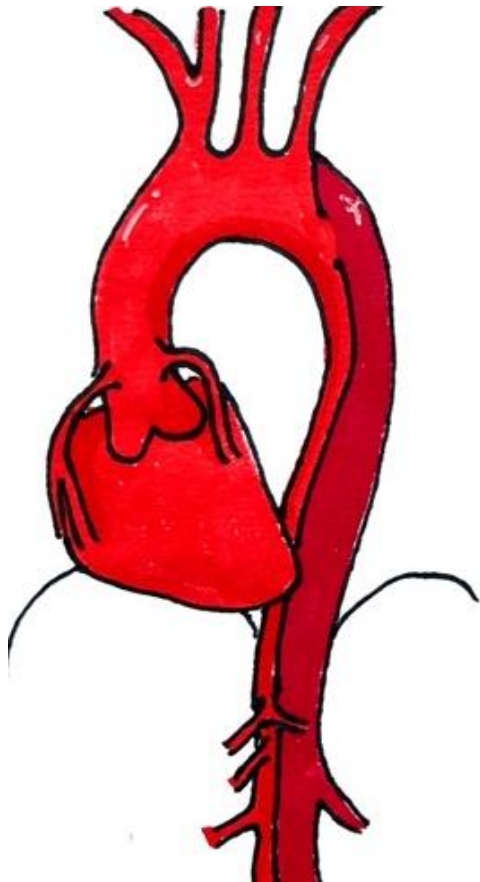


CIV
WORLD
CHALLENGES & INNOVATIONS IN VASCULAR WORLD

31 MARS
1^{ER} AVRIL **2026**

MÉRIDIEN PARIS ARC DE TRIOMPHE
PARIS

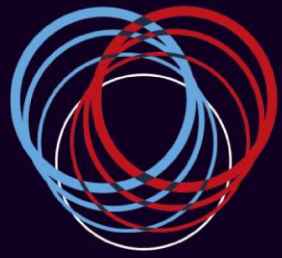


Acute type B aortic dissection: surveillance, stenting, or inclusion in a randomized trial?

Colin D Bicknell

Division of Surgery, Department of Surgery & Cancer, Imperial College London, UK
Imperial Vascular Unit, St Mary's Hospital, London, UK

Imperial College London



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PARIS

Déclaration de conflit d'intérêts :

Nom : Bicknell

Prénom : Colin

Fonction : Professor of Vascular Surgery

Etablissement : Imperial College London

I have the following potential conflicts of interest to report unrelated to this talk:

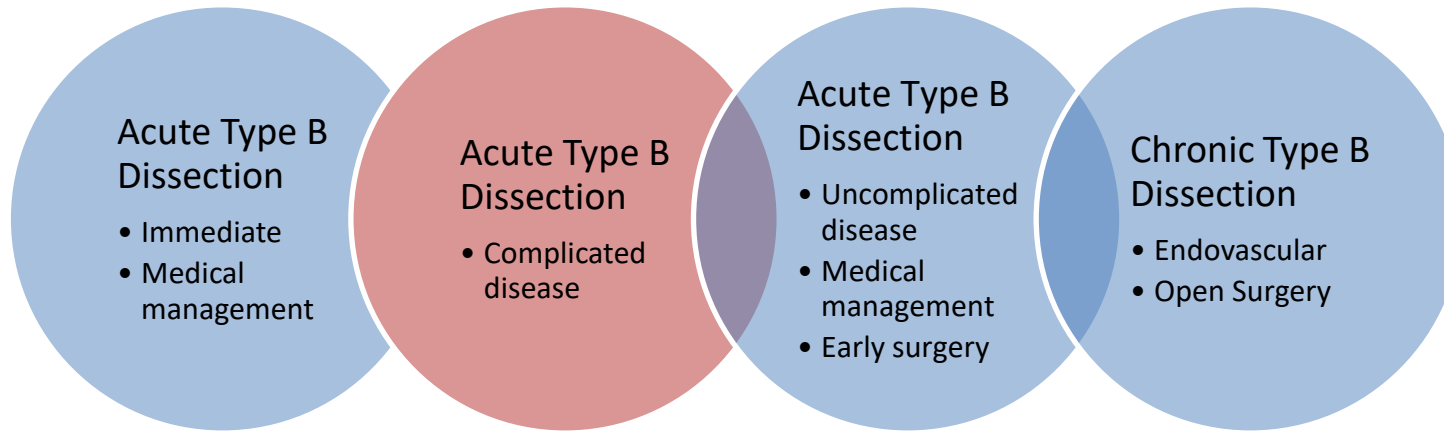
Consulting – Medtronic, Gore, Invastec

Grant funding – Medtronic, Gore, Terumo

I have the following potential conflicts of interest to report related to this talk:

Chief Investigator for NIHR EARNEST trial

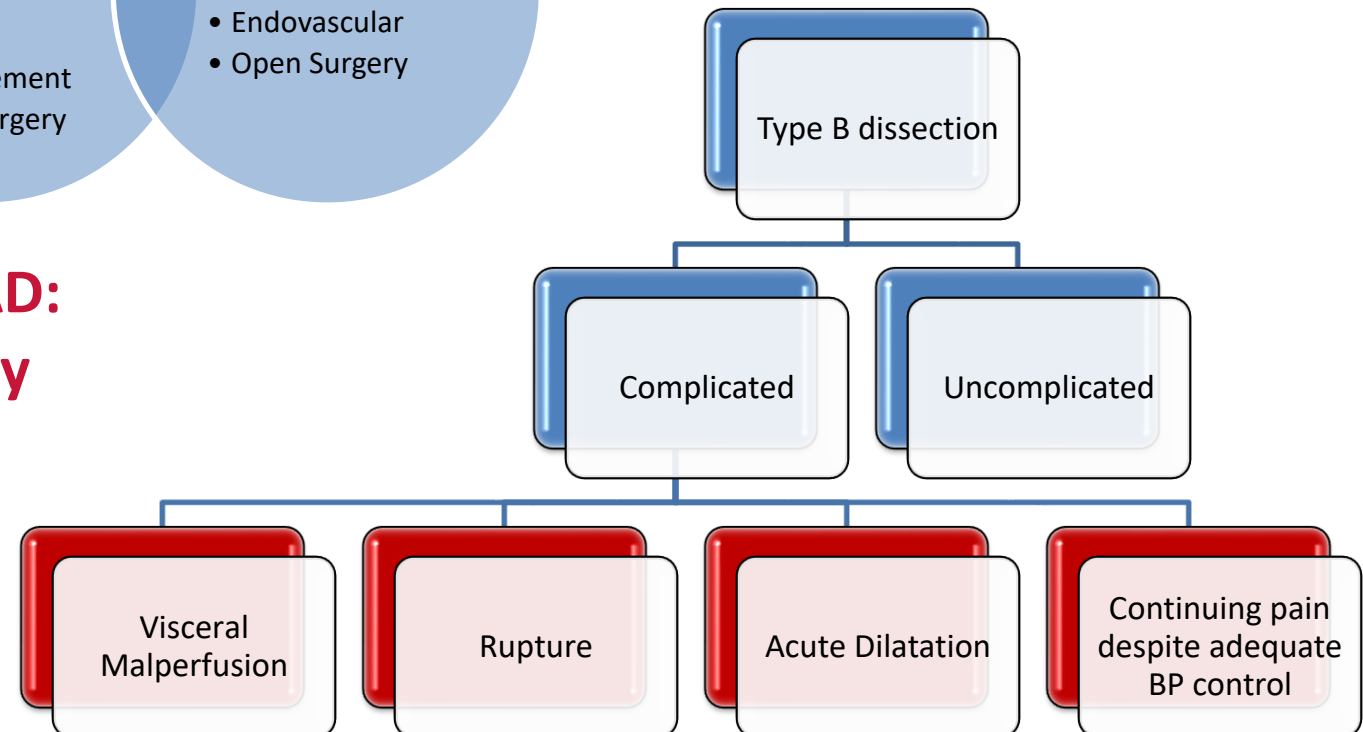
TYPE B AORTIC DISSECTION – complicated disease



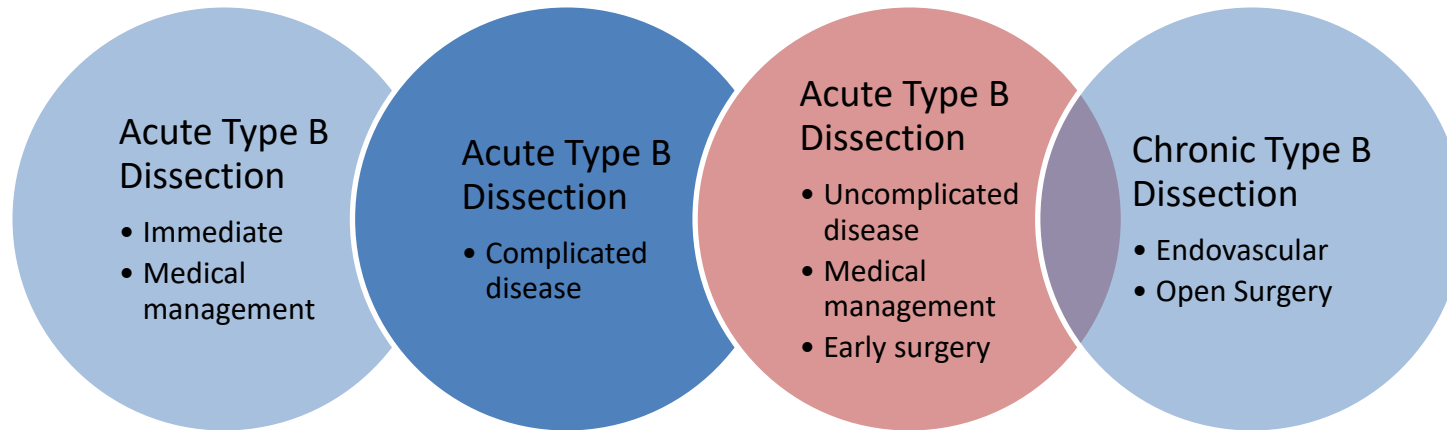
**(IMMEDIATELY) Complicated Acute TBAD:
Should be treated immediately/urgently**

Treatment options:

- Stent aorta and proximal dissection tear
- Stent branch vessels
- Extra-anatomical approach
- Open Surgery

