



IMPROVE-AD

IMPRoving Outcomes in
Vascular DisEase-Aortic Dissection

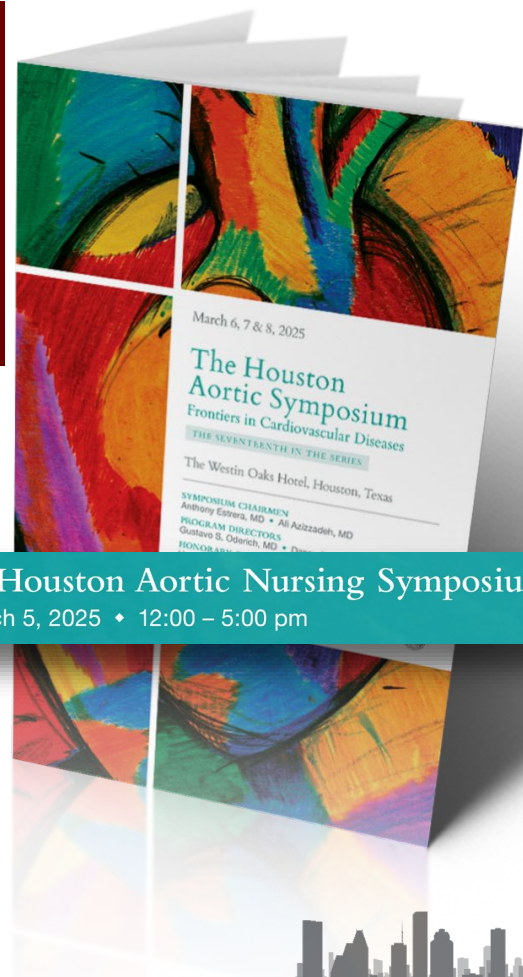
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7th Annual Houston Aortic Nursing Symposium

Wednesday, March 5, 2025 • 12:00 – 5:00 pm

IMPROVE-AD (IMPRoving Outcomes in Vascular DisEase – Aortic Dissection) is a clinical research study. The study aims to understand how best to treat **type B aortic dissection**. This is a condition involving a tear in the wall of the lower part of the aorta.

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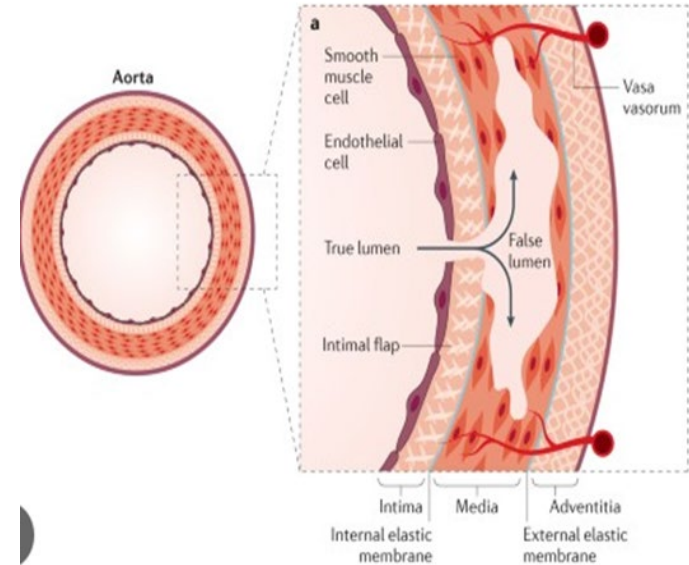
What is Aortic Dissection?

- Aortic dissection is a life-threatening condition where a tear occurs in the inner layer of the aortic wall, allowing blood to flow between the layers of the vessel wall.
- This can cause a separation of the layers and potentially rupture the aorta, leading to massive internal bleeding and death if untreated.
- Aortic dissection is rare but has high mortality if not promptly diagnosed and treated.
- Incidence: Approximately 2.9–3.5 cases per 100,000 people annually.
- Most common in individuals aged 60-80, though it can affect younger populations, especially in the presence of connective tissue disorders.
- Risk Factors for Aortic Dissection-Hypertension, Genetic and Connective Tissue Disorders, Atherosclerosis, Age, family history, smoking, and previous heart surgery



