What is the best solution for uncomplicated type B-AD?

No, Early Endovascular treatment of uncomplicated aortic dissection is not the best choice

Imperial College London

Colin Bicknell

Clinical Reader and Consultant Vascular Surgeon

Imperial College London, UK

DISCLOSURES

I have the following potential conflicts of interest to report :

Consulting – Medtronic, Gore

Grant funding –Medtronic, Gore

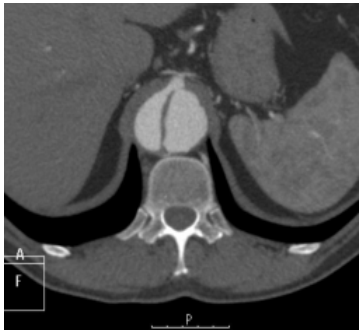
Imperial College London: Institutional level funding from Orzone

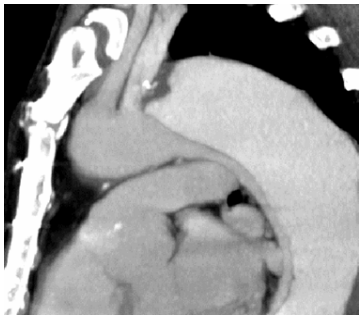
The long term sequalae of uTBAD

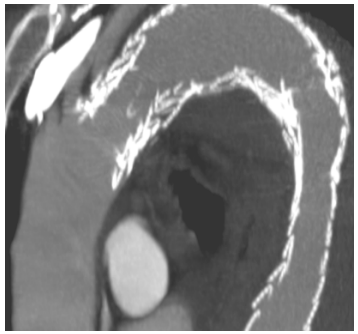
20-50% of patients with acute TBAD dilate over time:

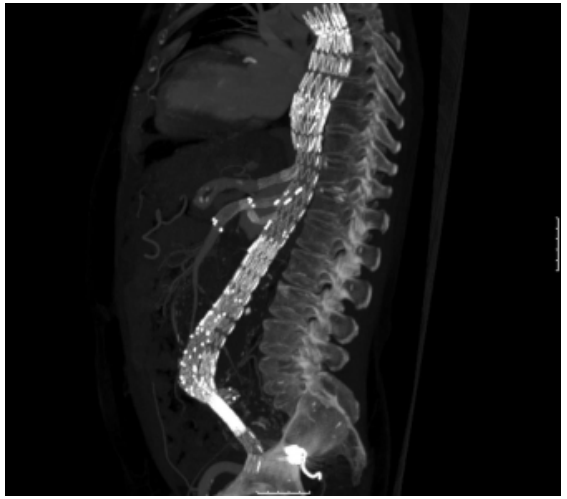
- At risk of rupture
- Do not remodel adequately with TEVAR
- Require significantly more complex procedures

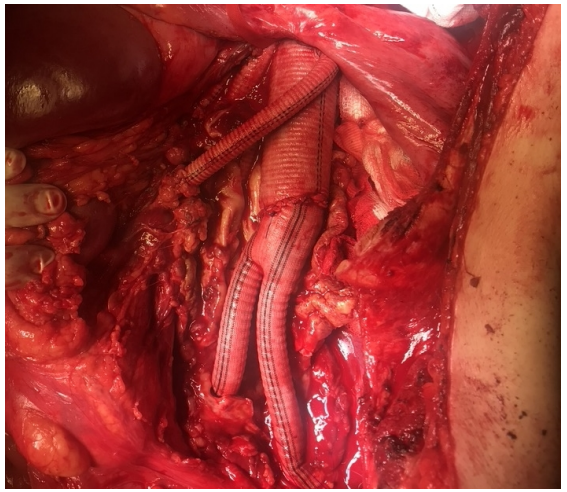
Akin I, Kische S, Ince H, Nienaber CA. Indication, timing and results of endovascular treatment of type B dissection. Eur J Vasc Endovasc Surg. 2009 Mar;37(3):289-96.





