



ADSORB: A Study on the Efficacy of Endovascular Grafting in Uncomplicated Acute Dissection of the Descending Aorta

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WHAT THIS PAPER ADDS

- This is the first randomised trial on acute dissection. It compares best medical treatment (BMT) with BMT and stent grafting of the primary entry tear in patients having acute uncomplicated type B aortic dissection. Patients are randomised within 14 days of the onset of symptoms.
- The study is a multicentre European trial with a clear definition of uncomplicated dissection with a double lumen in the thoracic aorta. Patients with malperfusion, rupture, penetrating ulcer and intramural haematoma are excluded.
- The study will bring evidence as to whether stent grafting will produce thrombosis and remodelling of the false lumen with a reduction in aneurysm formation and re-intervention.

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ABSTRACT

Acute dissection of the descending thoracic aorta carries a 30-day mortality of around 10% with best medical treatment (BMT). In addition, about 25% will develop an aneurysm during the following 4–5 years.

This is the first ever randomised trial on acute dissections comparing BMT with BMT and stent grafting of the proximal tear in patients having an uncomplicated acute dissection of the descending aorta. The commonly used temporal definition of acute dissection being within 14 days of onset of symptoms is applied.

A total of 61 patients will be randomised and followed at regular intervals (1, 3, 6, 12, 18, 24, 30 and 36 months) after acute dissection. Thrombosis of the false lumen, aortic enlargement and rupture are the primary end points.

The study will examine whether aortic remodelling occurs after stent grafting in acute type B dissections, and its effect on aneurysm formation, rupture and re-intervention.

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Acute dissection of the ‘ascending’ aorta¹ has a 55% mortality during the first 14 days, and requires prompt surgical therapy,² which lowers the mortality to 20%. By contrast, acute dissection of the ‘descending’ thoracic aorta carries a lower initial mortality, but the mortality is higher if it is complicated by refractory pain,³ paraplegia, hypertension, lower limb ischaemia, haemothorax or

rupture.⁴ The original classification of acute dissection of the aorta by DeBakey comprises DeBakey I (affecting both the ascending and descending aorta), DeBakey II (only the ascending aorta) and DeBakey III (IIIa including the descending aorta only, IIIb descending aorta with involvement of the abdominal aorta).⁵ The later more commonly used Stanford classification (A; involving the ascending aorta and B; only involving the descending aorta) does not describe the entry tear, which is less helpful in the new era of endovascular techniques.⁶

Endovascular repair is a viable alternative to open repair in the treatment of both abdominal and thoracic aortic aneurysms (thoracic endovascular aneurysm repair (TEVAR))^{7–9} and in

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traumatic aortic rupture.^{10,11} Since the first report of stent grafts in acute dissection by Dake et al. in 1994, several case and cohort studies have demonstrated the feasibility and efficacy of endovascular repair for complicated acute dissection type DeBakey III, including patients with malperfusion of the viscera, kidneys spinal cord and the lower limbs.⁴ In addition, a meta-analysis showed better results with TEVAR than open surgery.¹²

The evidence for TEVAR in acute dissection is from registry data such as International Register on Acute Dissection (IRAD); however, no systematic study on the effect of TEVAR for the treatment of 'acute dissection' has been published. The Interventional Stent Treatment Acute Dissection (INSTEAD) trial included patients with chronic dissection who presented from 2 weeks up till 1 year after onset of symptoms. That study showed aortic remodelling during follow-up over 2 years, but this had no statistically significant effect on mortality, as the study was not powered for that.¹³ The mortality in acute DeBakey III dissections is highest within 10–14 days after the acute onset, and thereafter the mortality rate decreases,^{2,14} but many survivors need an aortic intervention as 25% of the patients develop aortic dilatation/aneurysm.¹⁵

No level I evidence exists to support endovascular treatment of acute uncomplicated DeBakey III dissections, and medical treatment is still therefore considered the best treatment. The aim of the present study is to compare best medical treatment (BMT) with BMT plus thoracic stent grafting with respect to aortic remodelling and re-intervention in patients with an uncomplicated acute dissection of the descending aorta.

