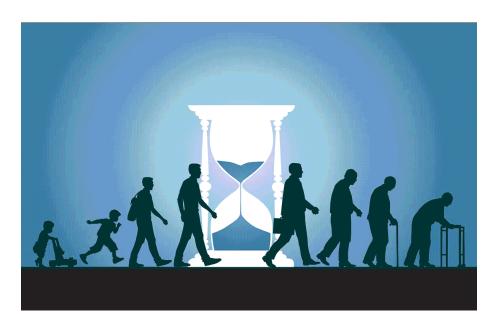
The Brief



TAVR Patients Get Younger as Technology Ages

To understand how changing guidelines and clinical practice have impacted TAVR's utilization compared to SAVR across age groups over the last decade and what they portend for the future, Health Advances conducted a comprehensive analysis of real-world data of US aortic valve replacement procedures.

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ranscatheter agric valve replacement (TAVR) has been one of the fastest growing medtech markets for the last decade, and as it begins to mature, predictions vary as to the remaining potential for penetration into total aortic valve replacement (AVR) procedures. With frequent changes in recommendations and guidelines, real-world data can help us understand shifts in the age demographics of patients who undergo TAVR versus surgical aortic valve replacement (SAVR) and how these trends might point to expected changes in future market dynamics.

Recent Recommendation Updates

Historically, the choice between SAVR and TAVR has primarily been based on surgical risk as determined by age, medical history, overall health status, and comorbidity. However, further robust data from clinical trials of TAVR in patients beyond just the high-risk segment has led to changes in guidelines and recommendations. In the US, TAVR indications expanded to include intermediate-risk patients in 2016, and low-risk patients in 2019. The 2020 American College of Cardiology (ACC)/American Heart Association (AHA) guideline was the first to introduce age rather than surgical risk as a decision-making factor and recommended SAVR for patients under 65 years or with a life expectancy over 20 years, and TAVR for patients over 80 years with a life expectancy of fewer than 10 years. This open-ended guideline recommendation based on age has created uncertainty and variability between offering SAVR or TAVR to the 65-80 years group, in which decision-making is shared by the individual institutions' cardiology teams.

Real-World Data Findings

To understand how the guideline changes and clinical experience have affected trends in TAVR and SAVR share over the last decade, Health Advances conducted a comprehensive analysis of real-world data of AVR procedures. By 2016, TAVR had emerged as the predominant treatment option for patients aged 80 years and above, consistent with its original label for high-risk patients. However, the most notable increase in TAVR utilization over the last decade has been in the 65-79 years group, where its use surged from 24% of AVR procedures in 2014 to 67% in 2024. This growth is likely the result of multiple factors, including low-risk trial readout and low-risk approval in 2019, as well as the updated guideline that places this group in a gray area where treatment decisions are made by individual institutions and clinicians (see Figure 1).

In 2020, there was a spike in TAVR utilization for both the under 65 years and the 65-79 years groups, likely driven by low-risk indication approval. However, this trend normalized over time. In the under 65 years group, TAVR utilization has steadily increased: from less than 1 in 10 patients in 2014 to 1 in 4 patients in 2024. This shift is particularly interesting given that the ACC/ AHA guideline still recommends SAVR for this cohort, suggesting that TAVR's success in older, more high-risk patients is leading to its further adoption and off-label use among

younger patients with lower risk. These findings underscore the dynamic nature of AVR preferences and the importance of data-driven decision-making in shaping future guidelines and clinical practice.

Future of TAVR

The last major update to the ACC/ AHA guideline was in 2020. Given the advances in transcatheter options for valvular heart disease, the guideline is likely due for another major update in the next 12-24 months. With TAVR's continual push into younger patients, we're hearing more discussion of lifetime management of aortic stenosis. Valve durability, patient's age and life expectancy, surgical risk, as well as anatomical features are all factors that require careful consideration. As patients will likely require more than one valve

in their lifetime, selecting the most optimal intervention and device type today that gives the patient a greater chance of success if a future intervention, such as valvein-valve, is needed, becomes even more important.

The boundary separating TAVR and SAVR utilization continues to be pushed, but eventually it will hit a ceiling. Based on the realworld data analysis, that ceiling is approaching sooner rather than later as TAVR utilizations in all three age groups have remained stable for the past few years. The TAVR eligible population will continue to grow in the near term, likely not from shifting surgical procedures to transcatheter, but from extending to new patient populations with indication expansion to aortic regurgitation, asymptomatic severe aortic stenosis, and moderate aortic stenosis. MTS



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