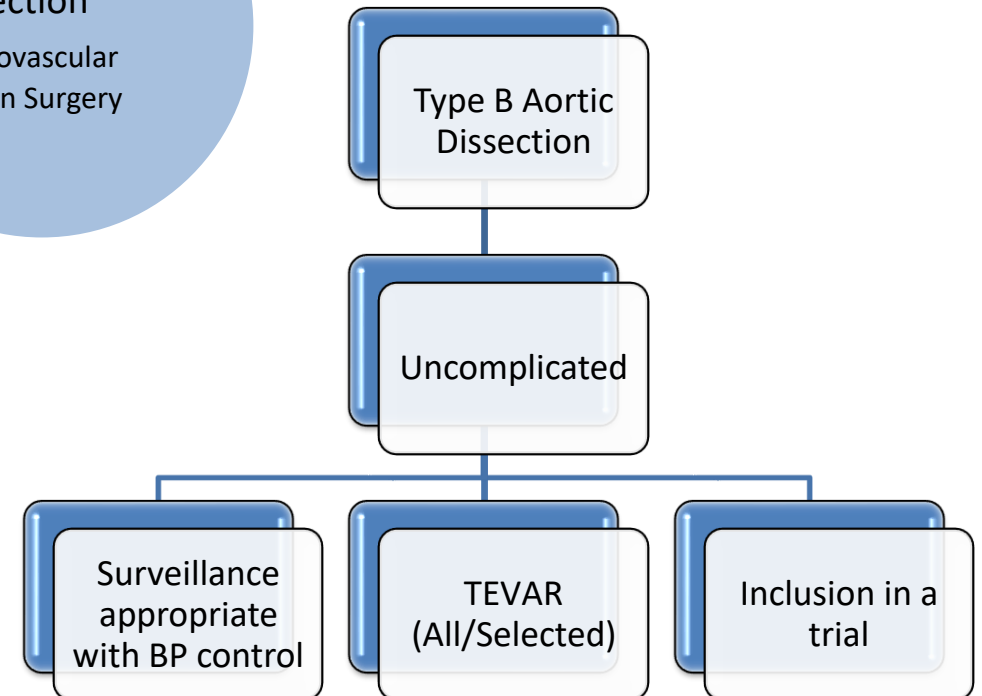


TYPE B AORTIC DISSECTION – uncomplicated

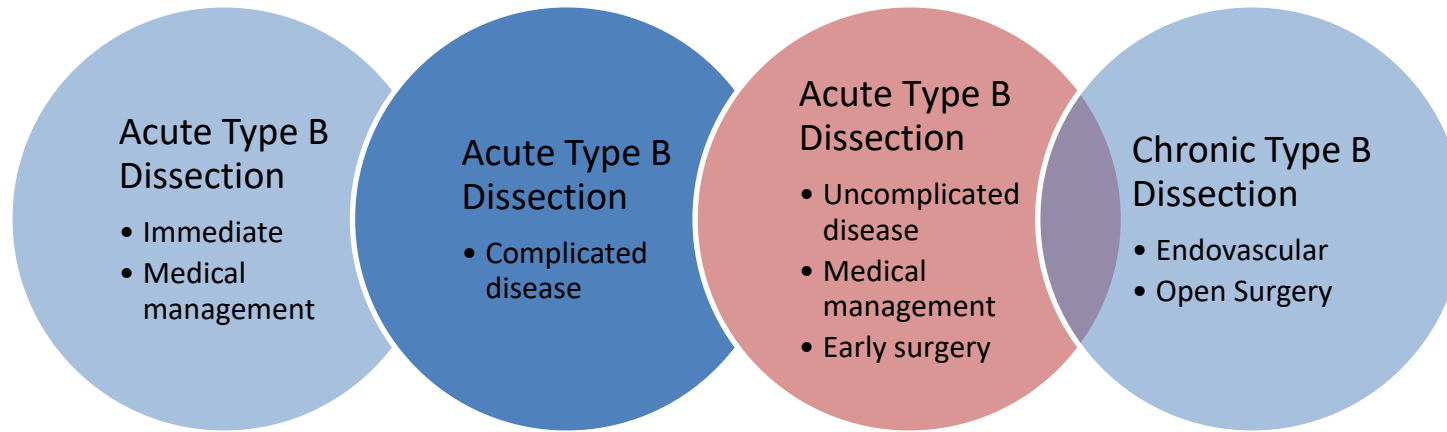


Uncomplicated Type B Aortic Dissection:

- Can be managed safely conservatively with strict blood pressure control
- TEVAR can promote remodelling

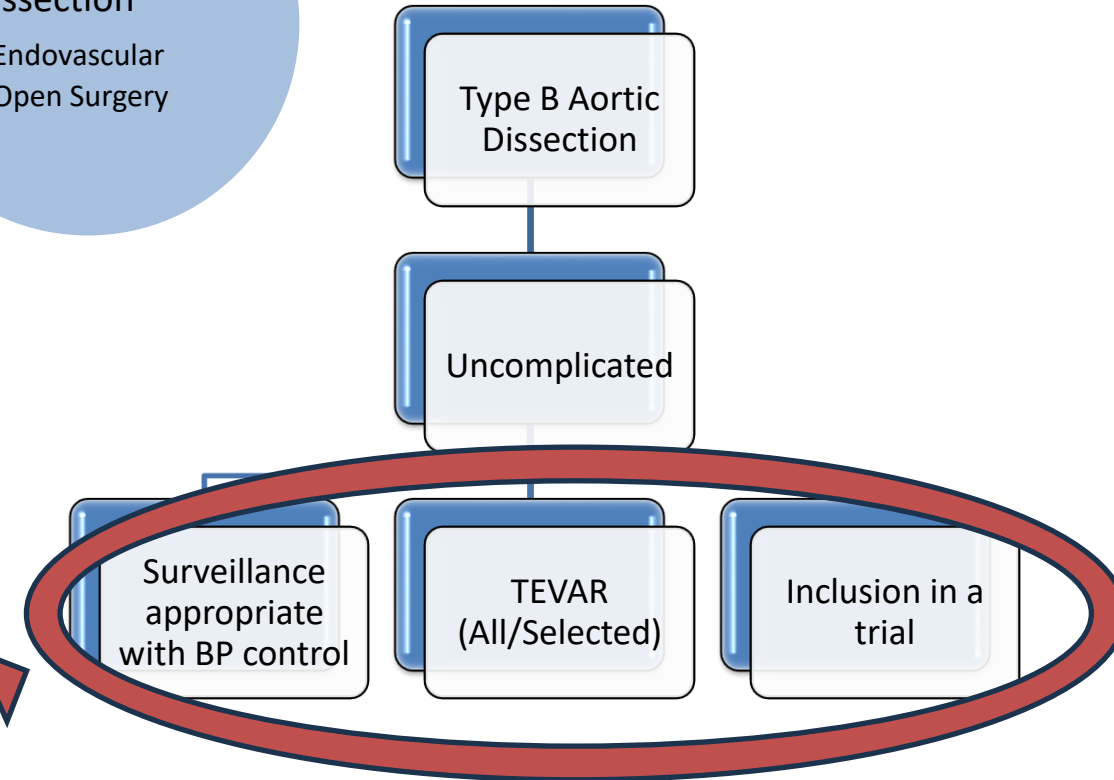


TYPE B AORTIC DISSECTION – uncomplicated



Uncomplicated Type B Aortic Dissection:

- Can be managed safely conservatively with strict blood pressure control
- TEVAR can promote remodelling



WHERE DO YOU SIT IN THIS DEBATE?

