



THE 2007 RED CARPET CARDIOVASCULAR SYMPOSIUM

Wilson Garrett, MD – Endovascular Repair of Thoracic Aneurysm

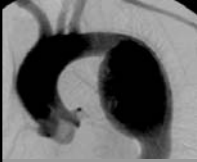


Endovascular Repair Of Thoracic Aneurysm



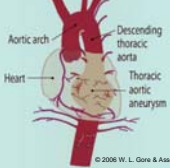
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Definition



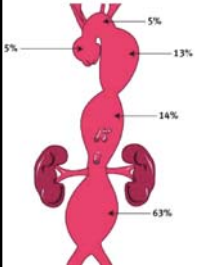
Aortic aneurysm – a dilation or bulge of the wall of the aorta which causes the diameter of the aorta to grow to more than 1.5 times its normal diameter¹

Descending Thoracic Aorta – the portion of the aorta between the left subclavian artery and the diaphragm²



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TAA Epidemiology



Incidence:

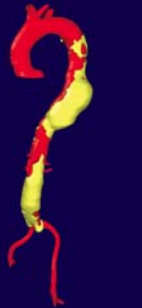
- TAA is diagnosed in approximately 15,000 to 25,000 people in the US annually¹⁻³
- TAA is diagnosed in 5.9 to 10.4 per 100,000 people per year^{4,5}
- Incidence is increasing due to⁶:
 - Aging population (increased prevalence)
 - Increased access to sophisticated imaging

Incidence and Location of Aortic Aneurysms in 1500 patients⁷

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TAA Facts

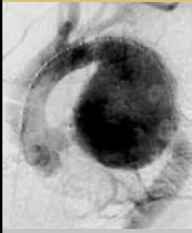


- **Mortality:** 6,000 deaths annually due to TAA³
- **Male to female ratio⁶:** ~ 1:1
- **Average age at diagnosis:** 76 for women and 63 for men⁵
- **5-year Survival (untreated patients):** 19 to 39%^{4,9}
- **Annual procedures volume:** >18,000 thoracic aortic repair procedures (includes TAA and other aortic diseases)³
- **Percent of AAA patients who also have TAA:** 12%¹⁰

Clinical Challenge

- The majority of patients with thoracic aortic aneurysms are asymptomatic¹¹
- 5-year cumulative probability of rupture: 20% (31% for Thoracic Aortic Aneurysms 6 cm or more)⁵
- Over 75% of patients with ruptured thoracic aortas die within 24 hours after the onset of symptoms¹²
- Overall fatality as a result of rupture: 94 to 97%^{4,12}


Risk Factors for Aneurysm Development¹



- Over 60 years of age
- High blood pressure
- Current or former smoker
- Arteriosclerosis
- Family history of aneurysms

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Symptoms


TAA is often called a "silent killer" because there are no obvious symptoms of the disease. Only half of patients with TAAs notice symptoms.¹

- Most thoracic aortic aneurysms are found incidentally during testing for other disorders¹¹
- Possible TAA symptoms include:
 - Pain in the chest, back, neck, or jaw¹
 - Coughing, hoarseness, or dyspnea¹
 - Plethora and edema (from compression of superior vena cava)¹¹
 - Most patients are hypertensive¹³
- Symptoms indicating a rupture may include:^{14,15}
 - Chest or back pain
 - Hemoptysis/hematemesis
 - Cardiovascular collapse



Diagnostic Methods: Imaging Evaluation¹¹

- Chest X-Ray
- Magnetic Resonance Imaging (MRI)
- Computed Tomography (CT)
- Angiography
- Transesophageal Ultrasound (TEU)

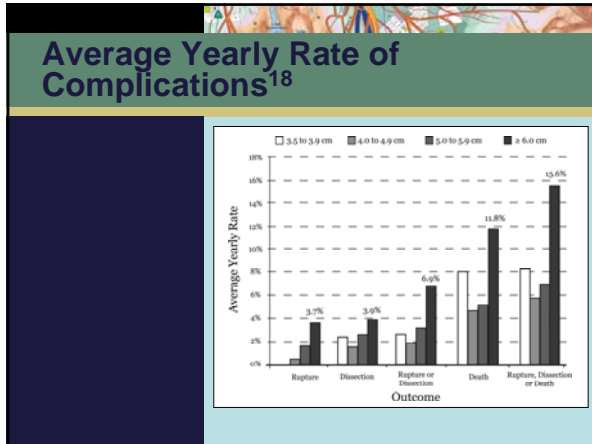


When to Treat?