Medical Treatment

Early outcome

The primary aim of BMT in DeBakey III is to reduce the blood pressure to a level of around 120 mmHg systolic and 80 mmHg diastolic, with preservation of urinary function. The preferred medication is selective beta blockade, which lowers the blood pressure by decreasing the force of left ventricular ejection (dp/dt).¹⁶ Diuretics are used to decrease blood volume, as are angiotensin-converting-enzyme (ACE) inhibitors and calcium channel antagonists, and alpha blockade may be required in refractory cases. A meta-analysis showed a reduction in 30-day mortality with BMT from 40% in the 1960s to around 10% at present.¹⁷

Late outcome

The long-term risk of developing aneurysm and malperfusion syndromes still exists despite effective medical therapy. The IRAD study followed 342 patients, of which 189 had medical therapy, 26 open surgery and 27 endovascular therapy. The 3-year survival was $77.6 \pm 6.6\%$, $82.8 \pm 18.9\%$ and $76.2 \pm 25.2\%$, respectively.¹⁸ However, the groups were not comparable as surgical or endovascular treatment was only used in patients with complicated dissections, and BMT in uncomplicated dissections. Another confounding factor was the inclusion of patients with intramural haematoma making evaluation less reliable. A study of 189 patients, with 111 being treated medically and the rest surgically, showed no difference between the groups with a 1-year survival of 70% and a 5-year survival of 60%.¹⁹ In a recent study, the mortality after medical treatment of DeBakey type III dissection was 10% although the number of patients developing complications requiring intervention was not given.²⁰ In another publication, 14% of medically treated patients required intervention.²¹

Study Objectives

The objective of the acute dissection stent grafting or best medical treatment (ADSORB) trial is to assess the safety and efficacy of BMT and endoluminal stent graft (TAG[®] device) compared to BMT alone in patients with acute uncomplicated type B (DeBakey III) aortic dissection. The multicentre, prospective, randomised controlled trial will be conducted in Europe and will randomise patients to one of two treatment groups.

End point

Primary end point

The primary end point for this study is a composite of the following events:

Incomplete or no false lumen thrombosis (FLT) at 1 year

Test Group: Incomplete thrombosis will be defined as the presence of blood flow in any portion of the false lumen parallel to the stent graft, excluding the distal 2 cm; Complete thrombosis will be defined as absence of blood flow in any portion of the false lumen parallel to the stent graft, excluding the distal 2 cm; No FLT will be defined as the presence of blood flow throughout the entire false lumen within the descending thoracic aorta parallel to the stent graft.

Control Group: Incomplete thrombosis will be defined as the presence of blood flow in any portion of the false lumen at any point in the descending thoracic aorta. Complete thrombosis will be defined as absence of blood flow in any portion of the false lumen at any point in the descending thoracic aorta. No FLT will be defined as the presence of blood flow throughout the entire false lumen within the descending thoracic aorta.

Aortic dilatation at 1 year

An increase of ≥ 5 mm in the maximum diameter of the descending thoracic aorta compared to the pre-treatment computed tomography (CT) measurement or the maximum diameter of the descending thoracic aorta ≥ 55 mm at the 1-year follow-up visit.

Aortic rupture (descending thoracic aorta or abdominal aorta) through the 1-year follow-up visit

Disruption of the descending thoracic or abdominal aorta with fresh blood outside the adventitia observed on CT, radiograph or other radiological modalities at any time through the 1-year follow-up visit.

Sample size calculation

Based on published calculations, the expected incidence of an acute aortic dissection is three out of 100 000 persons.^{22,23} 40% are confined to the descending aorta² giving 1.2–2/100 000 persons/year. The definition of an acute dissection is less well defined in the various publications where intramural haematoma and penetrating aortic ulcers have been included. Only acute dissection with a double lumen aorta will be included, and penetrating ulcer and intramural haematoma will be excluded.