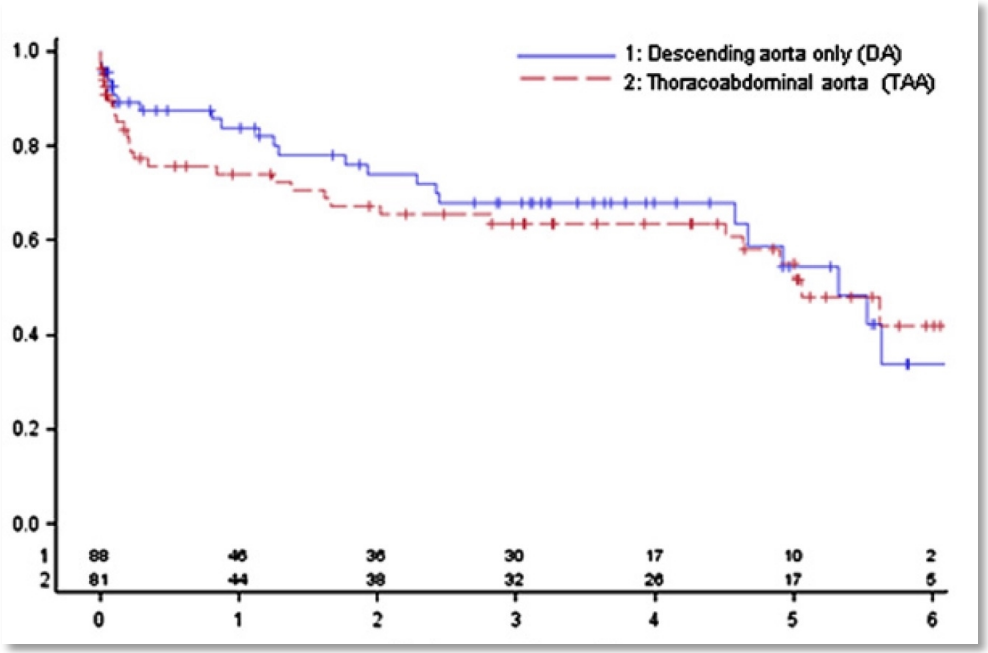






Outcomes for Chronic TBAD after open repair

Pujara et al JTCVS 2012; 144: 866



Time (years)

161 patients after open surgical repair:

- 5y ACM – 46%
- 5y Reintervention – 19%
- 5y event free survival – 51%

Early outcomes are good and late outcomes are less than desirable after open repair of chronic distal aortic dissection…Select patients at risk for aneurysmal degeneration should undergo a more aggressive initial approach with aortic dissection repair.

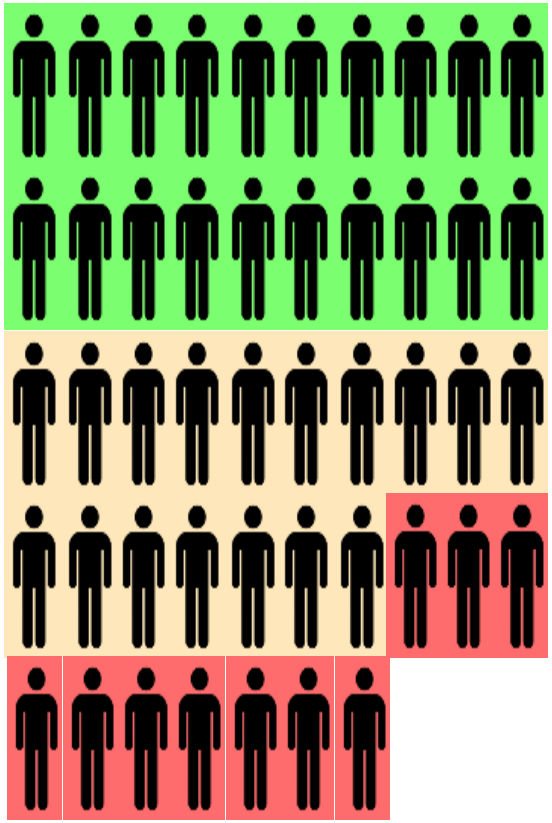
CROSS SECTIONAL ANALYSIS OF TBAD PATIENTS

JVS Journal of Vascular Surgery
Official Publication of the Society for Vascular Surgery

Martin G, Patel N, Grant Y, Jenkins M, Gibbs R, Bicknell C.

Antihypertensive medication adherence in chronic type B aortic dissection is an important consideration in the management debate.

J Vasc Surg. 2018 Sep;68(3):693-699.



High Adherence
20/47 (42.5%)

Medium Adherence
17/47 (36.2%)

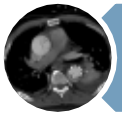
Low Adherence
10/47 (21.3%)

Outcomes for Type B AD: What We Trying To Achieve?

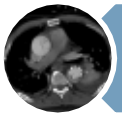
EARLY TREATMENT OF TYPE B AORTIC DISSECTION HAS A NUMBER OF CLEAR AIMS:

- Open true lumen, induce false lumen thrombosis and aortic remodelling
- Minimise the risk of complex late intervention
- Minimise late aortic related events (malperfusion/expansion/rupture)


Does it work?

