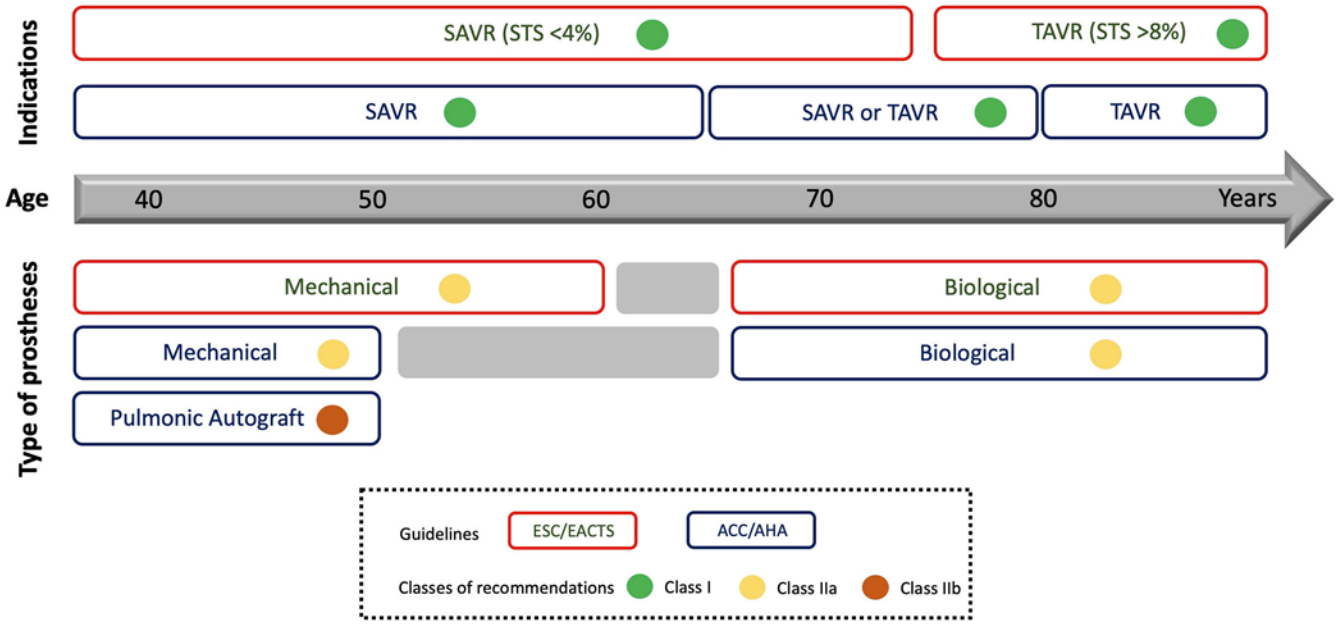
Lifetime Management of Aortic Stenosis - October 3, 2024

BACKGROUND

The heart team approach has become an integral part of discussions with the patient's regarding management of severe symptomatic aortic stenosis. In this context, early outcomes are often the focus of both patients and multidisciplinary care teams. With the approval of low risk transcatheter aortic valve replacement, a shift to lifetime management has now gained focus. This is because younger and healthier patient populations are more likely to outlive their first surgical or transcatheter bioprosthetic aortic valve.

There are multiple considerations for the multidisciplinary aortic valve team, and for patients in shared decision-making that are considered. These include the mechanism of aortic stenosis such as; senile calcific tricuspid, bicuspid, rheumatic, or other congenital; The presence of concomitant coronary artery disease; Other valve pathology including mitral and/or tricuspid; Concomitant aortic pathology including aortic aneurysm; Concomitant atrial fibrillation; And importantly, individual patient anatomy and suitability for both surgical and or transcatheter approaches.