It was deduced from published series on acute aortic descending thoracic dissection, that 35% of the patients treated medically would thrombose the false lumen over a 1-year period. From the IRAD data and other published series on TEVAR for acute complicated dissections, it was deduced, that on average 55% of TEVAR-treated patients would thrombose the false lumen.

Hypothesis

The null hypothesis upon which the study design was based is that there will be no difference in the proportion of patients event

free at 1 year between the test (π_T) and control (π_C) groups. The alternative hypothesis is that the proportion of patients being event free at 1 year will be greater for patients treated with stent grafts and medical therapy than the medically managed patients alone.

Sample size calculation (initial design)

For the composite end point, it was assumed that the primary difference between the groups would be largely determined by the proportion of patients experiencing FLT. It was assumed that FLT in medically managed subjects would be relatively infrequently observed.

Therefore, the sample size calculation was based on the following assumptions:

- π_T , the test event proportion = 0.35
- π_C , the control event proportion = 0.55
- Clinically meaningful target effect size ($\delta = \pi_C - \pi_T$) = 0.20
- Significance level (α) = 0.05, two-sided

Under these assumptions, a sample size of 250 patients (125 per group) would provide 89% power to test the primary hypothesis under the intent-to-treat analysis. This sample size would also provide at least 85% power for the evaluation of the test using the per protocol analysis, assuming a 10% rate of protocol violations. These calculations assume the use of a two-sided Chi-square test for the primary analysis of the 1-year end point.

Sample size calculation (reduced sample size)

During the design of the TAG 05-04 (ADSORB) trial, much uncertainty remained surrounding the end point event rate. Very conservative estimates for FLT were therefore used in the sample size calculation. During the recruitment phase of this study, two things became apparent; first it was realised that much fewer patients than expected met the inclusion criteria and, secondly, new studies on the thrombosis rate in BMT groups and after TEVAR were published.^{13,15} This new information, in combination with the slower than expected enrolment, led us to recalculate the sample sizes as the enrolment period using the old methodology would be more than 7 years.

Event rates for FLT for patients treated with a stent graft in recently published studies were:

- TAG 04-01 – 86% FLT at 1 year ($\pi_T = 0.14$)
- INSTEAD – 91% FLT at 2 years ($\pi_T = 0.09$)
- Song et al. – 88% FLT at 1 year ($\pi_T = 0.12$)
- Medical patients
- INSTEAD – 21% FLT at 2 years ($\pi_C = 0.79$)

Given this, it was determined that ADSORB was overpowered at 250 patients and therefore it was re-designed to test the same hypotheses with a smaller sample size, based on the following assumptions. In addition, more patients would be enrolled than were required which would be unethical.

- π_T , the test event proportion = 0.12
- π_C , the control event proportion = 0.70
- Clinically meaningful target effect size ($\delta = \pi_C - \pi_T$) = 0.58
- Significance level (α) = 0.05, two-sided

A sample size of 60 patients (30 per group) would provide 86% power to test the primary hypothesis under the intention-to-treat analysis. This sample size also provides over 90% power for the evaluation of the test using the per protocol analysis, assuming a 10% rate of protocol violations. These calculations assume the use

of a two-sided Chi-square test for the primary analysis of the 1-year end point.

Primary end point analysis population

The analysis of the primary end point will be based upon the intention-to-treat principle. All subjects randomised into the study will be analysed for the 1-year primary end point as randomised, regardless of actual treatment received. Any treatment crossovers (e.g., BMT subjects who receive a GORE TAG device following randomisation) will be included with the originally assigned treatment group.

Patient Selection

BMT is normally started as soon as the diagnosis of aortic dissection has been made. All eligible patients (see inclusion and exclusion criteria below) will be requested to give informed consent, both for treatment and for follow-up. Patients will undergo laboratory and imaging studies to identify eligibility for the study. If all inclusion and no exclusion criteria are met, patients will be randomised immediately, which is designed to balance the number of test and control patients.

Patients randomised to the test group will receive their treatment within 48 h.

