

Identifying at risk patients: who could benefit from TEVAR in uncomplicated type B dissections



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Disclosure

Speaker name:

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- I have the following potential conflicts of interest to report:
 - Consulting
 - Employment in industry
 - Stockholder of a healthcare company
 - Owner of a healthcare company
 - Other(s)
- I do not have any potential conflict of interest



What is the definition of an Uncomplicated Type B Dissection?

Complicated TBAD

- Traditionally
 - ~~1. Rupture~~
 - ~~2. End organ malperfusion~~
 - ~~3. Refractory pain~~
 - ~~4. Refractory HHT~~
 - ~~5. Rapid aortic expansion~~



Rest are classified
'Uncomplicated'



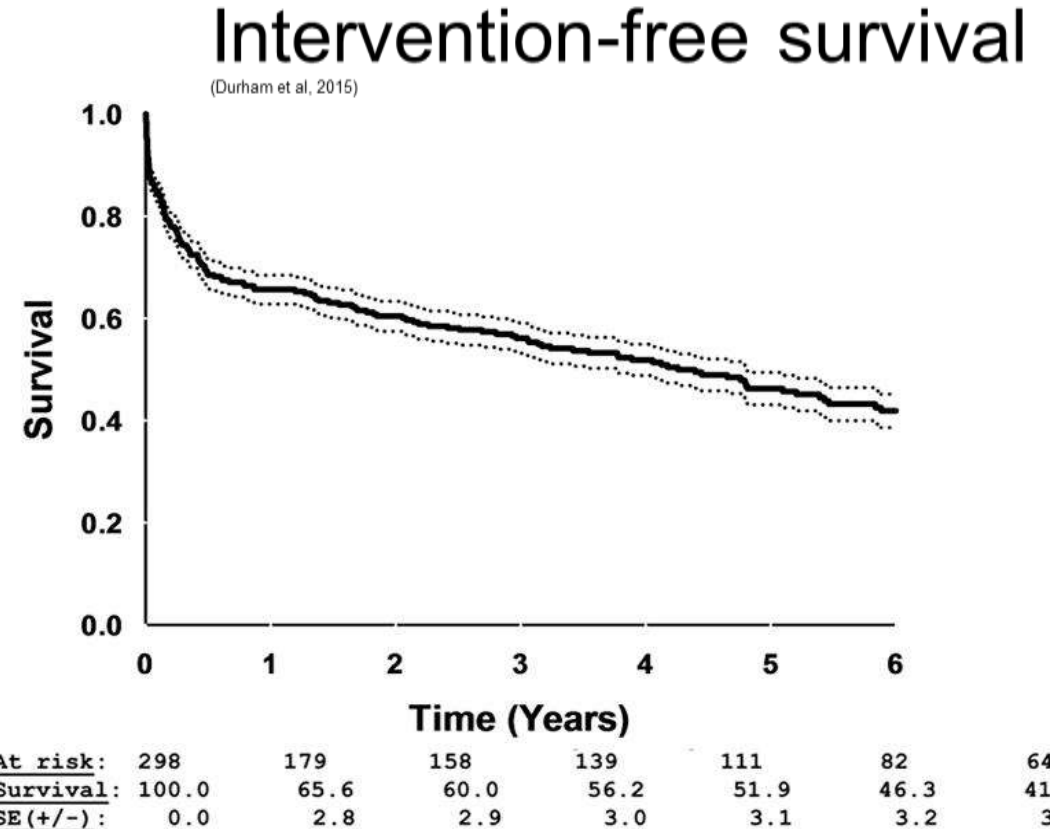
Uncomplicated Type B Dissections (uTBAD)

- uTBAD represent 70% of all presentations of TBAD
- A smorgasboard of different pathologies
 - Dissection +/- IMH / penetrating ulcers
 - Different proximal and distal entry tear positions
 - Degree of thrombus
 - Size of false lumen
 - Thickness of dissection flap
 - Etc. etc.
- Which of these uTBAD are at risk?



Data sets showing risk over time for TBAD

- Durham et al (2015) managed 298 type B dissections with medical management only.
 - **12.0%** (37) failed medical therapy within 2 weeks.
 - **58.4%** (174) had treatment failure over 6 years: 119 deaths (38.3%), 87 interventions (29.2%).
 - **38%** of patients develop aneurysmal degeneration



What factors make these uTBAD patients more at risk?

