Two-Year Outcomes of Endovascular Repair of Isolated Thoracic Aortic Lesions Using a Single-Branch Thoracic Endograft with Left Subclavian Artery Preservation

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Introduction

- TEVAR has become preferred management strategy for most pathologies involving the descending thoracic aorta
- When coverage of left subclavian artery (LSA) required to achieve adequate PLZ, revascularization is recommended
- Branched aortic endografts represent an alternative to surgical revascularization

Commentary: Left subclavian artery revascularization during zone 2 thoracic endovascular aortic repair: Bypass versus transposition? Just do it!

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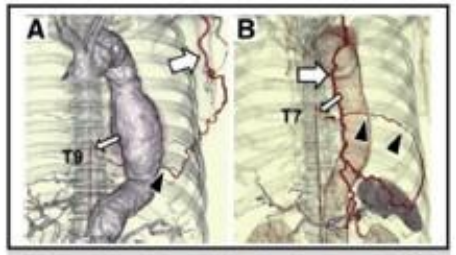
Revascularization of the left subclavian artery (LSA) is almost certainly the most important method available to mitigate the risk of spinal cord ischemia during thoracic endovascular aortic repair (TEVAR) with zone 2 coverage given the unproven benefit of lumbar cerebrospinal fluid drainage in this setting,[1,2] as well as case reports of spinal cord rescue after TEVAR via urgent LSA revascularization when cerebrospinal fluid drainage failed.[3]



Collateral circulation to Adamkiewicz artery via LSA: thoracodorsal artery (A) and left internal thoracic artery (B).

