

# Commentary: The Never-Ending Debate on the Type of Aortic Prosthesis in Patients Aged 50–70, as TAVR Peaks in Popularity: Which Prosthesis Should Be Used for Aortic Valve Replacement?

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Mechanical prostheses and bioprostheses each have their own advantages and disadvantages. Typically, a mechanical prosthesis is recommended for younger patients (<50 years old), while a bioprosthesis is often suggested for those over 70 years of age. Recently, there has been a shift towards considering bioprostheses for patients aged between 50 and 65 years, driven by advancements highlighted in updated reference studies and guidelines [1,2]. Recent studies have shown a 32.8% increase between 1997 and 2014 in the annual number of bioprosthesis implantations in patients aged 18–50 years [3]. As the field evolves with new developments in both types of prostheses and ongoing research into non-vitamin K antagonist oral anticoagulants (NOACs), comparing the outcomes of survival and complications by valve type could offer valuable insights [2]. In this context, debate continues regarding which type of prosthesis is better for middle-aged patients (50 to 70 years old) receiving aortic valve replacement (AVR).

A recent meta-analysis by Tasoudis et al. [4], which identified 25 studies incorporating 8,721 bioprosthetic and 8,962 mechanical valves, suggested that mechanical valves provide a survival advantage for patients aged 50–70 years. In contrast, for patients older than 70 years, bioprosthetic

valves in the aortic position offer better survival outcomes [4]. In an article published in a 2023 issue of *JACC: Advances*, Lu et al. [5] analyzed data from 6,907 patients aged 50 to 69 years from the SWEDEHEART registry. They concluded that survival was better in those who received mechanical prostheses than in those who received bioprostheses. This cohort included 3,831 patients in the bioprosthesis group. Subgroup analyses were also performed for patients aged 50 to 59 years and 60 to 69 years. At 15 years of follow-up, the estimated cumulative all-cause mortality rate was approximately 8% higher in the bioprosthesis group than in the mechanical prostheses group (45%; 95% confidence interval [CI], 42%–48% versus 37%; 95% CI, 35%–40%). The survival advantage with mechanical valves at 15 years was less pronounced in patients aged 60 to 69 years. However, among those aged 50 to 59 years, survival with a mechanical prosthesis was 15% greater 15 years postoperatively than in patients who received bioprostheses. The risks of late stroke and heart failure were similar between the prosthetic valve groups. The risk of late re-intervention was lower, but the cumulative risk of bleeding was higher with mechanical prostheses [5].

The authors' results were generally consistent with those

previous studies, with mechanical prostheses demonstrating better overall survival compared to bioprostheses despite associations with a higher risk of stroke and anticoagulation-related bleeding [6]. Conversely, bioprostheses were linked to an increased risk of aortic valve reintervention. The study analyzed a middle-aged population at a single institution, comparing mechanical and bioprosthetic valves from January 2000 to March 2019. For this comparison, competing risk analysis and the inverse probability of treatment weighting (IPTW) method based on propensity scores were utilized. A total of 1,580 patients were enrolled in the study, including 984 with mechanical AVR and 596 with bioprostheses. There was no significant difference in early mortality between the groups (0.9% for mechanical prostheses versus 1.7% for bioprostheses,  $p=0.177$ ). After adjusting for IPTW, the risk of all-cause mortality was significantly higher in the bioprosthesis group than in the mechanical prosthesis group (hazard ratio [HR], 1.39; 95% CI, 1.07–1.80;  $p=0.014$ ). Competing risk analysis indicated lower risks of stroke (sub-distributional hazard ratio [sHR], 0.44; 95% CI, 0.28–0.67;  $p<0.001$ ) and anticoagulation-related bleeding (sHR, 0.35; 95% CI, 0.23–0.53;  $p<0.001$ ) in the bioprosthesis group. However, the risk of aortic valve reintervention was significantly higher in this group (sHR, 6.14; 95% CI, 3.17–11.93;  $p<0.001$ ).