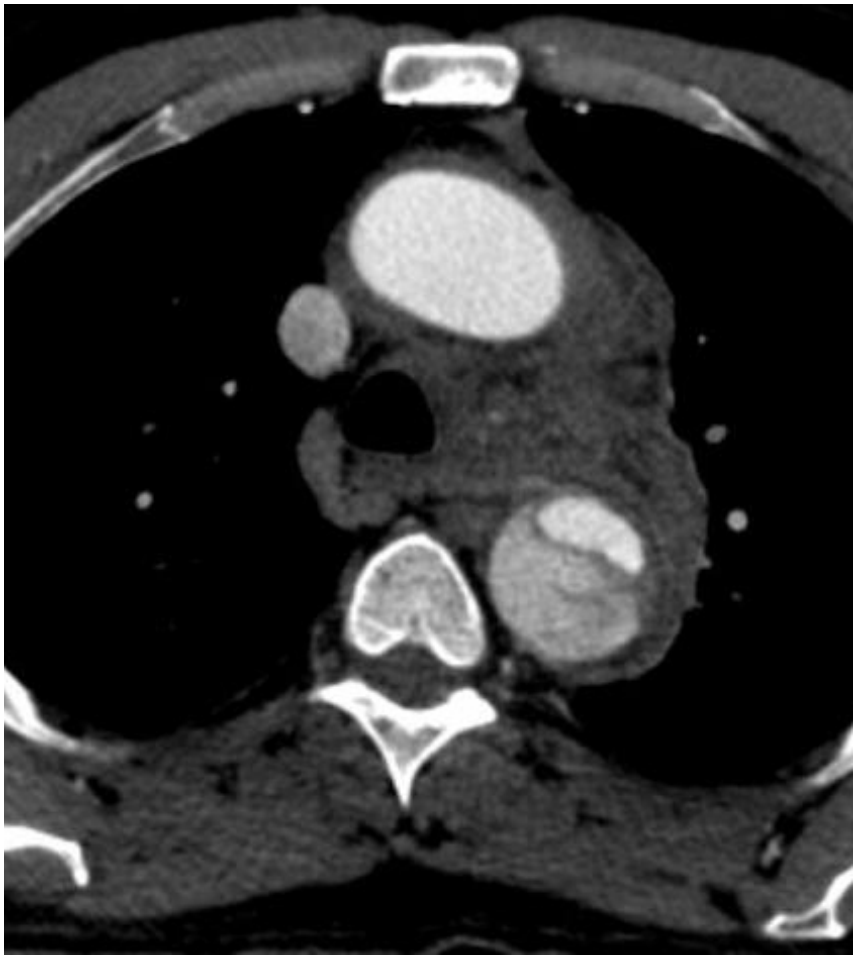

What is the evidence?


Can we identify a high risk group?


Is it cost effective?


What do the patients want?

Does it work?



