Early Endovascular Treatment of Type B- Dissections
Facts to consider and technical learnings

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Disclosures

• Consultant
  - Cook, Endologix, Gore, Medtronic
• Research Grant
  - Cook, Gore, Maquet, Medtronic, Siemens
• Advisory Board
  - Endologix, Gore, Maquet, Medtronic, Siemens
• Speaker Honoraria
  - Cook, Endologix, Gore, Maquet, Medtronic, Siemens
• Major Stakeholder
  - none
Therapeutic Goal of TEVAR in Acute Type B Dissection

- **entry closure**
  - **true lumen**
  - **false lumen**
  - **remodelling**
    - **reperfusion of malperfused organs**
    - **fl -thrombosis**
      - **prevention of expansion and rupture**
Todays Management of Type B Dissection Sub-Categories

- **Acute Complicated**
  - Rupture
  - Malperfusion

- **Chronic (> 6 cm max. diam.)**
  - Potential reasons for intervention
    - Aneurysm degeneration
      - Up to 30% become aneurysmal
      - Rupture
    - Dissection extension
    - Malperfusion or ischemic events

- **Acute Uncomplicated**
  - TEVAR established!
  - BMT

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1 Riambau V. et al. ESVS Guidelines Management of Descending Thoracic Aortic Disease *EJVES* 2017;53:4-52
IRAD-Data\textsuperscript{1}: Natural Course for Acute Uncomplicated B-Dissections

- 6-10\% mortality within 30 days
- 59\% of aortic expansion within 2 yrs.
- unknown risk for rupture and death

DISSECT: A New Mnemonic-based Approach to the Categorization of Aortic Dissection

M.D. Dake M, M. Thompson, M. van Sambeek, F. Vermeulen, J.P. Morad

Objective/Background: Classification systems for aortic dissection provide important guides to clinical decision-making, but the relevance of traditional categorization schemes is being questioned in areas where endovascular techniques are assuming a growing role in the management of this frequently complex and catastrophic entity. In recognition of the expanding range of interventional therapies now used as alternatives to conventional treatment approaches, the Working Group on Aortic Diseases of the DEFINITE Investigators developed a novel classification system that is designed to guide clinical decisions and management strategies in the management of aortic dissection.

Methods and results: The DISSECT classification system is a mnemonic-based approach to the evaluation of aortic dissection. It guides clinicians through an assessment of six critical characteristics that are most recent advances in this area. The six characteristics are: duration, intimal tear location, size of the dissection, segmental extent of dissection, clinical condition, and thrombosis or dissection lumen.

Conclusion: In current clinical practice, endovascular therapy is increasingly considered as an alternative to medical management or open surgical repair in select cases of type B aortic dissection. Currently, endovascular aortic repair is not used for patients with type A aortic dissection, but catheter-based techniques direct at peripheral branch vessel dissection may be more feasible and provide a viable therapeutic adjunct. We will serve as a guide to support a critical analysis of contemporary therapeutic options and inform management decisions based on specific features of the disease process.
CT-based Risk Predictors of Disease Progression

- Primary entry tear diameter ≥ 10 mm
- Primary entry tear location on the concavity of the thoracic aorta
- Total aortic diameter ≥ 4 cm
- False lumen diameter ≥ 22 mm
- Partial false lumen thrombosis
- Fusiform index ≥ 0.64

Prevalence of the Computed Tomographic Morphological DISSECT Predictor in Uncomplicated Stanford Type B Aortic Dissection

Marios Ante 1, Spyridon Mylona 1, Dieter Singgren 2, Moritz S Rosch 3, Fabian Rengger 3, Jan Bockenhoff 4, Ottmar Böckler 4

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On average > 2 morphological predictors are found in each pat.

Significant aortic expansion in every 2nd patient under BMT

Positive correlation of No. of predictors and aortic expansion

CT-based predictors help to define patients at risk for aortic diameter expansion and potential TEVAR
Device Conformability and Morphological Assessment After TEVAR for Aortic Type B Dissection: A Single-Centre Experience with a Conformable Thoracic Stent-Graft Design

Background: The aim of this study was to analyze device conformability in TEVAR of acute and chronic (a/1) type B aortic dissections (TBAD) using the Gore Conformable Thoracic Aortic Stent-graft (CTAG).