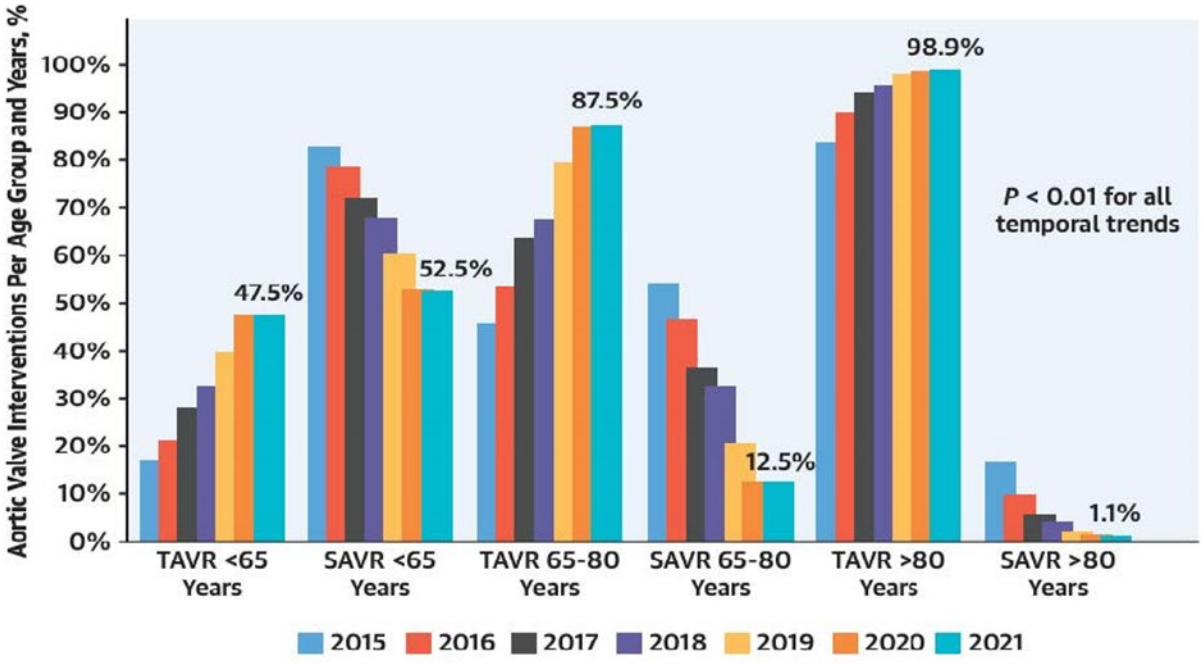
GUIDELINES FOR AORTIC VALVE REPLACEMENT



Giulio Russo. Circulation: Cardiovascular Interventions. Lifetime Management of Aortic Stenosis: Transcatheter Versus Surgical Treatment for Young and Low-Risk Patients, Volume: 15, Issue: 11, Pages: 915-927, DOI: (10.1161/CIRCINTERVENTIONS.122.012388)

As above, European and United states guidelines for aortic valve replacement differ, particularly in lower risk populations. European guidelines recommend surgical aortic valve replacement for patients less than 75 who are low risk for SAVR. TAVR is recommended for patients greater than 75 who are high or greater risk for surgical aortic valve replacement. U.S. guidelines suggest SAVR for patient's less than 65 years of age, SAVR or TAVR for patients between the ages of 65 to 80, and TAVR for patients greater than 80 years.

