- disease: executive summary: a report of the American College of Cardiology/American Heart Association Joint Committee on clinical practice guidelines. *Circulation*. 2021;143:e35-71.
- Dayan V, Garcia-Villarreal OA, Escobar A, Ferrari J, Quintana E, Marin-Cuarteras M, et al. The Latin American Association of Cardiac and Endovascular Surgery statement regarding the recently released American Heart Association/American College of Cardiology Guidelines for the Management of Patients With Valvular Heart Disease 2020. *J Thorac Cardiovasc Surg*. 2021;162:584-6.
 - Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, Svensson LG, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med*. 2011;364:2187-98.
 - Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med*. 2010;363:1597-607.
 - Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med*. 2016;374:1609-20.
 - Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med*. 2019;380:1706-15.
 - Stone GW, Lindenfeld J, Abraham WT, Kar S, Lim DS, Mishell JM, et al. Transcatheter mitral-valve repair in patients with heart failure. *N Engl J Med*. 2018;379:2307-18.
 - Obadia JF, Messika-Zeitoun D, Leurent G, Jung B, Bonnet G, Piriou N, et al. Percutaneous repair or medical treatment for secondary mitral regurgitation. *N Engl J Med*. 2018;379:2297-306.
 - Feldman T, Kar S, Elmariah S, Smart SC, Trento A, Siegel RJ, et al. Randomized comparison of percutaneous repair and surgery for mitral regurgitation: 5-year results of EVEREST II. *J Am Coll Cardiol*. 2015;66:2844-54.

See Article page 584.

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

J. James Edelman, MBBS(Hons), PhD,^a and
Vinod H. Thourani, MD^b

J. James Edelman, MBBS(Hons), PhD, and Vinod H. Thourani, MD

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 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

CENTRAL MESSAGE

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.

From the ^aDepartment of Cardiothoracic Surgery, Fiona Stanley Hospital, Perth, Australia; and ^bDepartment of Cardiovascular Surgery, Marcus Valve Center, Piedmont Heart Institute, Atlanta, Ga.

Disclosures: Dr Thourani Advisor/Research: Abbott Vascular, Boston Scientific, Cryolife, Edwards Lifesciences, Jenavalve. Dr Edelman reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

Received for publication Feb 17, 2021; revisions received Feb 17, 2021; accepted for publication Feb 18, 2021; available ahead of print Feb 27, 2021.

Address for reprints: Vinod H. Thourani, MD, Department of Cardiovascular Surgery, Piedmont Heart Institute, 95 Collier Rd, Suite 5015, Atlanta, GA 30308 (E-mail: vinod.thourani@piedmont.org).

J Thorac Cardiovasc Surg 2021;162:588-90

0022-5223/\$36.00

Copyright © 2021 by The American Association for Thoracic Surgery

<https://doi.org/10.1016/j.jtcvs.2021.02.080>

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 must 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 populations¹⁰ 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!¹¹

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,^{6,8} 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.¹² 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 patients¹³⁻¹⁵; 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.² 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.¹⁶ 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

1. Dayan V, Garcia-Villarreal OA, Escobar A, Ferrari J, Quintana E, Marin-Cuatas M, et al. The Latin American Association of Cardiac and Endovascular Surgery statement regarding the recently released American Heart Association/American College of Cardiology Guidelines for the Management of Patients With Valvular Heart Disease 2020. *J Thorac Cardiovasc Surg.* 2021;162:584-6.
2. Otto CM, Nishimura RA, Bonow RO, Carabello BA, Erwin JP, Gentile F, et al. 2020 ACC/AHA guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Joint Committee on clinical practice guidelines. *Circulation.* 2021;143:e72-227.
3. Mack MJ, Leon MB, Smith CR, Miller DC, Moses JW, Tuzcu EM, et al. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet.* 2015;385:2477-84.
4. Gleason TG, Reardon MJ, Popma JJ, Deeb GM, Yakubov SJ, Lee JS, et al. Self-expanding transcatheter aortic valve replacement or surgical valve replacement in high-risk patients: 5-year outcomes. *J Am Coll Cardiol.* 2018;72:2687-96.
5. Makkar RR, Thourani VH, Mack MJ, Kodali SK, Kapadia S, Webb JG, et al. Five-year outcomes of transcatheter or surgical aortic-valve replacement. *N Engl J Med.* 2020;382:799-809.
6. Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med.* 2019;380:1706-15.
7. Søndergaard L, Popma JJ, Reardon MJ, Van Mieghem NM, Deeb GM, Kodali S, et al. Comparison of a complete percutaneous versus surgical approach to aortic valve replacement and revascularization in patients at intermediate surgical risk: results from the randomized SURTAVI Trial. *Circulation.* September 3, 2019 [Epub ahead of print].
8. Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med.* 2019;380:1695-705.
9. Thyregod HGH, Ihlemann N, Jørgensen TH, Nissen H, Kjeldsen BJ, Petursson P, et al. Five-year clinical and echocardiographic outcomes from the Nordic aortic valve intervention (NOTION) randomized clinical trial in lower Surgical risk patients. *Circulation.* February 1, 2019 [Epub ahead of print].
10. Alperi A, Voisine P, Kalavrouziotis D, Dumont E, Dagenais F, Perron J, et al. Aortic valve replacement in low-risk patients with severe aortic stenosis outside randomized trials. *J Am Coll Cardiol.* 2021;77:111-23.
11. Edelman JJ, Shults C, Thourani VH. Transcatheter aortic valve replacement valve durability: good enough for young, low-risk patients? *J Thorac Cardiovasc Surg.* 2020;159:1249-55.
12. Stone GW, Lindenfeld J, Abraham WT, Kar S, Lim DS, Mishell JM, et al. Transcatheter mitral-valve repair in patients with heart failure. *N Engl J Med.* 2018;379:2307-18.
13. Hahn RT. Transcatheter edge-to-edge repair for secondary mitral regurgitation. *JACC Cardiovasc Imaging.* 2021;103:1759.
14. Grayburn PA, Sannino A, Packer M. Proportionate and disproportionate functional mitral regurgitation. *JACC Cardiovasc Imaging.* 2019;12:353-62.
15. Obadia J-F, Messika-Zeitoun D, Leurent G, Iung B, Bonnet G, Piriou N, et al. Percutaneous repair or medical treatment for secondary mitral regurgitation. *N Engl J Med.* 2018;379:2297-306.
16. Baron SJ, Wang K, House JA, Magnuson EA, Reynolds MR, Makkar R, et al. Cost-effectiveness of transcatheter versus surgical aortic valve replacement in patients with severe aortic stenosis at intermediate risk. *Circulation.* 2019;139:877-88.