Material/Methods: From January 1991 to February 2016, a total of 40 out of 453 patients in our center received TEVAR for TBAD. Since November 2009, 23 patients (16 men; median age: 62 years) were treated with the CTAG. Indications were complicated TBAD in 15 (65.2%) and expanding TBAD in 8 (34.8%) patients. Primary endpoints were the assessment of device conformability by measuring the distance (D) from the radiopaque gold band marker (GBM) at the proximal CTAG end to the inner curvature (IC) of the arch on parasagittal multiplanar reformations of CT angiography, as well as the evaluation of aortic diameter changes following TEVAR. Median follow-up was 13.3 months (range: 2 days to 25 months).

Results: Primary and secondary success rates were 91.3% (21/23) and 95.7% (22/23), respectively. There was 1 type Ia endoleak, retrograde dissection or primary conversion was not observed. Median GM-C-D was 5 mm (range: 0 mm to 10 mm). GM-C-D was associated with zone 2 placement compared to zone 3 (P=0.034). There was no association between GM-C-D formation and arch type. In TBAD cases the true lumen significantly increased after TEVAR (P=0.017) and the false lumen underwent shrinkage (P=0.025). In TBAD patients the false lumen decreased after TEVAR (P=0.036).

Conclusions: The CTAG shows favorable conformability and wall apposition in challenging arch pathologies such as TBAD.

MeSH Keywords: Aneurysm, Dissecting • Cardiovascular Diseases • Endovascular Procedures

Full-text DOI: http://www.sciencedirect.com/science/article/pii/S030241301001701

Bischoff M, Böckler D, Med Sci Research 2015,
CTAG with ACTIVE CONTROL System (ACS)

- Staged deployment > enables adjustment of device placement in challenging landing zones
- Active proximal active control > enables apposition in the gothic arches (often seen dissection)
<table>
<thead>
<tr>
<th>Condition</th>
<th>Total</th>
<th>Elective</th>
<th>Emergency (47.5%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thoracic aortic aneurysm (TAA)</td>
<td>122</td>
<td>86</td>
<td>36</td>
</tr>
<tr>
<td>Ruptured TAA</td>
<td>44</td>
<td>-</td>
<td>44</td>
</tr>
<tr>
<td>Thoracoabdominal aneurysm</td>
<td>93</td>
<td>63</td>
<td>30</td>
</tr>
<tr>
<td>Penetrating aortic ulcer (PAU)</td>
<td>103</td>
<td>57</td>
<td>46</td>
</tr>
<tr>
<td>Traumatic aortic rupture</td>
<td>35</td>
<td>-</td>
<td>35</td>
</tr>
<tr>
<td>Chronic Typ B dissection</td>
<td>80</td>
<td>62</td>
<td>18</td>
</tr>
<tr>
<td><strong>Acute/subacute Typ B dissection</strong></td>
<td>104</td>
<td>42</td>
<td>62</td>
</tr>
<tr>
<td>Intramural haematoma (IMH)</td>
<td>47</td>
<td>28</td>
<td>19</td>
</tr>
<tr>
<td>Typ A Dissection</td>
<td>13</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>Aortobronchial/-esophageal fistula</td>
<td>20</td>
<td>-</td>
<td>20</td>
</tr>
<tr>
<td>Patch Rupture</td>
<td>3</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Post CoA Aneurysm</td>
<td>10</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Anastomotic aneurysm</td>
<td>10</td>
<td>9</td>
<td>1</td>
</tr>
</tbody>
</table>
Heidelberg Experience with CTAG & ACS in B-Dissections
July 2017 – Januar 2021 – 3.5 years

684 TEVAR Procedures

361 Patients with 556 CTAG

145 Patients with 217 devices
CTAG with Active Control

46 %
### Use of Active Control (n = 104)

<table>
<thead>
<tr>
<th>When / Where</th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optional angulation used</td>
<td>22 % (23)</td>
</tr>
<tr>
<td>intermediate deployment alone</td>
<td>78 % (18)</td>
</tr>
<tr>
<td>intermediate and full deployment</td>
<td>22 % (5)</td>
</tr>
<tr>
<td>after full deployment alone</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Depending on Arch Type</th>
<th>Type I</th>
<th>8 % (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Type II</td>
<td>52% (12)</td>
</tr>
<tr>
<td></td>
<td>Type III</td>
<td>39 % (9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Underlying Pathology</th>
<th>Degenerative disease (TAA &amp; PAU)</th>
<th>35 % (8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dissection (AoD &amp; IMH)</td>
<td>48 % 11)</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td></td>
<td>17 % (4)</td>
</tr>
</tbody>
</table>
Aortic Remodelling in Early TEVAR with CTAG (n= 49, unpublished data)

- Good aortic remodelling at 40 months FU
- No 30d hospital mortality
- 2% aortic related mortality at 3 yrs.
- Sec. Reintervention rate 6%
Impact of IFU Implantation (CTAG) on Survival

Outcomes of thoracic endovascular aortic repair in thoracic aortic aneurysm and penetrating aortic ulcer using the Conformable Gore TAG within and outside the instructions for use

Katrin Meisenbacher, Matthias Hagedorn, Caspar Grond-Ginsbach, Dorothea Weber, Dittmar Böckler and Moritz S Bischoff

Abstract

Objective: To describe the outcome of thoracic endovascular aortic repair (TEVAR) in thoracic aortic aneurysm and penetrating aortic ulcer with respect to instructions for use status.

