografting should be the first line intervention</td>
<td>I</td>
<td>C</td>
</tr>
</tbody>
</table>

Complicated BAD

- Urgent repair
- TEVAR recommended
Insights From the International Registry of Acute Aortic Dissection
A 20-Year Experience of Collaborative Clinical Research

Type B Dissection: Outcome

B

Type B Acute Aortic Dissection

- Surgical Management
- Medical Management
- Endovascular Management
- Mortality

17 to 8 %
75 to 57 %
7 to 31 %

<table>
<thead>
<tr>
<th>Group</th>
<th>(Date)</th>
<th>Surgical Management</th>
<th>Medical Management</th>
<th>Endovascular Management</th>
<th>Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>12/26/95-2/14/99</td>
<td>13 (30.2%)</td>
<td>34 (26.7%)</td>
<td>19 (8.7%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Group 2</td>
<td>2/16/99-3/25/02</td>
<td>12 (26.7%)</td>
<td>34 (26.7%)</td>
<td>20 (7.7%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Group 3</td>
<td>3/25/02-8/1/05</td>
<td>1 (3.6%)</td>
<td>34 (26.7%)</td>
<td>20 (9.1%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Group 4</td>
<td>8/7/05-11/22/07</td>
<td>3 (7.0%)</td>
<td>34 (26.7%)</td>
<td>20 (9.1%)</td>
<td>1 (4.3%)</td>
</tr>
<tr>
<td>Group 5</td>
<td>11/22/07-2/24/10</td>
<td>0 (0.0%)</td>
<td>34 (26.7%)</td>
<td>35 (14.3%)</td>
<td>1 (3.6%)</td>
</tr>
<tr>
<td>Group 6</td>
<td>2/24/10-2/6/13</td>
<td>4 (21.1%)</td>
<td>34 (26.7%)</td>
<td>35 (14.3%)</td>
<td>1 (3.6%)</td>
</tr>
</tbody>
</table>

Insights From the International Registry of Acute Aortic Dissection
A 20-Year Experience of Collaborative Clinical Research

Evidence about Optimal Timing of TEVAR for TBAD

Acute (n=50), subacute (n=24) and chronic dissections (n=26) treated with TEVAR

- FL decrease less in chronic dissection

*Mid-term Outcomes and Aortic Remodelling After Thoracic Endovascular Repair for Acute, Subacute, and Chronic Aortic Dissection: The VIRTUE Registry*

The VIRTUE Registry Investigators*
TABLE 3. Perioperative outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Acute-Early intervention (N = 70)</th>
<th>Acute-Delayed intervention (N = 44)</th>
<th>Subacute intervention (N = 18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-hospital mortality</td>
<td>8.6%</td>
<td>4.5%</td>
<td>0%, 0%</td>
</tr>
<tr>
<td>Mortality at 30 d</td>
<td>12.7%</td>
<td>6.8%</td>
<td>0%, 0%</td>
</tr>
</tbody>
</table>

P value:
0.28
0.14
## Optimal Timing of TEVAR for TBAD

### TABLE 3. Perioperative outcomes

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<th>Subacute intervention (18)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>In-hospital mortality</td>
<td>8.6</td>
<td>6</td>
<td>4.5</td>
<td>2</td>
</tr>
<tr>
<td>Mortality at 30 d</td>
<td>12.7</td>
<td>9</td>
<td>6.8</td>
<td>3</td>
</tr>
<tr>
<td>Any paralysis</td>
<td>7.0</td>
<td>5</td>
<td>4.5</td>
<td>2</td>
</tr>
<tr>
<td>Paralysis (permanent)</td>
<td>1.4</td>
<td>1</td>
<td>2.2</td>
<td>1</td>
</tr>
<tr>
<td>Any stroke</td>
<td>5.6</td>
<td>4</td>
<td>4.6</td>
<td>2</td>
</tr>
<tr>
<td>Stroke (permanent)</td>
<td>1.4</td>
<td>1</td>
<td>2.3</td>
<td>1</td>
</tr>
<tr>
<td>New renal failure</td>
<td>8.5</td>
<td>6</td>
<td>6.8</td>
<td>3</td>
</tr>
<tr>
<td>Retrograde type A dissection</td>
<td>8.5</td>
<td>6</td>
<td>6.8</td>
<td>3</td>
</tr>
<tr>
<td>Overall major complication</td>
<td>38.7</td>
<td>27</td>
<td>27.3</td>
<td>12</td>
</tr>
</tbody>
</table>

