European Experience with a New Thoracic Device

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Disclosures

• Speaker name: Dittmar Böckler
• I have the following potential conflicts of interest to report:
  • Consulting
  • Employment in industry
  • Stockholder of a healthcare company
  • Owner of a healthcare company
  • Research Grant
• I do not have any potential conflict of interest
Influencing Factors of Outcome after TEVAR

- **Patient related Factors**
  - age & comorbidities
  - underlying pathology
  - arch morphology

- **Device related Factors**
  - flexibility
  - radial force
  - conformability

- **Procedure & operator related factors**
  - operator & center volume
  - intraoperative imaging
  - elective or emergency

Ref: Böckler et al., CX 2015 Book Chapter, Biba Medical
TEVAR - Limitations in the Past

Material fatigue

Bird-beaking

Collapse
Device Modifications and its on Impact of Conformability
Conformable TAG

- Designed to treat multiple etiologies
  - Aneurysm
  - Traumatic Transection
  - Type B Dissection
- Engineered to be conformable and compression resistant in 6-33% oversizing conditions
- 20 years of clinical history
- More than 125,000 devices distributed
- 10 clinical studies and a global registry data
CLINICAL STUDY RESULTS

Results of a prospective multicenter trial of CTAG thoracic endograft

William D. Jorde Jr, MD,1 Jordan Banovic, MD,1 Sina Mestari, MD,1 Joseph Babica, MD,1 Richard Comstock, MD,1 Mark Hillman, MD,1 William M. Lilienthal, MD,1 and Tim S. Mathers, MD,2


Objective: The thoracic aorta aneurysm (TAA) is more frequently being treated with endografts, the anatomic challenges of the thoracic aorta have led to design modifications of endografts. The Conformable GORE® TAG (CTAG) device (WL Gore & Associates, Flagstaff, AZ) was specifically designed to be more pliable than current products, more compliant to compression, and, more accommodating to various anatomic differences compared with the original Gore® TAG device. This allowed for a more conical anatomical shape in smaller and more tortuous thoracic aneurysms. The purpose of this study was to evaluate the safety and efficacy of the CTAG endograft system in the treatment of patients with a thoracic aneurysm involving the left subclavian artery (LSA).

Methods: Between October 2009 and November 2013, 25 patients (mean age 65 years, 21 males) with TAA and LSA anastomosis were treated with the CTAG device in 17 academic centers. Indications were LSA anastomosis (n = 17), Type B dissection (n = 2), transection (n = 1), penetrating atherosclerotic ulcer (n = 1), severe thoracic aortic aneurysm (n = 1), and chronic type B dissection (n = 1). All patients were treated with a CTAG endograft system. Mean follow-up was 29 months (range 10–67 months).

Results: The primary 1-year survival rate was 87%, renal revascularization was successful in 100% of the cases, and no aneurysm expansion occurred. Mean follow-up was 29 months (range 10–67 months). There were no endoleaks, type 1 or 2, or type 3 endoleaks, or endograft migration observed. The primary TASC II success rate was 90%.

Conclusion: The CTAG endograft shows high deployment success, good conformability, and clinical efficacy in the treatment of LSA anastomosis. However, thoracic endografts with a stent or aortic arch is associated with a relatively high endoleak rate. Further studies with more patients and longer follow-up are needed to validate the long-term results.

REFERENCE:
CTAG 08-03 Aneurysm Study (USA)

8 sites: 66 patients
all aneurysms (DTAA)
Oct 2009- Sept. 2011

30 d results:
Mortality 1.5 %
Any SAE 23 %
Paraplegia 2 %
Stroke 2 %

2 yrs. results
Type Ia Endoleak 3.2 %
TAA rupture 0 %
5 mm decrease 86%

1Jordan W et al. , JVS 2015:61:589-95
Thoracic Endovascular Aortic Repair of Aortic Arch Pathologies with the Conformable Thoracic Aortic Graft: Early and 2 year Results from a Europea Multicentre Registry

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WHAT THIS PAPER ADDS
The conformable TAG is a next generation device specifically designed for aortic arch pathologies showing high conformability with a low rate of major device related events. Endovascular therapy of aortic arch pathologies is technically demanding and associated with significant stroke risk.

Objective: To assess safety, effectiveness and clinical outcome of the conformable thoracic aortic endograft (CTAG) in the treatment of aortic arch pathologies.

Methods: Between October 2009 and December 2010, 100 consecutive patients (70 male, mean age 65 years) with aortic arch pathologies were treated with the CTAG device in five European centres. Indications were thoracic aortic aneurysm (n = 57), type B dissection (n = 11), intramural haematoma (n = 4), penetrating aortic ulcer (n = 9), and traumatic transection (n = 6). Emergency procedures were performed in 33%. The proximal landing zone (LZ) was LZ 0 in 7%, LZ 1 in 14%, LZ 2 in 43%, and LZ 3 in 36%. Data were collected prospectively and analysed for technical and clinical success. Conformability and deployment accuracy were analysed on intra-operative angiography and postoperative computed tomography. Mean follow up was 24 ± 13 months (range, 0.1–36 months).

Results: The 30 day, 1 and 2 year survival rates were 90%, 81% and 74% respectively. 2 year survival was 80% in the elective and 62% in the emergency groups (p = .02). The major 30 day complication rate was 34%; primary Type I endoleak affected 1%, retrograde dissection 1%, and the paraplegia and stroke rates at 30 days were 4% and 11%. Age ≥ 55 years was an independent predictor for mortality and complications. The primary technical success rate was 99%; device deployment was successful in 100% and accurate in 99%. Conformability to the aortic arch was achieved in 95%.