Methods: Between October 2009 and September 2017, a total of 532 patients underwent TEVAR, of which 195 have been treated using the Conformable Gore® TAG® thoracic endoprosthesis (CTAG). Fifty-six patients of this cohort underwent TEVAR for thoracic aortic aneurysm/pénétrating aortic ulcer using the CTAG. Depending on the preoperative computed tomography angiography findings, patients were classified as inside or outside the device’s instructions for use. All inside instruction for use patients underwent postoperative reclassification regarding the instructions for use status. Study endpoints included TEVAR-related reintervention, exclusion of the pathology (embolization type III), TEVAR-related mortality, and graft-related serious adverse events. The median duration of follow-up was 29.7 months (range: 0–109.4 months).

Results: Of the 56 patients, 17 were primarily classified as outside instruction for use, and in additional 13 patients, TEVAR was performed outside instruction for use, leading to 30 outside instruction for use patients (53.6%). Twenty-six patients (46.4%) were treated inside instruction for use. Reintervention-free survival was lower in outside instruction for use patients (P = 0.014) with a hazard ratio of 9.74 (confidence interval 1.2–80.2; P = 0.034) for TEVAR-related reintervention. With respect to endoleak type III, relevant difference was detected between inside/outside instruction for use status (P = 0.012). The serious adverse event rate was 30.4%, mainly in outside instruction for use patients (P = 0.004). Logistic regression analysis indicated an association between graft-related serious adverse event/instructions for use status (odds ratio 6.11; confidence interval 1.6–30.06; P = 0.012). In-hospital death was seen more frequently in outside instruction for use patients (P = 0.12) as was procedure-related death (log-rank test: P = 0.21).

Conclusion: TEVAR for thoracic aortic aneurysm/pénétrating aortic ulcer is frequently performed outside instruction for use despite preoperative inside instruction for use eligibility, leading to important consequences for technical/clinical outcome. Instructions for use adherence in TEVAR should be of interest for further large-scale studies.

Keywords
TEVAR, instructions for use, thoracic aortic aneurysm, penetrating aortic ulcer, reintervention, outcome
## IFU of CTAG

### IFU - Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Gore CTAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic neck diameter</td>
<td>Inner diameter min. 16 mm -max. 42 mm</td>
</tr>
<tr>
<td>Proximal landing zone</td>
<td>min. 20 mm distal to LSA or ACC</td>
</tr>
<tr>
<td>Distal landing zone</td>
<td>min. 20 mm prox. Celiac axis</td>
</tr>
<tr>
<td>Overlap</td>
<td>Multiple devices min. 30 mm</td>
</tr>
<tr>
<td>Oversizing</td>
<td>min. 5 cm</td>
</tr>
<tr>
<td>Multiple Devices with differing</td>
<td>6-33%</td>
</tr>
<tr>
<td>diameters -&gt; treatment length</td>
<td>≥13cm</td>
</tr>
<tr>
<td>Aortic neck angulation</td>
<td>≥ 60°</td>
</tr>
<tr>
<td></td>
<td>&lt; 60° more treatment length</td>
</tr>
</tbody>
</table>

*Multiple Devices with differing diameters -> treatment length ≥13cm*
Technical Notes and Known Facts

- Low or no oversizing (0-10%)
- Sizing based on diameters of proximal landing zones
- Stent graft design without bare stenting
- No post-ballooning
- Intraoperative use of 2D-TEE
Induced Hypotension during SG Placement

- i.v. Medication (sodium nitroprusside)
- Adenosin induced heart arrest
- Rapid Pacing

## CTAG ACS without Rapid Pacing

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group 1 C-TAG with Active Control % (n=20)</th>
<th>Group 2 C-TAG with rapid pacing % (n=20)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedural time (min)</td>
<td>109 ± 59</td>
<td>152 ± 99,8</td>
<td>0.1</td>
</tr>
<tr>
<td>Fluorotime (min)</td>
<td>9,8 ± 5</td>
<td>13,1 ± 7</td>
<td>0.1</td>
</tr>
<tr>
<td>Contrast Volume cc</td>
<td>113 ± 54,0</td>
<td>148 ± 76</td>
<td>0.05</td>
</tr>
<tr>
<td>Average DAP mGy/cm²</td>
<td>11476.7</td>
<td>25452</td>
<td>0.001</td>
</tr>
<tr>
<td>Hospital stay (days)</td>
<td>17,4 ± 14,9</td>
<td>17,4 ± 8,9</td>
<td>0.3</td>
</tr>
</tbody>
</table>
## Comparative Results

