TAVR for AR Spotlight: Do We Have a Pacemaker Issue?

Challenges with nondedicated and dedicated devices, uncertain predictors, and long-term implications.

By Hendrik Wienemann, MD

Transcatheter aortic valve replacement (TAVR) has emerged as an alternative for patients with symptomatic aortic regurgitation (AR) who are unsuitable for surgical aortic valve replacement (SAVR).[1,2] Unlike the treatment of patients with severe aortic stenosis (AS), the treatment of patients with AR presents significant anatomic challenges, including larger stroke volumes, a dilated aortic root, and often bicuspid valve anatomy. The absence of calcification in AR prevents utilizing the calcium-based fixation mechanism used in TAVR for AS. As a result, using TAVR systems designed for AS in AR leads to suboptimal outcomes, including higher rates of valve embolization, residual AR, and need for a second valve implantation.[3,4]

PACEMAKER RATES AFTER TAVR FOR AORTIC REGURGITATION WITH NONDEDICATED DEVICES COMPARED TO BOTH SAVR AND AORTIC STENOSIS COHORTS

New permanent pacemaker implantation (PPMI) remains a significant concern in the context of TAVR for patients with AR. Yoon et al evaluated various generations of TAVR devices and observed an overall PPMI rate of 18.2%. Specifically, device-specific rates were 21.4% for the Evolut R (Medtronic), 18.2% for the Sapien 3 (Edwards Lifesciences), and 15.8% for the transapical JenaValve (JenaValve Technology, Inc.).[3] In a study by Sanchez-Luna et al, PPMI rates after TAVR with the Myval (Meril Life Sciences) were 13.4% at hospital discharge, 15% at 30 days, and 22.1% at 1 year in patients with AR.[5] The Pantheon registry, which analyzed 201 patients, reported PPMI rates of 22.6% for self-expanding valves and 21.8% for balloon-expandable valves at hospital discharge.[4] Zhang et al observed a PPMI rate of 29.4% after TAVR with the VitaFlow device (MicroPort).[6]

Overall, PPMI rates in AR patients undergoing TAVR are consistently higher than those observed in AS patients, even with newer-generation devices. For example, the Evolut FX (Medtronic) demonstrated a PPMI rate of 11.9%, whereas the Sapien 3 Ultra Resilia (Edwards Lifesciences) showed a PPMI rate of 5.6% in AS patients.[7,8] Alharbi et al reported on a propensity score–matched cohort of TAVR and SAVR patients with pure aortic insufficiency/AR, finding a pacemaker rate of 11.5% in the SAVR cohort, further highlighting that AR is associated with a higher risk of new PPMI compared to AS patients undergoing SAVR.[9,10] These findings suggest that AR, with its associated pathophysiologic features—such as annular dilation, altered valve dynamics, and ventricular remodeling—may inherently predispose patients to conduction abnormalities.

DEDICATED TRANSFEMORAL TAVR DEVICES FOR AR

Recently, dedicated transcatheter heart valves have been developed to mitigate the risks of valve mispositioning, paravalvular regurgitation, and frequent need for a second valve. Two transfemoral devices, the JenaValve Trilogy (JenaValve Technology, Inc.) and J-Valve (JC Medical), have been introduced.[11-13] The JenaValve Trilogy is the only CE Mark–approved device for the treatment of AR, featuring an active fixation mechanism that uses locators that directly attach to the native valve leaflets to anchor and, therefore, provide stable securement before deployment.

The ALIGN-AR trial demonstrated a high device success rate but reported a PPMI rate of 24% (36/150) at 30 days.[12] The pacemaker rates in this study decreased over time according to the tertile of enrollment (first tertile: 30%, second tertile: 28%, last tertile: 14%), which may also be attributed to improvements in implantation techniques.[12] Of note, in patients with AS treated with the JenaValve device, pacemaker rates were notably low, at just 4.9% in a small cohort. This suggests that design features may play a less critical role, although further research is needed to confirm this.[14]

The J-Valve system features nitinol anchor rings that conform to the native aortic sinuses.[13] A compassionate use experience with the J-Valve in 27 patients with AR showed encouraging procedural outcomes, with a PPMI rate of 13% (3/27) in this cohort. Interestingly, the pacemaker rates in this much smaller J-Valve cohort were lower. However, the rates of paravalvular regurgitation were higher. This suggests that differences in radial forces between the two devices may play a role, highlighting the need for further research on this topic.

PREDICTORS OF NEW PPMI

Anatomic, electrocardiographic, and procedural predictors of PPMI have been well-established in AS patients undergoing TAVR.[15] Among these, right bundle branch block (RBBB) has been identified as a significant risk factor for the need for PPMI.[16] However, the relevance of RBBB as a predictor in AR patients after TAVR remains unclear and warrants further investigation. Modifiable factors, such as implantation depth and valve oversizing, have also been suggested as potential predictors, but their precise role in AR remains to be fully elucidated. In a study by Zhang et al, preoperative RBBB, first-degree atrioventricular block, implantation depth, nontubular left ventricular outflow tract, and aortic root angle were identified as independent predictors of conduction disturbances after TAVR with the VitaFlow system in AR patients.[6]

These findings highlight the importance of considering both anatomic and procedural factors when assessing the risk of conduction abnormalities and the subsequent need for PPMI in AR patients undergoing TAVR. Further research is needed to clarify the impact of these predictors and refine strategies to minimize pacemaker dependency in this patient population, particularly concerning the dedicated J-Valve and JenaValve devices.

LONG-TERM IMPLICATIONS

High right ventricular pacing rates have been associated with adverse outcomes after TAVR in AS patients,[17] although their direct impact on mortality remains controversial.[18-20] The potential consequences of various pacing strategies in the context of AR, particularly regarding clinical outcomes, long-term data, and survival, have not been thoroughly investigated. Therefore, more research is needed to develop individualized treatment plans that minimize the risks associated with pacing while optimizing patient prognosis. ■

Acknowledgment: The author acknowledges the use of automated assistive writing technologies for proofreading.