Conclusion: The CTAG stent graft shows high deployment accuracy, good conformability, and clinical effectiveness in the treatment of aortic arch pathologies. However, thoracic endovascular aortic repair in the arch is associated with a relatively high stroke rate. Further studies with more patients and longer follow up are needed to evaluate the long-term results.

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Keywords: Aorta, Aneurysm, TEVAR, Stentgraft, Arch, Stroke

5 sites: 100 patients
56 TAA, 32 B-Diss., 4 Trauma
30 day Results

Technical success 92 %
Mortality 3.3%
Complication rate 34 %
Stroke rate 11%

2 yr. Results
Overall survival 74%
- Elective 80%
- Emergency 62%
Conformable Gore® TAG® Thoracic Device Designed to Provide Optimal Outcomes in a Wide Range of Pathologies

Treatment Performance in All Lesions of the DTA

<table>
<thead>
<tr>
<th></th>
<th>Procedure N = 580</th>
<th>One Month N = 269</th>
<th>One Year N = 131</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type IA</td>
<td>0.2%</td>
<td>0.4%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Migration</td>
<td>0%</td>
<td>0.4%</td>
<td>0%</td>
</tr>
<tr>
<td>Compression</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Two Year Cumulative Results in the DTA

- 1.7% stroke / TIA²
- 1.2% paraplegia, paraparesis, spinal cord ischemia²
- 0.5% retrograde Type A dissection
# GREAT - Real World Registry

<table>
<thead>
<tr>
<th>Zone 2</th>
<th>Zone 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 179</td>
<td>N = 246</td>
</tr>
</tbody>
</table>
| **Occurrence of Type 1 Endoleaks** | **Occurrence of Device Migration** | **Freedom from Device-Related Reintervention**
| 1.3% | 0.9% | 98.3% |
| 0% | 0% | 98.8% |

* For outcome data, GREAT only collects site-reported serious adverse events. Based on one-month follow-up data (0–59 days), all pathologies.

** Device-related reinterventions include any invasive or minimally invasive measure related to a deficiency of the device(s) implanted into the aorta performed at any time following the initial procedure.
TEVAR Experience Heidelberg (n=532)
March 1997 – November 2017

- 532 TEVAR Procedures
- 190 Pat. (male 58%; mean age 66 yrs.)
- 295 CTAG Devices
- Mean 1.5 devices per patient
- 80% arch involvement (Zone 0-3)
Heidelberg Single Center 6 yr Experience

30 day Results:
- Technical success: 97.5%
- Mortality: 3.3%

Follow up Results:
- Reintervention rate: 21%
- Overall mortality (43/166): 26%
- Aortic related mortality (8/166): 5%
CTAG-Conformability in B-Dissection

- Apposition to inner wall 100%
- No association between apposition and arch type
- Less apposition in LZ 2 versus 3 (p=0.03)

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N = 1 (5.0%)
N = 13 (65.0%)
N = 6 (30.0%)

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Device Conformability and Morphological Assessment After TEVAR for Aortic Type B Dissection: A Single-Centre Experience with a Conformable Thoracic Stent-Graft Design

N = 1 (5.0%)
N = 13 (65.0%)
N = 6 (30.0%)

19 Years of Stent Graft Evolution

- TAG (1998)
- Conformable TAG (2009)
- CTAG with active control (2017)
CTAG with **ACTIVE CONTROL** System

- **Staged deployment** enables adjustment of placement and angulation
- Continuous blood flow ensures **hemodynamic stability**
- Opportunities to visualize & **refine device placement**
  - C-arm parallax correction
  - Device placement
CTAG with **ACTIVE CONTROL** System

- Intuitive deployment system allow physicians to focus on the patient, not the deployment system
  - **Optional steps** can be skipped

- **Lockwire keeps stent graft attached** to catheter throughout the procedure, **enhancing control** of the stent graft
CTAG with ACTIVE CONTROL System
Partial deployment and active control
Early Heidelberg Experience since July ‘17
(n = 13 patients, 20 devices)

N=1 - Arch Aneurysm
(out of recent IFU)

N=6 - PostCoA - Aneurysm
- B-Dissection
- PAU

N=2 - DTA aneurysm
- B-Dissection

N=4 - TEVAR-Redo w. distal extension
- TAA
- chronic B-Diss.
- PAU
CTAG - Personal Experience in 190 pat. & 295 implants (20 with active control)

- approved for aneurysms, dissections, traumatic transection
- radial force adapted to underlying disease
- highly conformable > ideal for aortic arch pathologies
- short precurved nose cone > zone 0 (ascending !)
- unsheathed > multiple devices with one access
- partial deployment > paralaxis correction, no rapid pacing
- fixed on stent graft system, total placement control
- deployment distal to proximal > accurate at celiac trunk
- time to optimize accuracy, angulation and apposition
GORE® TAG® Thoracic Branch Endoprosthesis

- Intended for treatment of the aortic arch and descending thoracic aorta
- Aortic Component
- Side Branch (SB) Component
- Aortic Extender (Optional)

Optional TBE accessory
- GORE® DrySeal Side Branch Delivery Sheath (SBDS)

European Experience to be awaited

CAUTION: Investigational Device. Limited by United States law to investigational use only.
GORE® TAG® Thoracic Branch Endoprosthesis

US Clinical Experience

Zone 2 Feasibility completed enrollment
- 31 patients

Zone 0/1 Early Feasibility completed enrollment
- 9 patients

US pivotal IDE trial began enrolling in Sept 2016
- Min 175 patients, Max. 435

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Conclusions

- TEVAR in the arch remains very challenging
- Various factors influence TEVAR
- Device design & performance have high impact on results
- New devices are about to overcome limitations
- CTAG with active control is promising but needs larger experience and longer follow up
- Thoracic branch endoprosthesis awaited in Europe
European Experience with a New thoracic device

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