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EDITORIAL

Transcatheter aortic valve implantation or replacement? Valve durability in the context of patient life expectancy

Shakirat O. Oyetunji [1] **and Catherine M. Otto** [2]*

[1]Division of Cardiothoracic Surgery, Department of Surgery, University of Washington School of Medicine, Seattle, WA, USA; and [2]Division of Cardiology, Department of Medicine, University of Washington School of Medicine, Seattle, WA, USA

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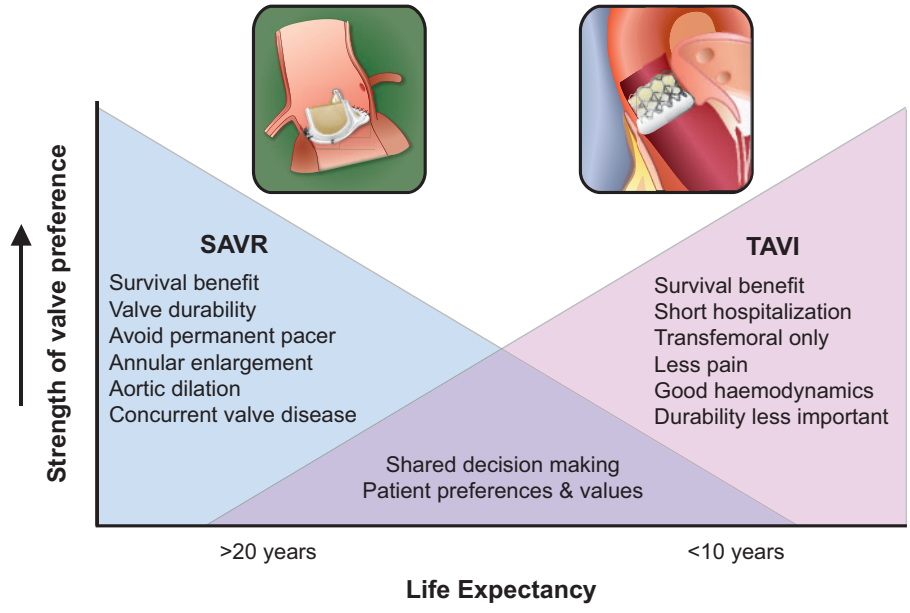
This editorial refers to 'Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter versus surgical aortic valve replacement', by T.H. Jorgensen *et al.*, doi: 10.1093/eurheartj/ehab375.



Graphical Abstract Balance of factors determining strength of valve preference versus expected remaining years of life.

Transcatheter aortic valve implantation (TAVI) via the transfemoral approach is now recommended as an alternative to surgical aortic valve replacement (SAVR) in older adults with severe symptomatic aortic stenosis (AS) based on the evidence provided by several prospective randomized trials. Initially, these trials included only patients with a prohibitive or high estimated surgical risk, with more recent studies confirming the benefits of TAVI even in patients with a lower surgical risk.[1–3] Even so, SAVR remains appropriate in many

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* Corresponding author. Division of Cardiology, Department of Medicine, University of Washington, Box 356422, Seattle, WA 98195, USA. Tel: +1 206 685 1397, Fax: +1 206 616 4847, Email: cmotto@uw.edu

