Commentary: American Heart Association/American College of Cardiology Valve guidelines: Starting point for discussion by the heart team or dictum?

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We read with interest the position statement of the Latin American Association of Cardiac and Endovascular Surgery (LACES) regarding the recently released American Heart Association/American College of Cardiology Cardiology Guideline for the Management of Patients With Valvular Heart Disease.1,2 The LACES disagrees with a number of the guideline recommendations for the use of surgical aortic valve replacement (SAVR) or transcatheter aortic valve replacement (TAVR) for aortic stenosis and edge-to-edge repair for functional mitral regurgitation (FMR). We congratulate the LACES group for such a passionate letter regarding the management of valve disease and believe that this discussion is extremely timely.

AORTIC STENOSIS

The randomized trials comparing SAVR with TAVR have been the most rigorous investigation performed of any valve trials in history with more than 10,000 patients studied with independent Data Safety Monitoring Boards, Clinical Events Committees, and core-laboratory adjudicated echocardiography.3-9 These trials were performed in 3 cohorts of high-, intermediate-, and low-risk patients and overall have...
shown similar safety of both SAVR and TAVR. Five-year follow-up is available for those in the high- and intermediate-risk groups and 2-year follow-up in low-risk patients, with no signal for inferiority of TAVR compared with SAVR. Ten-year follow-up is anticipated for the low- and intermediate-risk patients. However, it remains incumbent that the heart team make individualized decisions for patients with characteristics that were not included in the trials, such as the young who want to have a mechanical prosthesis and those with concomitant coronary or other severe valvular disease, ascending aortic or root dilatation, a heavy burden of left ventricular outflow tract calcium, or bicuspid valves (especially those heavily calcified). These may account for approximately 40% in real-world patient populations, and commonly will include those who are younger. It is unlikely that large randomized trials will be performed in these cohorts.

The age recommendation for SAVR in patients aged less than 65 years is warranted, and discussion is highly advisable because few patients younger than this were included in the randomized trials. Given similar safety of each treatment across risk cohorts, recommendations for patients aged 65 to 80 years must focus on life expectancy, given the uncertain durability of TAVR prostheses at 10 to 15 years. However, long-term durability data for SAVR are flawed by a lack of protocolized follow-up with no Clinical Events Committees, Data and Safety Monitoring Committee, or core-laboratory adjudicated echocardiography in most analyses. Surgical studies have commonly used reintervention as a metric for structural valve deterioration, which does not adequately represent the true functionality of the biologic valve. Ironically, the major TAVR trials are the first to provide core-laboratory adjudicated, per-protocol (rather than per-symptom) follow-up of surgical bioprostheses.

We agree about the detrimental long-term effects of both paravalvular regurgitation and new permanent pacemaker implantation. However, in the PARTNER 3 trial, there was no difference in pacemaker rates up to 1 year between TAVR and SAVR, and the rates of paravalvular regurgitation have significantly reduced over the past couple of years with third- and fourth-generation TAVR devices.

When given a choice of noninferiority, the procedure that provides the least physiologic insult is generally preferable to patients. This is the case of those patients deemed high risk for SAVR. For these elderly patients, commonly aged more than 80 years of age, TAVR provides a shorter recovery and decreased resource use. Specifically, durability data for TAVR valves are less concerning and were proven in first-generation transcatheter technology to be of minimal concern. Should anatomic factors in this patient cohort make TAVR less attractive, such as concomitant coronary or multivalve disease, nonfemoral access, or severe left ventricular outflow tract calcium, then SAVR should be considered.

**MITRAL REGURGITATION**

The inclusion of transcatheter edge-to-edge technology to treat FMR in the Guidelines is a result of the mortality benefit demonstrated in the COAPT trial, the first of any study to demonstrate a benefit in this population of patients. We agree with the LACES authors that FMR is a condition of the left ventricle, yet COAPT has demonstrated that some patients may benefit from repair. The failure of MITRA-FR to achieve similar results can be explained by a different patient population to COAPT and the intense guideline-directed pre- and postprocedures in the COAPT patients; the guidelines recommend treatment of only those patients included in COAPT: those on maximum goal-directed medical therapy with left ventricular diameter 70 mm or less and pulmonary artery systolic pressures 70 mm Hg or less. We believe this is appropriate. We do agree that continuing to follow these patients, as is done by the national The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapies registry, will be critical in understanding the real-world outcomes in this difficult patient population. The authors are correct that surgery is sometimes needed in these patients, but the guidelines give us an outline that the heart team should use as they individualize the care for each patient.

**CONCLUSIONS**

The role of the guidelines is to provide expert interpretation of the available evidence to help guide, not mandate, clinical practice. Furthermore, the American Heart Association/American College Cardiology Valve Guidelines in the spirit of a heart team incorporated within the writing group representatives from the American Association for Thoracic Surgery and The Society of Thoracic Surgeons, among others. Patient-level decisions should take into account patient characteristics (anatomic, life expectancy, and their preferences) together with the available health care resources that must be made by the heart team, which uses the guidelines as a framework for discussion. We acknowledge that health care resources differ between various nations and recognize that most economic analyses examining the cost of aortic stenosis treatment favor TAVR at 1 year. When choosing between SAVR and TAVR in patients eligible for bioprosthetic valves or treatment for FMR, the guidelines highlight the need for shared decision making among patients, surgeons, and cardiologists that must focus on a patient’s anatomic factors, life expectancy, and preferences. We believe that the cases in which the surgeons and cardiologists are aligned with equal representation in the heart team and the clinic on initial evaluation of the patient will receive the most optimal care, leading to excellent short- and long-term outcomes.
References


