

CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE  
CONTROVERSIES & UPDATES IN VASCULAR SURGERY

**JANUARY 19-21 2017**

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER

**PARIS, FRANCE**



# Why We Need Another Trial For Uncomplicated TBAD?

**Firas F Mussa, MD**



JANUARY 19-21 2017

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER

PARIS, FRANCE

## Disclosure

Speaker name: Firas F Mussa

X I do not have any potential conflict of interest



# INSTEAD....

- Effect size: 23% OMT → 5% TEVAR → 80% RRR
- OVERESTIMATED → NEVER seen in RCT
- UNDERPOWERED
- Clinical PLUS Surrogate Endpoints (false lumen thrombosis/aortic remodeling as in indication impact of TEVAR).



## Uncomplicated Type B Aortic Dissection

**TEVAR + Medical  
Therapy**

**Medical Therapy**  
TEVAR/Surgery reserved for  
complications during follow-up

Primary endpoint:  
**Major Aortic Complications-Free Survival over  
median follow-up of 5 yrs**





# Why Do We Need A Trial?

- Is TEVAR indicated in ALL uTBAD?
- What is the best/optimal medical therapy?
- What happens to the false lumen with TEVAR/OMT?
- Imaging/genetic predictors for aneurysmal degeneration after TBAD?
- Who needs to be repaired with OMT?
- Predictors of mortality after TEVAR or OMT?
- When to intervene with TEVAR?
- How frequent to follow up?
- Covering the LSA?
- Extent of TEVAR coverage, fate of abdominal aorta



# Feasibility of a proposed randomized trial in patients with uncomplicated descending thoracic aortic dissection: Results of worldwide survey



Firas F. Mussa, MD, MS,<sup>a</sup> Joseph S. Coselli, MD,<sup>b</sup> and Kim A. Eagle, MD<sup>c</sup> *New York, NY; Houston, TX; and Ann Arbor, MI*

The trial we propose will be the first multicenter, randomized, trial investigating the role of thoracic endovascular aortic repair (TEVAR) of uncomplicated type B aortic dissection (TBAD) compared to conservative (medical) management. To document the current management approaches for uncomplicated TBAD, we performed an international survey in 130 centers (in US and worldwide), of whom 114 (89%) responded. Sixty-three (54.8%) respondents do not routinely stent uncomplicated TBAD, and 43 (37.4%) perform TEVAR based on various imaging criteria. One hundred and one respondents (88.6%) agreed that equipoise was present. Almost all respondents agreed that demonstrating an improvement in major aortic complication-free survival with TBAD would lead to change in practice. The results of the survey demonstrate that a major randomized trial to determine the optimal management strategy for uncomplicated TBAD is warranted. (*Am Heart J* 2016;181:1-8.)



# Methods

- We identified 130 centers in US and abroad that treat patients with aortic dissection by TEVAR from within IRAD and Society for Vascular Surgery-Vascular Quality Initiative.
- Both registries include experts from vascular and cardiac surgery, cardiology, radiology and vascular medicine.
- Study data were collected and managed using REDCap electronic data capture tools hosted at NYU
- A link to the survey was sent by individual communication to investigators as well as group email to the membership of the International Registry for Aortic Dissection (IRAD).
- A second request was sent two weeks later. A third request was sent 6 month later



# Results

- 114 replied yielding a response rate 89%, including 79 centers in the US, 4 in Canada, 30 in EU, and 1 in Israel.
- Eighty-six respondents were vascular surgeons, 18 cardiac surgeons, 10 cardiologists, and 2 radiologists.
- All centers indicated the existence of an adequate research infrastructure, including prior trial participation, dedicated coordinators, and number of research staff with NIH/FDA trial experience.

