Status of the Multicenter RCT (IMPROVE-AD_ To Evaluate the Value of TEVAR Versus Medical Therapy in Acute And Subacute TBADs

Rationale And Recruitment To Date?

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VEITH SYMPOSIUM

Faculty disclosures

F. F. Mussa: None

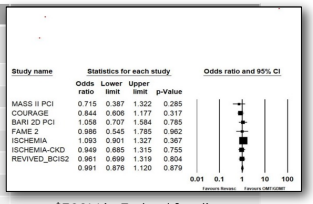
- **Special thank you FJV**

IS THERE EVER A REASON FOR TEVAR IN uTBAD OUTSIDE RCT??

SCREEN AND ENROLL YOU PATIENT
IT IS THE RIGHT THING TO DO

PCI vs. OMT in SIHD

Study Name	N	
MASS II	661	
COURAGE	2287	
BARI 2D	2368	
FAME 2	1220	
ISCHEMIA	5179	
ISCHEMIA-CKD	777	
REVIVED_BCIS2	700	
Total	> 13000	> $300M in Federal funding



Why IMPROVE-AD

- We do not have a SOC that is based on high quality data
- OMT was the practice we inherited and it works/fails
- TEVAR is the practice we enjoy and think it might work in some but not without risks and failures

OMT is DEFINITELY NOT the SOC and NEITHER IS TEVAR

EQUIPOISE

What will IMPROVE-AD Answer?

- Timing
- Extent (proximal and distal LZ)
- How many actually need open or endovascular repair?
- Genetics?
- Cost-effectiveness and quality of life (QOL)?
- Imaging….10000 CT scans?
- What about BP medications and treatment goals?
- PROM?
- What does FLT and remodeling mean?
- HRF?!

All You Need to Know about TBAD!!!

The New England Journal of Medicine

Please review the Supplemental Files folder to review documents not compiled in the PDF.

Management of Acute Type B Aortic Dissection

Journal:	*New England Journal of Medicine*
Manuscript ID	24-05257.R1
Article Type:	Review Article
Date Submitted by the Author:	n/a
Complete List of Authors:	Mussa, Firas; McGovern Medical School at UTHealth Houston, Cardiothoracic and Vascular Surgery Kougias, Panos; SUNY Downstate Health Sciences University, Department of Surgery; Brooklyn VA Medical Center,
Keywords:	
Abstract:	

IMPROVE - AD

IMPRoving **O**utcomes in **V**ascular dis**E**ase **A**ortic **D**issection

NIH National Heart, Lung, and Blood Institute

UTHealth Houston Heart & Vascular

Duke Heart
Duke Clinical Research Institute

DOWNSTATE HEALTH SCIENCES UNIVERSITY

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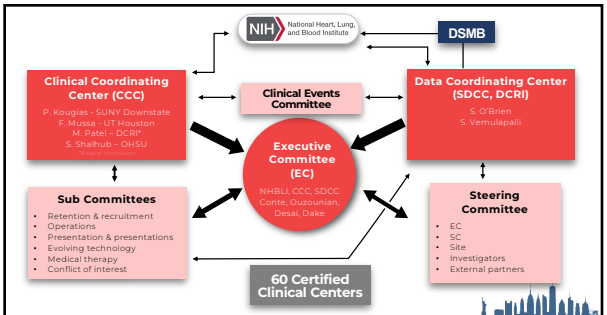
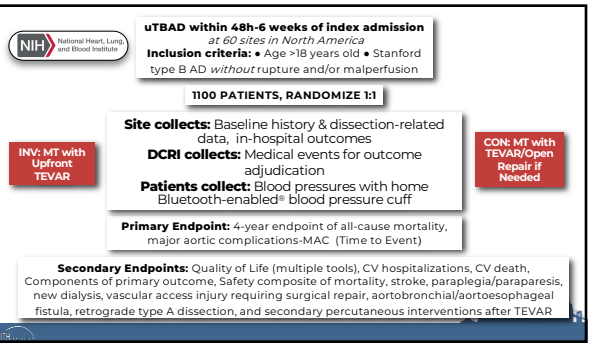


Hypothesis

In patients with **uTBAD**, **upfront TEVAR** is superior to **SOC** of medical therapy + TEVAR and/or Open Repair when needed



Primary Outcome

4-year endpoint of All-Cause Death & Major Aortic Complications (MAC):

