Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

UNIVERSITÀ DEGLI STUDI DI MILANO

# Endovascular Treatment of the Ascending Aortic Diseases; what can be currently – what cannot – what does the future hold from a Systematic Review

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Fondazione IRCCS Cà Granda - Ospedale Maggiore Policlinico Milan

VEITH SYMPOSIUM 2024

Connecting The Vascular Community

COI:

Consultant and Speaker: WL Gore, Medtronic Inc, Terumo Aortic

Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

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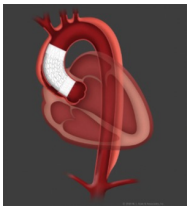
## Ascending TEVAR

- **Ascending Thoracic Endovascular Aortic Repair (aTEVAR)**
- **Last resort alternative for high surgical risk patients / patients refusing open surgery**
- **Anatomical and procedural difficulties**
- **No dedicated ascending endograft**
- **Low number of reported procedures**



## Systematic Review: aTEVAR

- **Significant increase in studies on aTEVAR since it's first description**
- **No significant increase per year in the last 10 years**


## aTEVAR previous experience

**8 pts, all with PAU or Pseudoaneurysm**

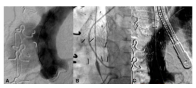


**TABLE 2. Case series summary: anatomical and technical details**

| Gender | Age (y) | CS type | Etiology | Infection | Symptomatic | TEVAR | EuroSCORE | Diameter | ASCAD | CA-IA | EG type | EGD | EG (n) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Male | 57 | CABG | Cannulation | No | No | Elective | 8.80 | 20 | 26 | 70 | CM | 30 × 65 | 1 |
| Male | 71 | BAV | Cannulation | No | Thoracic pain | Urgent | 9.93 | 70 | 30 | 80 | OS | 36 × 45 | 3 |
| Male | 73 | CABG | PAU | No | Thoracic pain | Urgent | 8.46 | 53 | 35 | 75 | OS | 45 × 50 | 1 |
| Male | 81 | no | PAU | No | Thoracic pain | Urgent | 11.75 | 60 | 41 | 83 | OS | 45 × 60 | 1 |
| Female | 73 | BAV | cannulation | No | Thoracic pain | Urgent | 16.49 | 35 | 37 | 90 | OS | 45 × 60 | 2 |
| Male | 65 | CABG | Cannulation | Yes | Thoracic pain | Urgent | 14.49 | 41 | 39 | 80 | OS | 45 × 70 | 1 |
| Female | 75 | Bentall | Suture line | No | No | Elective | 23.79 | 53 | 22 | 70 | CM | 38-48 × 70 | 1 |
| Male | 70 | no | PAU | No | Thoracic pain | Urgent | 14.25 | 50 | 29 | 48 | OS | 36 × 45 | 4 |

**Endograft repair for pseudoaneurysms and penetrating ulcers of the ascending aorta**

Gabriele Piffaretti, MD, PhD,[1] Mario Galli, MD,[2] Chiara Lomazzi, MD,[1] Marco Franchin, MD,[1] Patrizio Castelli, MD,[1] Giovanni Mariscalco, MD, PhD,[3] and Santi Trimarchi, MD, PhD[3]
**The Journal of Thoracic and Cardiovascular Surgery • Volume 151, Number 6 JUNE 2016**

## aTEVAR previous experience

**8 pts, all with PAU or Pseudoaneurysm**

**In-Hospital Results**

Primary clinical success was achieved in 7 (87.5%) patients. One patient with an acute symptomatic PAU treated with multiple endografts had a type 3 endoleak at the end of the intervention.

**Late Results**

No patient was lost at a mean follow-up of 40 ± 33 (range: 4-93) months. Ongoing primary clinical success was maintained in all patients. Specifically, aortically related reintervention, either open or endovascular, was never required. No patient died during follow-up.