**RANDALL B. GRIEPP HONORARY PAPER**

**Impact of timing on major complications after thoracic endovascular aortic repair for acute type B aortic dissection**

Nimesh D. Desai, MD, PhD, a,b Jean-Paul Gottret, MD, a,b Wilson Y. Szeto, MD, b Fenton McCarthy, MD, a,b Patrick Moeller, BS, b Rohan Menon, BS, b Benjamin Jackson, MD, a Prashanth Vallabhajosyula, MD, b Grace J. Wang, MD, a Ronald Fairman, MD, a and Joseph E. Bavaria, MD a

*(J Thorac Cardiovasc Surg 2015;149:S151-6)*
Evidence about Complicated Type B Dissection: Extensive Mng

Staged endovascular treatment for complicated type B aortic dissection
Peter J Mosse, Craig S McLachlan, Shalini A Amukotuwa and Ian K Nixon


Provisional Extension to Induce Complete Attachment After Stent-Graft Placement in Type B Aortic Dissection: The PETTICOAT Concept
Christoph A. Nienaber, MD; Stephan Kische, MD; Thomas Zeller, MD; Tim C. Rehders, MD; Henrik Schneider, MD; Björn Lorenzen, MD; Carsten Bünger, MD; and Huseyin Ince, MD
The STABLE Trial

Staged Total Aortic and Branch Vessel Endovascular

Results:

• 10 centers; 40 pts between 2007 and 2009

• 60% acute complicated BAD: impending rupture in 31/40 pts (77%)

• 30-day Mortality: 5%

• Complete FL Thrombosis at 12 months: 31%
The STABLE Trial

2 yrs FU

Descending Thoracic Aorta

Acute dissections

Nonacute dissections

Diameter (mm)

Pre Post 12 mo 24 mo

Pre Post 12 mo 24 mo

Total lumen

True lumen

False lumen

True lumen

False lumen

Abdominal Aorta

Acute dissections

Nonacute dissections

Diameter (mm)

Pre Post 12 mo 24 mo

Pre Post 12 mo 24 mo

Total lumen

True lumen

False lumen

Aortic remodeling after endovascular treatment of complicated type B aortic dissection with the use of a composite device design

Joseph V. Lombardi, MD; Richard P. Cambria, MD; Christoph A. Nienaber, MD; Roberto Chiesa, MD; Peter Mossop, MD; Stephan Haulon, MD; Qing Zhou, PhD; and Fei Jia, PhD

on behalf of the STABLE investigators, Camden, NJ; Boston, Mass; Rome, Germany; Milan, Italy; Melbourne, Victoria, Australia; Lille, France; and West Lafayette, Ind

(J Vasc Surg 2014;59:1544-54.)
The STABLE Trial vs Regular TEVAR

Volume analysis of true and false lumens in acute complicated type B aortic dissections after thoracic endovascular aortic repair with stent grafts alone or with a composite device design.

Jonathan Sobocinski, MD, PhD,1 Joseph V. Lombardi, MD,2 Nuno V. Dias, MD, PhD,2 Ludovic Berger, MD, PhD,2 Qing Zhou, PhD,2 Fei Ji, PhD,2 Timothy Resch, MD, PhD,2 and Stéphan Haoulon, MD, PhD,2 Lille and Caen, France; Camden, NJ; Malmö, Sweden; and West Lafayette, Ind

(J Vasc Surg 2016;63:1216-24.)
The STABLE Trial vs Regular TEVAR

Conclusions: According to this volume analysis, thoracic endografting for acute complicated type B dissections promotes significant thoracic aortic remodeling. The use of bare-metal dissection stents leads to significant true lumen expansion and false lumen regression in the early follow-up and to subsequent continued true lumen expansion in the abdominal aorta; however, a definitive benefit in aortic remodeling over TEVAR alone was not demonstrated at 1 year.