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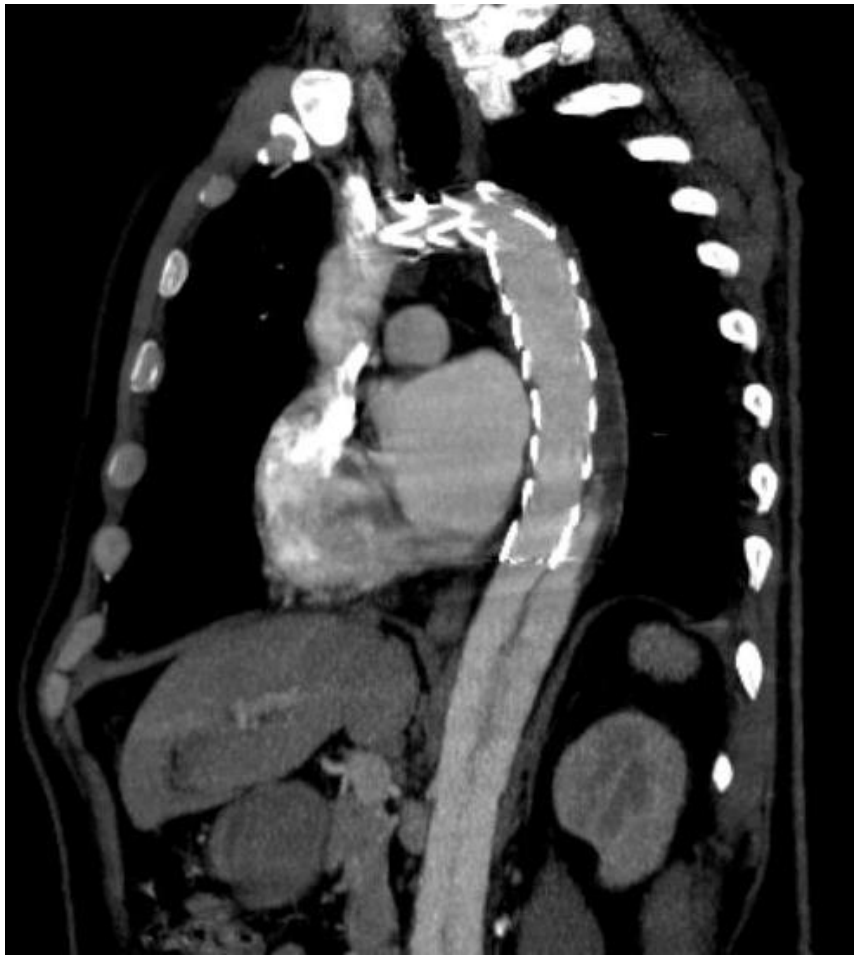
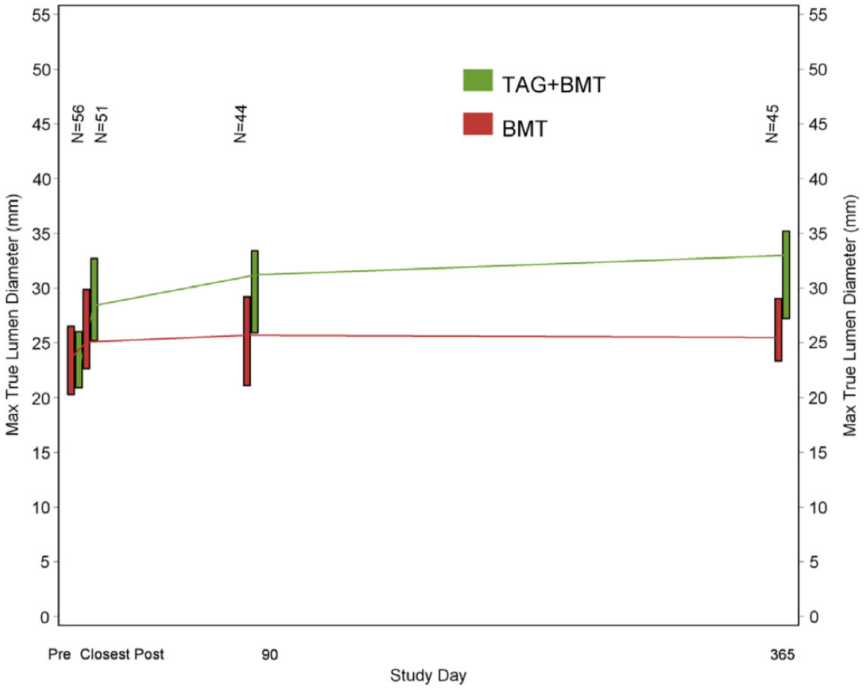
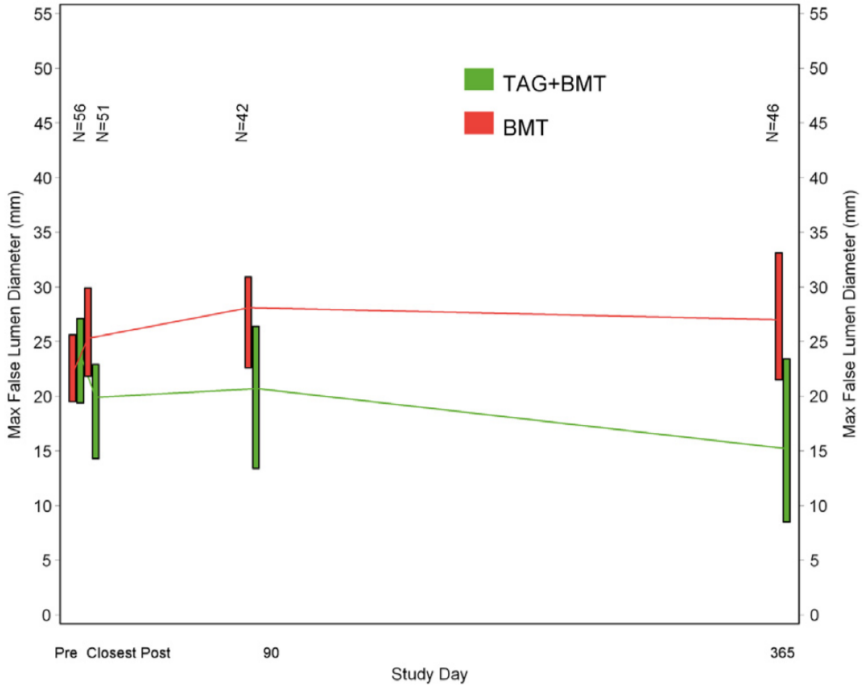