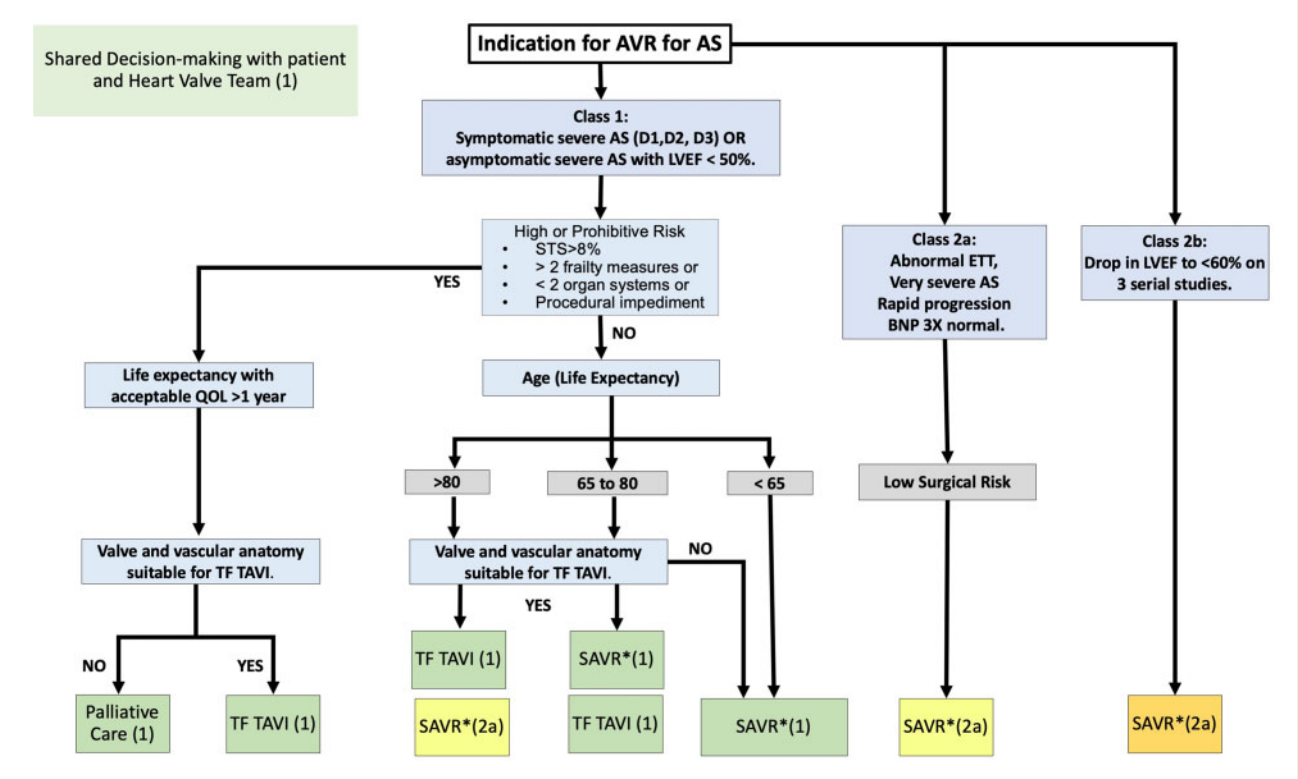

Figure 1 Summary of the ACC/AHA 2020 guidelines for the management of adults with severe aortic stenosis (AS).[6] The choice between transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (AVR) is limited to patients with a Class 1 indication for valve replacement; specifically symptomatic adults with severe AS, including those with high-flow (Stage D1) or low-flow low-gradient severe AS with either reduced (Stage D2) or preserved (Stage D3) left ventricular ejection fraction (LVEF), and asymptomatic patients with severe AS and a low LVEF. These recommendations only apply to the transfemoral (TF) approach to TAVI because outcomes are not equivalent with alternative access approaches. Class 1 indications (recommended) are shown in green, Class 2a (reasonable) in yellow, and Class 2b (may be considered) in orange. BNP, B-type natriuretic peptide, ETT, exercise treadmill test; QOL, quality of life. *When surgical valve replacement is appropriate, a mechanical valve is reasonable in patients aged 50 years or less, although a pulmonic valve autograft procedure may also be considered. In patients aged 50–65 years, either a mechanical or a bioprosthetic valve is reasonable, based on shared informed decision-making. In patients over age 65 years, a bioprosthetic valve is reasonable.

patients for several reasons, for example patients with valve or vascular anatomy not suitable for TAVI, associated valve or coronary disease requiring surgical intervention, the need for an annular enlargement procedure, or associated aortopathy requiring ascending aortic or aortic root replacement. More importantly, we have only limited data on long-term durability of TAVI valves because the mean age of patients enrolled in the prohibitive, high and medium risk trials was 81–84 years; obviously echocardiographic data are available only in the subset of patients still alive at long-term follow-up. These studies included very few patients under the age of 65 years. Robust data on valve durability even in a somewhat younger (mean age 73 years) lower risk population extend to only 2 years in previous published studies.[4] Although valve durability appears to be adequate for patients in older age groups, whether the data from these studies can be extended to younger adults with a longer life expectancy remains unclear.

In this issue of the *European Heart Journal*, Jorgensen *et al.* contribute important data to the growing body of literature on the TAVI vs. SAVR debate and provide 8-year echocardiographic and clinical data on valve durability in a lower risk patient population.[5] The Nordic Aortic Valve Intervention (NOTION) trial randomly assigned 280 patients at lower surgical risk to TAVI (n = 145) vs. SAVR (n = 135) over a 3-year period from 2010 to 2013. The baseline characteristics of their patient population included a mean age of 79.1 ± 4.8 years and a Society of Thoracic Surgeons Predicted Risk of Mortality Score (STS-PROM) of 3.0 ± 1.7%. In the 121 patients who were still alive and had echocardiographic data at the 8-year mark,[5] the composite outcome of all-cause mortality, stroke, and myocardial infarction (54.5% vs. 54.8%) as well as the individual components were not significantly different between the TAVI and SAVR groups. Although the risk of structural valve deterioration (SVD) was significantly lower after TAVI when compared with SAVR (13.9% vs. 28.3%), the definition of SVD includes several imaging findings that often do not result in clinical symptoms or a need for medical or surgical therapy. The more clinically relevant rate of bioprosthetic valve failure was similar between the two groups (8.7% vs. 10.5%),[5] defined as death due to valve dysfunction, haemodynamically severe valve dysfunction, or aortic valve reintervention.

How do these new data align with the recommendations in the recently published 2020 ACC/AHA guideline for the management of patients with valvular heart disease?[6] *(Figure 1)*.