MEDICALLY MANAGED UNCOMPLICATED TBAD

The long term sequelae of uTBAD

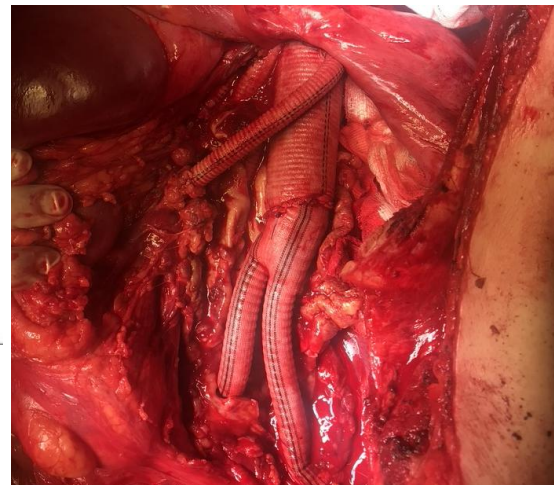
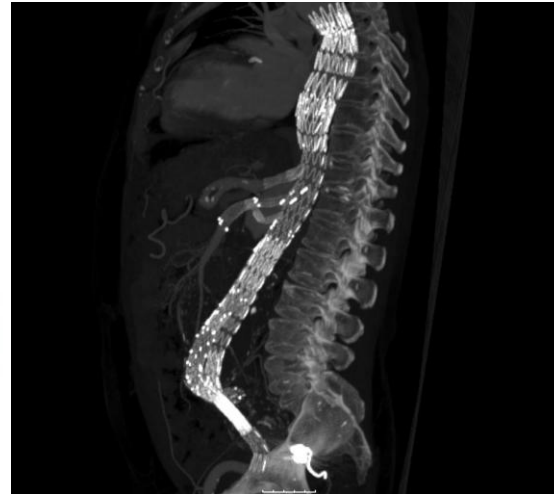
20-50% of patients with acute
TBAD dilate over time:

- 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.



**Late aneurysmal
degeneration**



Patient concerns

“You cannot underestimate the concerns with waiting, it is like a sword hanging over you”.

Medically treated patients do not fare well after uTBAD

HES and CPRD matched dataset



20,580 with Aortic disease

192 Dissections



Unique dataset combining BP
measures, compliance and
outcomes

Analysis of relationship
between BP, drug class,
Compliance and outcome

ADMINISTRATIVE DATA SET UK ANALYSIS

- 70% have SBPP > 140mmHg on at least one occasion
- Only 17.7% consistently below 120mmHg Systolic
- Compliance is poor

Medically treated patients do not fare well after uTBAD

CROSS SECTIONAL ANALYSIS OF TBAD PATIENTS

- Mixed methods study in tertiary centre for complex aortic disease

Demographics
Patient disease specific knowledge
Psychological and behavioural predictors of adherence Health Belief Model

Validated Measure of Medication Adherence Morisky Medication Adherence Scale 8
--

Morisky. J Clin Hyperten 2008;10(5):348-354
Prochaska. Am J Heal Promot 1997;12(1):38-48



High Adherence
20/47 (42.5%)

Medium Adherence
17/47 (36.2%)

Low Adherence
10/47 (21.3%)

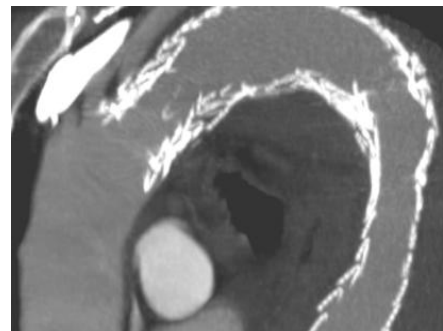
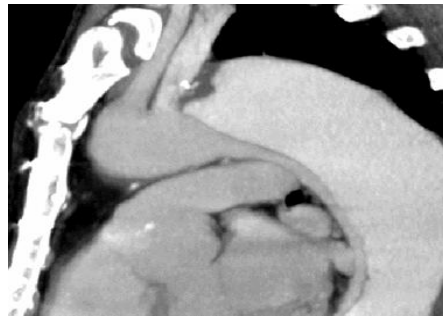
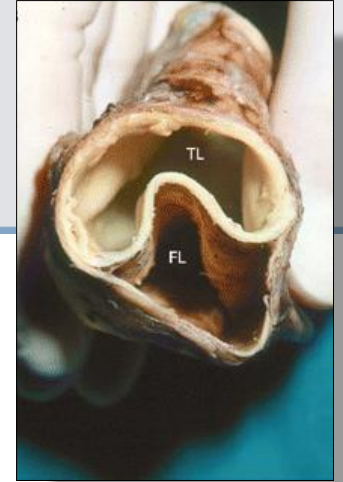
- Overall medication adherence was poor
 - Mean MMAS-8 = 6.51/8
- Definite psychological and behavioral predictors of adherence
- Knowledge of consequences of TBAD poor



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

Martin G et al

Stenting of TBAD in the sub-acute phase

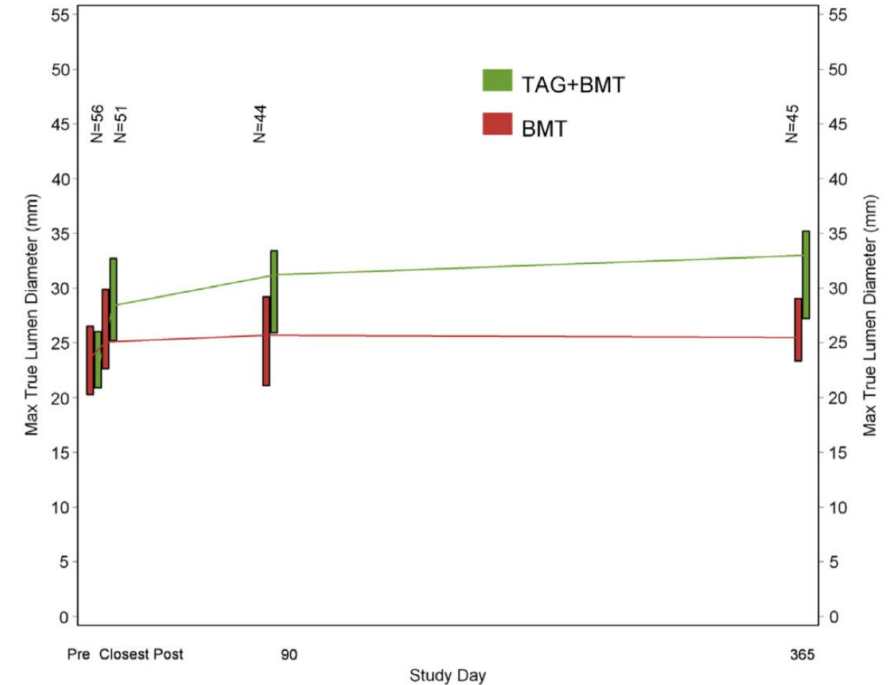


It has been proposed that, for patients with uTBAD, endovascular stent placement (TEVAR) in the subacute phase will:

- Allow enhanced remodelling of the aorta
- Reduced rates of long-term dilatation and recurrent dissection
- Reduced rate of later complex TAAA repair
- Decrease rupture rates
- Ultimately lessen aortic related death and major intervention

EVIDENCE for TEVAR in uTBAD

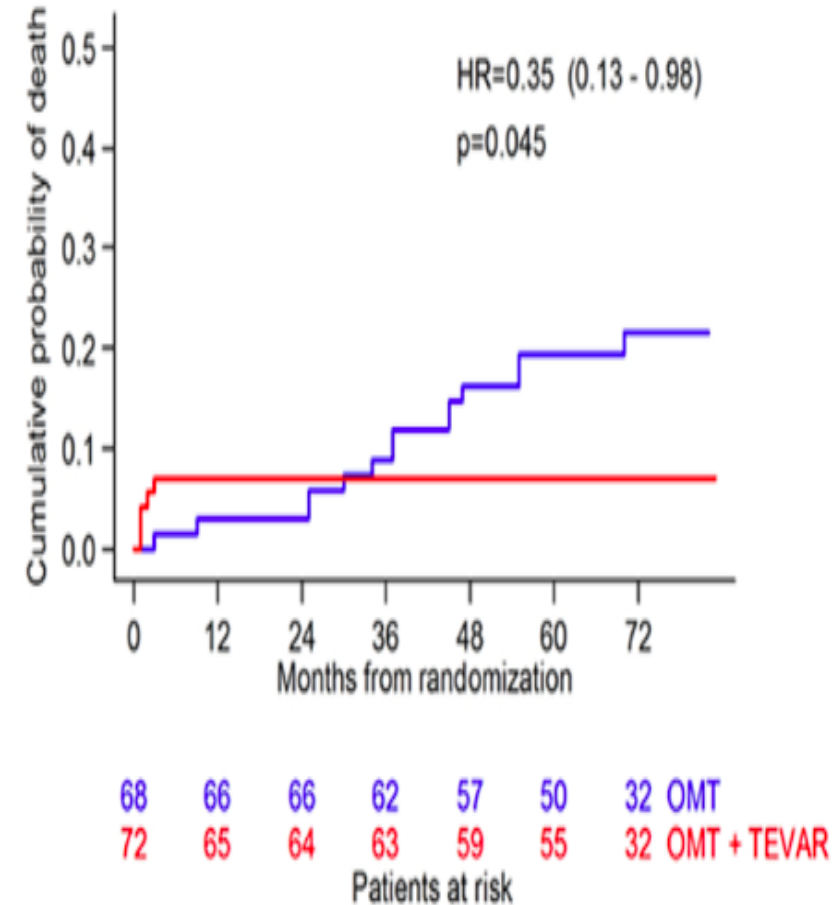
- Two Randomised trials
 - Early stenting safe
 - Remodelling good
 - Late mortality may be improved
- Propensity matched analyses
- A number of large registry studies
- Systematic reviews
 - OR 2.71 late ARM with BMT



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.

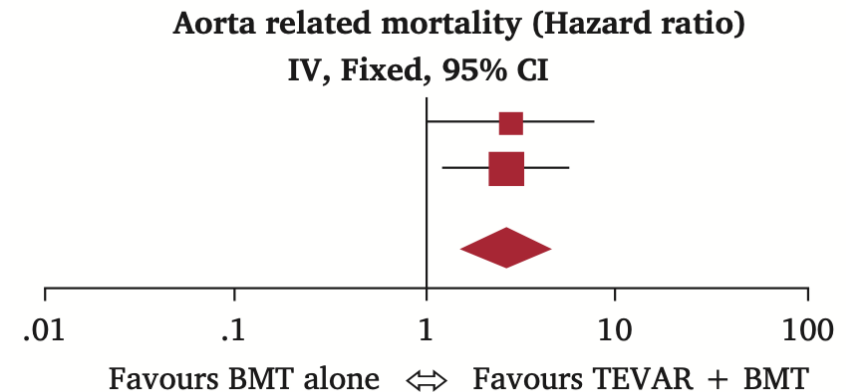
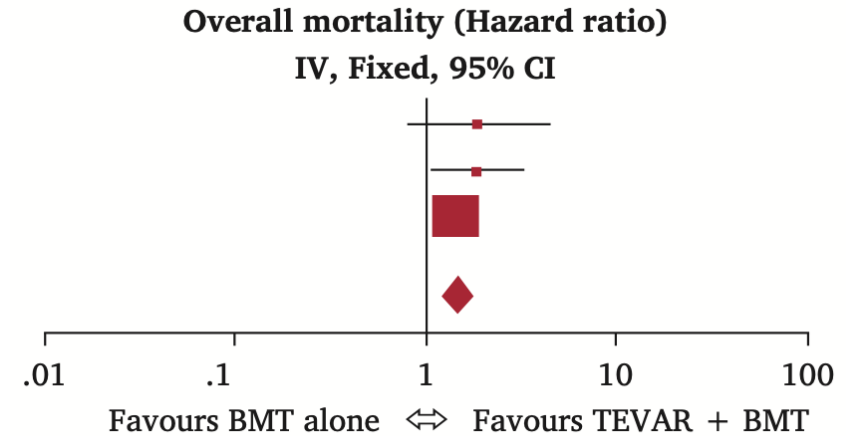
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Equipose: Many physicians are not convinced of the benefit of TEVAR...

In the UK there is significant variation in practice from centre to centre.