(J Vasc Surg 2016;63:1216-24.)
The STABILISE Technique

Stent-Assisted Balloon-Induced Intimal Disruption and Relamination in Aortic Dissection Repair

Stent-Assisted Balloon-Induced Intimal Disruption and Relamination in Aortic Dissection Repair: The STABILISE concept

Sophie C. Hofferberth, MBBS, BSc,\(^1\) Ian K. Nixon, MBBS, FRACS,\(^4\) Raymond C. Boston, PhD,\(^5\) Craig S. McLachlan, PhD, MPH,\(^6\) and Peter J. Mossop, MBBS, FRACR\(^7\)

\(\text{(J Thorac Cardiovasc Surg 2014;147:1240-5)}\)
Evidence about the STABILISE Technique

Stent-Assisted Balloon-Induced Intimal Disruption and Relamination in Aortic Dissection Repair

<table>
<thead>
<tr>
<th>Mid-Term Results (mean FUp 19 months)</th>
<th>Mid-Term Results (at 12 months)</th>
<th>Early Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 1 late death (not aorta-related)</td>
<td>• Reinterventions: 20% (8 ps)</td>
<td>• Technical success rate 100%</td>
</tr>
<tr>
<td>• No aortic reintervention</td>
<td>• No deaths</td>
<td>• FL thrombosis 100%</td>
</tr>
<tr>
<td>• No aortic dilatation</td>
<td>• Complete FL Thrombosis:</td>
<td>• No Type I EL</td>
</tr>
<tr>
<td>• Complete FL Thrombosis:</td>
<td>- 100% at TEVAR / bare-stent level</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 90% at abdominal level</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 100% at thoracic level</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 39% at not-stented infrarenal aorta</td>
<td></td>
</tr>
</tbody>
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(J Thorac Cardiovasc Surg 2014;147:1240-5)

(Satisfactory short-term outcomes of the STABILISE technique for type B aortic dissection)

Germano Melissano, MD, a Luca Bertoglio, MD, a Enrico Rinaldi, MD, a Daniele Mascia, MD, a Andrea Kahlberg, MD, a Diletta Loschi, MD, a Monica De Luca, MD, a Fabrizio Monaco, MD, a and Roberto Chiesa, MD, a Milan, Italy

(J Vasc Surg 2018;68:966-75.)

Mid-term Outcomes of Stent Assisted Balloon Induced Intimal Disruption and Relamination in Aortic Dissection Repair (STABILISE) in Acute Type B Aortic Dissection

Elisa M. Faure a,b, Salma El Batti a, Marwan Abou Rjell a, Pierre Julia a, Jean-Marc Alsac a

Evidence about Predictors of Late Aortic Growth

- Diameter of Proximal Entry Tear
- > # vessels from FL
- Diameter FL > 22
- Saccular FL formation
- Total initial diameter > 40 mm
- Partial FL thrombosis
## Predictors of Remodeling and Complications

