

# 2020 ACC/AHA Guideline for Management of Patients With Valvular Heart Disease

Experts share their views on how these new guidelines will impact practice.

With Gorav Ailawadi, MD; Mario J. Garcia, MD, FACC; Rishi Puri, MD, PhD; and Vinod H. Thourani, MD

**O**n December 17, 2020, the American College of Cardiology (ACC) and the American Heart Association (AHA) announced the release of the “2020 ACC/AHA Guideline for Management of Patients With Valvular Heart Disease.”<sup>1</sup> *Cardiac Interventions Today* spoke with a panel of experts in transcatheter aortic valve replacement (TAVR) to get their take on what these guidelines mean for patients and for practice.

***Cardiac Interventions Today:* The new recommendations provide that all patients are referred for evaluation at centers that provide both TAVR and surgical aortic valve replacement (SAVR). What happens at the various SAVR-only centers currently operating? How do they incorporate a multidisciplinary team (MDT) into the patient evaluation process?**

**Dr. Puri:** This is a good question and politically sensitive, depending also on local referral patterns as well as hospital/health care networks that likely vary widely across the United States. From a patient’s perspective, it would clearly be optimal for SAVR-only centers to facilitate their cardiologists (interventional and noninterventional) to either convene or direct patients to nearby institutions that do have a MDT evaluating patients with aortic valve disease. If a patient is ultimately rendered for SAVR, then they could be directed back

to the referring institution. I’ve worked in European centers that drew on referrals from regional cardiologists who brought their patients to the MDT held in central aortic valve centers, and if rendered for TAVR, then those regional interventional cardiologists were allowed to be TAVR operators always with a local TAVR operator working alongside and proctoring them. This model empowered local interventional cardiologists to not only think of both the percutaneous and surgical options for all their patients with aortic valve disease, but they also felt motivated to be trained as TAVR operators in a controlled fashion. This also centralized procedural volume, which we know is associated with superior outcomes.

**Dr. Ailawadi:** As the number of TAVR centers expands, the number of SAVR-only centers is declining. Furthermore, to ensure guidelines are followed, SAVR-only centers will need to partner with local TAVR referral centers to complete the multidisciplinary evaluation for a shared decision-making approach with the patient. These local relationships hopefully allow for the SAVR-only site to continue to offer surgical intervention should it be determined that is what is best for a patient.

**Dr. Garcia:** Due in great part to advances in medical care, life expectancy in the United States has increased

by almost 10 years over the last 5 decades. In particular, the number of individuals > 65 years has quadrupled over that period, of whom it is estimated that 7% will develop aortic stenosis (AS). Fortunately, treatment of this condition has rapidly advanced, currently achieving 30-day mortality rates barely above 1% for both TAVR and SAVR.

It is very likely that the observed improvement in outcomes has been due to the availability of both treatment modalities and the careful selection of the optimal treatment, guided by data generated from registries and randomized clinical trials. In other words, the exclusion of high-risk patients who in the past may have undergone SAVR has contributed to the observed reduction in mortality. Accordingly, it should be expected that centers who are currently offering SAVR-only will most likely disappear over the next few years. The 2020 ACC/AHA guideline for management of valvular heart disease clearly recommends that patients with AS who meet criteria for intervention should be evaluated by a MDT to determine the optimal management strategy.

**Dr. Thourani:** In the United States, there remains a heterogeneous pathway for patients to get evaluated for and undergo treatment for symptomatic, severe AS. Currently, there are approximately 1,100 cardiac surgical programs in the United States, and approximately 750 of these sites offer both SAVR and TAVR. It is conceivable that patients could be seen and treated in centers that do not have both treatment options available. Moreover, it is feasible that patients are not given the options for TAVR in centers that do not have this technique available. It remains critically important that with the approval for TAVR in all risk categories, patients are given an equal representation of the pros and cons of both techniques in a heart team, multidisciplinary fashion. Optimally, patients would be seen simultaneously with the surgeon and cardiologist and then their anatomy reviewed with imaging specialists in a valve conference. We have adopted that patient throughput at the Piedmont Heart Institute, which we feel allows the patient with the most comprehensive and well-balanced approach. Included in this would be the patient shared decision-making process.

### **Cardiac Interventions Today: Does switching from using risk scores to age make more sense? If so, why?**

**Dr. Thourani:** Although there remain some inadequacies regarding the Society of Thoracic Surgeons (STS) score in the prediction of short-term outcomes after TAVR, it has been shown to be a very effective

predictor of those undergoing SAVR. There are some variables not categorized in the STS score, including liver failure, dementia, porcelain aorta, and frailty that may underrepresent the true mortality in these patients. I think that a multidisciplinary heart team should take into account the patient's age, STS score, and other variables in determining the appropriate procedure (TAVR or SAVR) in relation to short- and long-term outcomes. Significantly, the expected longevity of the patient is very important.

