European Journal of Vascular and Endovascular Surgery 44 (2012) 37

Contents lists available at SciVerse ScienceDirect

European Journal of Vascular and Endovascular Surgery

journal homepage: www.ejves.com

Invited Commentary

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

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To the Editor, Jean-Baptiste Ricco

We would like to congratulate the ADSORB trialists with the initiative of the much awaited trial on management of acute type B aortic dissections. Many of us in the vascular community are looking forward to hearing the answers ADSORB set out to provide. The trial design printed in this Journal is well written, but it does raise a few methodological questions.

Firstly, the primary endpoint of this study comprises a composite of aortic rupture, aortic dilatation and/or observation of blood flow in the false lumen. However, aortic dilatation and complete false lumen thrombosis (surrogates of aortic remodelling) correspond to outcomes on imaging studies, but their true clinical significance is not completely understood.[1,2] Consequently, this study may fail to answer the question of added clinical benefit from stent grafting acute uncomplicated dissections.

Also, bias may be introduced by the endpoint definitions. For instance, complete false lumen thrombosis, is defined as total thrombosis of the descending thoracic false lumen for the medical therapy arm. In the stent group, however, complete thrombosis is defined as thrombosis of only the segment parallel to the stent graft, excluding the last 2 cm, meaning the remainder of the false lumen may be patent. Since the lamella is slim and mobile in the (sub)acute stages, implantation of a correctly sized endograft would expectantly compress the majority of the false lumen, as confirmed by INSTEAD.[3] It is doubtful that medical therapy alone will result in false lumen collapse. Since this is the "driving force" behind the primary endpoint, it may seem that the trial is designed to favour stengrafting.

Finally, a reflection is required regarding the dramatic change in sample size, based on data from false lumen thrombosis (which was published long after the initial ADSORB-trial design). Is a trial still required to show such a large difference in the rates of false lumen thrombosis in medical vs. stent graft groups (target effect size = 0.58)? In other words, is there still equipoise to justify a randomized trial? Naturally, if more "conventional" endpoints had been chosen (such as long-term freedom from rupture, dissection-related complications, re-intervention or death) much larger numbers would be required, but more definitive and clinically relevant data would be obtained.

The vascular community is eagerly looking for final answers on how to manage uncomplicated type B dissections, but it is still unclear if ADSORB will deliver these.

References

1 Tsai TT, Evangelista A, Nienaber CA, Myrmel T, Meinhardt G, Cooper JV, et al. Partial thrombosis of the false lumen in patients with acute type B aortic dissection. *N Engl J Med* 2007;**357**:349–59.

2 Akutsu K, Nejima J, Kiuchi K, Sasaki K, Ochi M, Tanaka K, et al. Effects of the patent false lumen on the long-term outcome of type B acute aortic dissection. *Eur J Cardiothorac Surg* 2004;**26**:359–66.

3 Nienaber CA, Rousseau H, Eggebrecht H, Kische S, Fattori R, Rehders TC, et al. Randomized comparison of strategies for type B aortic dissection: the INvestigation of STEnt Grafts in Aortic Dissection (INSTEAD) trial. *Circulation* 2009;**120**:2519–28.

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

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doi:10.1016/j.ejvs.2012.04.005