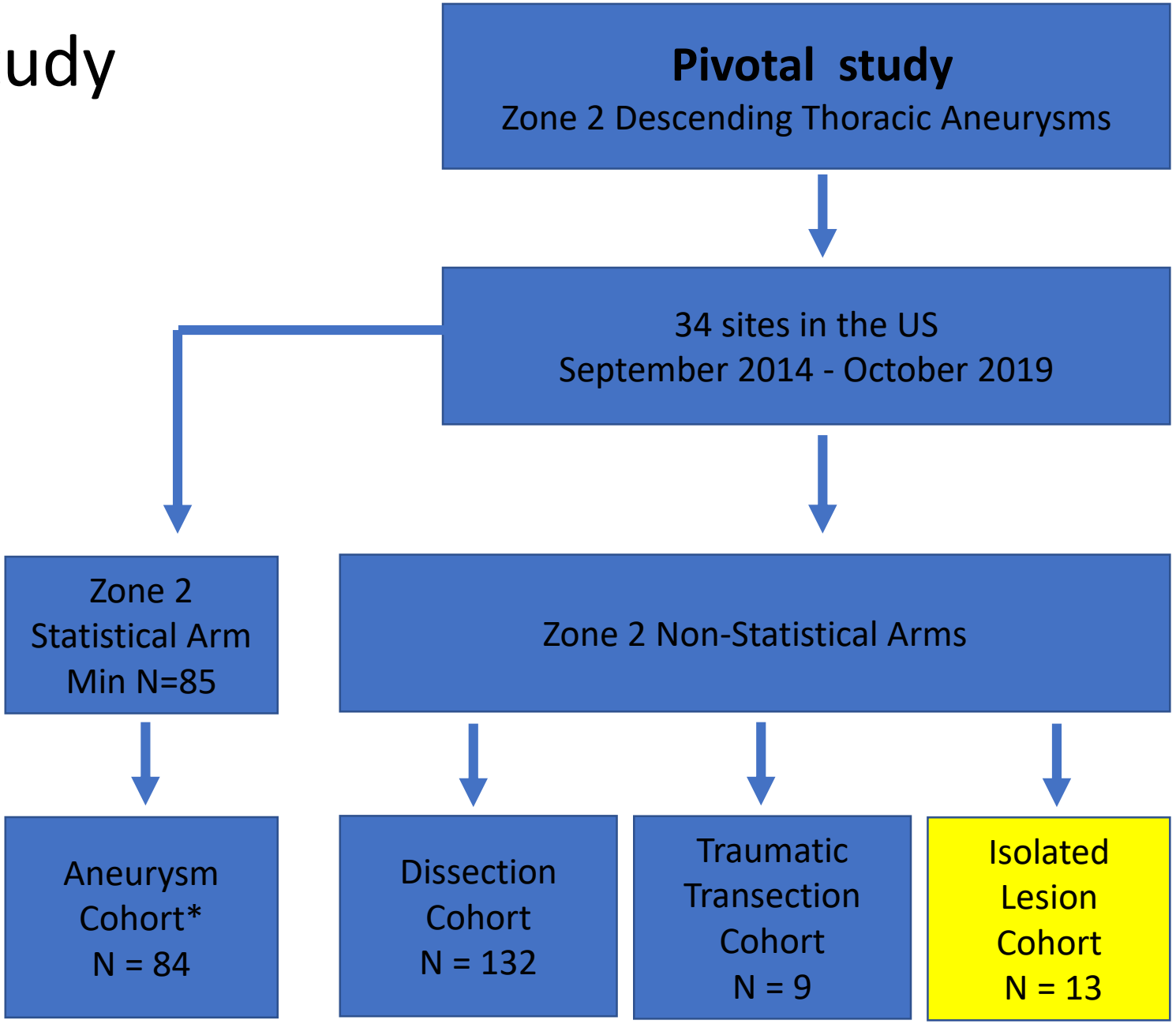
Central Message

LSA revascularization is the most important way to mitigate spinal cord ischemia during TEVAR. Whether bypass or transposition, one should revascularize the LSA whenever covered.

Methods: TBE Pivotal Study

- Non-randomized, multicenter, prospective trial
  - 34 sites
  - Zone 2 indication approved May 2022
  - Zone 0/1 indication still under investigation

- Pre-specified sub-study investigating outcomes in patients with isolated lesions (non-aneurysm, non-dissection, non-trauma) of descending aorta requiring zone 2 PLZ
  - IMH
  - PAU
  - Other isolated lesions (e.g. pseudoaneurysm, etc)