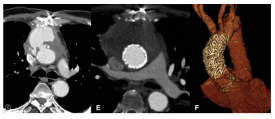



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**Table 3:** Case series summary: patient data, anatomy, technical details and outcome

| Patient | Gender, age (years) | Aortic disease | Aortic diameter (mm, proximal) (months) | EuroSCORE-II | Aortic diameter (mm, distal) | CA-BCT distance (mm) | Device design | EG oversizing (%) | Size (mm diameter × length) | Outcome | ARM | Follow-up |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| # 1 | M, 66 | PSA | 40 | 5.7 | 40 | 113 | Straight | 15 | 46/46 × 65 | Alive | No | 38 |
| # 2 | M, 61 | PSA | 34 | 6.1 | 20 | 65 | Tapered | 18 | 40/36 × 65 | Dead | Yes | 24 |
| # 3 | M, 81 | Rupture | 35 | 25.8 | 37 | 115 | Straight | 10 | 40/40 × 75 | Alive | No | 21 |
| # 4 | M, 75 | Dissection | 30 | 2.8 | 30 | 78 | Straight | 20 | 36/26 × 65 | Alive | No | 12 |
| # 5 | M, 57 | PSA | 26 | 1.0 | 30 | 70 | Straight | 15 | 30/30 × 65 | Alive | No | 84 |
| # 6 | F, 75 | PSA | 37 | 4.9 | 44 | 74 | Reverse tapered | 18 | 38/48 × 65 | Alive | No | 36 |
| # 7 | M, 84 | Dissection | 32 | 23.8 | 34 | 69 | Straight | 10 | 38/38 × 65 | Dead | No | 2 |
| # 8 | F, 62 | Dissection | 33 | 10.9 | 31 | 87 | Straight | 15 | 38/38 × 65 | Dead | No | 6 |
| # 9 | M, 81 | PSA | 42 | 40.9 | 40 | 94 | Tapered | 10 | 48/44 × 90 | Alive | No | 14 |

ARM: aorta-related mortality; BCT: brachiocephalic trunk; CA: coronary artery; EG: endograft; F: female; M: male; PSA: pseudoaneurysm.

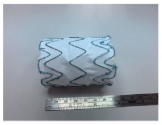

Figure 1: Customization of the Relay® NBS (non-bare stent) Plus (Terumo Aortic, Sunrise, FL, USA). This endograft is made by a single-component tubular, fully-covered custom-made endograft.

**Endovascular repair of ascending aortic diseases with custom-made endografts**

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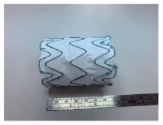

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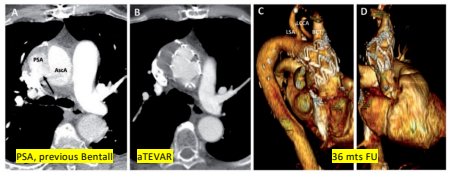


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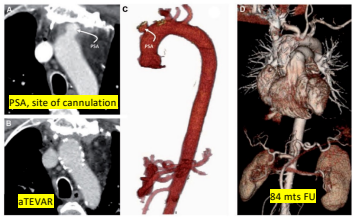


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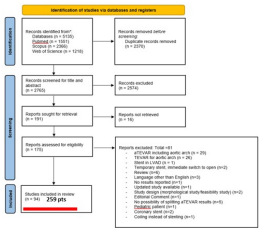
## Systematic Review: aTEVAR




European Journal of Vascular and Endovascular Surgery
Available online 8 November 2024
In Press, Journal Pre-proof What's this?