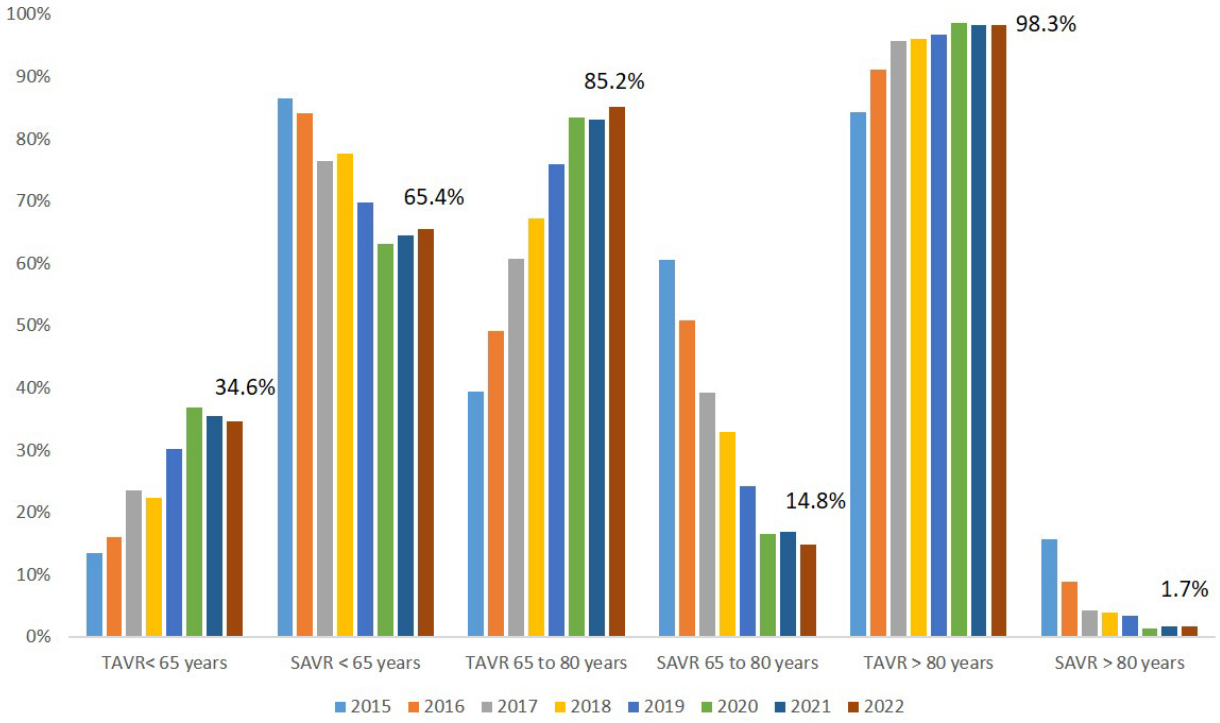
CURRENT TRENDS IN SAVR AND TAVR, U.S. DATA



Sharma T, et al., *J Am Coll Cardiol*. Data from The Vizient Clinical Data Base contains de-identified clinical data from ~800 U.S. academic centers, including >250 U.S. centers performing both TAVR and SAVR. 2023;80(2):2054-2056.

Data from the Vizient Clinical Data Base contains de identified clinical data from approximately 800 U.S. academic medical centers. This data includes greater than 250 US centers that performed both TAVR and SAVR. This data suggests that 47.5% of patients under the age of 65 are received TAVR in 2020 and 2021. The implications for lifetime management in this younger population are unknown.

CURRENT TRENDS IN TAVR AND SAVR, THE MICHIGAN EXPERIENCE



In Michigan, data from MSTCVS and MISHC suggest similar trends in TAVR and SAVR based upon age. In 2022, 34.6% of patients under the age of 65 who underwent AVR had a TAVR.

