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TRANSCATHETER AORTIC VALVE IMPLANTATION: CLINICAL EVIDENCE VERSUS CLINICAL PRACTICE

To the Editor:

Enthusiasm and use of transcatheter aortic valve implantation (TAVI) have grown exponentially since the first TAVI procedure was performed a decade ago. Critics of this relatively novel technique, however, argue that clinical practice has far outpaced robust clinical evidence. The recent summary by Agnihotri¹ provides a broad overview of the recent consensus statement approved by a dozen professional societies, including the American Association for Thoracic Surgery. Agnihotri¹ correctly emphasizes the subjectivity of the patient selection process for TAVI and a number of postprocedural complications such as stroke, requirement for permanent

pacemaker, vascular injury, and severe aortic regurgitation, all of which are significantly more likely to occur than after conventional surgical aortic valve replacement (AVR). Agnihotri¹ also stated, "There is limited information regarding durability beyond 5 years in registry data." One should also point out there are no published comparative data between TAVI and surgical AVR beyond 5 years in the current literature.

From an evidence-based perspective, level I evidence has only been presented from 2 randomized controlled trials. The better known of these, the PARTNER (Placement of Aortic Transcatheter Valve) trial financed by Edwards Lifesciences (Irvine, Calif), involved patients who were either deemed to be at "high surgical risk" (cohort A) or "inoperable" (cohort B).^{2,3} Recently, Van Brabandt and colleagues⁴ highlighted the significant ethical, scientific, and industry-related challenges to the PARTNER trial related to publication bias, lack of data transparency, unbalanced patient characteristics, and incompletely declared conflicts of interest.⁴ The lesser known STACCATO trial, which was not cited by Agnihotri¹ or the consensus statement, included patients who were considered to have "low surgical risk." This trial was prematurely terminated by a data safety monitoring board after unexpectedly poor results for patients in the TAVI arm.⁵ The chief investigator of the STACCATO trial stated that TAVI should not be considered in patients who are at a low surgical risk because of the excellent and established outcomes offered by surgical AVR.

In summary, patients with severe aortic stenosis should be considered in three subgroups, according to their surgical risk with conventional AVR, as illustrated in Figure 1. Results from randomized, controlled trials suggest that "inoperable" patients may benefit from TAVI in terms of mortality and symptomatic outcomes, although at the cost of increased stroke risk. The evidence for "high surgical risk" patients is limited by short-term follow-up, and existing data suggest a higher risk of stroke or transient ischemic attack than that associated with conventional AVR without any significant all-cause mortality benefit. With respect to "low surgical risk" patients, the STACCATO trial has shown that TAVI should not be offered to these patients in the current clinical setting. Finally, there is a fourth recognized subgroup of patients who are considered to be at too high a risk for any form of interventional treatment.^{2,3}

In the future, the development of novel devices should also be complemented by the development of standardized, stringent patient selection processes to allow meaningful comparison of outcomes between institutions. On the basis of the available evidence, the use of TAVI for eligible surgical candidates should only be considered within clinical trials or registries.⁶

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FIGURE 1. Spectrum of patients with severe aortic stenosis according to surgical risk for conventional aortic valve replacement (AVR). TAVI, Transcatheter aortic valve implantation.

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IS RECONSTRUCTION OF THE LEFT ANTERIOR DESCENDING ARTERY WITH SAPHENOUS VEIN PATCHING EQUAL TO ONLY PATCH RECONSTRUCTION USING THE LEFT INTERNAL THORACIC ARTERY?

To the Editor:

We read with interest the recent report by Myers and associates.¹ The

authors presented their experience and outcomes of extensive endarterectomy and reconstruction of the left anterior descending artery (LAD) and compared 2 different reconstruction methods: vein patch reconstruction with the left internal thoracic artery (LITA) and LITA onlay patch grafting. The authors showed that the early results were excellent and that the reconstruction method did not have a significant effect on long-term survival in this challenging group of patients. However, we have several concerns about, and comments on, this retrospective review.

First, the actuarial 10-year survival in both groups was less than 50%, which seems lower than expected compared with the overall long-term results of off-pump coronary artery bypass surgery.² The causes of death were not clearly documented in their report. Because patients who required extensive coronary endarterectomy might have had severe coronary artery disease, it is important to know the early and late causes of deaths. Nevertheless, we also recently published long-term results of long segmental reconstruction of the LAD using the LITA in 112 patients.³ Of these patients, 37 underwent endarterectomy, and their 10-year survival rate was approximately 75%, comparable with the results of the previous report for patients who underwent conventional coronary artery bypass surgery.² Although we have no data on vein patch reconstruction with the LITA, we believe that onlay patch reconstruction of the LAD using the LITA is quite important to achieve a favorable outcome in the treatment of patients with diffusely diseased coronary arteries. In patients with LITA onlay patch grafts, the wall of the LITA forms a new coronary lumen, and the atheromatous plaques are almost totally excluded from the LAD lumen. Intimal hyperplasia rarely occurs in a LAD reconstructed with the LITA, although vein graft disease has been proved to progress with time.⁴

An optimal endarterectomy technique and appropriate postoperative anticoagulation strategy are vital to achieve excellent long-term outcomes in these group of patients. We routinely tack the divided intima of the distal LAD with 8-0 polypropylene sutures. We believe this maneuver, coupled with postoperative anticoagulation, is important to prevent obstruction of distal run-off by residual intima, where thrombosis readily occurs. Our current anticoagulation strategy is as follows. First, low-molecular-weight heparin (5000 U/d) is initiated, after confirmation of hemostasis in the intensive care unit. Second, low-dose aspirin, clopidogrel, and warfarin (with a target international normalized ratio of 2.0) are started after the patients have resumed oral intake. Third, low-molecular-weight heparin is discontinued after warfarin is effective. Finally, clopidogrel is continued for 1 month and warfarin for 6 months. We reported immediate postoperative angiographic results with a 97% LITA patency rate (34/35) in patients undergoing long onlay patch reconstruction of the LAD with endarterectomy. Their long-term (approximately 10 years) patency rate was 100% (7/7).³ In our recent study, we also reported a 94% immediate postoperative LITA patency in 134 patients using the same technique.⁵ A similar survival rate between vein patch reconstruction with the LITA and LITA onlay patch grafting does not always mean a similar patency rate. Reconstruction of the LAD with a vein patch can result in a lower patency rate. We all know that postoperative angiography is rarely performed unless patients have significant symptoms. However, it is important to know the fate of these 2 different reconstruction techniques late after surgery. We wonder whether any late angiographic data were available for these 2 groups of patients. We congratulate the authors for their effort in tackling this difficult group of