Endovascular Repair of Acute Uncomplicated Aortic Type B Dissection Promotes Aortic Remodelling: 1 Year Results of the ADSORB Trial

J. Brunkwall [a,*], P. Kasprzak [b], E. Verhoeven [c], R. Heijmen [d], P. Taylor [d], the ADSORB Trialists [e]

[a] Department of Vascular and Endovascular Surgery, University Clinics, University of Cologne, Cologne, Germany
[b] Section of Vascular Surgery, Department of Surgery, University of Regensburg, Department of Vascular Surgery, Klinikum Nuernberg, Nuremberg, Germany
[c] Department of Cardiovasc Surgery Antonius Hospital, Nieuwegein, The Netherlands
[d] Department of Vascular Surgery, St Guys Hospital, London, UK

WHAT THIS PAPER ADDS

This is the only prospective randomised trial on acute type B dissection. The definition of the acute dissection is clearly defined as is the outcome. In the highly specialised centres participating, the outcome was good and the rate of thrombosis of the false channel can be estimated and be used as reference. Stent grafts induced thrombosis of the false channel and were safe to implant.

Objectives: Uncomplicated acute type B aortic dissection (AD) treated conservatively has a 10% 30-day mortality and up to 25% need intervention within 4 years. In complicated AD, stent grafts have been encouraging. The aim of the present prospective randomised trial was to compare best medical treatment (BMT) with BMT and Gore TAG stent graft in patients with uncomplicated AD. The primary endpoint was a combination of incomplete/no false lumen thrombosis, aortic dilatation, or aortic rupture at 1 year.

Methods: The AD history had to be less than 14 days, and exclusion criteria were rupture, impending rupture, malperfusion. Of the 61 patients randomised, 80% were DeBakey type IIIB.

Results: Thirty-one patients were randomised to the BMT group and 30 to the BMT+TAG group. Mean age was 63 years for both groups. The left subclavian artery was completely covered in 47% and in part in 17% of the cases. During the first 30 days, no deaths occurred in either group, but there were three crossovers from the BMT to the BMT+TAG group, all due to progression of disease within 1 week. There were two withdrawals from the BMT+TAG group. At the 1-year follow up there had been another two failures in the BMT group: one malperfusion and one aneurysm formation ($p = .056$ for all). One death occurred in the BMT+TAG group. For the overall endpoint BMT+TAG was significantly different from BMT only ($p < .001$). Incomplete false lumen thrombosis, was found in 13 (43%) of the TAG+BMT group and 30 (97%) of the BMT group ($p < .001$). The false lumen reduced in size in the BMT+TAG group ($p < .001$) whereas in the BMT group it increased. The true lumen increased in the BMT+TAG ($p < .001$) whereas in the BMT group it remained unchanged. The overall transverse diameter was the same at the beginning and after 1 year in the BMT group (42.1 mm), but in the BMT+TAG it decreased (38.8 mm; $p = .062$).

Conclusions: Uncomplicated AD can be safely treated with the Gore TAG device. Remodelling with thrombosis of the false lumen and reduction of its diameter is induced by the stent graft, but long term results are needed.

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[e] P. Alric and L. Canaud, CHU Arnaud de Villeneuve, Montpeiller; M. Janotta, Section of Vascular Surgery, Department of Surgery, University of Regensburg; D. Raithel, Klinikum Nuernberg; M. Malina and Ti. Resch, Dept. Vascular Diseases, University Hospital, Malmö; H.-H. Eckstein and S. Ockert, Dept. Vascular Surgery TUM Munich; T. Larzon, Section of Vascular Surgery; F. Carlsson, Department of Cardiology, Örebro University Hospital, Örebro; H. Schumacher, S. Classen, and P. Schaub Dept. Vascular Surgery, Hanau; J. Lammer, Dept. Radiology, General Hospital, Vienna; L. Lönn, Dept. Vascular Surgery and Radiology, Rigshospitalet, Copenhagen; Rachel E. Clough, Dept. Vascular Surgery, St Guys Hospital, London; V. Rampoldi and S. Trimarchi, Policlinico San Donato, Milan; J.-N. Fabiani, APHP Hopital Europeen Georges Pompidou, Paris; D. Böckler and D. Kotelis, Dept. Vascular Surgery, University Clinics, Heidelberg; H. von Tenng-Kobligk, Dept. Radiology, University Clinics, Heidelberg; N. Mangialardi and S. Ronchey, Azienda Ospedaliera S. Filippo Neri, Rome; G. Dialetto, V. Monaldi Hospital, Naples; V. Matoussevitch, Department of Vascular and Endovascular Surgery, University Clinics, University of Cologne. ClinicalTrial.gov identifier: NCT00742274.

* Corresponding author. J. Brunkwall, Department of Vascular and Endovascular Surgery, University Clinics, University of Cologne, Kerpener Strasse 62, 50931 Cologne, Germany.
E-mail address: jan.brunkwall@uk-koeln.de (J. Brunkwall).