**Dr. Puri:** It absolutely does. The Canadian guidelines have already moved away from STS scores for some time now. Traditional risk scores (eg, STS) have been shown time and time again not to correlate with TAVR-associated risk, nor futility. In fact, these risk scores were never designed for such purposes. Age/life expectancy (which relates to the need for a second or possibly third biologic valve) and various anatomic features are what's important for determining suitability for one approach over another and when in the patient's life cycle one approach predominates over the other.

**Dr. Garcia:** In the new guidelines, age now plays a central role for selection of TAVR versus SAVR, taking precedence over the use of previously recommended risk scores. This makes sense because life expectancy is the most important consideration for the majority of patients who are at low risk for either type of intervention. Additionally, in patients < 80 years, TAVR is recommended because life expectancy is anticipated not to exceed the durability of the procedure. This is the same reason SAVR is recommended over TAVR for patients < 65 years of age. These recommendations seem reasonable but are based primarily on the absence of long-term durability data for percutaneous valves and do not take into account the cumulative risk/benefits of future valve-in-valve repeated procedures if TAVR is used as the initial approach. Nevertheless, it is doubtful that trends in utilization will change significantly because younger patients represent a minority and, in many of them, the decision to perform SAVR will be determined by the presence of a bicuspid valve with limited valvular calcification.

**Dr. Ailawadi:** Conceptually, moving away from risk scores for a shared decision-making approach to decide between TAVR and SAVR makes sense given low-risk approval for TAVR. However, age alone should not be the prime factor. As we think about the lifetime management of patients with aortic valve disease and reintervention risk, we really should be thinking about the life expectancy of an individual patient along with

the potential likelihood and risks of reintervention in the future. Our team at the University of Michigan has become a large referral center for TAVR explantation in low-, intermediate-, and high-risk patients. The mortality in these patients is much higher than expected because many of them need more extensive surgery than SAVR alone (root replacement, coronary artery bypass grafting [CABG], and mitral surgery are common). As a consequence of this experience, an older patient in good health who is expected to outlive their valve should be thoroughly considered for all options, including SAVR.

**Cardiac Interventions Today: The guidelines state TAVR first for patients aged > 80 years. Is that threshold supported by the data? Other countries, such as Japan, use a threshold > 75 years. Why use > 80 years in these guidelines?**

**Dr. Puri:** Age is a number. There are clearly some 80-year-old patients who appear to be better candidates than some 65-year-old patients. I hesitate about endorsing “hard” stops and arbitrary cutoffs when it comes to dealing with human beings, biology, and medicine, but yes, generally speaking and all things being equal, those aged > 80 years should try and avoid an open heart operation and the data for TAVR in this population are established.

**Dr. Ailawadi:** As noted, rather than moving away from absolute age, we should evaluate what is best for the patient not just today, but also for future interventions. The median life expectancy of a 75-year-old patient is 11 years. Thus, a healthy 75-year-old is likely going to outlive an aortic prosthesis and need to be considered for some reintervention. Meanwhile, the life expectancy for an 80-year-old patient is 8 years and that patient is much less likely to outlive their aortic prosthesis.

**Dr. Thourani:** It is quite fair to use 80 years as an age for patients to undergo TAVR as first-line therapy regardless of the STS score. This is supported by randomized data from the high- and intermediate-risk studies in which the average age was just above 80 years. Furthermore, we now have 5-year data in these patient categories and age in which there is similar morbidity and mortality between TAVR or SAVR. In our practice, TAVR is undoubtedly the standard of care in patients aged ≥ 80 years. Furthermore, in this age group, we commonly combine TAVR with percutaneous coronary interventions in those with severe coronary artery disease or edge-to-edge repair or transcatheter mitral valve replacement in those with mitral regurgitation.

**Cardiac Interventions Today: For patients aged 65 to 80 years, there is a heavy emphasis on shared decision-making and patient preference. Based on your experience with patients, what do you think will be the practical impact of that guideline?**

**Dr. Puri:** The majority of patients aged > 65 years do come with a premeditated notion of “TAVR-first.” Sometimes, we have to talk them away from this mentality, particularly in the setting of bicuspid disease, heavy left ventricular outflow tract (LVOT) calcification, and dilated aortas, where surgery, particularly in good hands, is preferred. I don’t see any seismic shift in terms of what this means practically as we’ve essentially been practicing this way for some time.

**Dr. Ailawadi:** The onus is on the heart team to really explain the short- and long-term pros and cons of all approaches ranging from medical therapy to transcatheter therapy to simple (eg, SAVR) and more advanced surgical therapy (eg, annular/root enlargement). This really must be done with as little bias as possible. One could envision a standardized risk calculator for both short- and long-term outcomes based on patient risk factors that can help patients make a decision. We must be clear to patients that it is their ultimate decision, but we should also guide them about the limitations of each approach.