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. Circulation. 2021;143:72-227. doi: 10.1161/CIR.0000000000000923
2. Vahanian A, Beyersdorf F, Praz F, et al. 2021 ESC/EACTS guidelines for the management of valvular heart disease. Eur Heart J. 2022;43:561-632. doi: 10.1093/eurheartj/ehab395
3. Yoon SH, Schmidt T, Bleiziffer S, et al. Transcatheter aortic valve replacement in pure native aortic valve regurgitation. J Am Coll Cardiol. 2017;70:2752-2763. doi: 10.1016/j.jacc.2017.10.006
4. Poletti E, De Backer O, Scotti A, et al. Transcatheter aortic valve replacement for pure native aortic valve regurgitation. JACC Cardiovasc Interv. 2023;16:1974-1985. doi: 10.1016/j.jcin.2023.07.026
5. Sanchez-Luna JP, Martín P, Dager AE, et al. Clinical outcomes of TAVI with the Myval balloon-expandable valve for non-calcified aortic regurgitation. 2023;19:580-588. doi: 10.4244/EIJ-D-23-00344
6. Zhang X, Liang C, Zha L, et al. Predictors for new-onset conduction block in patients with pure native aortic regurgitation after transcatheter aortic valve replacement with a new-generation self-expanding valve (VitaFlow Liberty™): a retrospective cohort study. BMC Cardiovasc Disord. 2024;24:77. doi: 10.1186/s12872-024-03735-z
7. Zaid S, Attizzani GF, Krishnamoorthy P, et al. First-in-human multicenter experience of the newest generation supra-annular self-expanding Evolut FX TAVR system. JACC Cardiovasc Interv. 2023;16:1626-1635. doi: 10.1016/j.jcin.2023.05.004
8. Yamamoto M, Yashima F, Shirai S, et al. Performance and outcomes of the SAPIEN 3 Ultra RESILIA transcatheter heart valve in the OCEAN-TAVI registry. EuroIntervention. 2024;20:579-590. doi: 10.4244/EIJ-D-23-00996
9. Alharbi AA, Khan MZ, Osman M, et al. Transcatheter aortic valve replacement vs surgical replacement in patients with pure aortic insufficiency. Mayo Clin Proc. 2020;95:2655-2664. doi: 10.1016/j.mayocp.2020.07.030
10. Blankenberg S, Seiffert M, Vonthein R, et al. Transcatheter or surgical treatment of aortic-valve stenosis. N Engl J Med. 2024;390:1572-1583. doi: 10.1056/NEJMoa2400685
11. Baumbach A, Patel KP, Kennon S, et al. A heart valve dedicated for aortic regurgitation: review of technology and early clinical experience with the transfemoral Trilogy system. Catheter Cardiovasc Interv. 2023;102:766-771. doi: 10.1002/ccd.30795
12. Vahl TP, Thourani VH, Makkar RR, et al. Transcatheter aortic valve implantation in patients with high-risk symptomatic native aortic regurgitation (ALIGN-AR): a prospective, multicentre, single-arm study. Lancet. 2024;403:1451-1459. doi: 10.1016/S0140-6736(23)02806-4
13. Garcia S, Ye J, Webb J, et al. Transcatheter treatment of native aortic valve regurgitation. JACC Cardiovasc Interv. 2023;16:1953-1960. doi: 10.1016/j.jcin.2023.05.018
14. Tamm AR, Wienemann H, Treede H, et al. Initial multicenter experience with a novel self-expanding TAVR system in patients with aortic valve stenosis. JACC Cardiovasc Interv. 2025;18:60-68. doi: 10.1016/j.jcin.2024.10.056
15. Sammour Y, Krishnaswamy A, Kumar A, et al. Incidence, predictors, and implications of permanent pacemaker requirement after transcatheter aortic valve replacement. JACC Cardiovasc Interv. 2021;14:115-134. doi: 10.1016/j.jcin.2020.09.063
16. Kiani S, Kamioka N, Black GB, et al. Development of a risk score to predict new pacemaker implantation after transcatheter aortic valve replacement. JACC Cardiovasc Interv. 2019;12:2133-2142. doi: 10.1016/j.jcin.2019.07.015
17. Bruno F, Munoz Pousa I, Saia F, et al. Impact of right ventricular pacing in patients with TAVR undergoing permanent pacemaker implantation. JACC Cardiovasc Interv. 2023;16:1081-1091. doi: 10.1016/j.jcin.2023.02.003
18. Rück A, Saleh N, Glaser N. Outcomes following permanent pacemaker implantation after transcatheter aortic valve replacement: SWEDEHEART observational study. JACC Cardiovasc Interv. 2021;14:2173-2181. doi: 10.1016/j.jcin.2021.07.043
19. Hochstadt A, Merdler I, Meridor Y, et al. Effect of pacemaker implantation after transcatheter aortic valve replacement on long- and mid-term mortality. Heart Rhythm. 2021;18:199-206. doi: 10.1016/j.hrthm.2020.10.013
20. Jørgensen TH, Backer O, Gerds TA, et al. Mortality and heart failure hospitalization in patients with conduction abnormalities after transcatheter aortic valve replacement. JACC Cardiovasc Interv. 2019;12:52-61. doi: 10.1016/j.jcin.2018.10.053

Hendrik Wienemann, MD
Clinic III for Internal Medicine
Faculty of Medicine and University Hospital Cologne
Cologne, Germany
hendrik.wienemann@uk-koeln.de
Disclosures: Consultant fees and travel grants from JenaValve Technology.