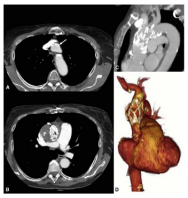
Systematic Review

Outcomes of Endovascular Repair for Ascending Aortic Diseases: A Systematic Review and Meta-analysis

Jesper F. de Kort, Tim J. Mandigers, Daniele Bissacco, Maurizio Domanin, Gabriele Piffaretti, Christopher P. Twine, Anders Wanhainen, Joost A. van Herwaarden, Santi Trimarchi, Carlo de Vincentiis

## Systematic Review: aTEVAR

**Study & baseline characteristics**

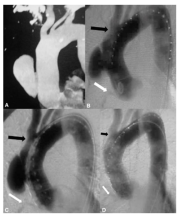



| Study Type | Studies (n = 94) | Patients (n = 259) |
|---|---|---|
| Case-report | 70 (74.5 %) | 70 (27.0 %) |
| Case-series | 5 (5.3 %) | 11 (4.2 %) |
| Cohort study | 19 (20.2 %) | 178 (68.7 %) |

## Systematic Review: aTEVAR

### Study & baseline characteristics

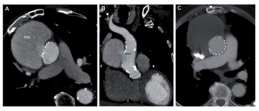
| Variable | Patients (n = 259) |
|---|---|
| Mean age | 69.1 (±14.3 [95%CI; 65.0 – 73.1]) |
| Mean follow-up | 19.6 (±19.0 [95%CI; 14.5 – 24.6]) |
| Number of male patients | 142 (57.7 %) |
| Comorbidities | |
| Hypertension | 117 (45.1 %) |
| Dyslipidaemia | 31 (11.9 %) |
| Stroke | 32 (12.7 %) |
| Diabetes | 38 (14.7 %) |
| Renal insufficiency | 37 (14.3 %) |
| Coronary artery disease | 78 (30.1 %) |
| Myocardial infarction | 21 (8.1 %) |
| Heart failure | 37 (14.3 %) |
| Carcinoma | 18 (7.3 %) |
| COPD | 48 (18.5 %) |
| Connective tissue disease | 4 (1.5 %) |
| Peripheral artery disease | 36 (13.9 %) |
| Previous cases of thoracic surgery | 191 |
| Symptoms at presentation | |
| Chest Pain | 49 (18.9 %) |



## Systematic Review: aTEVAR

### Study & baseline characteristics

| Variable | Patients (n = 259) |
|---|---|
| Aortic disease | |
| Type A dissection | 113 (44.8 %) |
| Chronic Dissection | 8 (3.1 %) |
| Pseudoaneurysm | 100 (38.8 %) |
| Intramural Haematoma | 5 (1.9 %) |
| Rupture | 3 (1.2 %) |
| PAU | 10 (3.9 %) |
| Ascending Aorta Aneurysm | 8 (3.1 %) |
| Compression on Aorta | 1 (0.4 %) |
| Rescue during TAVI | 4 (1.6 %) |
| Floating Thrombus | 1 (0.4 %) |
| Aortic stenosis | 2 (0.8 %) |
| Haemolytic anaemia due to kinking of aortic graft | 2 (0.8 % ) |
| Flap of bovine material | 1 (0.4 %) |



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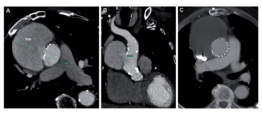
| Flap of bovine material | 1 (0.4 %) |
| Urgent procedure | 73 (52.9%) |
| Planned procedure | 65 (47.1%) |



## Systematic Review: aTEVAR

| Type of stent graft used | Number of stent grafts used (n = 200) | Number of SM stent grafts (n=0) |
|---|---|---|
| Custom-made stent-graft | 13 (6.5 %) | 0 |
| Medtronic | 34 (17.0 %) | 0 |
| Abdominal | 3 (1.5 %) | 0 |
| Thoracic | 25 (12.5 %) | 4 |
| Unclear | 6 (3.0 %) | 0 |
| Cook | 47 (23.5 %) | 0 |
| Abdominal | 6 (3.0 %) | 0 |
| Thoracic | 24 (12.0 %) | 1 |
| CAO* | 12 (6.0 %) | 1 |
| Unclear | 17 (8.5 %) | 0 |
| Gore | 88 (44.5 %) | 0 |
| Abdominal | 33 (16.5 %) | 0 |
| Thoracic | 49 (24.5 %) | 1 |
| ASO* | 15 (7.5 %) | 0 |
| Unclear | 7 (3.5 %) | 0 |
| Gianturco | 1 (0.5 %) | 0 |
| Terumo | 6 (3.0 %) | 0 |
| Cordis | 2 (1.0 %) | 0 |
| AnaConStent XL | 1 (0.5 %) | 0 |
| Bolton | 3 (1.5 %) | 0 |
| Optimed | 1 (0.5 %) | 0 |
| Jotec Evita | 1 (0.5 %) | 1 |
| EVT-Endovascular | 1 (0.5 %) | 0 |