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group 1 C-TAG with Active Control</th>
<th>Group 2 C-TAG with rapid pacing</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical success</td>
<td>20 (100%)</td>
<td>20 (100%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Accurate Positioning average distance in mm</td>
<td>3 mm</td>
<td>2 mm</td>
<td>n.s.</td>
</tr>
<tr>
<td>Type Ia Endoleakage</td>
<td>0</td>
<td>1 (5%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Reintervention Rate</td>
<td>0</td>
<td>1 (5%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>30 day mortality</td>
<td>0</td>
<td>1 (5%)</td>
<td>n.s.</td>
</tr>
<tr>
<td>Combined CV &amp; neurological event rate</td>
<td>1 (5 %)</td>
<td>3 (15%)</td>
<td>n.s.</td>
</tr>
</tbody>
</table>
Spot-Stent Grafting in TBAD and IMH (Non IFU!)

• Technical success 100%
• False lumen thrombosis 95.5%
• Aortic remodelling 68.2%
• SINE or retrograde dissection 0%
• 30 day mortality 0%

Key question
Is spot stent grafting (SSG) an option in type B aortic dissection/intramural haematoma?

Key finding(s)
- SSG showed 100% technical success, promising false lumen thrombosis/aortic remodelling rates and low complication rates.

Take-home message
SSG provides a viable treatment option in selected cases; large-scale long-term data may allow refinement of the application.
Immediate Versus Delayed Endovascular Treatment of Post-Traumatic Aortic Pseudoaneurysms and Type B Dissections: Retrospective Analysis and Premises to the Upcoming European Trial

Alessandro S. Bortone, MD, PhD, FESC; Stefano Schena, MD; Donato D’Agostino, MD; Giovanni Dielotto, MD; Vito Paradiso, MD; G. Mammatiziu, MD; Tommaso Fiore, MD; Mauronte Costino, MD; Luigi de Luca Tappi Schinina, MD

Background—Stent grafting has been reported as a viable therapeutic option for the delayed treatment of traumatic rupture of the aortic intimas as well as re-rupture of thoracic aortic dissections. We tested the hypothesis of whether immediate endovascular management offers clinical and pathological advantages over a delayed approach in patients with post-traumatic aortic pseudoaneurysms (PAPs) and Stanford type B dissections (TBDs).

Methods—Thirty-one consecutive patients who were admitted with diagnosis of either PAP (n = 10; 33.3 ± 18.7 years) or TBD (n = 21; 35.2 ± 19.4 years) were respectively divided into 2 groups according to the timing of diagnosis and endovascular treatment: the traumatic or pathologic event: immediate (n=17) group; PAP (n=6) and TBD (n=7) and delayed (2±2 weeks; PAP (n=4) and TBD (n=14). Excluded: Group 1 (n=16 in PAP and 8 in TBD) and Tertiary-Medico (1 in PAP and 7 in TBD) endovascular stents were deployed. Follow-up was performed at 3 months, 6 months, and 1 year and based on laboratory tests, chest angiographic computed tomography scans of chest, abdomen, and pelvis, and transphalangeal echocardiography.

Results—The endovascular procedure proved effective in all PAP patients who underwent either immediate or delayed treatment. In 1 PAP patient with delayed treatment, surgical removal of the pseudoaneurysm was still necessary because of further compression of the adjacent aorta. All immediately treated TBD patients were also successful. In 8 out of 13 TBD patients with delayed treatment (61.5%), a stent graft deployment was not possible because of complicated progression of the false lumen and multiple intimal entry tears: 1 patient benefited by fenestration of the false lumen and 7 patients underwent medical therapy. One patient (8.3%) died because of stent graft dislocation involving the aortic arch. All patients treated with endovascular stent grafts were discharged within 5 days.

Conclusions—An immediate endovascular management of PAP and TBD patients offers important advantages such as avoidance of high-risk surgical procedures and postoperative complications with short hospital stay. However, it has been observed that an immediate endovascular treatment allows a safe management of all patients with complete healing of the aortic wall and reduction of the pseudoaneurysm in PAP group and thrombosis of the false lumen in TBD patients. (Circulation. 2002;106(suppl I):I-334–I-340).

