



## Invited Commentary

## ADSORB: A Prospective Randomised Study on the Efficacy of Endovascular Grafting vs. Best Medical Treatment in Uncomplicated Acute Dissection of the Descending Aorta

R.J. Hinchliffe\*, M.M. Thompson

*St George's Vascular Institute, London, United Kingdom*

Many of the arterial lesions that vascular surgeons treat are on the decline, and those that currently are may soon be offered more effective drug therapy. In contrast, dissections of the aorta are increasing and are likely to represent a significant future workload and challenge for vascular surgeons. Traditionally acute Stanford type B dissections of the aorta were managed by a variety of specialists, often cardiologists. Vascular surgeons only became involved where peripheral ischaemia supervened.

Dake demonstrated the feasibility of placing endovascular stent-grafts in to dissected aortas.<sup>1</sup> This approach appeared to offer an attractive alternative to traditional open surgical approaches for complicated aortic dissection which carried high rates of complications.<sup>2</sup> Consequently stent-grafts have been used increasingly in this group of patients.<sup>3</sup>

Early efforts to reduce mortality from acute type B dissection demonstrated that effective blood pressure control in the early stages reduced mortality. Medical therapy did not necessarily prevent long-term aortic related complications. The INSTEAD Trial attempted to answer the question whether there was any benefit from placing a stent-graft in type B aortic dissection in the sub-acute phase (2–52 weeks).<sup>4</sup> There was no reduction in aortic related mortality 2 years after the initial dissection but preliminary data from INSTEAD suggests that stent-grafting might be protective in the longer term (5 years).

The next question is whether there would be any additional benefit (or harm) from stenting patients within the first 2 weeks of their initial uncomplicated type B dissection? There remains scope for improvement in the 10% in-hospital mortality when treated with medical therapy.<sup>5</sup> It is possible that stenting might reduce mortality. However, concerns remain (due in part to a lack of data) that stenting within the first 2 weeks may be associated with significant risks even when the aortic dissection is uncomplicated.

It is for these reasons that we have been following the development of the ADSORB trial keenly since its inception in 2002. Recruitment has been slow, suggesting a lack of clinical equipoise and the change of power calculation is regrettable but seems realistic if

the trialists are to complete their study. It is a pity that the trial will not have the power to demonstrate significant differences in the more robust clinical endpoints (aortic related or all-cause mortality). It is not clear whether the primary trial composite endpoint of a variety of aortic related events (false lumen thrombosis, aortic dilatation >5 mm, aortic rupture) at 1-year will be a clinically relevant one for patients. In the INSTEAD Trial 20% of patients managed non-operatively achieved false lumen thrombosis. It is quite possible that this group of patients receiving early stent-grafting in the ADSORB trial might not derive any benefit at all (and may be harmed).

Significant ADSORB trial design issues exist. The inclusion of patients who are very young (lower limit of 18 years old) means significant numbers of patients with connective tissue disease (previously diagnosed or otherwise) may be recruited. We know this group appear to behave differently.<sup>6</sup> Because the trial was initiated some 10 years ago emerging evidence on the length of coverage of aortic stent-graft and on medical therapy have not been incorporated and may skew outcomes.<sup>7,8</sup> The trialists also need to be clear on what they consider to be 'complicated'. For example does a DeBakey type IIIb dissection with one renal artery emerging from the false lumen with only minor renal functional impairment constitute a complicated or uncomplicated type B dissection?

The authors are to be congratulated on performing a randomised trial in an acute setting. The ADSORB trial will be a useful addition to the literature. But are the findings of the ADSORB trial likely to change clinical practice? The results would only change practice if there were significant increases in the proportion of patients who developed aortic remodelling or there was a significant reduction in the early mortality compared with best medical therapy. The trouble is that we already know aortic remodelling occurs in the overwhelming majority (90+%) of patients who are stented up to 3 months or longer after their acute dissection. And the trial is not powered to detect a reduction in early mortality.

### References

- Walker PJ, Dake MD, Mitchell RS, Miller DC. The use of endovascular techniques for the treatment of complications of aortic dissection. *J Vasc Surg* 1993 Dec; **18**(6):1042–51.
- Fattori R, Tsai TT, Myrmet T, Evangelista A, Cooper JV, Trimarchi S, et al. Complicated acute type B dissection: is surgery still the best option?: a report

DOI of original article: 10.1016/j.ejvs.2012.03.023.

\* Corresponding author. Tel.: +44 (0) 2087252816.

E-mail address: [rhinchli@sgul.ac.uk](mailto:rhinchli@sgul.ac.uk) (R.J. Hinchliffe).

- from the International Registry of Acute Aortic Dissection. *JACC Cardiovasc Interv* 2008 Aug;**1**(4):395–402.
- 3 Sachs T, Pomposelli F, Hagberg R, Hamdan A, Wyers M, Giles K, et al. Open and endovascular repair of type B aortic dissection in the nationwide inpatient sample. *J Vasc Surg* 2010 Oct;**52**(4):860–6.
  - 4 Nienaber CA, Rousseau H, Eggebrecht H, Kische S, Fattori R, Rehders TC, et al, INSTEAD Trial. Randomized comparison of strategies for type B aortic dissection: the INvestigation of STEnt Grafts in Aortic Dissection (INSTEAD) trial. *Circulation* 2009 Dec 22;**120**(25):2519–28.
  - 5 Nienaber CA, von Kodolitsch Y. Meta-analysis of the prognosis of thoracic aortic dissection: changing mortality in the last four decades. *Herz* 1992 Dec;**17**(6):398–416.
  - 6 Nordon IM, Hinchliffe RJ, Holt PJ, Morgan R, Jahangiri M, Loftus IM, et al. Endovascular management of chronic aortic dissection in patients with Marfan syndrome. *J Vasc Surg* 2009 Nov;**50**(5):987–91.
  - 7 Lombardi JV, Cambria RP, Nienaber CA, Chiesa R, Teebken O, Lee A, et al, STABLE investigators. Prospective multicenter clinical trial (STABLE) on the endovascular treatment of complicated type B aortic dissection using a composite device design. *J Vasc Surg* 2012 Mar;**55**(3):629–40.
  - 8 Suzuki T, Isselbacher EM, Nienaber CA, Pyeritz RE, Eagle KA, Tsai TT, et al. IRAD Investigators. Type-selective benefits of medications in treatment of acute aortic dissection (from the International Registry of Acute Aortic Dissection [IRAD]). *Am J Cardiol* 2012 Jan 1;**109**(1):122–7.