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INTRODUCTION

Acute type B aortic dissection (AD) involving the descending thoracic aorta has an approximately 10% 30-day mortality.[1] The mortality of open surgery for complicated acute type B dissection is up to 30%, and in malperfusion it reaches 50%.[2,3] Alternative endovascular techniques such as aortic membrane fenestration and stenting of side branches have good patency rates but still result in high mortality.[4–7] Placing a stent graft to cover the primary entry tear shows good results in complicated acute type B dissection, with a lower mortality.[8–11]

Systolic blood pressure around 100–120 mmHg after treatment of acute uncomplicated type B AD results in a 30-day mortality of 6–10%.[1,12] Dilation of the false lumen affects up to 50% of patients over 5 years, and survival ranges from 50% to 82%.[12,13] Complete thrombosis of the false lumen is associated with better survival than a fully patent false lumen in non-stent-grafted patients, but partial thrombosis has the worst outcome.[14] Another study, though, shows that thrombosis of the false lumen was not an independent factor for intervention.[15] Involvement of the abdominal aorta by dissection (DeBakey IIIb) also carries a worse outcome than those affecting only the thoracic aorta (DeBakeyIIIa).[16]

There are only two prospective randomised trials on uncomplicated dissection, the present ADSORB (Acute Dissection Stentgraft OR Best Medical Treatment) trial for acute dissections and the INSTEAD trial (Investigation of STEnt grafts in Acute Dissection) for dissections between 14 days and 1 year (chronic). A newly published article revealed different outcomes in those patients receiving TEVAR between 2 weeks and 3 months,[17] indicating that this time period could be defined as subacute instead of chronic.

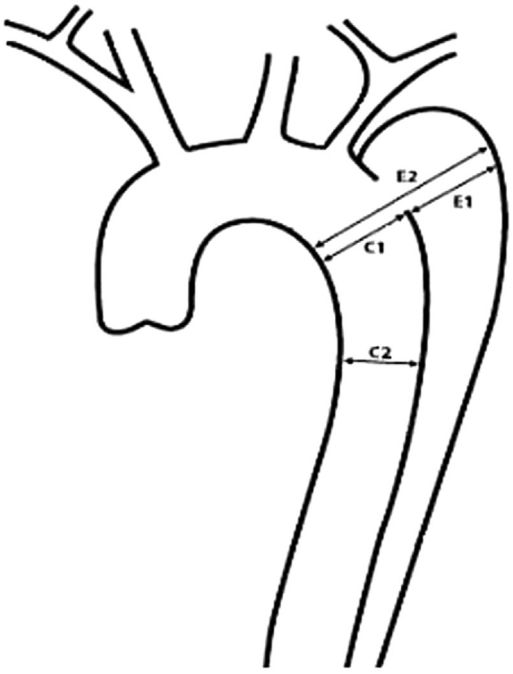

Figure 1. Measurement sites performed by the Corelab. C1 = maximum diameter of true lumen, C2 = minimum diameter of true lumen, E1 = maximum diameter of false lumen, E2 = overall transverse aortic diameter.

The INSTEAD trial, including 136 patients with chronic dissection showed that stent graft repair was associated with expansion of the true lumen compared with those treated medically and a lower all-cause and aortic-related mortality than medical treatment alone at 5 years.[18–20] The ADSORB trial is the only prospective randomised trial for acute uncomplicated type B dissection.

The aim of the present prospective multicentre randomised European study in uncomplicated type B dissection (DeBakey III) is to compare the primary endpoint with freedom from all of the following events at 1 year:

1. *Incomplete or no false lumen thrombosis* in any portion of the false lumen parallel to the stent graft, excluding the distal 2 cm, and in the BMT group at any point in the descending thoracic aorta.
2. *Aortic dilatation* of ≥5 mm or the maximum diameter of the descending thoracic aorta ≥55 mm.
3. *Aortic rupture (descending thoracic or abdominal aorta)* with fresh blood outside the adventitia observed on computed tomography (CT).

Ethical approval was given by the corresponding ethics committee at each site.

MATERIALS AND METHODS

The protocol for the ADSORB trial has already been published and will only be briefly summarised here.[21] Between December 2008 and December 2010, patients presenting with an acute uncomplicated type B dissection and without any evidence of connective tissue disease were randomised within 14 days of onset of symptoms. All patients were immediately treated with blood pressure control and were randomised to best medical treatment (BMT) alone or BMT with endoluminal repair using a Gore TAG device (TAG+BMT). The TAG treatment had to be done within 48 hours of randomisation. The analysis of the primary endpoints was based upon the intention-to-treat principle and when separately noted, per protocol.

Patients with a double lumen dissection were included, but not other variants of acute aortic syndrome. The proportion of type IIIB dissections using DeBakey's classification criteria was determined if the dissection involved the superior mesenteric artery (SMA), inferior mesenteric artery (IMA), any renal artery or the abdominal aorta. Otherwise it was a type IIIA dissection. The proximal landing zone had to be 2 cm in length and the device at least 15 cm long. The oversizing should not be more than 10%, but the total length of the device was left up to the treating team to decide. Coverage of the left subclavian artery was allowed in order to achieve an adequate proximal sealing zone, and the local team decided upon the need for revascularisation of the left subclavian artery. Coverage of the left common carotid artery was not allowed. Blood pressure control aimed to regulate the blood pressure to ≤120/80; blood pressure was monitored during follow-up.