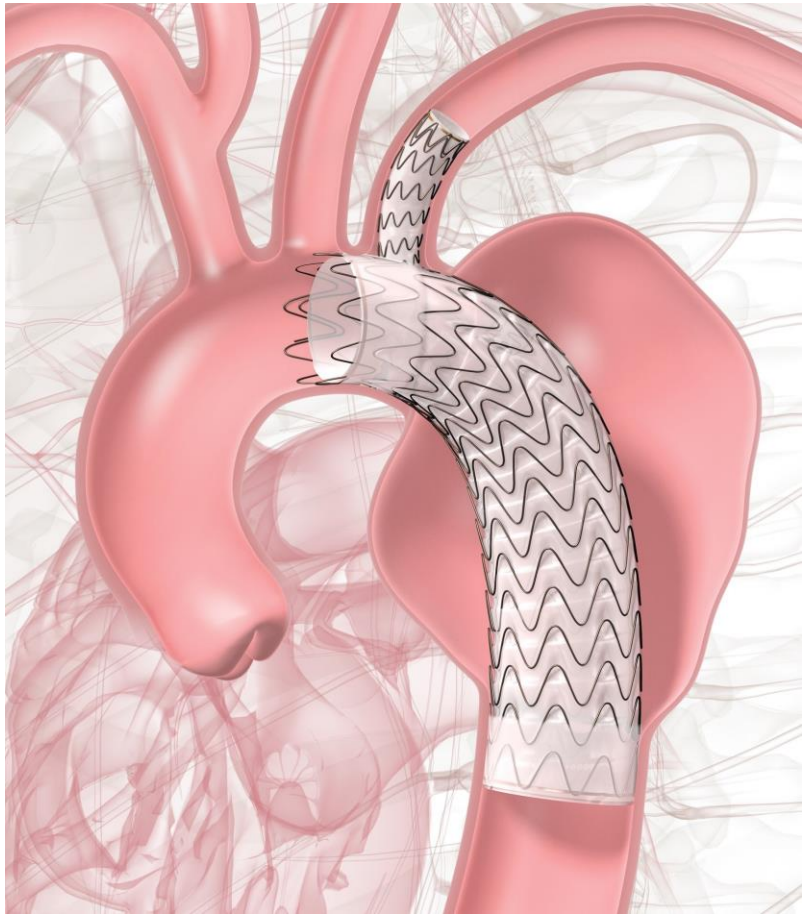


*Sites were required to enroll in the Aneurysm cohort prior to enrolling in the other cohorts

Clinical Trial Identifiers: NCT02777528

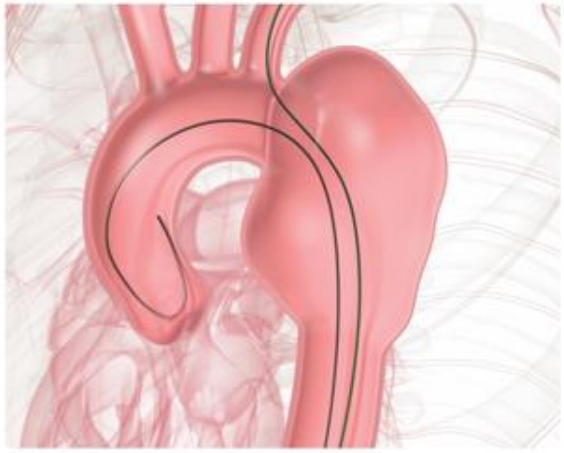
GORE® TAG® Thoracic Branched Endoprosthesis (TBE)

- Aortic Component (AC)
  - Diameter range 21-45mm
- Side Branch (SB) Component
  - Zone 2: 8- & 12-mm portals
  - Diameter range 8mm – 20mm
- Proximal Aortic Extender (Optional)
  - Diameter range 21-45mm
  - Length range 3.6 – 4.6cm

