Device discordancy: Lost cords, quick-fix seekers, quality, and ethics

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Our modern world is so accustomed to instant gratification and efficiency with the accompanying expectations of little effort or pain that people will often choose the easy path at the cost of a poorer outcome over the long term. There are many examples of these choices by both consumers and patients, particularly when they are not fully informed, including use of catheter-based devices rather than open procedures.

In this issue of the *Journal*, Flores and colleagues¹ present their experience with combined open aortic arch repair and descending thoracic aortic stenting in the hopes of avoiding a second procedure, either open or endovascular, to treat patients more speedily. The results are sobering. First, their circulatory arrest times must have been prolonged, thus risking greater brain injury to the patients. Second, postoperative spinal cord injury occurred at an unacceptably high percentage of 24%. The finding of an increased complication rate of spinal cord injury is not new. For example, acute aortic dissection repair with replacement of the entire aortic arch (a questionable procedure except in rare cases) and stenting of the descending aorta has resulted in a similarly high rate of lost spinal cord function.²⁻⁷ Furthermore, in our early experience with the modified inverted elephant trunk insertion method in 84 patients,⁸ we noted that too long of an elephant trunk graft in the descending aorta resulted in complete paraplegia in 1 patient and paraparesis in 2 patients. This led to our recommendation that an elephant trunk graft should be no longer than 10 to 15 cm.

Why then is stenting or a long elephant trunk graft a problem? The obvious answer is that the intercostal arteries are occluded by the graft material, and the cord becomes dependent on collateral circulation.⁹ Second, it is likely that pump-related nonpulsatile hypotension and perioperative hypotension are inadequate for sufficient perfusion of the spinal cord in many patients who are dependent on their collateral arteries.^{9,10} In addition, it is worth noting that the squeezing of atheroma, somewhat akin to the texture of toothpaste, into intercostal arteries by stents could likely cause embolic obstruction of the blood supply. Whether these factors completely explain the high risk of paralysis when stenting is combined with cardiopulmonary bypass cannot be determined from this study.

In our review of 832 descending aortic open repairs,¹¹ paralysis occurred mostly in those patients who underwent replacement of either the entire descending aorta or the distal third or in those patients who had previously undergone abdominal aortic replacements. In 132 patients with descending aortic repairs, Borst and colleagues¹² found paralysis was higher in patients with replacement below T8. Similarly, others¹³⁻¹⁶ noted a higher paralysis rate with distal descending aorta replacements.

It appears that these hard lessons are now being relearned for descending aortic stenting. The Stanford group¹⁷ reported in 2004 that the risk of paralysis increased with either distal descending aortic stents or combined descending aortic stents in patients with previous aortic abdominal replacements. In our experience with descending aortic

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and thoracoabdominal stenting,¹⁸ we have also noted that distal descending stents are associated with increased paralysis. Of particular concern is that if the hypogastric arteries are not patent, then the risk is considerably increased, probably because the cruciate and iliolumbar blood supply to the cord is interfered with. Also of concern is the rate of paralysis in 16 patients in whom we have performed thoracoabdominal type II and III aortic stenting procedures where the intercostal and lumbar arteries have also been occluded. In these latter patients, the paralysis rate was 12.5%. The same applies to our series of 22 patients who had second-stage endovascular stenting of elephant trunk grafts,¹⁹ with 3 (13.6%) patients experiencing transient paraparesis.

The greater risk with occlusion of arteries between T7 and L2 is clearly related to the importance of adequate blood supply to the spinal cord in this particular segment, including, among others, the largest of the radicular arteries, the arteria radicularis magna, also known as the artery of Adamkiewicz.⁹ Thus the poor findings by Flores and colleagues,¹ including an increased risk of paralysis in patients with either previous abdominal aortic replacements or stents below T7, should not come as an unexpected disappointment. Indeed, for stents below T7, an astounding 62.5% had loss of cord function.

The 3% to 13% risk of paralysis with descending aortic stents (not inserted through the arch) is no better than the 3.8% risk reported by us¹⁰ for descending and thoracoabdominal repairs or the 3% to 5% for descending repairs reported by several different groups,^{11,13-16} including mortality rates of 3% to 5%. Therefore these must be the standards, or better, that should be met for elective descending endovascular stents. Clearly, particularly for distal descending aortic stents, whether the problems of occluding intercostal and lumbar arteries with stents will ever be overcome still requires considerable research. Potentially bypassing the intercostal and lumbar arteries by means of open procedures detracts from the aims of stenting procedures that do not require the chest to be opened.

Of further concern, patients with stents require yearly follow-up with CT scans and concurrent radiation for a lifetime because of the risks of various types of endovascular leaks, stent fractures, or graft migrations. In a sense, one disease process has been replaced by another. There is also no reason to suspect that thoracic stent grafts will perform any better than abdominal stent grafts, and similarly, on the basis of previous reports and extrapolations from the Stanford data,¹⁷ a 50% five-year event-free survival after thoracic stent replacement can be expected. Thus before the endovascular procedures, patients need to be fully informed that they will require a lifetime of careful follow-up and that in those patients who have a life expectancy of more than 5 to 10 years, it is likely they will require multiple repeat procedures. Indeed, in an independent audit of stented patients in France,²⁰ 45% of patients had an event in the first year, excluding deaths.

Certainly some of the subgroups of descending aortic stenting have been shown to do well with thoracic aortic stent grafting in comparison with open procedures, such as traumatic ruptures of the aorta, saccular aneurysms, penetrating ulcers, second-stage elephant trunk procedures in high-risk patients, ischemic complications related to distal dissection, ruptures, and localized aneurysms. Nonetheless, the natural history of medial degenerative aneurysms is such that the aorta increases in both size and length, and hence it is logical to conclude that over time, stent grafts will likely have problems until we have developed more securely anchored and advanced material grafts.

Therefore as practicing surgeons we are faced with discordance between what we know as far as quality of outcome and a patient's desire for less pain. Our ethical dilemmas are as follows: Should we bend to the seekers of "quick fixes"? How involved should we be with companies developing and promoting new devices? Can we afford to lower our academic standards and not perform prospective randomized studies, despite pressures to not do them? How are we going to maintain our ethical values yet deal with the developing "turf" wars over thoracic aortic stenting?

How we answer these questions will influence how we approach the burgeoning "percutaneous" transcatheter-based valve and other device-related procedures. Every practicing surgeon accustomed to a 1% mortality rate and 1% stroke rate for coronary artery bypass or valve surgery with excellent long-term outcome of patients will have to confront these ethical dilemmas and the issues involved with the survival of cardiovascular and vascular surgery. The high risk of stroke with transcatheter devices will also need to be lowered (Stanford First Generation 10%, Medtronic Valor High Risk 8%, and Cribier PVT 7.1%).¹⁷

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