## Systematic Review: aTEVAR

| Access route | Number of times used (n = 223) |
|---|---|
| Femoral artery | 118 (56.1 %) |
| Right femoral artery | 29 (13.0 %) |
| Left femoral artery | 10 (4.5 %) |
| Unclear Femoral artery | 86 (38.6 %) |
| Axillary artery | 22 (9.9 %) |
| Right axillary artery | 3 (1.3 %) |
| Left axillary artery | 10 (4.5 %) |
| Unclear Axillary artery | 9 (4.0 %) |
| Common carotid artery | 12 (5.4 %) |
| Right common carotid | 7 (3.1 %) |
| Left common carotid | 5 (2.2 %) |
| Subclavian artery | 5 (2.2 %) |
| Right subclavian artery | 3 (1.3 %) |
| Left subclavian artery | 2 (0.9 %) |
| Transapical | 31 (13.9 %) |
| Direct aortic access | 1 (0.4 %) |
| Supraaxillary | 1 (0.4 %) |

## Systematic Review: aTEVAR

### Mortality

| Mortality | Number of patients (n, %) |
|---|---|
| All studies | Total (n = 259) |
| In-hospital mortality | 19 (7.3% [95%CI; 4.7 – 11.2]) |
| 30-day mortality | 20 (7.7% [95%CI; 5.1 – 11.6]) |
| Overall mortality | 44 (17.0% [95%CI; 12.9 – 22.0]) |
| Day of discharge | 9.3 (±7.2 [95%CI; 5.9 – 12.7]) |
| Cohort studies | Total (n = 178) |
| In-hospital Mortality | 18 (10.1% [95%CI; 6.5 – 15.4]) |
| 30-day mortality | 18 (10.1% [95%CI; 6.5 – 15.4]) |
| Overall mortality | 40 (22.5% [95%CI; 17.0 – 29.1]) |
| Case reports | Total (n = 70) |
| In-hospital mortality | 1 (1.4% [95%CI; 0.3 – 7.7]) |
| 30-day mortality | 2 (2.9% [95%CI; 0.8 – 9.8]) |
| Overall mortality | 4 (5.7% [95%CI; 2.2 – 13.8]) |
| Type A dissection | Total (n = 113) |
| In-hospital mortality | 14 (12.4% [95%CI; 7.5 – 19.7]) |
| 30-day mortality | 15 (13.3% [95%CI; 8.2 – 20.8]) |
| Pseudoaneurysm | Total (n = 100) |
| In-hospital mortality | 4 (4.0% [95%CI; 1.6 – 9.8]) |
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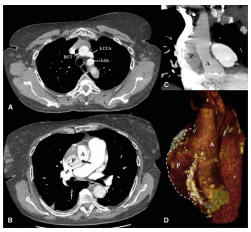


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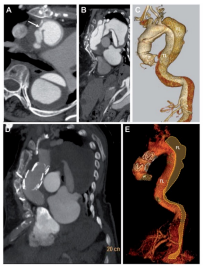
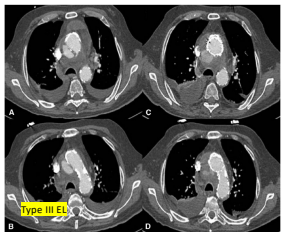