There are significant early and late risks

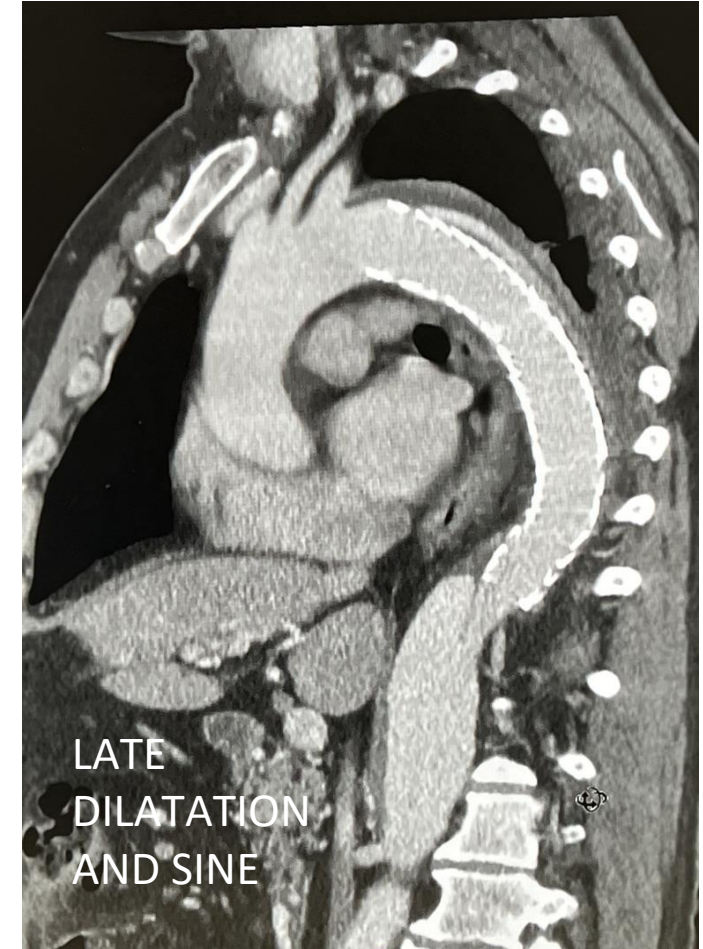
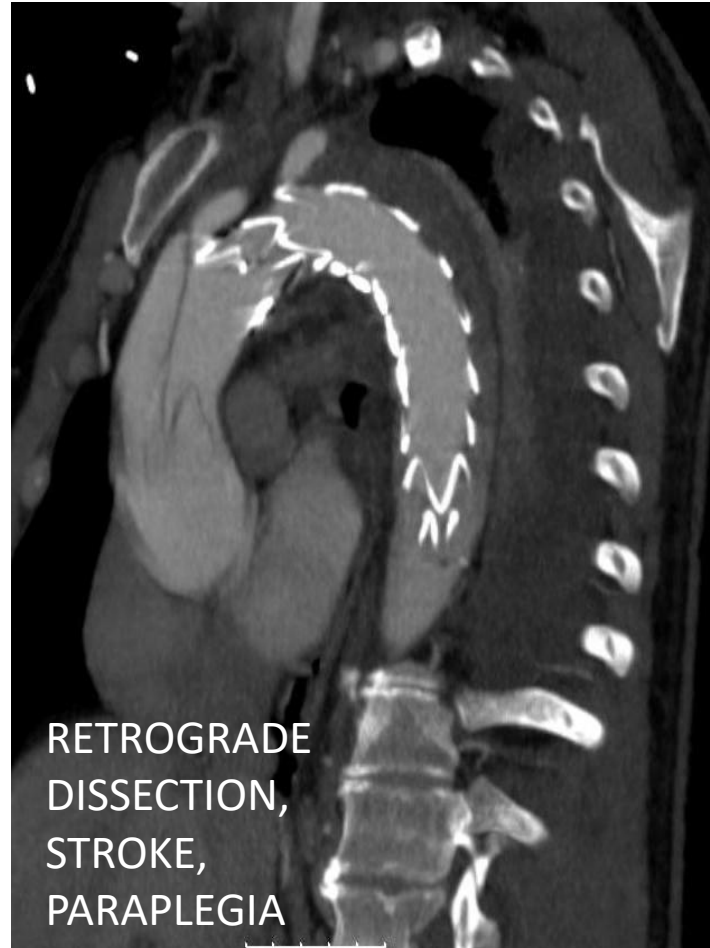
Cost effectiveness has never been proven

Recent international expert survey of the management of uTBAD:

- “About half of surgeons recommended pre-emptive TEVAR [TEVAR in the sub-acute phase] in selected cases”.

Surgical Decision Making in Uncomplicated Type B Aortic Dissection: A Survey of Australian/New Zealand and European Surgeons

Bijl R. Munshi ¹, Barry J. Doyle ², Jens C. Ritter ³, Shirley Jansen ⁴, Louis P. Parker ⁵, Vincent Riambau ⁶, Collin Bicknell ⁷, Paul E. Norman ⁸, Anders Wanhaiainen ⁹



The High-Risk Group

FACTORS ASSOCIATED WITH DILATATION

Radiological high-risk features:

- **Maximum aortic diameter $\geq 40\text{mm}$**
- Patent or partially thrombosed false lumen
- Primary entry tear $\geq 10\text{mm}$
- Elliptic formation of the true lumen
- Saccular formation of the FL
- One entry tear
- Entry tear in aortic concavity/inner curve
- False lumen diameter $\geq 22\text{mm}$
- Rapid aortic enlargement
- Radiographic-only organ malperfusion
- FL located at the inner aortic curvature

Clinical high-risk features:

- Age < 60 years
- White race
- Marfan syndrome
- High FDP level (20 mg/mL) at admission

Except perhaps larger diameters at presentation, no proven group that predict late degeneration

There is no robust evidence that we have got anywhere near defining a high-risk group

Selected patients with uncomplicated* acute type B aortic dissection and suitable anatomy with early aortic expansion or large initial diameter ($> 4.0\text{ cm}$) may be considered for thoracic endovascular aortic repair, preferably during the subacute phase.

Class	Level	Reference
I Ib	C	Consensus

* No signs of rupture or malperfusion.

The EARNEST trial

EARNEST

Early Aortic Repair in patients Needing Endovascular/open Surgery for Type B Aortic Dissection
A randomised trial to assess the clinical and cost-effectiveness of thoracic endovascular aortic repair in the subacute phase after uncomplicated type B aortic dissection.

