requires painstaking validation. We certainly plan to look into cause of death data. Your point is well taken that in other studies the incidence of nonaortic death in patients undergoing TEVAR is quite high, and is perhaps the biggest factor regarding the disappointing midterm outcomes in TEVAR recipients—these patients are very sick and often die of their other comorbidities.

Dr Cohen. Finally—and we for instance see this in California in Sea Corp where volume does not necessarily equate to quality—what is the key to quality in the treatment of aortic disease?

Dr Schaffer. That is the million-dollar question. I can't tell you the answer from the Medicare database. I think the major factor

underlying interhospital variability is patient selection. With TEVAR there is a very high incidence of late nonaortic death that we don't observe with other cardiac surgical procedures. This late incidence of death is probably secondary to the significant patient comorbidities found in TEVAR recipients. If an institution focuses only on perioperative mortality and not long-term outcomes, I think TEVAR will be indiscriminately applied to patients who are at high risk for nonaortic death within the next year or 2, and this may not be an appropriate allocation of health care expenditures. Again, this is only my intuition, but I really think that it all comes down to strict guidelines to patient selection when deciding in whom we should implant these devices.

EDITORIAL COMMENTARY

Thoracic endovascular aortic repair: Satisfying early results but still a high midterm attrition rate

Thierry Carrel, MD

See related article on pages 808-23.

Thoracic endovascular aortic repair (TEVAR) has become an alternative treatment for an increasing number of thoracic aortic pathologies, and the immediate results have been promising. In the opinion of most of our patients, TEVAR allows us to avoid open surgery. The high attrition rate during midterm follow-up reported in the article by Schaffer and colleagues in this issue of the *Journal*, however, is somewhat alarming and requires in-depth analysis. This is of paramount importance, because with accumulating experience, improving device technology, and better imaging modalities, the indications for TEVAR are now slowly expanding to ascending aortic and aortic arch pathologies.

In this respect, Schaffer and colleagues¹ must be congratulated for performing a careful analysis in more than 10,000 patients treated by TEVAR for various aortic diseases. As could be expected, they found different outcomes for

different pathologies. In this regard, this work has the potential to become an important reference for decision making in the care of patients scheduled for repair of any type of thoracic aortic pathology.

The article provides several interesting pieces of information to the surgical community.¹ One is that broadening the indications is a classic event when new technologies enter into clinical routine. If, however, one of the most common indication for TEVAR, repair of a descending thoracic aortic aneurysm, is considered, active treatment is justified only when the annual risk of rupture would exceed the perioperative risk of repair by either method (endovascular or surgical).² Conservative treatment with medications leaves the patient exposed to the risk of the disease, but sometimes less is more: Schaffer and colleagues¹ demonstrate that in acute aortic dissection type B, for instance, midterm and late results after TEVAR are not significantly better than those after conservative treatment, confirming that there is no reason to overtreat the disease.

In the treatment of descending thoracic aneurysms, a previous study³ found an impressive 97% freedom from aneurysm-related death. The 25% 2-year mortality, however, underscored the fact that successful TEVAR does not guarantee long-term survival.

Numerous studies in the past have reported results in cases in which the indications for TEVAR were broadened. The Investigation of Stent Grafts in Patients with Type B Aortic Dissection trial⁴ (comparing TEVAR with optimal medical management) has been the only randomized controlled trial of TEVAR. This trial demonstrated no

From the Clinic for Cardiovascular Surgery, University Hospital Bern, Bern, Switzerland.

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Address for reprints: Thierry Carrel, MD, Department of Cardiovascular Surgery, University Hospital Bern, CH-3010 Bern, Switzerland (E-mail: thierry.carrel@insel.ch).

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improvement in 2- or 5-year all-cause mortality: there was a high incidence of nonaneurysmal death in this study and thereby a low overall survival benefit of TEVAR in patients with uncomplicated type B aortic dissection.

Independently of some landmark articles and the results reported, there has been a change of paradigm as a result of increasing experience with endovascular technologies. In general, the threshold to perform TEVAR has become lower (in part because of the smaller surgical trauma), and more patients with borderline indications have therefore undergone TEVAR, irrespectively of a cost-benefit analysis.

Although the primary end point of all-cause mortality is important, it is difficult to use this parameter in decision making for TEVAR. Many patients who are treated for thoracic aortic disease are elderly with, many competing illnesses and comorbidities that may limit their long-term survival. It is therefore not easy or even possible to predict of which disease such a patient will die; thus when the patient presents with a sizable descending thoracic aortic aneurysm or aortic dissection, the surgeon will often focus on the treatment of the aortic disease only.