## Systematic Review: aTEVAR

### Complications

| Intra-operative complications | Total (n = 38) (range) |
|---|---|
| Coverage of brachiocephalic trunk or coronary artery | 1 (0-1) |
| Endoleak | 24 (0-2) |
| Cerebrovascular accident | 3 (0-1) |
| Aortic insufficiency | 6 (0-1) |
| Ventricular rupture | 1 (0-1) |
| Thrombosis of coronary | 1 (0-1) |
| Conversion* | 6 (2.3 %, 0-2) |
| **Post-operative complications** | **Total (n = 88)(range)** |
| New dissection | 6 (0-2) |
| New Pseudoaneurysm | 6 (0-2) |
| Endoleak | 27 (0-4) |
| Tamponade | 5 (0-2) |
| Rupture | 1 (0-1) |
| Aneurysm | 2 (0-1) |
| De Novo Ulceration | 1 (0-1) |
| Spinal Cord Ischemia | 2 (0-1) |
| Aortic insufficiency | 3 (0-1) |
| Septic Shock (stent-graft infection) | 2 (0-1) |
| Cerebrovascular accident | 13 (0-4) |
| Myocardial infarction | 7 (0-2) |
| Pulmonary Oedema | 6 (0-1) |
| Pulmonary Embolism | 2 (0-1) |
| Fever | 3 (0-1) |
| Late-cooperation* | 34 (12.7 %, 0-7) |

*Conversion and late-reoperation rate are % of total population




## aTEVAR

Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY

**ARISE: First-In-Human Evaluation of a Novel Stent Graft to Treat Ascending Aortic Dissection**

Eric E. Roselli, MD[1], Marvin D. Atkins, MD[2], William Brinkman, MD[3], Joseph Coselli, MD[4], Nimesh Desai, MD[5], Anthony Estrera, MD[6], Douglas R. Johnston, MD[7], Himanshu Patel, MD[8], Ourania Preventza, MD[9], Patrick R. Vargo, MD[1], Fernando Fleischman, MD[10], Bradley S. Taylor, MD[2], and Michael J. Reardon, MD[2] On behalf of the ARISE Investigators

Figure 2a. GORE® ASG device deployed with curvature. Image of the GORE® ASG device in the deployed state with curvature (2a) with various sizes shown. Image provided by Gore and reproduced with permission.

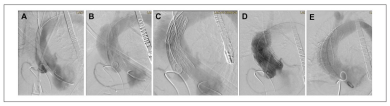



**Figure 4.** Intraoperative Fluoroscopy demonstrating the staged delivery into the ascending aorta (A), first stage deployment with partial expansion (B), device curvature aligned with coronary origins (C), second stage deployment with full expansion (D), and completion aortogram after delivery and full deployment of the second distal device (E).

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**Figure 2b.** GORE® ASG device mounted. Image of the GORE® ASG device mounted on the delivery catheter (2b). Image provided by Gore and reproduced with permission.