POST

ADSORB Trial





Brunkwall J, Kasprzak P, Verhoeven E, Heijmen R, Taylor P. the ADSORB Trialists. Endovascular repair of acute uncomplicated aortic type B dissection promotes aortic remodelling: 1 year results of the ADSORB trial. Eur J Vasc Endovasc Surg 2014;48: 285e91.

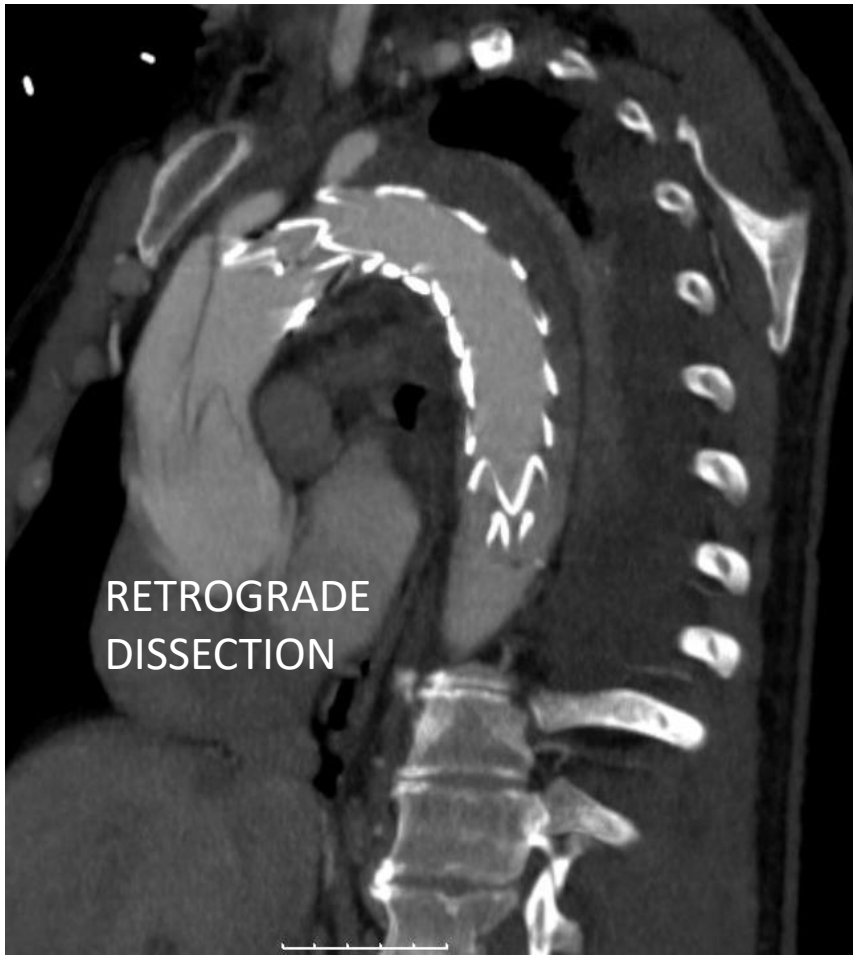
Risks of the early intervention

There are significant risks both early:

- Retrograde TAAD
- CVA
- Paraplegia
- Rupture
- SINE

…and late:

- Expansion in non-covered segment
- Need for reintervention



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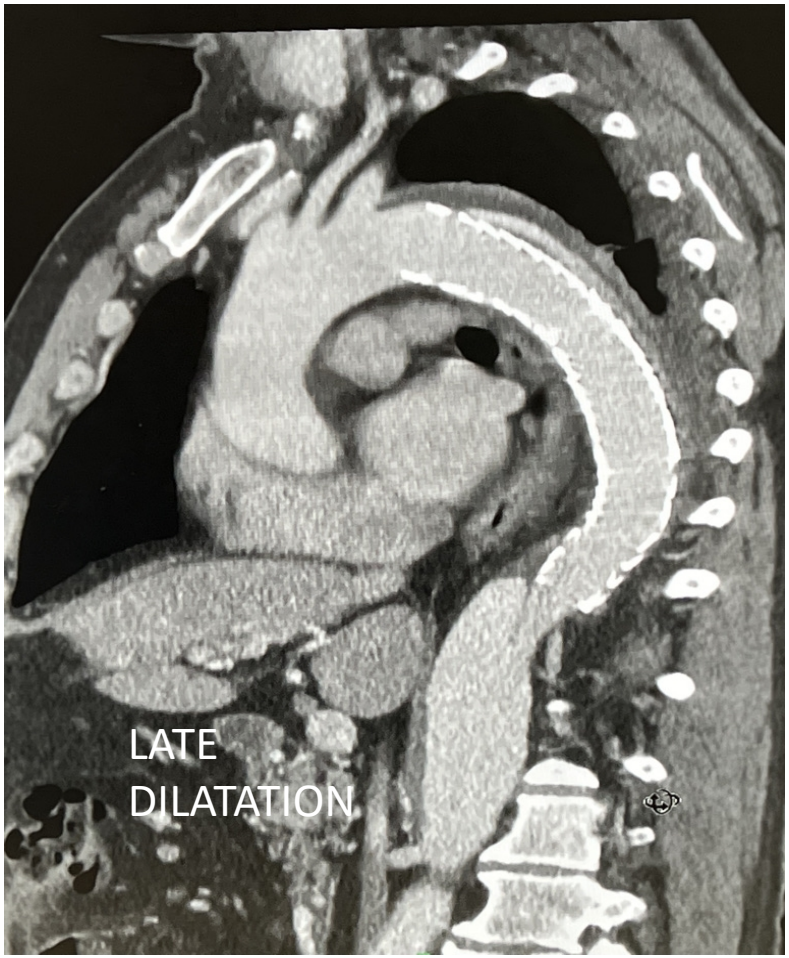


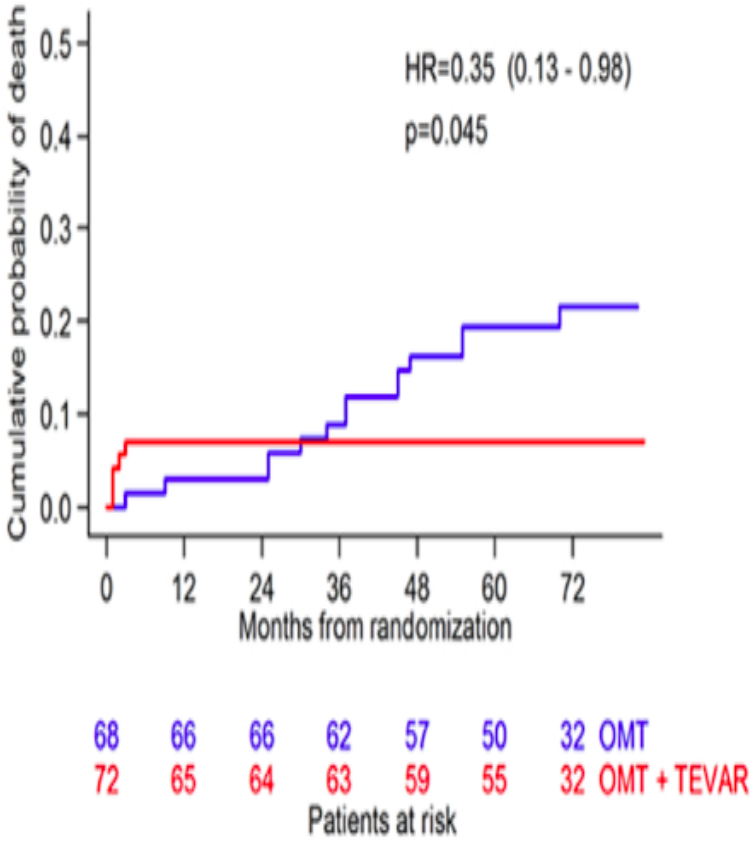
EVIDENCE

Nienaber Circ 2013;6:407-416

Two randomised controlled trials were conducted to compare TEVAR with best medical therapy (BMT) in uncomplicated TBAD patients:

- INSTEAD trial (140 patients in the subacute phase)
  - No mortality benefit at two years,
  - Significantly improved aortic-related mortality in TEVAR group at 5 years.
- ADSORB trial (acute phase):
  - Demonstrated more positive aortic remodelling in the TEVAR group.