First, they support the Class 1 recommendation for TAVI in patients over age 80 with the mean age of 79 years in the NOTION trial and similar clinical outcomes between TAVI and SAVR.

However, concerns for the widespread use of TAVI in younger, low-risk patients persist (*Graphical Abstract*). The clinical incidence of SVD is likely to be underestimated,[7,8] and recent short-term data in studies in low-risk patients reported higher rates of subclinical valve thrombosis in TAVI vs. SAVR in lower risk patients (2.6% vs. 0.7%).[4] SVD is seen earlier in younger patients, with rates up to 30% at 15 years in patients <65 years of age.[9] The significant rate of SVD might become clinically relevant with longer follow-up data. Increased rates of paravalvular leak (PVL) in TAVI compared with SAVR is also an area of concern. While no mortality difference was appreciated in this study between patients with moderate/severe PVL and patients with no/trace/mild PVL, other randomized clinical trials have reported higher rates of PVL in the TAVI vs. SAVR patients, with associated increased mortality with increasing severity.[1,2,10,11] Thus, the clinical equipoise for TAVI vs. SAVR in the guidelines for aortic valve intervention in the 65- to 80-year-old cohort holds until we have longer term data.

Second, the life expectancy of patients after correction of aortic stenosis has to be taken into consideration with informed shared decision-making between the patient and the Heart Valve Team. The provisional life expectancy of a 65-year-old based on the 2020 report from the US National Center for Health Statistics is 19.1 years (17.8 years for males and 20.4 for females).[12] Thus, the choice of aortic valve replacement in patients under age 65 years might have significant impact on their life expectancy if the valve is not durable for 20 or more years. In a study using simulation models of low-risk surgical patients, there was no difference in life expectancy when the durability of TAVI valves is 70% shorter than that of surgical valves. However, in younger patients, this threshold for TAVI valve durability was much higher, with decreased life expectancy seen when TAVI durability was 40%, and 50% shorter than that of surgical valves in 50- and 60-year-old patients.[13] With the mean age of 81–84 years in the intermediate and higher risk groups and mean age of 73 years in the lower risk groups, there are sparse data in low-risk patients under age 65 in any of the TAVI clinical trials. The Class 1 recommendation in the ACC/AHA guidelines for patients younger than 65 is for SAVR;[6] consideration for TAVI should be made in this age cohort only for patients with high or prohibitive surgical risk or anticipated limited longevity due to comorbid conditions.

In patients under the age of 50, consideration should be given for mechanical prosthesis or for a pulmonic valve autograft procedure.[6] For patients aged 50–65 years, the guidelines favour a shared decision-making process with the patient, balancing the risks associated with lifelong anticoagulation with the risk of potential re-intervention. In patients over age 65 years who undergo SAVR, a bioprosthetic valve is reasonable, with special consideration given to the next aortic valve intervention the patient will need; valve-in-valve TAVI is an appealing option; however, it is not suitable for all patients and long-term outcome data are limited.

Third, the higher rates of permanent pacemaker implantation in TAVI compared with SAVR[1,2,11] raise serious concerns for widespread TAVI use in younger patients due to associated increased morbidity and mortality related to the pacemaker. In a study of patients who received pacemaker implantation after aortic valve replacement, pacemaker implantation was independently associated with increased mortality rates; it was associated with a greater hazard ratio of increased death compared with comorbid medical conditions of diabetes and peripheral vascular disease.[14] Morbidity associated with permanent pacemaker implantation includes development of significant tricuspid valve regurgitation, right ventricular dysfunction, bleeding, erosion, infection, and need for revision.[13]

The TAVI vs. SAVR choice for aortic valve intervention has been an area of vast research over the past two decades, yet there are still a lot of questions that need to be answered. While the results are reassuring for TAVI regarding both clinical outcomes and valve durability, longer term data are needed before indiscriminately applying transcatheter valve therapy to younger, low surgical risk patients. As longer term data on TAVI valve durability become available, the age range for recommending TAVI over SAVR may shift, but at this time patients younger than 65 should undergo SAVR and patients aged 65–80 should be engaged in a shared decision-making between the patient and the Heart Team, with special attention given to the next aortic valve intervention. TAVI is preferred over SAVR for most patients over the age of 80 unless valve or vascular anatomy is unfavourable, other conditions warrant concurrent surgical treatment, or the patient prefers SAVR after consideration of patient-specific factors, preferences, and values.

The AHA/ACC guidelines provide comprehensive recommendations based on the current published evidence. Ideally, significant deviations from these guidelines should occur in the context of a Heart Valve Team with enrolment of the patient in a randomized clinical trial. Of course, guidelines are not rigid rules, and treatment should always be tailored to individual patient circumstances. However, as clinicians, we should be aware of the relevant guidelines, inform each patient of the applicable recommendations, and provide a clear rationale for any proposed modifications to guideline-directed therapy.

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