**Table 3.** Serious Adverse Events Through 30 Days.

| | All | TBE device | ASG device |
|---|---|---|---|
| **Number of Enrolled Subjects** | 19 | 4 | 15 |
| MACCE events | 5 (23.8%) | 2 (50%) | 3 (20%) |
| †Death | 3 (15.8%) | 0 (0%) | 3 (20.0%) |
| †Major stroke | 1 (5.3%) | 1 (25%) | 0 (0%) |
| †Myocardial infarction | 1 (5.3%) | 1 (25%) | 0 (0%) |
| **Other 30-Day Serious Adverse Event** | 11 (57.9%) | 3 (75.0%) | 8 (53.3%) |
| Aortic valve insufficiency (>2+) | 3 (15.8%) | 1 (25.0%) | 2 (13.3%) |
| Cerebrovascular accident | 3 (15.8%) | 2 (50.0%) | 1 (6.7%) |
| Embolic stroke | 1 (5.3%) | 0 (0%) | 1 (6.7%) |
| Acute kidney injury | 2 (10.5%) | 1 (25.0%) | 1 (6.7%) |
| Atrial fibrillation | 2 (10.5%) | 0 (0%) | 2 (13.3%) |
| Cardiac tamponade | 2 (10.5%) | 1 (25.0%) | 1 (6.7%) |
| Respiratory failure | 2 (10.5%) | 1 (25.0%) | 1 (6.7%) |
| Aortic rupture | 1 (5.3%) | 0 (0%) | 1 (6.7%) |
| Complete atrioventricular block | 1 (5.3%) | 0 (0%) | 1 (6.7%) |
| Pacemaker wire myocardial perforation | 1 (5.3%) | 1 (25.0%) | 0 (0%) |
| Ischemic cardiomyopathy | 1 (5.3%) | 0 (0%) | 1 (6.7%) |
| Pleural effusion | 1 (5.3%) | 0 (0%) | 1 (6.7%) |
| Sepsis | 1 (5.3%) | 0 (0%) | 1 (6.7%) |
| Stent-graft endoleak | 1 (5.3%) | 0 (0%) | 1 (6.7%) |
| Ventricular arrhythmia | 1 (5.3%) | 0 (0%) | 1 (6.7%) |
| Paraplegia | 0 (0%) | 0 (0%) | 0 (0%) |

## Ascending TEVAR

**ESVS Consensus on the use of TEVAR in the ascending aorta**

↓

**Systematic review 1: ascending TEVAR (aTEVAR) confined to the ascending aorta, irrespective of disease**

↓

**First consensus meeting**

↓

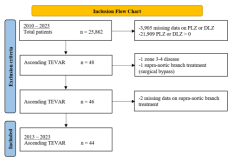
**Systematic review 2: Endovascular treatment of diseases originating in the ascending aorta**

Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

UNIVERSITÀ DEGLI STUDI DI MILANO

## aTEVAR in the VQI

- Retrospective data collection from the VQI (2010 – 2023)
- 44 pts
- Inclusion:
  - All adult patients with endovascular treatment of the ascending aorta, with proximal and distal landing zone in Z0 and no additional treatment of supra-aortic trunks.

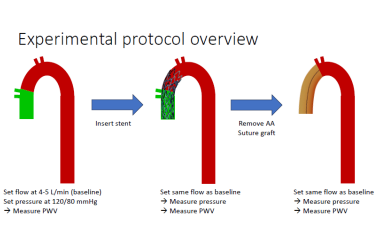



J de Kort, M Schermehorn, et al



## aTEVAR

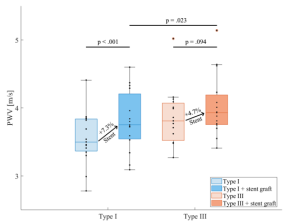
**Ex-Vivo research**






## aTEVAR

**Ex-Vivo research**




Type III aortic arch angulation increases aortic stiffness: Analysis from an ex vivo porcine model

JTCVS Open • February 2024

Tim J. Mauligers, MD,[1,2] Ariel F. Pascaner, PhD,[1] Michele Conti, PhD,[1] Matteo Schembri, MS,[1] Sonja Jelic, BS,[1] Alessandra Favilli, DVM,[1] Daniele Bissacco, MD,[1] Maurizio Domanin, MD,[1,2] Joost A. van Herwaarden, MD, PhD,[3] Ferdinando Auricchio, PhD,[1] and Santi Trimarchi, MD, PhD[1,2]



## Conclusions

- aTEVAR appears to be a technically feasible alternative to open surgery, particularly in patients of advanced age.
- The complication rate appears acceptable.
- Current aTEVAR outcomes are based on studies with a high risk of publication and selection bias.
- There is a clear need for a specific stent-graft design for the treatment of the ascending aorta.
- There is a need for a consensus regarding how and when to use aTEVAR.
- Further research on aTEVAR needs a framework to create more homogenous and less biased outcomes.



## Thank you

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