**Dr. Thourani:** Shared decision-making is a very important adjunct to the management of patients with valvular heart disease. Our heart team spends an immense amount of time on education for new consults presenting with severe valvular disease in this age group. We believe in presenting early and 5-year outcomes for both TAVR and SAVR, especially because most patients in this age group are choosing a bioprosthetic prosthesis and not a mechanical valve. Given anatomic criteria that allows TAVR, most patients do choose the less invasive therapy. This is not in contradiction to most therapies, in that, when given a choice with similar outcomes, patients choose a less invasive therapy. Our conversations revolve around the lifetime management of AS, not just this specific procedure. Fortunately, we are able to let the patients know that we have < 1% risk of major complications or mortality in either TAVR or SAVR and allow our conversations to be performed in a collaborative manner among cardiologists, surgeons, and the patient with their family.

**Cardiac Interventions Today: The guidelines claim that there is no evidence to support TAVR in patients < 65 years. Do you agree with that?**

# AGE REPLACES RISK SCORE AS PRIMARY FACTOR IN TREATMENT DECISIONS

## NEW (2020) GUIDELINES

- > 80 years: Transfemoral TAVR is recommended (regardless of risk score)
- 65 to 80 years: Transfemoral TAVR and SAVR are both recommended as safe and effective procedures (both are class I recommendations)
- < 65 years: SAVR is recommended
- For these patients in which both SAVR and TAVR are an option, there is accompanying text outlining the risks and benefits of each therapy, with a focus on valve durability and life expectancy of the patient. Other considerations include procedural outcomes, length of stay and recovery, and patient preference

## PREVIOUS (2017) GUIDELINES

- Prohibitive surgical risk: TAVR is recommended
- High surgical risk: Equal recommendation for TAVR and SAVR
- Intermediate risk: SAVR is recommended above TAVR

**Dr. Puri:** The mean age across both low-risk trials was approximately 73 to 74 years. We have to bear that in mind. In patients < 65 years, particularly those with minimal comorbidities, one would anticipate that after an uncomplicated aortic valve replacement, their life expectancy should hover around 83 to 85 years. This likely means two biologic aortic valve replacements, given the anticipated mean durability of transcatheter aortic valves is likely to be similar to that of surgical aortic bioprostheses (around 10 years). Unless a non-comorbid patient aged < 65 years harbored good anatomy for transfemoral TAVR both now and for valve-in-valve TAVR in the future (ie, capacious sinuses of Valsalva, high coronary takeoff), one must remain very cautious about freely recommending TAVR in those relatively noncomorbid individuals. Meanwhile, innovative efforts are underway to develop novel adjunctive strategies to optimize future valve-in-valve procedures.

**Dr. Ailawadi:** When it comes to randomized trial data, this is a correct statement. There is only circumstantial evidence to support this at this time. Randomized trials were only performed in select patients > 65 years, thus limiting our understanding in younger populations. Moreover, most trials have

relatively short follow-up in the context of a lifetime approach to managing these patients. Sadly, we have a growing experience of TAVR explantation and recent data from the STS regarding surgical explantation has indicated mortality rates in excess of 15% to 20%. These experiences should put the brakes on treating patients who are expected to easily outlive their valve replacement until we have further evidence. Furthermore, at the time of SAVR, we as surgeons must do better to prepare the anatomy for a future TAVR with respect to the valve size and coronary height.

**Dr. Thourani:** To date, the randomized trials that led to the approval of TAVR in the United States did not have many patients who underwent TAVR in this age group. However, at the Marcus Valve Clinic, we are faced daily with patients in this age group who inquire about TAVR for the management of their severe AS. In those patients who are at intermediate or high risk, age becomes less important to us and TAVR remains our procedure of choice. As is similar to other patients' conversations aforementioned, we have very robust shared decision-making conversations with these patients. For those < 60 years and at low risk, we do discuss SAVR with a mechanical prosthesis. If the patient requests

a bioprosthetic valve, then the discussion of SAVR and TAVR becomes relevant in those < 65 years. We do utilize anatomic data from CT in our discussions with these patients. Our conversations revolve around the lifetime management of AS, not just this specific procedure. We commonly choose the pathway that will map this patient's next 20 years. Although we are okay with TAVR in these patients and have performed this commonly, there are scenarios that would lean toward SAVR, such as patients with Sievers 0 bicuspid aortic valve (BAV) morphology with severe LVOT calcification, low ostial coronary arteries, ascending aortic aneurysm, and other concomitant severe cardiac disease requiring intervention. We are vigilant that those patients who undergo SAVR should have a large prosthesis implanted to ensure the feasibility of valve-in-valve in the future, again with the premise that they would require one surgery for their lifetime.

