Endovascular Repair of Aortic Transection can be a Durable Treatment Option

We enjoyed reading the paper by Mohan et al.1 Our experience in the endovascular management of aortic transection began in 1997. This patient was an 18-year-old male who on initial presentation underwent operative management of both splenic and liver injuries, with the diagnosis of aortic transection not made until 6 weeks after the event. He subsequently underwent successful deployment of a Vanguard device (Boston Scientific, Natick, MA) via an infrarenal conduit and has remained well during both imaging and clinical follow-up.

Although this early generation device was not thought to be durable it has performed well in the thoracic aorta for 11 years. This may be due to the fact that this transection was not circumferential. It is possible that partial transections have the ability to heal and therefore the device is not subjected to the same forces as would be seen in a degenerative aneurysm.

Endovascular repair is so successful that it has become the treatment of choice for aortic transection. The problem of stent graft collapse will decrease with increasing experience, smaller stents and more compliant devices.

Reference


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We thank Messrs Clough and Taylor for their interest in our paper.1 The case presented, highlights many of the difficulties and challenges faced in this critically injured group of patients, and it is without doubt that stent grafts should now be the treatment of choice for thoracic aortic transections. Questions of graft durability are still of concern in this young patient cohort, and only time will provide the answers.

The pathology of thoracic aortic injury has been well documented.2 While some aortic tears may heal over, they are still at risk of chronic pseudoaneurysm formation, and late rupture.3 The mechanical forces on the stent graft in this condition may well be very different to that seen in patients with established thoracic aneurysms, and this may explain the longevity of the device used in their patient. Despite the difficulties encountered with the early generation commercially available endovascular devices in aneurysmal disease, the Vanguard Device (Boston Scientific, Natick, MA) has served this patient well.

We agree that continued evolution of the technique will further decrease both patient and graft-related complications and provide further answers regarding graft durability.

References


Comment on: “When does the ‘‘Learning curve’’ of innovative interventions become questionable practice?”, P. Healey and J. Samanta, Eur J Vasc Endovasc Surg 2008;36:253–257

Sir,

I write to congratulate the Authors and the Series Editor, Professor Naylor, for an excellent article on the medico-legal aspects of surgical intervention. In my view, this article should become compulsory reading for Consultants and Trainees in all surgical specialties. I do hope that this article will also be read by Lawyers involved with medico-legal work. Perhaps the article could be re-published in a Legal Journal? There should be no impediment to dual publication as the audiences of the two Journals are completely different, as long as copyright is acknowledged.

I disagree with the Authors in only one of their statements. That is that: "We do not support the claim that with any new surgical procedure a randomised trial should begin with the first patient as this could potentially stifle advancement in surgical technique."

I agree that a randomised trial cannot take place until a new surgical procedure or device has been developed to the point where a trial seems feasible. However, I disagree that a monitoring or audit period should be a requirement to enter a trial. The Authors themselves state that: "The ‘‘learning curve’’ needs careful monitoring to ensure safety and efficacy.’’ The best way to monitor this is within the confines of a randomised controlled trial. Relying on self-reporting or registries to monitor the ‘‘learning curve’’ can lead to over-optimistic results caused by a selection bias. Investigators worry that including the ‘‘learning curve’’ in a randomised trial might damage their results. This is not the case if a ‘Tracker Trial’ methodology is used where the results are analysed in a temporal fashion. The data generated from the early part of such a trial can give valuable information about the generalisability of the technique, if it subsequently becomes widely adopted.

I was also disappointed that the Authors did not address the dilemma posed during the period after a trial ends and before the results are known. What should a Clinician do during this time period? The obvious solution is for trials to include continued funding for randomisation during this period in their trial design. Clinicians and patients then do not have to make a difficult decision about which treatment to choose before the results are known and the additional data can be subsequently added to the main trial data at a later date.

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Response to Letter to the Editor re: “When does the ‘‘Learning curve’’ of innovative interventions become questionable practice?”

Sir

We would like to thank Professor J. D. Beard for his comments and observations on our recent publication “When does the ‘‘learning curve’’ of innovative interventions become questionable practice? Eur J Vasc Endovasc Surg 2008; 36: 253–257. These comments are warmly accepted and provide a welcome insight from a clinical perspective.

The authors acknowledge Professor Beard’s suggestion that use of a Tracker Trial methodology might be of benefit from a clinical viewpoint. We suggest, however, that this method would be of little benefit when viewed on legal and ethical grounds, particularly when considered from the patient perspective.

We agree that in principle, the Tracker Trial methodology could offer a useful means of preserving clinical equipoise and to assist in the early identification of the surgeon whose performance is not up to the required standard. This will not, however, be of any benefit to the first recipients of the new technique. Irrespective of additional safeguards, proposed in Tracker Trial