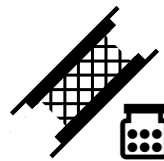


Patients with
Uncomplicated
Type B Aortic
Dissection
(5 days to 3
months
after index event)

N=470



Best Medical Therapy &
Surveillance



Early Thoracic
Endovascular Aneurysm
Repair (TEVAR) &
Best Medical Therapy & Surveillance

Primary Endpoint



Aortic Mortality



Cardio-
respiratory
failure
[permanent]



Neurological
deficit
[permanent]

**Composite
patient-selected
endpoint**



3.5-Year Recruitment

5-Year Follow-up

Inclusion criteria

- Patients with uncomplicated type B aortic dissection more than five days after initial dissection (index event) and before 12 weeks.
- Suitable for TEVAR+/- left subclavian artery coverage or bypass without planned visceral or renal artery intervention

Exclusion criteria

- Complicated disease
- Previous dissection or surgery
- Connective tissue disease
- Life expectancy less than two years
- Unable to attend follow up schedule
- Pregnancy at time of stenting

STANDARD CARE VS INTERVENTION

Best Medical Therapy and Surveillance

Goal directed

Best practice circulated

Following international guidelines

For those in BMT group, intervention as per ESVS guidelines

VS

TEVAR and Best Medical Therapy and surveillance

Best Medical Therapy

Centres credentialled

For those in TEVAR group, intervention at 10 days to three months

OUTCOMES

Primary (patient determined) outcome:

- Five year aortic-related mortality (ARM) AND/OR severe permanent neurological deficit AND/OR severe permanent cardiorespiratory failure.

Secondary outcomes :

- Risks of early stenting
- Aortic remodelling

Individual aspects of primary endpoint

- All-cause mortality
- Quality of Life
- Complications and reinterventions
- NHS and social care costs

EARNEST TRIAL PROGRESS – STARTED APRIL 2025

3 ½ year recruitment

18/12 internal pilot

National Vascular
Registry

Aligned with Aortic
Dissection Toolkit

Supported by major
charities and patient
groups

Patient decision aids

5-year follow-up

CT Surveillance

Core lab analysis

Independent
outcomes committee

At one year

Early outcomes for
TEVAR on a National
basis

Remodeling of aorta
with and without
TEVAR

National incidence

At five years

Primary endpoint – Five
year aortic-related mortality
(ARM) AND/OR severe
permanent neurological
deficit AND/OR severe
permanent
cardiorespiratory failure.

Secondary outcomes and
QoL

Cost effectiveness

PROGRESS....