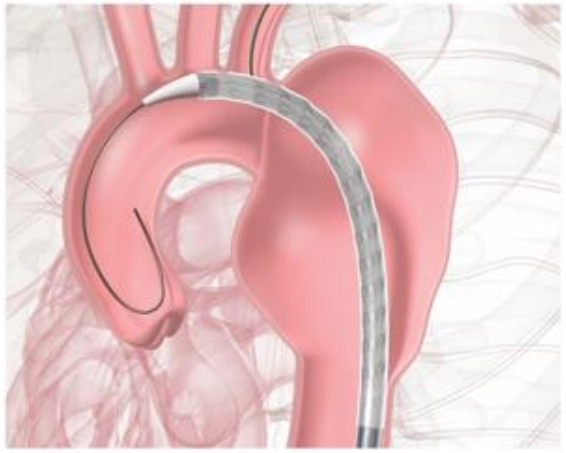


Zone 2 Aneurysm

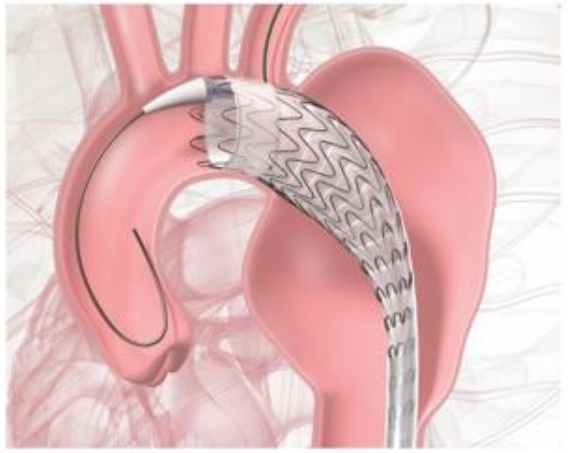
TBE Procedure in Zone 2



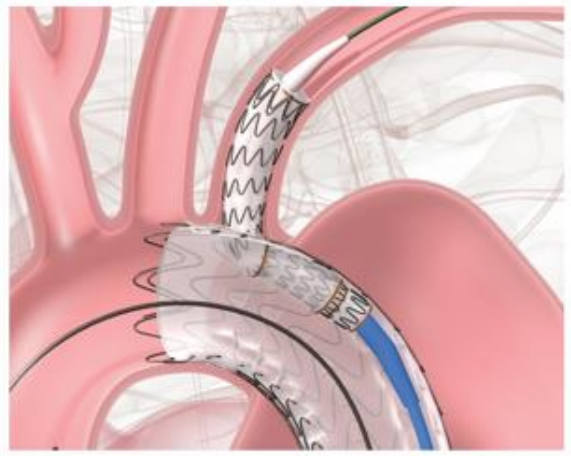
1 Insert guidewires in aorta and branch vessel.



2 Introduce Aortic Component over both guidewires into position within the arch.



3 Deploy Aortic Component and withdraw catheter.



4 Advance and deploy Side Branch Component.

Results: Demographics

- N=13 patients
  - Mean age 65±13 years
  - 54% female
- Multiple comorbidities typical of aortic surgery population

Demographics	Zone 2 Other Isolated Lesion
Number of Enrolled Subjects	13
Sex	
Male	6 (46.2%)
Ethnicity	
Not Hispanic or Latino	10 (76.9%)
Race	
White	9 (69.2%)
Black or African American	2 (15.4%)
Other	2 (15.4%)
Age (yrs)	
Mean (Std Dev)	64.8 (13.28)
BMI	
Mean (Std Dev)	25.8 (5.33)

Medical History	Zone 2 Other Isolated Lesion
Number of Enrolled Subjects	13
Atrial fibrillation	4/13 (30.8%)
Cardiac arrhythmia	5/13 (38.5%)
Chronic obstructive pulmonary disease	3/13 (23.1%)
Congestive heart failure	0/13 (0%)
Coronary artery disease	3/13 (23.1%)
Diabetes mellitus	2/13 (15.4%)
Great vessel stenosis	0/11 (0%)
Hypercholesterolemia	6/13 (46.2%)
Hypertension	11/13 (84.6%)
Myocardial infarction	2/12 (16.7%)
Nicotine use	7/13 (53.8%)
Paraplegia	0/13 (0%)
Peripheral vascular disease	1/13 (7.7%)
Prior aortic surgery	7/13 (53.8%)
Renal dialysis	0/13 (0%)
Stroke	1/13 (7.7%)
Transient ischemic attack	0/13 (0%)

Results: Prior Surgical History & Pathologies Treated

- 54% prior aortic surgery

- Pathologies treated:
  - IMH 23% (n=3/13)
  - PAU 39% (n=5/13)
  - Other isolated aortic lesion 39% (n=5/13)

Previous Aortic Surgeries	Zone 2 Other Isolated Lesion
Number of Enrolled Subjects	13
Had Previous Aortic Surgery...	7/13 (53.8%)
Ascending Aorta	3/13 (23.1%)
Aortic Arch, not involving proximal landing zone	2/13 (15.4%)
Within treatment zone, not involving distal landing zone	0/13 (0%)
DTA, outside treatment zone	0/13 (0%)
Abdominal Aorta	3/13 (23.1%)
Other Aortic Surgery	1/13 (7.7%)
Had Other Vascular Intervention	2/13 (15.4%)

Type of Other Lesion	Zone 2 Other Isolated Lesion
Number of Enrolled Subjects	13
Aortic Intramural Hematoma	3/13 (23.1%)
Penetrating Aortic Ulcer	5/13 (38.5%)
Aortic Other Isolated Lesion	5/13 (38.5%)

Results: Procedural

- 100% technical success rate
  - 31% with distal TEVAR, in addition to TBE device, to completely exclude aortic pathology
- Median procedure time 142 [66,357] minutes
- 30-day/in-hospital outcomes:
  - Mortality 0%
  - CVA 0%
  - Paraparesis/paraplegia 0%
  - New dialysis 0%