- Genetics
 - Confirmed connective disease (Marfans / Ehlers Danlos)
- Anatomical factors
- Physiological factors
- Treatment received early in the course and onset of the disease



Current evidence in predictors of aortic growth and events in acute type B aortic dissection

Domenico Spinelli, MD, PhD,^{a,b,c} Filippo Benedetto, MD, PhD,^a Rocco Donato, MD, PhD,^a Gabriele Piffaretti, MD, PhD,^d Massimiliano M. Marrocco-Trischitta, MD, PhD,^b Himanshu J. Patel, MD,^c Kim A. Eagle, MD,^c and Santi Trimarchi, MD, PhD,^{b,e} Messina, Milan, and Varese, Italy; and Ann Arbor, Mich

Acquired

Predictors of aortic dissection

Tomoaki Kudo
Noriyasu Mori

Partial Thrombosis in Patients with Acute Type B Aortic Dissection

Thomas T. Tsai, M.D., M.Sc., Arturo Evangelista, M.D., Christoph A. Nienaber, M.D., Truls Myrmel, M.D., Gabriel Meinhardt, M.D., Jeanna V. Cooper, M.S., Dean E. Smith, Ph.D., Toru Suzuki, M.D., Rossella Fattori, M.D., Alfredo Llovet, M.D., James Froehlich, M.D., Stuart Hutchison, M.D., Alessandro Distanto, M.D., Thoralf Sundt, M.D., Joshua Beckman, M.D., James L. Januzzi, Jr., M.D., Eric M. Isselbacher, M.D., and Kim A. Eagle, M.D., for the International Registry of Acute Aortic Dissection*

Kudo et al

te

The

Adult:



Predictors of late aortic intervention in patients with medically treated type B aortic dissection

Samuel I. Schwartz, MD, Christopher Durham, MD, W. Darrin Clouse, MD, Virendra I. Patel, MD, MPH, R. Todd Lancaster, MD, MPH, Richard P. Cambria, MD, and Mark F. Conrad, MD, MMSc, Boston, Mass

Fate

impair

aortic events

Takeshi Shimamoto, MD, PhD, Tatsuhiko Komiya, MD, PhD, and Hiroshi Tsuneyoshi, MD, PhD



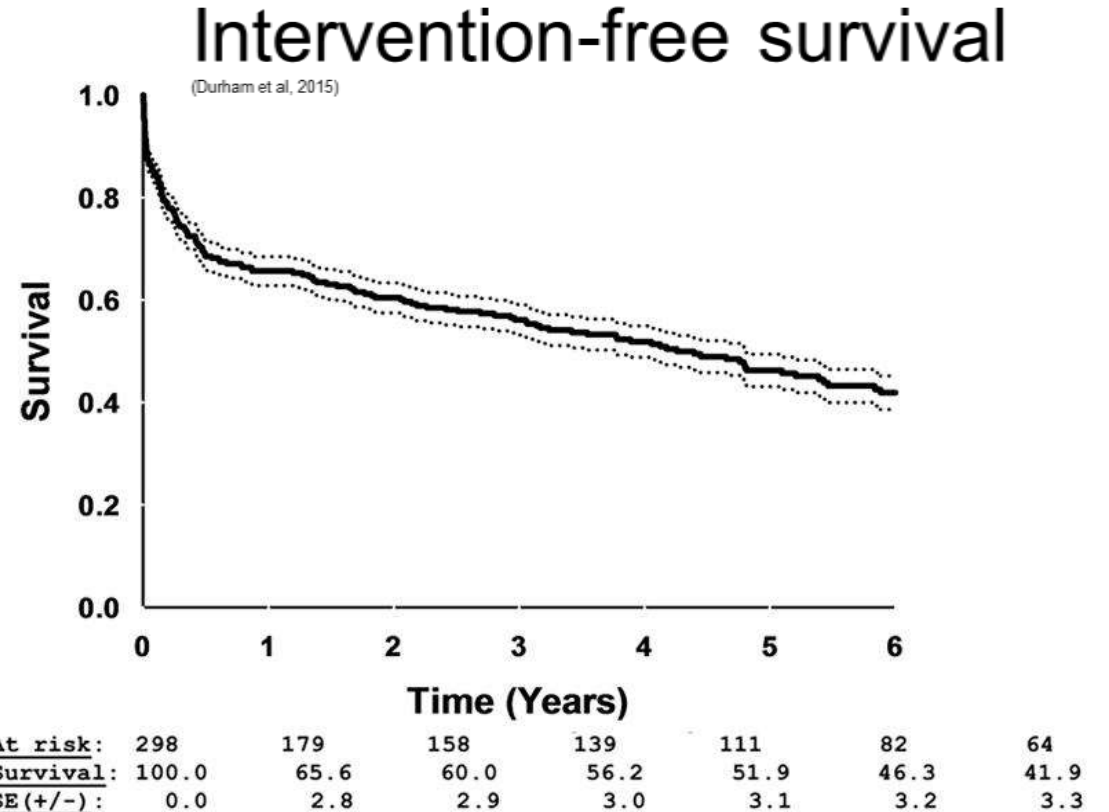
Higher risk uTBAD **anatomical** characteristics