Keywords aorta • pseudo • stents • grafting • surgery

Bortone A, Circulation 2001

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

The VIRTUE Registry Investigators

WHAT THIS PAPER ADDS

The VIRTUE Registry describes the mid-term clinical and morphological results of thoracic endovascular repair in patients with type B aortic dissection. Analysis of aortic morphology showed that patients with subacute dissection demonstrated a similar degree of aortic remodeling to patients with acute dissection. Retention of aortic plasticity in the subacute group lengthens the therapeutic window for the treatment of uncomplicated type B dissection.

Objectives: The VIRTUE Registry describes the mid-term clinical and morphological results of thoracic endovascular repair (TEVAR) in patients with type B aortic dissection.

Methods: This was a prospective cohort study. The VIRTUE Registry is a prospective, multicenter clinical trial that enrolled patients with complicated acute (<35 days), subacute (15~90 days), and chronic (>30 days) type B aortic dissections treated with the Valiant endograft. One hundred patients were enrolled and the clinical outcomes described at the 3-year follow-up. Analysis of the aortic area and false lumen thrombosis rates defined the morphological response to TEVAR in the three clinical groups.

Results: Three-year all-cause mortality (18%, 4%, and 24%), dissection related mortality (12%, 4%, and 9%), aortic rupture (2%, 0%, and 4%), stent graft type 4 dissection (5%, 0%, and 6%), and aortic reintervention rates (20%, 22%, and 58%) were, respectively, defined for patients with acute (n = 56), subacute (n = 24), and chronic (n = 26) dissections. Analysis of aortic morphology observed that patients with subacute dissection demonstrated a similar degree of aortic remodeling with patients with acute dissection. Patients with acute and subacute dissection exhibited greater aortic plasticity than patients with chronic dissection.

Conclusions: The principle clinical findings suggest that TEVAR is able to provide good protection from aortic-related death in the mid-term, but with a high rate of aortic reintervention. Analysis of aortic morphology suggested that aortic remodeling in subacute patients is similar to the acute group. Retention of aortic plasticity in the subacute group lengthens the therapeutic window for the treatment of uncomplicated type B dissection.

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Keywords: Aortic dissection, Endovascular, Type B

University Hospital Heidelberg | LINC 2021 | Prof. Dr. med. D: Böckler

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

Nimesh D. Desai, MD, PhD,1,2 Jean-Paul Gottret, MD,3,4 Wilson Y. Seeto, MD,5 Fenton McCarthy, MD,6,7 Patrick Moeller, BS,2 Rohan Menon, BS,2 Benjamin Jackson, MD,1 Prashanth Vallabhaipur, MD,6,7 Grace J. Wang, MD,5 Ronald Faiman, MD,1 and Joseph E. Baviara, MD2

Objective: Thoracic endovascular aortic repair (TEVAR) has been shown to have survival benefit in patients with complicated type B dissection compared with open surgery or medical therapy. We analyze the impact of timing of intervention from the onset of symptoms to TEVAR, and its relation to complications.

Methods: Between 2005 and 2012, we performed 132 TEVARs for acute and subacute (<6 weeks) type B dissection; 186 other patients were managed with medical therapy only. Patients were followed in a clinical registry. Standard univariate and survival methods were used.

Results: Of the 132 TEVARs for type B dissection, 70 were performed within 48 hours of presentation (Acute-Early); 44 between 48 hours and 14 days from presentation (Acute-Delayed); and 18 between 14 days and 6 weeks of presentation (Subacute). Demographic characteristics were similar among groups. Severe complications were more common in the Early-Acute and Delayed-Acute patients than in the Subacute patients (P = .04). Retrorgrade type A dissection tended to be more common in the Early-Acute group. Overall survival was similar among groups.

Conclusions: Delayed intervention appears to lower the risk of complications of TEVAR for aortic dissection in patients who are stable enough to wait. Among patients initially managed medically, new TEVAR indications were not uncommon, and such patients must be followed closely. (J Thorac Cardiovasc Surg 2015;150:S151–S156)
Summary

- Increasing evidence for early TEVAR in acute/subacute uncomplicated B dissections
- CT based predictors help to select appropriate candidates
- Optimal timing within a "window of aortic plasticity" is not yet exactly defined (> 15-90 d)
- CTAG with Active Control shows excellent early clinical results and remodelling after 3 yrs.
- Rapid pacing is abandoned with CTAG & ACS in our experience
- Spot-Stentgrafting (non IFU) shows promising preliminary results in highly selected cases
- Management of Acute Stanford Type B dissection is evolving