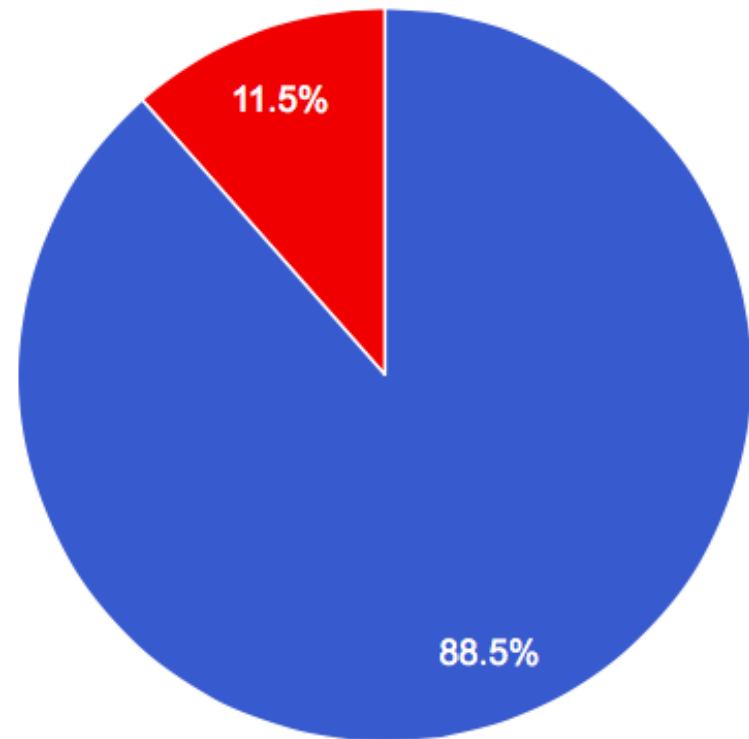




# Is there clinical equipoise in your center?

Total Count (N)	Missing	Unique
113	<a href="#">1 (0.9%)</a>	2

Counts/frequency: **Yes** (100, 88.5%), **No** (13, 11.5%)

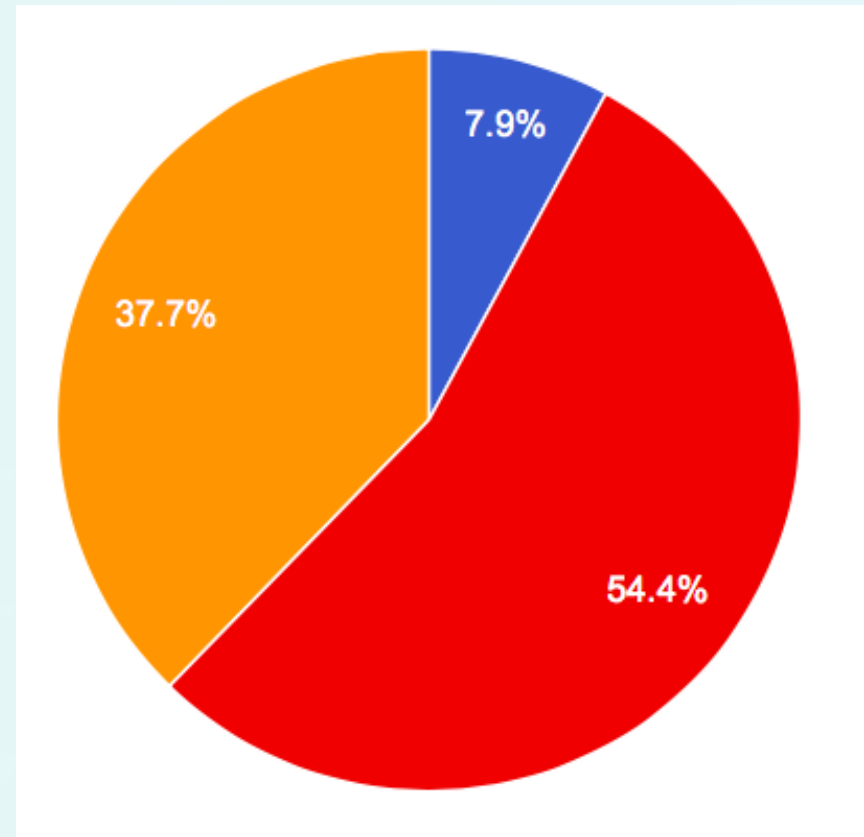




# Do you routinely stent uncomplicated type B aortic dissection?

Total Count (N)	Missing	Unique
114	0 (0.0%)	3

Counts/frequency: **Yes** (9, 7.9%), **No** (62, 54.4%), **Based on imaging** (43, 37.7%)





- The National Heart, Lung, and Blood Institute convened a Working Group in 2005, in Bethesda, Maryland to identify clinical research opportunities and critical gaps in our knowledge about thoraco-abdominal aortic diseases in order to facilitate clinical detection and treatment of these diseases.
- Support a large multicenter clinical trial to compare optimal medical therapy to endovascular repair in acute uncomplicated type B dissection.



# Conclusions

- We need a trial more than ever
- Pragmatic, simple, international, multicenter, prospective, randomized, open-label clinical trial
- Sample size may be an issue
- Funding