- Large native aortic diameter (>40mm),
- Total aortic diameter – true and false lumens >60mm
- Large size of entry tear (>10mm), large FL diameter and thickness, inner curve tear
- Partial false lumen thrombosis
- Ulcer like projections
- Progression of IMH
- Fusiform index >0.64
- Progressive enlargement of total aortic diameter or false lumen diameter



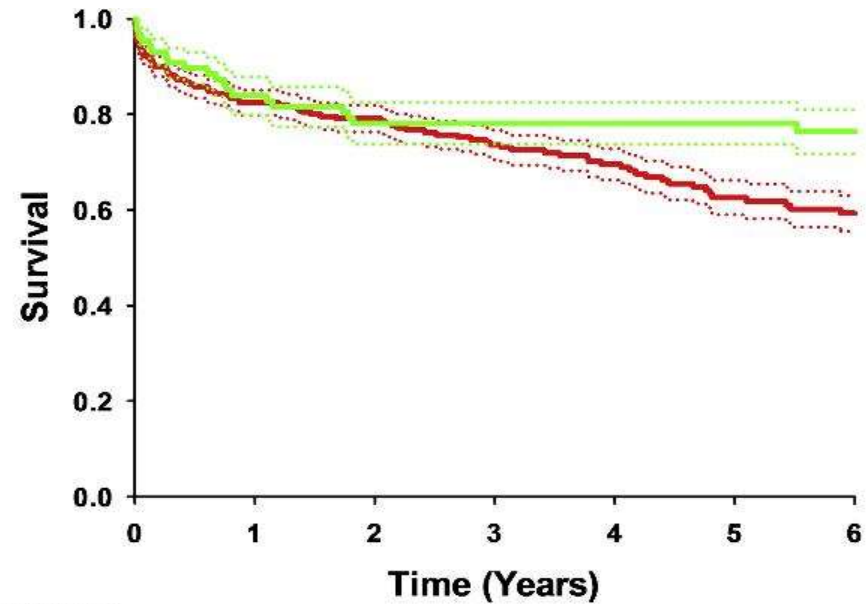
There is clear evidence that uTBAD treated without TEVAR are at risk

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 - 58.4% (174) had treatment failure over 6 years: 119 deaths (38.3%), 87 interventions (29.2%).
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6 Year survival TEVAR vs medical mx

(Durham et al, 2015)



<u>Intervention:</u>							
<u>At risk:</u>	87	73	68	65	59	53	43
<u>Survival:</u>	100.0	83.9	78.2	78.2	78.2	78.2	76.4
<u>SE(+/-):</u>	0.0	3.9	4.4	4.4	4.4	4.4	4.7
<u>Medically Managed:</u>							
<u>At risk:</u>	211	174	167	136	108	82	65
<u>Survival:</u>	100.0	82.5	79.2	73.6	68.9	62.6	59.3
<u>SE(+/-):</u>	0.0	2.6	2.8	3.1	3.3	3.6	3.8



Randomized Investigation of Stent Grafts in Aortic Dissection Trial

INSTEAD XL 5 YEARS FOLLOW-UP¹

Study Purpose

Characterize long-term outcomes and vessel morphology of **uncomplicated, TBAD patients** treated with OMT vs OMT+TEVAR

Study Design

RCT

- N = 140 subjects
- 7 European Centers, 2002 – 2005

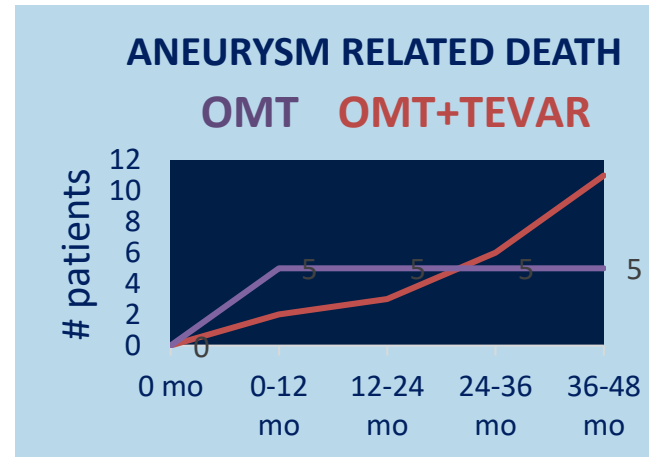
Primary Endpoint: All-cause mortality

Secondary Endpoints: Aorta-specific mortality and disease progression

The study was conducted with 1st generation of thoracic devices: Talent CoilTrack