SAVR-FIRST CONSIDERATIONS

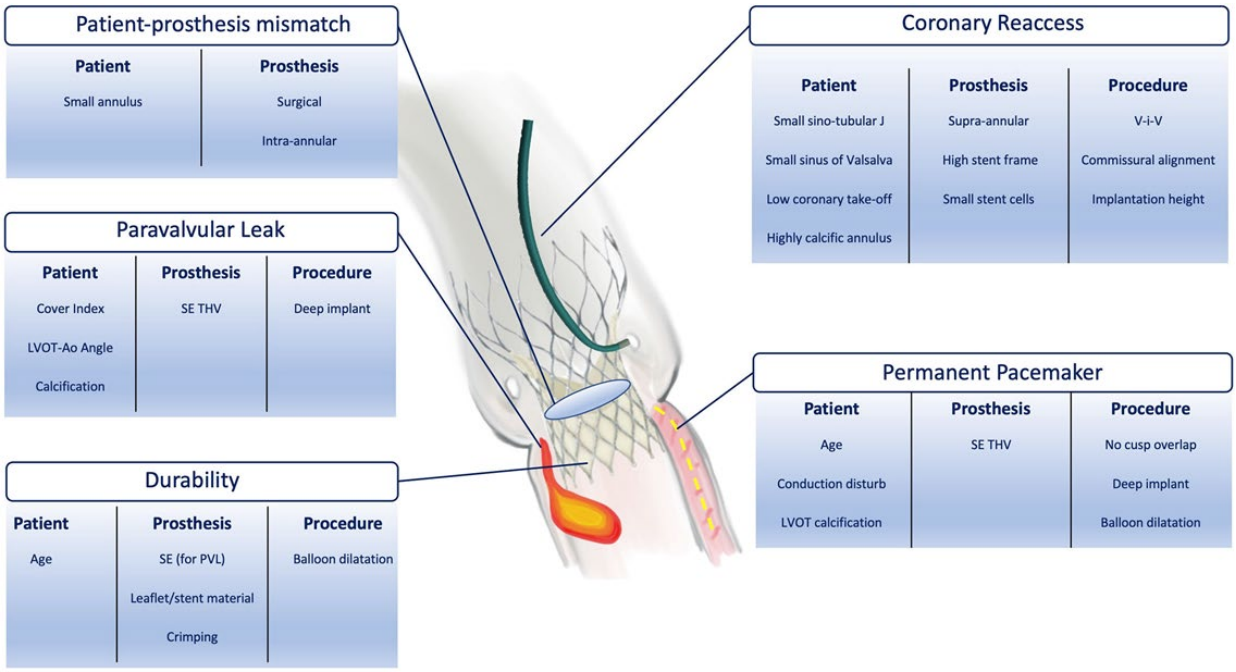
There are several considerations for patients who are offered and choose surgical aortic valve replacement. The type of SAVR is obviously an important factor. These include a bioprosthetic valve, a mechanical valve, or a pulmonary autograft (i.e. Ross procedure). In addition, the option of surgical annular enlargement is often addressed. The purpose is to avoid patient prosthesis mismatch and potentially facilitate TAVR-in-SAVR in the future. SAVR in a woman of child-bearing age might influence consideration of a valve type that would circumvent the need for anticoagulation.

Patient aortic anatomy is also relevant when considering SAVR including bicuspid anatomy with bulky calcification, a smaller aortic annulus (i.e. 23mm or less), sinus or coronary anatomy that might preclude TAVR-in-TAVR or TAVR-in-SAVR, concomitant severe coronary artery disease, valve disease, aortic disease (i.e. aortic aneurysm), or atrial fibrillation.

Other considerations that might favor a SAVR-first approach include the lower risk of permanent pacemaker. Considerations that might dissuade from a SAVR-first approach include the longer recovery time and return of normal quality of life and or return to work. In addition, the expertise in experience of the surgical team at individual centers could potentially influence heart team and shared patient discussions.

TAVR-FIRST CONSIDERATIONS

In low-risk populations, faster post procedure recovery and quicker return to normal quality of life and employment are important. However, there are many open issues and challenges for transcatheter aortic valve replacement.



Patient prosthesis mismatch in a younger, more active patient is potentially problematic. Perivalvular leak in earlier generation TAVR devices was a significant consideration, although more recent data suggest that this is less of an issue with current generation TAVR devices with appropriate patient selection. Durability of TAVR prostheses in low-risk populations is a concern and long-term follow-up in these populations is ongoing. Coronary reaccess for patients with significant coronary artery disease is also a significant consideration. In addition, patients after TAVR are more likely to require a permanent pacemaker which may have implications for multiple reasons, including but not limited to; loss of ventricular synchrony, tricuspid regurgitation and pacemaker device infection.