Clinical Study Plan

Patients will be evaluated pre-treatment, at discharge and will return for follow-up visits at 1 month (± 7 days), 3 months (± 14 days), 6 months and every 6 months thereafter for 3 years. Chest X-rays and CT scans are required either at discharge or at 1 month follow-up visit. CT scans will be performed at 3 months and annually thereafter. Patients in the control group will undergo identical follow-up evaluations, with the exception of chest X-rays, which will be performed only in the test group.

Morphological evaluation

The basis for the randomisation will be the judgement of the treating physicians, and all the morphology data will be entered by the treating physician. Fig. 1. An independent core lab situated in Heidelberg will separately evaluate all CT scans to standardise evaluation and reporting of the investigations. In this way, there will be no delay in randomisation, but there will be a standardised evaluation of all patients.

Discussion

The open surgical repair of acute dissection of the descending thoracic aorta reported by DeBakey in 1955 and 1965 comprised open fenestration, but the results were not encouraging. Closure of the false lumen at the proximal tear became more popular and improved outcome. Antihypertensive treatment has been shown to be an effective treatment for uncomplicated DeBakey type III dissection such that there is no role for open surgery in this setting.

In the acute phase, surgery may be indicated in patients with overt or pending rupture of the thoracic aorta. This includes replacing a section of the aorta with closure of the proximal tear and false lumen. Open fenestration in combination with a bypass procedure may rarely be necessary. In patients with ischaemic complications such as visceral or renal ischemia or paraplegia, the mortality of open surgery is high at 21–50%.²⁴ Interventional radiological techniques such as fenestration and stenting of the branch vessel orifices may produce good reperfusion as shown by 37 of 40 malperfused vessels being revascularised in one series;

Location			Measurement List single value used to select device(s)	Range List range of measurements taken	CT Frame or Table Position
Diameter					
D2	Aorta	2 cm proximal to primary entry tear	mm	mm	
D1	Aorta	1 cm proximal to primary entry tear	mm	mm	
C1	Maximum True Lumen Diameter		mm	mm	
C2	Minimum True Lumen Diameter		mm	mm	
C3	Distal Landing Zone Diameter		mm	mm	
E1	Maximum False Lumen Diameter		mm	mm	
E2	Overall Transverse Diameter		mm	mm	
F	R common Iliac Diameter		mm	mm	
G	L common Iliac Diameter		mm	mm	
H	R ext. Iliac / Femoral Diameter		mm	mm	
I	L ext. Iliac / Femoral Diameter		mm	mm	
Length					
L1	Proximal Neck	distance from primary entry tear to LSA	mm	mm	
L2	Proximal Neck	distance from primary entry tear to LCA	mm	mm	
L3	Distal Neck	distance from primary entry tear to celiac axis	mm	mm	

Vertical dissection extension	Type of measurements
Includes thoracic aorta <input type="checkbox"/>	Center line <input type="checkbox"/>
Includes thoracic aorta and abdominal aorta <input type="checkbox"/>	Axial <input type="checkbox"/>
Includes thoracic aorta, abdominal aorta, iliac artery <input type="checkbox"/>	MPR oblique <input type="checkbox"/>

Planned LSA procedure	No <input type="checkbox"/>	Coverage <input type="checkbox"/>	Bypass <input type="checkbox"/>	Transposition <input type="checkbox"/>
Is there significant thrombus at the proximal implantation site?	No <input type="checkbox"/>	Yes <input type="checkbox"/>		
Is there significant calcification at the proximal implantation site?	No <input type="checkbox"/>	Yes <input type="checkbox"/>		

Figure 1. (a) The protocol form for the measurements.

however, 10 of the 40 patients died. All these techniques do not deal with the dissection itself but only with the ischaemic complications.

Dake et al. in 1994 first reported using an endograft to treat acute DeBakey type III aortic dissections.²⁵ Endovascular repair can effectively seal the proximal tear with thrombosis of the false lumen in up to 90–98% of the cases.^{13,26} The rationale for endovascular therapy is to close the primary entry tear causing pressure reduction and thrombosis of the false lumen and restoring the normal anatomy. False lumen obliteration is associated with better long-term outcome in patients presenting with acute dissection.^{21,27} Stent graft therapy could also result in less aneurysm formation in the long term. However, the false lumen distal to the device may not be thrombosed by the stent graft. The reason for this is the presence of secondary tears in the distal aorta, which perfuse the false lumen. The rate of complete obliteration of the false lumen with apposition of the dissection flap to the outer wall after closure of the proximal tear is currently unknown.