Systematic reviews show some benefit to early stenting in the acute or sub-acute phase with respect to all cause and aneurysm related mortality.



However, there are significant concerns with adoption of early TEVAR for all uTBAD….

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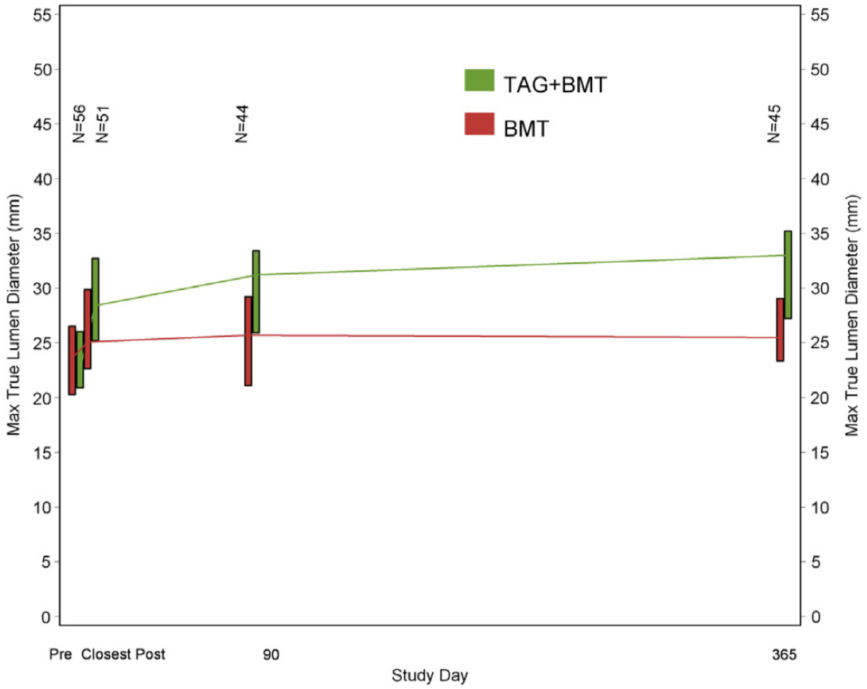

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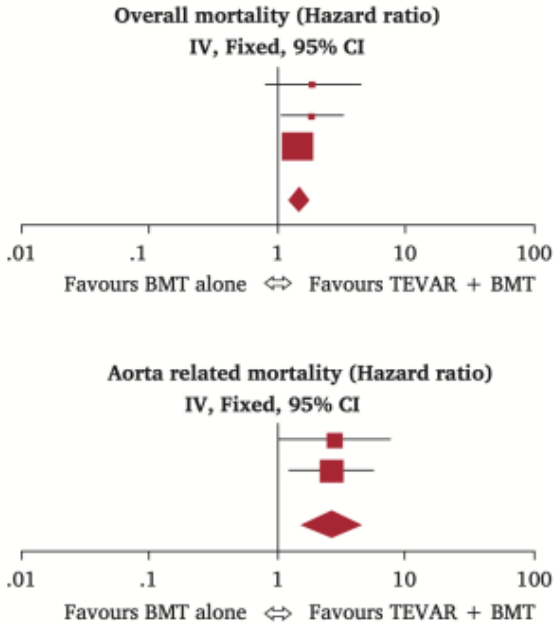

Hossack et al. Endovascular vs. Medical Management for Uncomplicated Acute and Sub-acute Type B Aortic Dissection: A Meta-analysis. Eur J Vasc Endovasc Surg. 2020 May;59(5):794-807.

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EVIDENCE

Significant concerns with adoption of early TEVAR for all uTBAD….

- *Numbers in the trials are low*
- *Only one trial (INSTEAD) looks at long term F/U powered for 2-years and non-significant, extended to 5-years*
- *The statistical analysis has been criticised*
- INSTEAD included patients 2-52 weeks after uTBAD and therefore many patients received a stent once the dissection lamella lost its plasticity, resulting in less effective aortic remodelling.
- *Patients in all retrospective series are highly selected…it would be foolhardy to suggest this treatment should be for all*
- *No studies examined cost-effectiveness*

Factors associated with increased growth rate

DILATATION

Radiological high-risk features:

- Maximum aortic diameter ≥ 40mm
- Patent or partially thrombosed false lumen
- Primary entry tear ≥ 10mm
- Elliptic formation of the true lumen
- Saccular formation of the FL
- One entry tear
- Entry tear in aortic concavity/inner curve
- False lumen diameter ≥22mm
- Rapid aortic enlargement
- Radiographic-only organ malperfusion
- FL located at the inner aortic curvature, fusiform dilated proximal descending aorta, and areas with ulcer-like projections.

