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TEVAR To Treat Uncomplicated Acute/Subacute Type B Aortic Dissections (uTBADs) Must Still Be Justified By An RCT: Is An Appropriate One Possible Or Not?

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DISCLOSURES

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

Consulting – Medtronic, Gore

Grant funding – Medtronic, Gore, Terumo

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Chief Investigator for NIHR EARNEST trial

Clinical lead for the UK National Vascular Registry (from next week)

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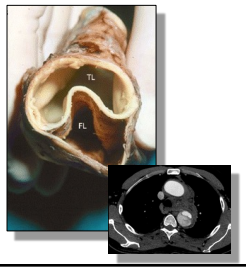
Rationale for a trial: Stenting of TBAD in the sub-acute phase



It has been proposed that early endovascular stent placement (TEVAR) in uTBAD will

- Allow remodelling of the aorta
- Lead to reduced rates of long-term dilatation and recurrent dissection
- Less aortic related death from rupture or major operative intervention.

This MUST be in the EARLY phase as the dissection flap is mobile, and there is greater true lumen expansion. After this the flap is rigid, remodelling is less and re-intervention higher.

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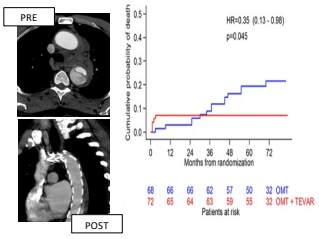
- Two RCTs showed early stenting safe, remodeling is excellent and late mortality may be improved.
- One or more systematic reviews from trials and observational studies showed OR 2.71 late ARM with BMT



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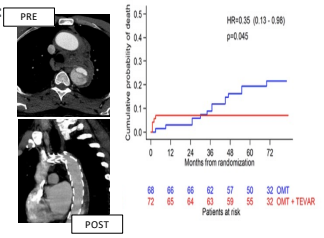
TEVAR To Treat Uncomplicated Acute/Subacute Type B Aortic Dissections (uTBADs) Must Still Be Justified By An RCT

- **But the evidence is not robust:**
  - **Numerous biases in all observational studies**
  - **Trials underpowered**
- Expert centers, not taking into account variability that exists
- Selected patients and not generalizable populations
- There is no robust method to select those that dilate
- Equipoise still exists



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	Arterial Centre	No.of TEVAR
1	St. Georges', London	71
2	Imperial College, London	70
3	Royal Brompton, London	47
4	North Bristol, Bristol	39
5	St. Thomas', London	38
6	Birmingham	38
7	Leeds	30
8	North Midlands, Stoke	26

NVR data 2016-21:

- 50% of high-volume units in London
- 6 units 11-25 cases
- 20 units 1-10 cases

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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

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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".
- This was largely influenced by the surgeon's predisposition towards intervention.

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

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

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Is An Appropriate One Possible Or Not?

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 (10 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

NIHR | National Institute for Health Research

Inclusion criteria
- Patients with uncomplicated type B aortic dissection more than ten 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

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
- 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

TADCT

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EXPECTED TRIAL PROGRESS – START MARCH 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

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YES IS THE ANSWER…

- A trial is needed given significant equipoise
  - Now is the time
  - Must be done to include all aortic centres
  - Must be a generalizable population
  - With a relevant endpoint
- It is possible
- EARNEST, SUNDAY, IMPROVE AD designed to provide evidence

NIHR | National Institute for Health Research

EARNEST

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