Several reports on the outcome of endovascular treatment of DeBakey type III dissection have been published. A search of PUBMED from 1990 and onwards, revealed 50 publications with a total of 3990 patients who had a dissection of the thoracic descending aorta. A total of 39 patients died immediately after admission. One of the feared complications of open surgery is paraplegia, which affected 6.6% in the open group and 2.4% in the endovascular group and 0% of the group treated medically. The role of endovascular treatment in uncomplicated acute aortic dissection DeBakey type III (Stanford B) has not been scientifically addressed.

The tissues in acute dissection are less rigid and fibrotic so endovascular repair may well result in aortic remodelling producing a single lumen aorta especially at the site of the device.

The mortality in the BMT group is thus not insignificant at 10%,² so the question arises as to whether endovascular treatment can reduce mortality further. This question though will not be answered by the present study. Furthermore, the optimal length to cover with TEVAR will also not be answered by this study.

There are at present no randomised studies on this subject in the literature. The ADSORB trial is currently recruiting patients and will report on thrombosis of the false lumen and both dissection-related and overall mortality after 1 and 3 years of follow-up.

Inclusion/Exclusion Criteria

Inclusion criteria

1. Presence of acute uncomplicated type B aortic dissection.
 - *Acute* is defined as time from symptom onset to diagnosis ≤ 14 days.
 - *Uncomplicated* course includes freedom from:
 - end-organ ischaemia or evidence of malperfusion.
 - paraplegia.
 - rupture (free or contained) or impending rupture.
 - uncontrollable pain (minimal pain after initial medical therapy is acceptable).
 - *Type B* dissection where the primary entry tear is distal to the left subclavian artery with no involvement of the ascending aorta or aortic arch.

- **Aortic dissection** is distinguished by radiological evidence of a dissection flap and dual aortic lumens. Dissection variants such as intramural haematoma and penetrating ulcer are not allowed in this study.
- 2. Maximum transverse diameter of the descending thoracic aorta <55 mm and absence of descending thoracic aortic aneurysm, regardless of aetiology.
- 3. Arterial anatomy is appropriate for stent graft therapy, defined as:
- 4. Proximal landing zone is not aneurysmal, dissected or significantly thrombosed.
- 5. Proximal landing zone length ≥ 2.0 cm.
- 6. Proximal landing zone diameters between 23 and 42 mm.
- 7. Non-tortuous or non-stenotic iliac and/or femoral arteries or ability to use a conduit for vascular access.
- 8. Able to tolerate endotracheal intubation and general anaesthesia.
- 9. Age 18–80 years.
- 10. Declaration of voluntary participation in the study with signed informed consent form.
- 11. Capable of complying with study protocol requirements, including long-term medical treatment with beta blockers, diuretics and/or ACE-inhibitors and follow-up for 3 years post-randomisation (patient must have ≥ 3 -year life expectancy and ability to return for scheduled follow-up visits).

Exclusion criteria

1. American Society of Anesthesiologists (ASA) classification = V.
2. Severe renal insufficiency defined as Society for Vascular Surgery (SVS) risk renal status = 3.
3. Severe respiratory insufficiency defined as SVS risk pulmonary status = 3.
4. Presence of connective tissue disease (Marfan's syndrome or Ehlers-Danlos syndrome).
5. Active infection or active vasculitis.
6. Positive pregnancy test.
7. Participation in another medical research study within 3 months of study enrolment.
8. Myocardial infarction or cerebrovascular accident within 6 weeks prior to study enrolment.
9. Planned concomitant surgical procedures (other than left subclavian artery transposition or bypass) or major surgery within 30 days of study enrolment.
10. History of drug abuse.

ADSORB triallists

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