Three statements made in this publication of Schaffer and colleagues¹ need special consideration:

1. The late incidence of death remains surprisingly high among TEVAR recipients, emphasizing that patient selection is paramount when delivering this therapy. On the other hand, if one overinterprets this finding, this could imply that some patients will not be treated in the acute situation only because of the dismal late outcome.
2. Hospital quality, but not hospital volume, is correlated with post-TEVAR survival: this finding may be difficult to interpret. I'm not totally happy with the definition of volume per institution; although I agree that more than 100 interventions means a high volume, I found the definition of 20 to 99 as a moderate volume to be quite optimistic. This is also a touchy statement without having defined the term *quality*. Finally, it might seem to suggest that 2 interventions per year across an interval of 10 years would be recognized as enough experience. The hazard of death at high-quality hospitals was about 50% of what it was at other hospitals. This is a clear statement that TEVAR should only be performed in institutions with a large experience in all facets of cardiovascular pathologies.
3. In their Discussion section, Schaffer and colleagues¹ pointed out that greater operative complexity was associated with worse survival. In general, this makes sense. I did not, however, find a definition of greater or lesser complexity in the article. Was complexity related to the anatomy of the lesion, the clinical presentation, or the type of TEVAR that was used?

Looking at the midterm results of TEVAR in the "real world," Miller,² one of the authors of this article, found

somewhat earlier that TEVAR use is more sobering. As reported by Lee and colleagues⁵ in 2011, 4-year overall survival after TEVAR was only 53% $\pm$ 4%. Even among those patients who survived 6 months after the initial TEVAR, 6% to 18% died per year thereafter, depending on aortic disease.

Finally, I believe that highly specialized medicine (endovascular therapy is one of these fields) will have to deal more and more with the evidence of different therapeutic strategies.⁶ Because of the rapid turnover of innovations, it has become more and more difficult to wait for the established evidence, to accept it, and also to practice according to this evidence. New technologies, but also new implants, are quickly introduced after first-in-human and small pilot studies; they receive market approval and are shortly thereafter replaced by newer technologies.

In some institutions, there is pressure for innovation, with industry partners involved in the definition of indications for treatment; they participate in the elaboration of study protocols and sometimes control the recruitment in studies (for instance, synergy between PCI with Taxus and Cardiac Surgery [SYNTAX] and Surgical Replacement and Transcatheter Aortic Valve Implantation [SURTAVI]). Not surprisingly, these partners have the sale of their products in front.

High-level prospective randomized trials are not uncommonly useless, because before the midterm results can be carefully considered, new treatments or next-generation medications or implants have entered the market.

The costs for endovascular devices are sometimes extremely high; a reasonable cost-benefits analysis would not justify their use. In addition, the follow-up after TEVAR needs lifelong surveillance, because late complications can always happen independent of the immediate result.

Finally, it cannot not be expected that patients with insufficient results after endovascular interventions can undergo surgery with the same operative risk as if they would have been operated on at first intention.

References

1. Schaffer JM, Lingala B, Miller DC, Woo YJ, Mitchell RS, Dake MD. Mid-term survival after thoracic endovascular aortic repair in more than 10,000 Medicare patients. *J Thorac Cardiovasc Surg*. 2015;149:808-23.
2. Miller DC. Through the looking glass: the first 20 years of thoracic aortic stent-grafting. *J Thorac Cardiovasc Surg*. 2013;145(3 Suppl):S142-8.
3. Brunkwall J, Lammer J, Verhoeven E, Taylor P. ADSORB: a study on the efficacy of endovascular grafting in uncomplicated acute dissection of the descending aorta. *Eur J Vasc Endovasc Surg*. 2012;44:31-6.
4. 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.
5. Lee WA, Daniels MJ, Beaver TM, Klodell CT, Raghinaru DE, Hess PJ Jr. Late outcomes of a single-center experience of 400 consecutive thoracic endovascular aortic repairs. *Circulation*. 2011;123:2938-45.
6. Appoo JJ, Tse W, Pozeg ZI, Wong JK, Hutchison SJ, Gregory AJ, et al. Thoracic aortic frontier: review of current applications and directions of thoracic endovascular aortic repair (TEVAR). *Can J Cardiol*. 2014;30:52-63.