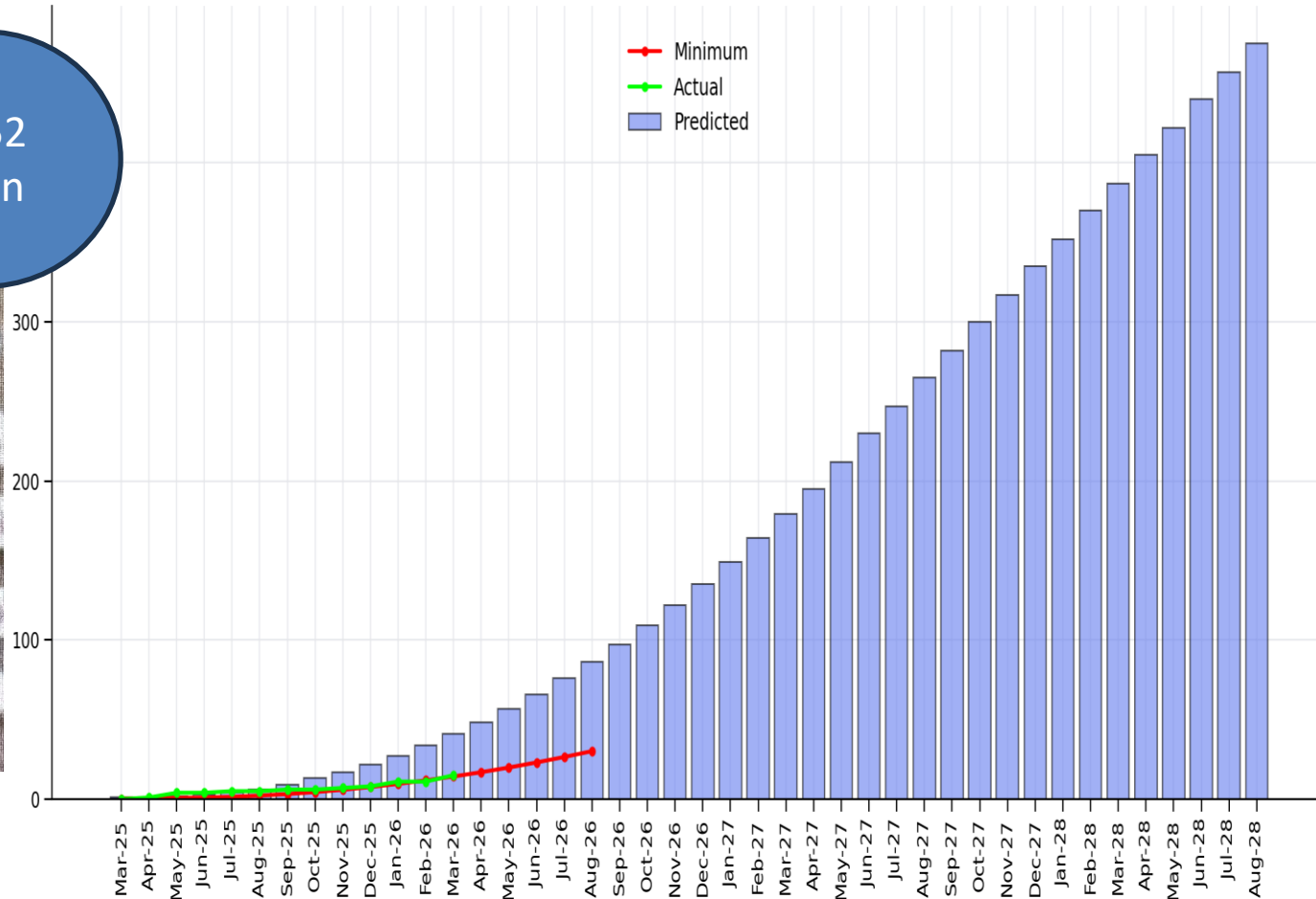
Surgery
10/7-
3/12

PATIENT 001

6/52
scan

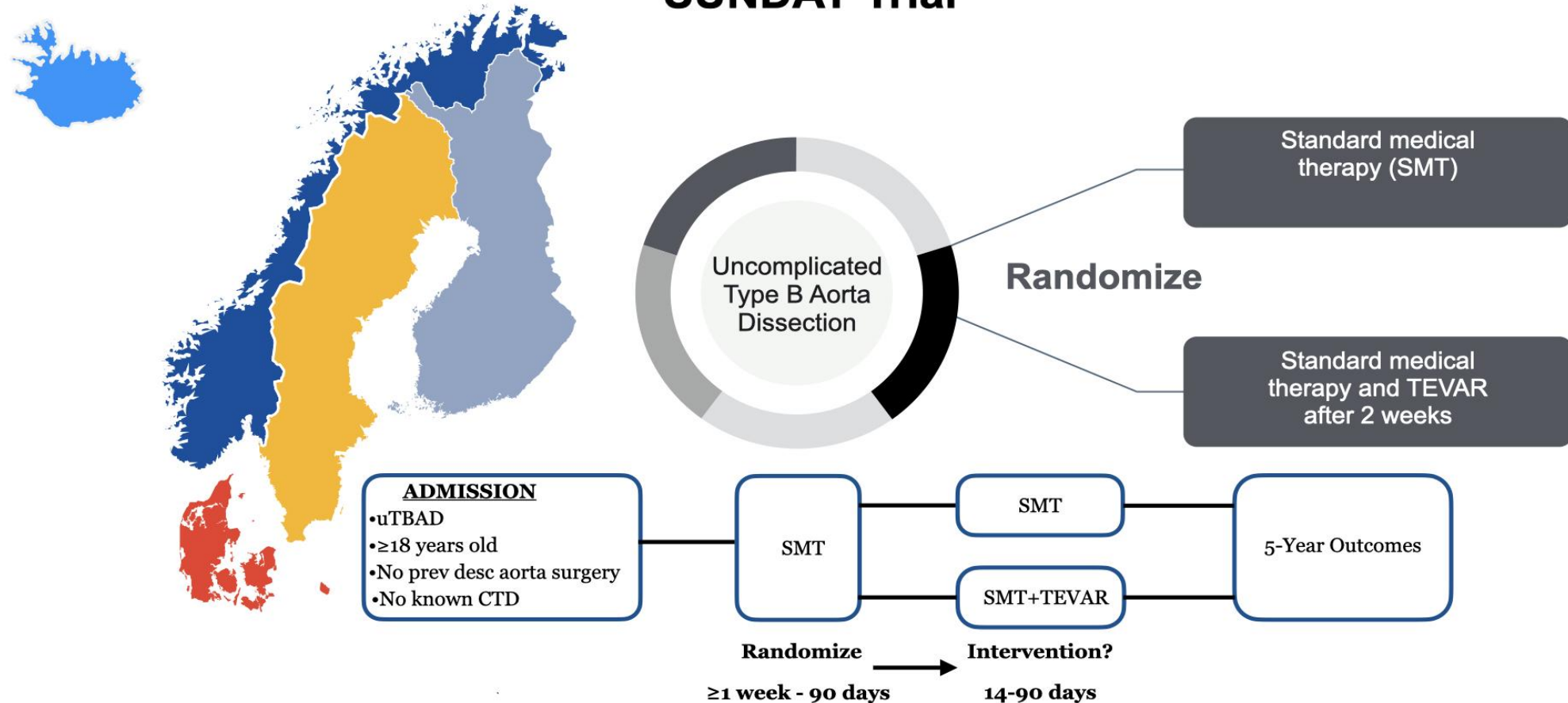
BP monitoring – home
and 24 hour assessment,
110/65mmHg

PREDICTED VS ACTUAL RECRUITMENT FOR EARNEST



The SUNDAY trial

Scandinavian Trial of Uncomplicated Aortic Dissection Therapy SUNDAY Trial





uTBAD within 48h-6 weeks of index admission

at 60 sites in North America

Inclusion criteria: • Age >18 years old • Stanford type B AD *without* rupture and/or malperfusion



1100 PATIENTS, RANDOMIZE 1:1

Site collects: Baseline history & dissection-related data, in-hospital outcomes

DCRI collects: Medical events for outcome adjudication

Patients collect: Blood pressures with home Bluetooth-enabled[®] blood pressure cuff

Primary Endpoint: 4-year endpoint of all-cause mortality, major aortic complications-MAC (Time to Event)

Secondary Endpoints: Quality of Life (multiple tools), CV hospitalizations, CV death, Components of primary outcome, Safety composite of mortality, stroke, paraplegia/paraparesis, new dialysis, vascular access injury requiring surgical repair, aortobronchial/aortoesophageal fistula, retrograde type A dissection, and secondary percutaneous interventions after TEVAR

INV: MT with Upfront TEVAR

CON: MT with TEVAR/Open Repair if Needed

IMPROVE-AD, EARNEST & SUNDAY

EARNEST: Early Endovascular Repair of Uncomplicated Type B Aortic Dissection trial

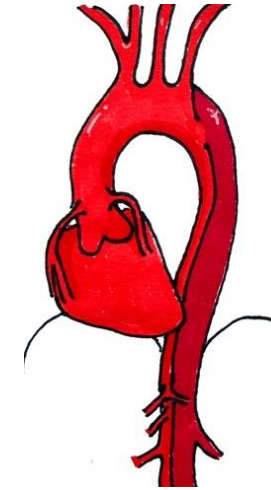
SUNDAY: Scandinavian Trial of Uncomplicated Aortic Dissection Therapy

IMPROVE-AD: IMPROving Outcomes in Vascular disEase - Aortic Dissection

	IMPROVE-AD	EARNEST	SUNDAY
# of Patients	1100	470	554 Event Driven
# Sites	60 US	25+ UK	22 sites in Scandinavia and elsewhere
Enroll/TEVAR	48h-6wks	5d-90ds	<30d-<90ds
Follow up	2.5-6 yrs Avg 4 yrs	5 yrs	5, 10 yrs
Primary EP	Death/MAC @ 4 yrs	ARM/severe permanent neurologic or cardiorespiratory failure @ 5 yrs	All-cause mortality
Statistical Plan	HR 0.73, 85%	HR 0.4, 90%	HR 0.52, 80%

Conclusion

- What to do with the uTBAD patient?
- Trials are needed given significant equipoise and is now up and running
- EARNEST, SUNDAY, IMPROVE AD designed to provide evidence
 - Trials aligned for joint analysis



NIHR | National Institute
for Health Research

EARNEST

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Endovascular/open Surgery for Type B Aortic Dissection

A randomised trial to assess the clinical and cost-effectiveness of thoracic endovascular aortic repair in the subacute phase after uncomplicated type B aortic dissection.