- Because of increased likelihood of rupture, elective repair of TAA is recommended when:
 - The maximal aneurysm diameter is 5 - 6 cm or more or^{5,9,11,16,17,18}
 - The aneurysm is symptomatic or,^{5,11}
 - The aneurysm is complicated by dissection⁹
 - Smaller aneurysms may be considered for repair if they are rapidly enlarging¹⁴

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Treatment Options

- Medical management/monitoring ("watchful waiting")
- Open surgical repair
- Endovascular stent-graft repair


Medical Management / Monitoring

- Wait, watch, and control hypertension¹
- Typically reserved for aneurysms < 5 or 6 cm that are not rapidly expanding or causing symptoms¹
- Most commonly monitored with CT or MRI scans every 6 months¹

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Open Surgical Repair



- Replacement of the weakened portion of the aorta with a synthetic graft¹⁹
- Access via anterior or lateral thoracotomy
- Often performed with either partial or full cardiopulmonary bypass to temporarily redirect blood flow around the aneurysm^{13,20}

Open Surgical Repair


Benefits

- 5-year survival: 58 - 70%^{10,14} vs. 19 to 39% for untreated patients^{4,9}

Challenges

- 30-day operative mortality (for elective procedures): 8 - 20%^{5,14,15,18,21}
- Survivors suffer from morbidity rates of up to 50% related to renal, intestinal, and spinal cord ischemia¹⁴
- Neurologic complication rate (paraplegia, paraparesis, stroke): 8 - 15%^{14,15}
- Average 7 to 10 days hospitalization¹

Endovascular Stent-Graft Repair



Endovascular Stent-Graft Repair

- Access via direct iliac, femoral, or aortic arteriotomy or via conduit²²
- Stent-grafts are deployed using angiographic guidance²²
- Anchoring of endoluminal device above and below TAA in normal arterial segments
- Tube-shaped stent-graft relines the vessel and excludes the aneurysm from circulation
- Exclusion and depressurization prevent TAA rupture
- May be performed under general, regional or local anesthesia

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Endovascular Technique



Pre Stent-Graft Deployment



Post Stent-Graft Deployment




Clinical Outcomes: Endovascular vs. Open Surgical Repair of DTA*

Study Methods

- A multi-center, prospective, non-randomized study conducted at 17 sites

Study Design

- Controlled clinical trial
 - Test subjects treated with the GORE TAG® Thoracic Endoprosthesis (n=140)
 - Control subjects treated by open surgical repair
- One year clinical study endpoints
- Five year follow-up ongoing

Results

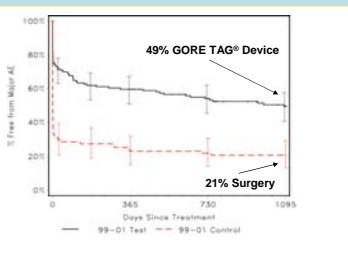
At one year, the endovascular group, as compared to the open surgical control group, had:

- One-fifth the paraplegia / paraparesis rate (3% vs. 14%)
- Paraplegia rates in the test and control groups of .07% and 8.5% respectively
- One-sixth the operative mortality (1% vs. 6%)
- Zero aneurysm ruptures at 3 years
- Lower aneurysm-related death through two years (3% vs. 10%)
- 80% less procedural blood loss on average (472 ml vs. 2,402 ml)
- Shortened average ICU stay (1 day vs. 3 days)
- Shortened average hospital stay (3 days vs. 10 days)
- Two times faster return to normal activity (30 days vs. 78 days)

*GORE TAG® Thoracic Endoprosthesis. Summary of Results from US Pivotal Trial
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Clinical Outcomes: Endovascular vs. Open Surgical Repair of DTA*

Freedom from major adverse events (MAE) through 3 years of follow-up.



Days Since Treatment	99-01 Test (GORE TAG Device)	99-01 Control (Surgery)
0	~80%	~30%
365	~65%	~25%
730	~55%	~20%
1095	49%	21%

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Clinical Outcomes: Endovascular Stent-Grafts*

Freedom from Any Major Device-Related Event (through 3 years) for the GORE TAG® Device Group: 94%

Regular and routine follow-up imaging visits (Chest x-ray and CT Scan) are required (1 month, 6 months, 12 months, and annually thereafter)

*GORE TAG® Thoracic Endoprostheses: Summary of Results from US Pivotal Trial

GORE TAG Device	
Freedom from Any Major Device-Related Event	94%
Major device-related events	
Incidence (%)	
Rupture	0
Treatment-related	2 (1%)
Endoprostheses migration	1 (1%)
Aneurysm enlargement	3 (2%)
Branch vessel occlusion	1 (1%)
Endoleak	4 (3%)

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Questions?

A 3D reconstruction of a thoracic aorta with a stent-graft in place. The stent-graft is a mesh-like structure that covers the aneurysm, preventing it from rupturing. The image shows the aorta in a curved, vertical orientation, with the stent-graft extending along its length.

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