5 YEAR RESULTS

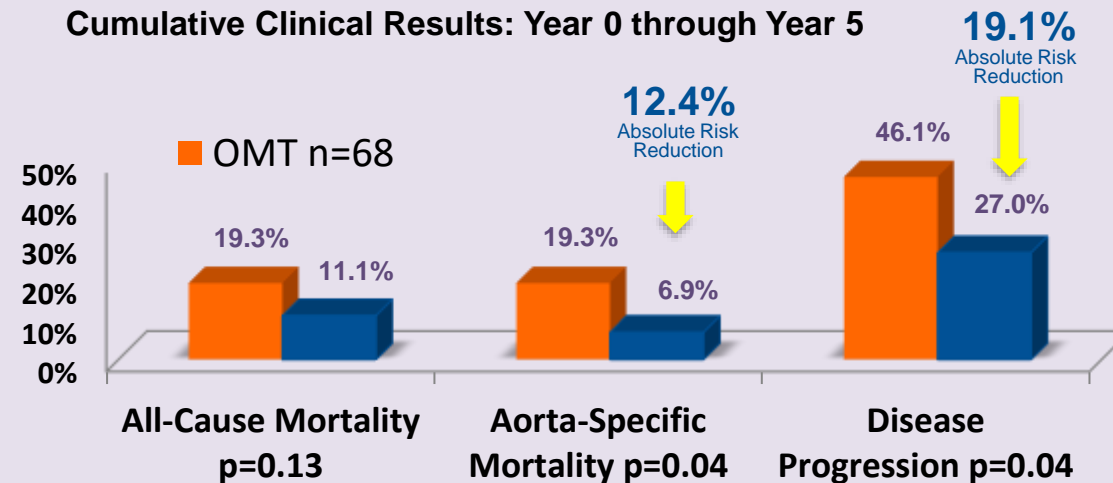
¹ Nienaber et al., CIRC. 2013 Aug.



Key Takeaways

- OMT ONLY showed significant mid and late term aneurysm related mortality
- OMT+TEVAR showed no mid or late term aortic related mortality (**long term survival**)
- TEVAR for aortic dissection **prevents late expansion and encourages aortic remodelling**

Cumulative Clinical Results: Year 0 through Year 5



“At risk” uTBAD?

- Uncomplicated TBAD is a **misnomer**
- All TBAD patients have long term risk and need lifelong monitoring and surveillance
- The risk for a uTBAD patient changes over time
 - **all are at risk, just some are higher risk than other**
- Their ongoing risk is partly dependent on their medical / surgical treatment and how effective it truly is
- We need a lot more data about TBAD



Type **B** acute aortic syndrome - **CL**arifying the need for early **E**ndovascular **A**ortic **R**epair

The **B-CLEAR** Registry
Royal North Shore Hospital



Why B-CLEAR?

- Complicated acute aortic syndrome has a definitive treatment algorithm
- Uncomplicated TBAD
 - Need more data regarding natural history, physiological factors involved in outcomes and treatment related outcomes
- Is there a physiological perfusion factor that increases medium- and long-term risk that we are not detecting?
- Does subclinical renal malperfusion in ‘uncomplicated’ dissections contribute to persistent hypertension, impaired remodelling and worse morbidity / mortality outcomes?



At risk patients: who could benefit from TEVAR in uncomplicated type B dissections?

- The majority of patients with uncomplicated TBAD are at risk
- The natural history data of uTBAD treated with OMT alone suggests that these patients will have poor medium term outcomes and remain at risk
- It seems that most will do better with OMT + TEVAR rather than OMT alone
- We need to change our mindset
 - We need to be thinking for reasons why we should not be treating with TEVAR and OMT rather than looking for a reason to use TEVAR
- Part of our problem is an inadequate classification system for TBAD



Royal North Shore Hospital AP Classification System for TBAD

- **Class 1 : Benign Uncomplicated**
 - **A** No at risk anatomical or physiological parameters
 - Treat with OMT and Surveillance for 5 years
 - **B** One anatomical or one physiological risk parameter
 - Physiological risk defined as pain req. **non-opiate** analgesics **or HTN** needing more than a beta-blocker and 1 other agent
 - Treat with OMT + frequent & lifelong surveillance / a change in parameters is likely and may require TEVAR / Surgery
- **Class 2 : At Risk Uncomplicated** (*will need TEVAR / timing to be determined*)
 - **A** Patient has multiple anatomical or physiological parameters or unable to surveil
 - Physiological risk defined as pain requiring **opiate** analgesics **and /or HTN** needing more than a beta-blocker and 1 other agent)
 - OMT + TEVAR – wait till subacute phase / Surveillance (if possible)
 - **B** Multiple risk factors esp. aortic diameter / size of entry tear / partial false lumen thrombosis / IMH / PUO
 - OMT + TEVAR after timing determined by clinical status / treatment during initial admission / Life-long Surveillance
- **Class 3 : Complicated**
 - Rupture / End organ malperfusion / Uncontrollable HTN or pain / Rapid aortic expansion
 - Immediate TEVAR / Surgery + OMT + Life-long Surveillance



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