Clinical high-risk features:

- Age <60 years
- White race
- Marfan syndrome
- High fibrinogen-fibrin degradation product level (20 mg/mL) at admission

PROTECTION AGAINST DILATATION

associated with negative or limited aortic growth

Radiological beneficial features:

- Thrombosed FL
- Two or more entry tears
- FL located at the outer aortic curvature
- Circular configuration of the true lumen

Clinical beneficial features:

- Tight heart rate control (<60 beats/min)
- Use of calcium-channel blockers

Is it cost effective?

The costs of treatment are high. In ETTAA, detailed micro-costing estimated NHS average costs:

- 97 TEVAR cases to be £30,675 (±£11,920)
- 16 complex TEVAR cases to treat thoracoabdominal aneurysms to be £49,768 (±£9,120)
- open repair to be £45,875 (±£43,023).

12-month follow up costs were

- £5,206 ±£11,585 for TEVAR
- £5,039±£11,994 for open surgery, driven by admission and procedure costs.

Sharples L, Sastry P, Freeman C, et al. Endovascular stent grafting and open surgical replacement for chronic thoracic aortic aneurysms: a systematic review and prospective cohort study. Health Technol Assess 2022; 26(6): 1-166.

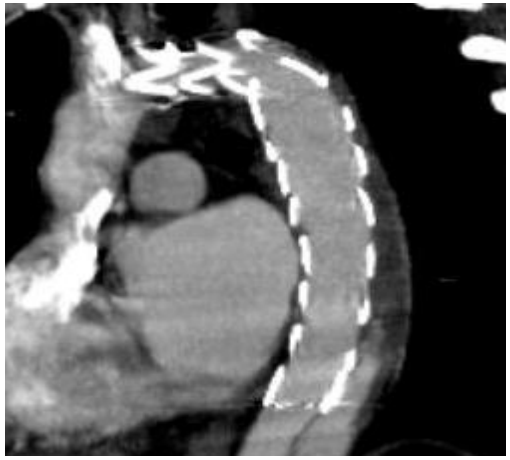
So should we intervene early in uTBAD?

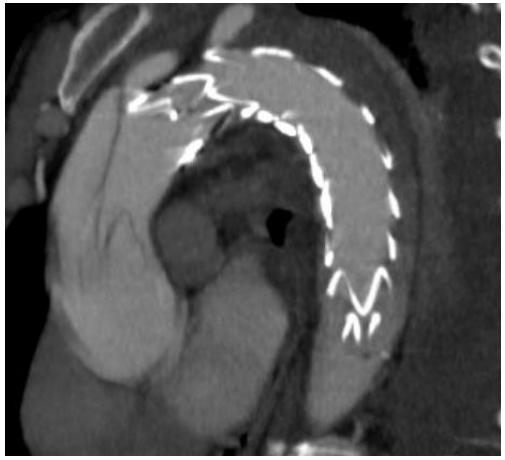
TEVAR in the sub acute phase, when the risks of further complications of acute TBAD are reduced, and the dissection lamella has not lost its plasticity:

- Works to lead to remodelling
- May reduce the risk of late intervention

However:

- TEVAR has significant risks (stroke, paraplegia, SINE, TAAD, rupture)
- A policy of stenting all uTBAD treats 2/3 of the population that never would need a procedure





We do not know:

- Whether there is a definite advantage
- Whether there is a high-risk population
- Whether this policy is in any way cost effective

We cannot support a motion that supports TEVAR …A TRIAL IS NEEDED…

What do the patients want?

NIHR | National Institute for Health and Care Research

Search nihr.ac.uk...

21/585 Early endovascular repair in type b uncomplicated sub-acute aortic dissection commissioning brief

Interviewed 25 patients with aortic dissection from different ethnic backgrounds, ages (46-81yrs) and sex (8F), and their relatives:

- Keen for an intervention to reduce uncertain surveillance
- There is unanimous support for a trial
- Our PPI group advised on the earliest acceptable recruitment opportunity (including ideal settings)
- A trial was reviewed and is supported by TADCT

In Summary, should we intervene early?

In summary no…

- There are significant risks
- The RCT evidence is lacking and simple to critique
- Reported series are small and in selected patients
- There is not a defined high-risk group
- There is no evidence that it is cost-effective
- Patients support a trial