### **Cardiac Interventions Today: What impact will the guidelines have on the National Coverage Determination (NCD)?**

**Dr. Puri:** I don't think there will be any immediate changes above and beyond what Centers for Medicare & Medicaid Services (CMS) have already made after the low-risk trial data. The continued importance of an MDT (involving a cardiac surgeon and an interventional cardiologist) and minimum operator and center requirements for structural/left heart/SAVR are established and will likely persist. There does remain active debate about treating TAVR and SAVR equally in terms of what the CMS demands. For example, to offer SAVR for AS, there is no CMS requirement of an MDT; surgeons can simply operate without a heart team discussion. Also, the requirement of a surgeon to actively participate in the TAVR procedure is questionable now in my mind. There are clear political sensitivities around this issue that may also vary from center to center.

**Dr. Ailawadi:** I do not think the NCD will affect the pathways for patient care. In some ways, the cat was out of the bag once FDA approval occurred in 2019. FDA approval was not limiting approval to those in whom the studies were done; TAVR was not studied in patients < 65 years, nor in those with bicuspid disease or heavy calcium burden, but is now approved irrespective of these challenges. Thus, the aortic valve heart team must remain in complete form to provide the safest therapies for patients.

**Dr. Thourani:** The NCD is not dictated by the guidelines and will require opening by the appropriate government agencies.

### **Cardiac Interventions Today: The guideline recommendation is that TAVR is an alternative to surgery in symptomatic patients with BAV and severe AS.**

**Dr. Ailawadi:** There remains great interest in studying this space even from those centers that have described a large successful individual experience with TAVR in bicuspid AS. This argument is somewhat reminiscent of the old argument that all three-vessel disease should be treated with CABG. For coronary artery disease, we eventually became more sophisticated at understanding the anatomy and determined that SYNTAX score can help differentiate the optimal therapy between CABG and percutaneous coronary intervention. Similarly, not all BAVs are equal both in terms of surgical risks as well as risks with TAVR. TAVR is less ideal in these patients with less circular valve annuli or with bulky calcified leaflets/LVOT calcium. Thus, we should not recommend that all bicuspid are TAVR candidates. Bicuspid, perhaps more than elderly tricuspid AS patients, must be carefully evaluated by a multidisciplinary aortic valve team focusing on anatomy and lifetime management. At present, the majority of BAV patients that are referred to our center are still recommended to undergo surgery after heart team evaluation due to the low-surgical-risk nature of many of these patients and the challenging anatomy/concomitant aortic disease.

**Dr. Thourani:** It remains difficult to group bicuspid aortic valve disease as a single entity. There remains a spectrum of BAV that range from leaflet calcium to severe annular and LVOT calcium. Moreover, there are variety of leaflet configurations, including Sievers 0 and 1, among others. For instance, those patients who are low risk and with severe leaflet and annular calcification with a Sievers 0 classification may be best served by surgery, whereas those with less calcium and a Sievers 1 classification would be well served by TAVR. It is important to note that there has been no prospective randomized trial evaluating the role of SAVR or TAVR in BAV and that all the trials that led to TAVR approval in the United States excluded BAV patients. Although prospective registries have shown good outcomes of TAVR in BAV, many patients with untoward anatomy were excluded in these trials. Lastly, it is very important to evaluate ascending aortopathy in these patients. Generally, low-risk patients with an ascending aorta or aortic root > 4.5 cm should most likely be evaluated for SAVR with an ascending aortic repair or a modified Bentall procedure. Interestingly, we are performing TAVR on many BAV patients with the right anatomy, but also, the majority of patients in whom I perform SAVR are also BAV patients with unfavorable TAVR anatomy.



### Cardiac Interventions Today: Do the guidelines impact your practice with these patients?

**Dr. Puri:** Decision-making (taking into account both patient preference and anatomic constraints) has been the norm in our institution for some time, particularly with the emerging evidence of the efficacy of TAVR in many patients with bicuspid pathology. The evidence and thus guidelines will only reaffirm our current practice.

**Dr. Ailawadi:** As a clinician with experience in all aspects of the management of AS, providing both TAVR and SAVR, I do not believe these guidelines dramatically change my practice. I try to provide the pros and cons of both TAVR and SAVR not just for the short term but also for the long term. Ultimately, if

the patient understands the limitations and risks and chooses a particular approach, I am fully supportive as I remain involved not just in the procedural phase of care, but also in the lifetime management of that patient.

**Dr. Garcia:** We expect that valve disease guidelines will be updated more frequently in the future. The results of ongoing clinical trials conducted in asymptomatic patients with severe AS, the development of new valves, and the updated results from registries will continue to modify the recommendations from professional societies. ■

1. Otto CM, Nishimura RA, Bonow RO, 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. *J Am Coll Cardiol.* 2021;77:e25-e197. doi: 10.1016/j.jacc.2020.11.018

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