### Table VIII. Quality of evidence

<table>
<thead>
<tr>
<th>Predictor of aortic growth or event</th>
<th>Study design</th>
<th>Class</th>
<th>Level of evidence</th>
<th>Studies</th>
<th>Patients</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased aortic diameter</td>
<td>Observational</td>
<td>Ila</td>
<td>B</td>
<td>26 6</td>
<td>3969 405</td>
<td>3, 4, 6, 8, 12, 13, 14, 16, 17, 18, 19, 21, 23, 24, 26, 29, 32, 37, 39, 40, 41, 43, 45, 46, 48, 49, 51, 55</td>
</tr>
<tr>
<td>Increased false lumen size</td>
<td>Observational</td>
<td>Ila</td>
<td>B</td>
<td>8 1</td>
<td>985 41</td>
<td>18, 36, 26, 32, 41, 48, 49, 52, 53</td>
</tr>
<tr>
<td>Increased entry tear size</td>
<td>Observational</td>
<td>Ila</td>
<td>B</td>
<td>1 2</td>
<td>184 107</td>
<td>32, 47, 52</td>
</tr>
<tr>
<td>Proximal location of entry tear</td>
<td>Observational</td>
<td>Ila</td>
<td>B</td>
<td>9 5</td>
<td>989 558</td>
<td>3, 9, 27, 30, 31, 32, 41, 45, 49, 52, 53</td>
</tr>
<tr>
<td>Location of ET in inner curvature</td>
<td>Observational</td>
<td>Ila</td>
<td>B</td>
<td>1 2</td>
<td>117 224</td>
<td>30, 31, 43</td>
</tr>
<tr>
<td>False lumen partial thrombosis</td>
<td>Observational</td>
<td>Ila</td>
<td>B</td>
<td>18 9</td>
<td>223 1291</td>
<td>35, 36, 38, 27, 33, 39, 41, 43, 51, 52, 53, 55</td>
</tr>
<tr>
<td>Increased number of branch vessels involvement</td>
<td>Observational</td>
<td>Ila</td>
<td>B</td>
<td>6 1</td>
<td>76 281</td>
<td>26, 51, 53, 39, 52, 53</td>
</tr>
<tr>
<td>Lower number of entry tears</td>
<td>Observational</td>
<td>Ila</td>
<td>B</td>
<td>2 2</td>
<td>122 326</td>
<td>36, 33, 52, 53, 54</td>
</tr>
<tr>
<td>False lumen distal extent (Type Illa vs Illb)</td>
<td>Observational</td>
<td>Ila</td>
<td>B</td>
<td>12</td>
<td>224 1189</td>
<td>45, 3, 5, 6, 13, 16, 19, 23, 29, 39, 50, 52, 53</td>
</tr>
<tr>
<td>False lumen arch extent</td>
<td>Observational</td>
<td>Ila</td>
<td>B</td>
<td>3 3</td>
<td>507 536</td>
<td>9, 50, 53, 23, 37, 52</td>
</tr>
<tr>
<td>False lumen extent to inner curvature</td>
<td>Observational</td>
<td>Ila</td>
<td>B</td>
<td>1 1</td>
<td>62 83</td>
<td>36, 52</td>
</tr>
<tr>
<td>False lumen length in cm</td>
<td>Observational</td>
<td>Ila</td>
<td>B</td>
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<td>76 83</td>
<td>26, 51, 52</td>
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</tbody>
</table>

**Green**: report data statistically significant for aortic growth and events; **Yellow**: report data not statistically significant; **Red**: report opposite data statistically significant

### Current evidence in predictors of aortic growth and events in acute type B aortic dissection

Domenico Spinelli, MD, PhD; Filippo Benedetto, MD, PhD; Rocco Donato, MD, PhD; Gabriele Piffaretti, MD, PhD; Massimiliano M. Marrocco-Trischitta, MD, PhD; Himanshu J. Patel, MD; Kim A. Eagle, MD; and Santi Trimarchi, MD, PhD. Messina, Milan, and Varese, Italy; and Ann Arbor, Mich.

(J Vasc Surg 2018;■:1-11.)
## Anatomical conditions

<table>
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<tr>
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Eur J Vasc Endovasc Surg (2017) 53, 4–52

**Editor’s Choice — Management of Descending Thoracic Aorta Diseases**

*Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS)*

### Anatomical conditions

#### TAA

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#### R TAA

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#### IMH B

<table>
<thead>
<tr>
<th>Recommendation 21</th>
<th>Class</th>
<th>Level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endovascular repair should be considered for complicated type B intramural haematoma</td>
<td>IIa</td>
<td>C</td>
</tr>
</tbody>
</table>