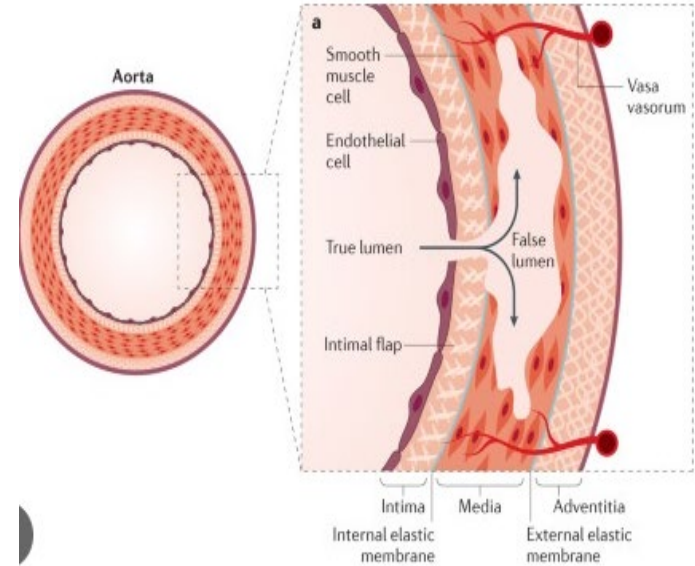
Pathophysiology of Aortic Dissection

- Aorta consists of three layers: intima (inner), media (middle), and adventitia (outer).
- Dissection occurs when there is a tear in the intima, allowing blood to enter the media and split the vessel layers.



What is type B aortic dissection?

- **Type B aortic dissection** is a condition involving a tear in the wall of the lower part of the aorta. More specifically Type B involves the descending thoracic or thoracoabdominal aorta distal to the left subclavian artery without involvement of ascending aorta.



What is type B aortic dissection?

- Most cases are uncomplicated. This means that the tear has only gone through the inner wall of the aorta and the blood supply to other organs has not been greatly decreased. Uncomplicated type B aortic dissection is defined as dissection without involvement of the aorta at or proximal to the innominate artery, without rupture and/or clinical malperfusion



Why is IMPROVE-AD being done?

- Doctors aren't sure how best to treat type B aortic dissection yet.
- Current data on treatments for type B aortic dissection do not provide enough information that applies to women or diverse racial and ethnic groups



What treatments are being studied in IMPROVE-AD?

- The study treatments are both already performed for the treatment of type B aortic dissection in the United States
- One study group will receive a minimally invasive procedure called TEVAR (thoracic endovascular aortic repair) along with medicine. A metal tube (called a stent), is inserted into the damaged part of the aorta through a small cut in the groin
- The other study group will receive medicine and routine check-ups.
- That means participants have a 50% chance of being in either group



Primary Study Objective

- whether an upfront invasive strategy of TEVAR plus medical therapy reduces the occurrence of a composite endpoint of all-cause death or major aortic complications (MAC) compared to an upfront conservative strategy of medical therapy with surveillance for deterioration in patients with uncomplicated type B aortic dissection



Inclusion/Exclusion Criteria

- Participants must be at least 21 years old, have received a diagnosis of type B aortic dissection in the last six weeks, not have a genetic condition that can affect the aorta (such a Marfan syndrome or Vascular Ehlers-Danlos syndrome), and be receiving treatment at a participating hospital



Randomization and Stratification

- Participants will be randomized using a 1:1 randomization scheme via an interactive web system, stratified by the presence of one of the high-risk features. High risk features include: total aortic diameter ≥ 40 mm, primary entry tear diameter ≥ 10 mm, maximum false lumen diameter of ≥ 22 mm



UPFRONT MEDICAL THERAPY WITH SURVEILLANCE FOR DETERIORATION (CON)

- Participants randomized to upfront Medical Therapy with Surveillance for Deterioration will be treated per routine clinical care with suggested antihypertensive therapy and cardiovascular risk factor reduction as per appropriate cardiovascular guidelines
- During follow up, participants randomized to the CON strategy may receive TEVAR and/or open repair for predefined disease complications (rupture, malperfusion, embolization, or fistula), aneurysmal degeneration of $> 55\text{cm}$ or significant growth ($> 5\text{ mm}$ over 6 months) or refractory symptoms.



UPFRONT TEVAR (INV) WITH MEDICAL THERAPY (INV)

- Participants randomized to upfront TEVAR will receive a commercially available device customized to their individual anatomical requirements.
- Recommendations regarding cardiovascular risk reduction will mirror those of the Medical Therapy with Surveillance for Deterioration (CON) arm



Study Follow-up

- Participant follow-up will be performed at 45 days, 6 months, 12 months, and every 6 months thereafter up to a maximum possible follow-up of 72 months. All study-related follow-up will be done via centralized call center.
- Meds, Heart Rate/ Blood Pressure, QOL Questionnaires, Major Aortic Complications, SOC Labs and Imaging, Prespecified Secondary Events



Conclusion

- Aortic dissection is a life-threatening condition that requires early diagnosis, aggressive blood pressure management, and often surgical intervention.
- People like you can help us understand how to treat type B aortic dissection by contacting study team at 713-486-5194 or email mariano.r.montemayor@uth.tmc.edu






Thank You!



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