The Ever-Increasing Choices for Aortic Valve Replacement

Which One Will Win In the Marketplace?*

Blase Carabello, MD

Symptomatic aortic stenosis (AS) is a fatal disease unless treated by transcatheter aortic valve replacement (TAVR). During the latter half of the 20th century, aortic valve replacement (AVR) was accomplished in the operating room using a variety of replacement valves, both mechanical and bioprosthetic, the choice of which steadily evolved over time. Bioprostheses avoid the need for vitamin K antagonist anticoagulation (VKA) but are subject to structural valve deterioration that occurs more rapidly when they are implanted in younger versus older patients (1). Mechanical prostheses are more durable but require VKA and its attendant risks of thromboembolism related to underanticoagulation versus hemorrhage in cases of overanticoagulation.

It is fair to add that mechanical valves are not entirely free of structural deterioration, and bioprostheses are not entirely free of thromboembolism. However, irrespective of data that show similar survival with mechanical and biologic valves (2-4), most patients prefer to avoid the risks of VKA, shifting their preference toward bioprostheses. A bioprosthesis is also made more attractive by a persistently decreasing risk of reoperation if required for a failed valve and also by the unproven but possible long-term strategy of inserting a valve percutaneously inside a failed bioprosthesis, avoiding reoperation. Pulmonary autografting (Ross procedure) offers the advantages of both durability in experienced hands and avoidance of VKA (5). However, this procedure is limited to surgeons who have extensive experience in performing the operation. Ultimately, the type and make of the valve implanted are based on patient and surgeon preference. Although some patients focus on avoiding reoperation, most prefer to avoid the risk of VKA and the need for international normalized ratio monitoring. Surgeon preference is usually predicated on familiarity with a given make of valve, its ease of implantation, and the implanting surgeon’s ultimate results with that valve.

ENTER TRANSCATHETER AVR

Describing TAVR as a game changer is an underestimation. The ability to accomplish AVR without surgery offers a life-saving device to inoperable patients and to those at very high surgical risk; this technology is still in its infancy (6,7). Progressive miniaturization, valve designs that limit paravalvular leak (PVL) (8), and devices that protect patients from cerebral embolism (9) will almost surely facilitate the use of TAVR in lower risk patients and facilitate enhanced outcomes with lower complication rates. Durability has been excellent in the typically elderly patient undergoing TAVR. We are likely to learn more about TAVR durability as TAVR indications become more liberal, permitting implantation in younger patients at lower surgical risk who will have a longer life expectancy.

THE 3F ENABLE VALVE

In this issue of JACC: Cardiovascular Interventions, a sutureless bioprosthesis the 3F Enable valve (Medtronic, Minneapolis, Minnesota) is compared with
TAVR using propensity matching (10). The 3f valve (and other sutureless valves) should be more easily implanted with shorter cross-clamp and cardiopulmonary bypass times than conventional AVR. Whether this would translate to a survival advantage can only be established by a randomized trial. In the current analysis, the sutureless valve had a substantially higher risk of patient prosthetic mismatch (perhaps) than TAVR, whereas TAVR had a higher risk of PVL. (The latter point is probably moot because new valve designs already have substantially reduced PVL [8]).

The most dramatic finding in the current study was a 17% reduction in stroke volume index (SVI) for the patients implanted with the 3f valve after surgery. Comparing groups without PVL (PVL complicates calculation of forward SVI), the SVI difference was even more dramatic, 27% less in the 3f valve patients. Even if this was not statistically significant, it would surely be clinically relevant. This difference helps to account for the large increase in patient-prosthesis mismatch and low flow in the 3f valve group...or does it? Stroke volume is controlled by 3 properties: preload, afterload, and contractility. Afterload should have been reduced in both groups of patients after relief of outflow obstruction, and, although there was a very slightly greater post-operative gradient in the 3f valve group, it is hard to imagine that a 2-mm Hg greater gradient caused such a large decrease in SVI. This assumption of reduced afterload would be vitiated if there were a large number of untreated hypertensive patients in the 3f valve group, in which case, vascular load would be substituted for valvular load. But why would such a difference be concentrated in 3f valve patients? Contractility could have been impaired because of a lack of myocardial protection during surgery, but the preserved ejection fraction (admittedly an awful guide to contractility) was actually a bit higher in the 3f valve group post-operatively. Could the 3f valve group have been so volume contracted as to impair SVI? It seems possible but very improbable. More likely there was a systematic error in SVI measurement. Because SVI is the product of outflow tract area and the time-velocity integral, a systematic undermeasurement of outflow tract area, perhaps because of the nature of the valve, is the most likely explanation for the finding of a reduced calculated valve area and reduced SVI in the 3f valve group.

However, a truly greater risk of severe patient prosthesis mismatch in the 3f valve group (instead of an apparent one) would be an adverse finding because the whole goal of AVR is to reduce obstruction of left ventricular outflow.

**THE FUTURE OF THERAPY FOR AS**

When the pathways leading to valve calcification are better understood, pharmacological approaches to prevent AS may become a reality but are currently a long way off. For now, symptomatic AS is a lethal mechanical obstruction of left ventricular outflow, and for the foreseeable future, AVR will be the only solution to the problem. TAVR is in its relative infancy and will gain increased use as improvements in valve design reduce risk and increase benefit. However, there will almost certainly always be patients who benefit more from surgical AVR than from TAVR, just as 37 years after the advent of percutaneous coronary intervention (PCI), it is clear that many patients with obstructive coronary disease are better treated with surgical bypass than with PCI. The substitute valves used in surgical AVR will also likely evolve. It is likely that mechanical valves will always require VKA for therapy, although a recent report indicates success with a lower level of anticoagulation (11). Even so, these findings are unlikely to completely reverse patient preference for valves that do not require VKA. Of course, if a mechanical valve were developed that required no VKA, the results might be different. In the meantime, bioprostheses that are dependable and easy to implant will continue to prevail as the dominant choices for AVR. Sutureless valves should offer a special advantage in complex multivalve procedures in which ischemic time becomes important and also may offer an advantage in limited-access AVR. Whether these advantages will translate into widespread use depends on post-operative durability, hemodynamic performance, and clinical outcomes determined by randomized trials. In any case, the increased options currently available can only help to benefit the AS patient of today compared with the few choices available just a few decades ago. Hold onto your hats—this is just the beginning of this revolution in the treatment of heart valve disease!

**REPRINT REQUESTS AND CORRESPONDENCE:** Dr. Blase Carabello, Department of Cardiology, Mount Sinai Beth Israel Hospital, 350 East 17th Street, 5th Floor, Baird Hall, New York, New York 10003. E-mail: bcarabello@chpnet.org.
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KEY WORDS aortic stenosis, aortic valve replacement, TAVR, valvular heart disease