- Rupture (clinical-pain, imaging-hemothorax/inflammation around aorta/hemoperitoneum)
- Visceral, renal or limb Malperfusion (Clinical, Laboratory and Imaging)
- New aortic tear requiring intervention
- Retrograde aortic dissection
- Dependence on outpatient dialysis (chronic)
- Major amputation (above ankle)
- Tracheostomy
- fistula formation (e.g., aorto-esophageal, aorto-tracheal)
- Spinal Cord Ischemia with paralysis or paresis (power 0-2)
- Stroke modified Rankin Scale 2-5
- **AD-related intervention in either group defined as:**
  - Open TAA/TAAA Repair
  - Fenestrated and/or Branched Endovascular Repair of TAAA
  - Repeat TEVAR

Measured at 30 days, 6 months, 1 year and every 6 months through end of follow up

Inclusion Criteria

1. Age > 21 years
2. Stanford type B aortic dissection not involving the aorta at or proximal to the innominate artery, without rupture and/or malperfusion (renal, mesenteric, or extremity)
3. Acuity: within 48 hours – 6 weeks of index admission
4. **Anatomically suitable to complete Zone 2 TEVAR within IFU of FDA-approved devices**
5. Ability to provide written informed consent and comply with the protocol

Exclusion Criteria

1. Ongoing systemic infection
2. Pregnant or planning to become pregnant in the next 3 months
3. Life expectancy related to non-aortic conditions < 2 years
4. Unwilling or unable to comply with all study procedures including serial imaging follow-up
5. **Known patient history of genetic aortopathy**
6. **Penetrating Aortic Ulcer and Intramural hematoma**
7. Iatrogenic (traumatic) aortic dissection
8. **Prior aortic surgery for dissection**

Proposed Ancillary Studies

- QOL and Health Economics and Outcomes Research (HEOR)-R01:
- GENETICS AND BIOREPOSITORY-R01
- IMAGING (INDUSTRY): Industry

Non-invasive hemodynamic and biomechanic imaging methods for early risk prediction in aortic dissection-Nick Burris-UM

The Geometric Evolution of Aortic Dissections: Predicting Surgical Success with Shape. Luka Pocivavsek-UChicago

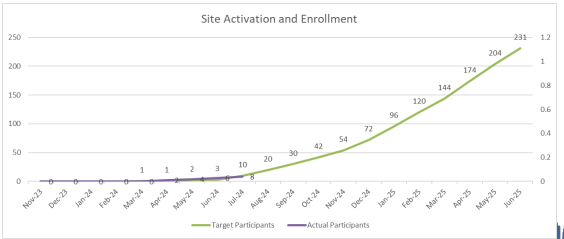
Study Updates: Enrollment

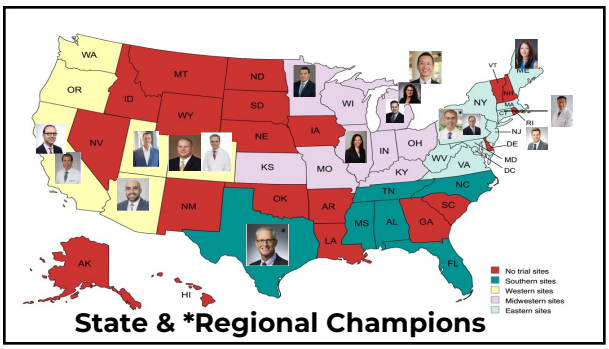
- First site activated 2/5/2024
- First Patient enrolled 04/2024
- Met year 1 milestones and funded for Year 2
- As off today: 49/60 sites activated
- 27 total enrollments

Target Enrollment

3-5/site/year

Enrollment Curve (over the next year)



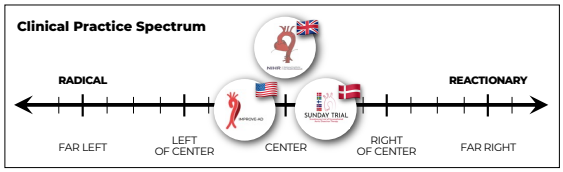


State & *Regional Champions

Tips for Enrolling

- Takes an hour to discuss with patient
- Let the dust settle (2-3 days)
- FIRST encounter: Residents screen→ coordinator→ PI
- Two known treatment which work fine. We do not know which is best
- Extra team to monitor BP, stent, medications
- Genetics
- Nothing different from what you would normally get
- Racial, ethnic, cultural sensitivities

It's a choice....really?



Only OMT | SOC: OMT + TEVAR | **SUPPORT PRODUCING DATA ENROLL in RCT** | TEVAR HRF | TEVAR ALL

Thank You!

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