Endovascular Procedure Data	Zone 2 Other Isolated Lesion
Number of Enrolled Subjects	13
Proximal Landing Zone	
Within Surgical Graft	1 (7.7%)
Within Native Aorta	12 (92.3%)
Procedure Time (minutes)	
Mean (Std Dev)	147.0 (68.99)
Access Method	
Percutaneous	6 (46.2%)
Cut-down	6 (46.2%)
Cut-down and conduit	1 (7.7%)
Access Vessel	
Left femoral	5 (38.5%)
Right femoral	8 (61.5%)
Estimated Blood Loss During Procedure (mL)	
Mean (Std Dev)	191.2 (242.02)
Blood Loss ≥ 1000mL	0 (0%)
Transfusion Required	0 (0%)

Results: Late (24 month) Outcomes

	Endovascular Procedure	Post-Procedure	1 Month	6 Months	12 Months	24 Months	Total (Through 24 Months)
Number of Enrolled Subjects	13	13	13	13	10	9	13
Number of Subjects with Imaging in Follow-Up Window	-	2	12	11	8	8	13
Number of Subjects with Imaging or Primary Endpoint Event	-	2	12	11	8	8	13
Subjects with Primary Endpoint Event Below	0/13 (0%)	0/2 (0%)	0/12 (0%)	0/11 (0%)	1/8 (12.5%)	0/8 (0.0%)	1/8 (12.5%)
Device technical success failure	0/13 (0%)	-	-	-	-	-	0/13 (0%)
Aortic rupture	0/13 (0%)	0/13 (0%)	0/13 (0%)	0/13 (0%)	1/10 (10.0%)	0/8 (0.0%)	1/13 (7.7%)
Lesion-related mortality	0/13 (0%)	0/13 (0%)	0/13 (0%)	0/13 (0%)	1/10 (10.0%)	0/8 (0.0%)	1/13 (7.7%)
Disabling stroke	0/13 (0%)	0/13 (0%)	0/13 (0%)	-	-	-	0/13 (0%)
Permanent paraplegia	0/13 (0%)	0/13 (0%)	0/13 (0%)	-	-	-	0/13 (0%)
Permanent paraparesis	0/13 (0%)	0/13 (0%)	0/13 (0%)	-	-	-	0/13 (0%)
New onset renal failure requiring permanent dialysis	0/13 (0%)	0/13 (0%)	0/13 (0%)	-	-	-	0/13 (0%)
Protocol-Defined Reintervention	0/13 (0%)	0/13 (0%)	0/13 (0%)	0/13 (0%)	0/10 (0%)	0/8 (0.0%)	0/13 (0%)

- 24 month complete core lab adjudicated imaging follow-up
- No type I or III endoleaks, loss of LSA branch patency, or re-interventions
- N=1 patient (8%) s/p index procedure for IMH suffered new aTBAD due to distal SINE postoperative day 533
  - Resulted in aortic rupture & death
- Additional 3 (23%) non-aortic late deaths: cerebral hemorrhage (n=1; POD 129); respiratory failure (n=2; POD 167 & 875)
- No late aortic enlargement (>5 mm) or late cases of wire fracture, migration, or compression

Case Example

- 43 yo male with enlarging pseudoaneurysm s/p prior patch repair of aortic coarctation at age 5
- 26 mm x 10 cm Gore TAG TBE device with 8 mm portal
- 12 mm x 6 cm Gore TAG branch device LSA
- No endoleak or residual pseudoaneurysm, patent LSA branch now 5 years postoperatively

Conclusions

- Two-year results from a multi-center, prospective, non-randomized cohort study
- Investigational single-branched thoracic endograft for maintaining LSA perfusion in patients with isolated lesions of DTA
- Excellent 30-day/in-hospital & early mid-term outcomes
- Avoids need for LSA revascularization in patients with appropriate anatomy
- Longer-term follow-up needed to ensure continued branch patency & sustained protection from aortic events