#### U TBAD

<table>
<thead>
<tr>
<th>Recommendation 18</th>
<th>Class</th>
<th>Level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>To prevent aortic complications in uncomplicated acute type B aortic dissection, early thoracic endografting may be considered selectively</td>
<td>IIb</td>
<td>B</td>
</tr>
</tbody>
</table>

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Eur J Vasc Endovasc Surg (2017) 53, 4-52

Management of Descending Thoracic Aorta Diseases |  
Guidelines of the European Society for Vascular Surgery (ESVS)


Kloth, G.J. de Borst, N. Chatibé, E.S. Debus, R.J. Hinchliffe, S. Rakitsis, I. Koncar, J.S. Lindahl, M. Vega de Canio, F. Verrasson, F. Verzini,

Document Reviewers

Uncomplicated Type B Dissection: Anatomical Considerations

Favorable Neck for **standard** TEVAR

Unfavorable Neck for **standard** TEVAR
Favorable Neck for **Standard** TEVAR
Favorable Neck for **Standard** TEVAR
Favorable Neck for **Standard** TEVAR
Unfavourable Anatomy for **Standard TEVAR**
Unfavourable Anatomy for Standard TEVAR
Unfavourable Anatomy for **Standard** TEVAR
Unfavourable Anatomy for **Standard** TEVAR
Unfavourable Anatomy for **Standard** TEVAR
Favourable Anatomy for **Standard** TEVAR, but CTD

Ehlers - Danlos
Evidence about aortic angulations & drag forces

1. severe angulation and tortuosity
2. high pulsatile forces

The Modified Arch Landing Areas Nomenclature (MALAN) Improves Prediction of Stent Graft Displacement Forces: Proof of Concept by Computational Fluid Dynamics Modelling

A geometric reappraisal of proximal landing zones for thoracic endovascular aortic repair according to aortic arch types

Eur J Vasc Endovasc Surg (2018) 55, 584–592

Uncomplicated Acute B Dissection: in search for a new Trial?

DO YOU THINK THERE IS CLINICAL EQUIPOISE IN THE MANAGEMENT OF UNCOMPLICATED TBAD?

DO YOU CURRENTLY STENT ALL COMERS?

BASED ON IMAGING?

ONLY IF THEY DEVELOP COMPLICATIONS?
## Conclusions

**When and how to perform TEVAR: evidence based insights**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Class</th>
<th>Level of evidence</th>
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<td>Iib</td>
<td>B</td>
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<td>C</td>
</tr>
<tr>
<td>18</td>
<td>Iib</td>
<td>B</td>
</tr>
</tbody>
</table>

**TAA**

In fit and unfit patients with favourable anatomy, endovascular repair may be considered for descending thoracic aorta aneurysms between 54 and 89 mm diameter.

**R TAA**

In patients with ruptured descending thoracic aorta aneurysm, endovascular repair should be the first treatment option when the anatomy is appropriate.

**TAI**

In patients with traumatic thoracic aorta injury and suitable anatomy, endovascular repair should be performed as the first option.

**IMH B**

Endovascular repair should be considered for complicated type B intramural haematoma.

**U TBAD**

To prevent aortic complications in uncomplicated acute type B aortic dissection, early thoracic endografting may be considered selectively.
Conclusions

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2 yrs FU after Medtronic Navion
Conclusions

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**INTACT-AD**

- Uncomplicated Type B Aortic Dissection
  - VQI
- Medical Therapy For All
- Upfront TEVAR
- Delayed Selective TEVAR (for AA 65 mm, increase by 5 mm/6m, acute events)

**Study Estimates**

- Total sample size is 1200
- Enrollment duration = 3 years
- Minimum follow-up = 3 years, Average = 4.5 years
- Study total period = 78 months
- 100 Centers
When and how to perform TEVAR: evidence based insights

Santi Trimarchi, MD, PhD

Associate Professor of Vascular Surgery, University of Milan
Head, Unit of Vascular Surgery
Fondazione IRCCS Cà Granda - Ospedale Maggiore Policlinico, Milan