In the discussion, the authors identified several limitations, including the nature of the study as observational and retrospective, as well as its single-center design. However, in my view, the most significant limitation is the enrollment period, which spanned from 2000 to 2019. The authors acknowledged advancements in surgical techniques and overall patient care during this period. However, these improvements are relatively limited in comparison to the enhancements in surgical materials, such as the design of bioprostheses and improvements in treatment techniques, which have been shown to significantly extend longevity. Since 2015, there has been a remarkable evolution in biomaterial treatment techniques aimed at preventing calcification and structural modifications to reduce shear stress during the cardiac cycle. Additionally, the anticipated introduction of transcatheter aortic valve replacement (TAVR) and the widespread use of anti-lipid agents, coupled with improvements in quality of life, are likely to play crucial roles in extending the lifespan of bioprostheses.

A reasonable interpretation for the better survival of middle-aged patients with mechanical prostheses is the hemodynamic consequences of living with a failing bioprosthesis. Although primary leaflet tissue failure in bioprostheses can progress rapidly (e.g., cusp tear), many patients

experience months or even years of exposure to hemodynamically significant regurgitation, stenosis, or both before critical prosthetic failure is identified and replacement is recommended. The impact of valve failure on mortality is often underestimated by the rates and risks associated with reoperation. Furthermore, is re-intervention for a bioprosthesis truly a hazard? TAVR has recently emerged as a game changer for failed bioprostheses, and its efficacy and safety have already been established.

Tam et al. [7] published a paper entitled “Transcatheter ViV (valve in valve) versus redo surgical AVR for the management of failed biological prosthesis: early and late outcomes in a propensity-matched cohort” in *JACC: Cardiovascular Interventions*, 2020. The study included a total of 558 patients who underwent interventions for failed biological prostheses between March 2008 and September 2017 at 11 institutions in Ontario (valve in valve [ViV],  $n=214$ ; redo AVR [surgical AVR],  $n=344$ ). The 30-day mortality rate was significantly lower for ViV than for RA (absolute risk difference, -7.5%; 95% CI, -12.6% to -2.3%). Additionally, the rates of permanent pacemaker implantation and blood transfusions were lower with ViV, as was the length of stay. The 5-year survival rate was higher with ViV (76.8% versus 66.8%; HR, 0.55; 95% CI, 0.30–0.99;  $p=0.04$ ) [7]. Therefore, re-intervention for a failed bioprosthesis has become a non-hazardous endpoint, which can be excluded from event comparison.

At the most recent American College of Cardiology/American Heart Association meeting in 2023, Fath et al. [8] presented findings suggesting that contemporary bioprostheses could be a reasonable option for AVR in patients aged 50 to 70 years. This recommendation was based on a retrospective study using the TriNetX global database (<https://trinetx.com/>), which included a total of 1,138 propensity-matched patients in each group. These patients, who underwent primary isolated surgical AVR between 2014 and 2020, showed less major bleeding risk and similar rates of survival, stroke, and reoperation compared to others. According to US national trends, the use of mechanical valves in patients aged 50 to 70 years declined significantly from 2008 to 2017. Consequently, long-term data on the increasingly used bioprostheses are essential to determine the future role of mechanical valve replacement in younger patients undergoing surgery [9]. Zhao et al. [10] from Fuwai Hospital, National Center for Cardiovascular Diseases, summarized their clinical data for middle-aged patients who underwent AVR. The findings indicated no significant difference in overall long-term mortality between recipients of mechanical valves and bioprostheses. However,

bioprostheses were associated with a lower risk of bleeding [10]. If larger studies reveal that bioprostheses have a similar survival rate, lower rates of bleeding or thrombosis, and a higher rate of re-intervention compared to mechanical prostheses, then choosing bioprostheses could be a better decision. This is especially true in anticipation of the upcoming exclusion of re-intervention risk due to the generalization of TAVR for ViV. Additionally, regardless of whether warfarin or NOACs are used, oral anticoagulant medication for mechanical prostheses may pose a greater challenge than the ViV procedure in an aging society comprised of a very active and healthy population.

The challenge of selecting the appropriate AVR prosthesis is expected to persist, as cardiologists and surgeons often have biases regarding patient age and post-AVR expectations. Therefore, the age category should be reevaluated as an absolute criterion for choosing an aortic prosthesis. Additionally, collaboration within the heart team is essential to make the most suitable decision regarding prosthesis type, aiming to predict the patient's clinical scenario for at least the next 20 years.

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### Author contributions

All the work was done by Seung Hyun Lee.

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