UNKNOWNS

VALVE DURABILITY

TAVR durability in older, high-risk patients appears to be similar to surgical bioprosthetic valves. However, durability in younger patients is less well-known with limited long-term follow-up available from higher risk cohorts.

DIFFERENCES IN VALVES

SAVR durability is variable and had not been as well studied. With the advent of transcatheter techniques and validated databases, a focus on SAVR durability has demonstrated significant differences in valve types. This has also led to removal of some surgical valves from market that appeared to have inferior long-term outcomes. The long-term outcome with newer annular enlargement techniques is unknown and should be studied.

In two recently published randomized trials in low-risk severe aortic stenosis patients treated with SAVR or TAVR;

- In the Edwards Sapien Low Risk Randomized Trial 5-year analysis, the balloon expandable intra-annular TAVR device vs SAVR, the first primary end point occurred in 111 of 496 patients in the TAVR group and in 117 of 454 patients in the surgery group (Kaplan–Meier estimates, 22.8% in the TAVR group and 27.2% in the surgery group; difference, −4.3 percentage points; 95% confidence interval [CI], −9.9 to 1.3; P=0.07). The win ratio for the second primary end point was 1.17 (95% CI, 0.90 to 1.51; P=0.25). TAVR durability in those treated with balloon expandable TAVR was equivalent to SAVR to 5 years (Partner Low risk 5-year outcome).
- In the Medtronic Evolut Randomized Trial Low-Risk 4-year analysis, the self-expanding supra-annular TAVR device vs. SAVR, the primary endpoint of all-cause mortality or disabling stroke at 4 years was 10.7% (n = 76) in the TAVR group and 14.1% (n = 90) in the SAVR group (HR: 0.74; 95% CI: 0.54-1.00; P = 0.05), representing a 26% relative reduction in the hazard for death or disabling stroke with TAVR compared with SAVR. TAVR and SAVR durability was similar at 4 years in this randomized trial. (Evolut Low Risk Four-year Outcomes).
- More data, out to 10 years of follow-up will be forthcoming in these and other studies.

BEST PRACTICES

- Lifetime management of patients with severe symptomatic aortic stenosis is a multifaceted issue
- Patient anatomy and concomitant cardiac disease might influence clinical recommendations for aortic valve replacement either surgical or transcatheter
- A thorough evaluation of all patients referred for aortic valve replacement should include
    - “TAVR” CT angiogram protocol for accurate annulus anatomical measurement
    - Echocardiography
    - Coronary angiography
    - Complete medical evaluation for comorbidities and management
    - Frailty evaluation
- Heart team multidisciplinary evaluation of all patients with severe aortic stenosis is advised

    - Specific discussion should be had regarding management of concomitant coronary, valve, aortic and arrhythmia diseases
- Shared decision making with patients and their families so that patients can make informed and patient centered treatment decisions is advised
- Patients should be aware of treatment options in the implications and risks of each
    - SAVR first mechanical
    - SAVR first pulmonary allograft
    - SAVR first with possible annular enlargement
        - Followed by TAVR in SAVR
        - Followed by redo SAVR
    - TAVR first
        - Followed by SAVR
        - Followed by TAVR in TAVR
- Heart teams should also consider the appropriate TAVR prosthesis and procedure based upon several factors
    - Patient anatomy
    - Valve durability where data continues to evolve
    - TAVR in TAVR plan based on the CTA and post-processing and modeling
    - Implant team experience
    - Leaflet modification and removal technology available and team experience

DISCLAIMER

MISHC Best Practice Protocols are based on consortium-wide consensus at the time of publication. Protocols will be updated regularly, and should not be considered formal guidance, and do not replace the professional opinion of the treating physician.

REFERENCES

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