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Breaking the Barrier: The Benefits and Drawbacks of TAVI in Low-Surgical Risk Patients

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Take Home Messages

- Transcatheter aortic valve implantation (TAVI) is a well-established therapy for patients with severe aortic stenosis (AS) where traditional surgical aortic valve replacement surgery (SAVR) carries intermediate or higher operative risk.
- Recent trials have shown that TAVI is non-inferior and even superior to SAVR in patients with low surgical risk. However, concerns remain that any complications could have a greater long-term impact on younger patients.
- There is favourable 8-year TAVI valve longevity data with non-inferiority to bioprosthetic surgical valve longevity.
- Conduction disorders, aortic regurgitation, coronary artery access and considerations of future approaches to repeat aortic valve intervention remain the key obstacles.
- Cardiologists in Heart Teams will need to consider not only the immediate patient care but also anticipate future developments and challenges to ensure optimal outcomes for their patients in the lifelong management of AS.

Introduction

Within two decades of its inception, transcatheter aortic valve implantation (TAVI) has emerged as a well-established treatment modality for patients diagnosed with severe aortic stenosis (AS), particularly in cases where conventional surgical aortic valve replacement (SAVR) poses intermediate or higher operative risk (1,2). Recent studies provide evidence indicating non-inferiority or even superiority of TAVI over SAVR in patients with low surgical risk, thus broadening the eligible patient population for TAVI (3,4). Despite encouraging 2-year outcomes (**Table 1**), the use of TAVI in younger, low surgical risk populations raises concerns regarding long-term complications which would have a greater impact on younger patients. Specifically, low-risk TAVI trials have demonstrated that certain complications are more frequent with TAVI when compared to SAVR, which could lead to undesirable cumulative effects with increased life expectancy. The landscape of TAVI has changed since previous reviews in 2019 (5,6) thus here I will revisit the literature and discuss these complications and other possible drawbacks of TAVI's widespread future use.

About the author

Dr. Debar Rasoul is a ST6 Cardiology Registrar subspecialising in Percutaneous Coronary Intervention. Currently out-of-programme, he holds the position of Regional BJCA representative and is concurrently pursuing his doctoral degree as a Clinical Research Fellow at the Liverpool Centre for Cardiovascular Science & University of Liverpool. His research focuses on developing and implementing innovative digital platforms, including Virtual Wards and community-based interventions with a goal to facilitate early supported discharge, reduce length of stay in hospital, and improve patient experiences, outcomes, and healthcare efficiency through safe and viable alternatives to secondary care-based inpatient care.

Table 1. Summary Findings: Incidence of 2-year complications following TAVI versus SAVR in low-risk surgical patients.

	Partner 3 (3)			Evolut (4)		
Mean age (years)	73.6 ± 5.8			74.0 ± 5.9		
STS score (%)	1.9 ± 0.7			2.0 ± 0.7		
	TAVI[a]	**SAVR**	**95% CI**	**TAVI[b]**	**SAVR**	**95% CI**
Pacemaker implantation	9.1	7	p-value: 0.21[c]	21.8	8.2	13.6 [9.7, 17.5]
Atrial fibrillation	7.9	41.8	p-value: <0.001[c]	9.8[d]	38.3[d]	28.5 [32.8, 24.1][d]
Major vascular complications	2.8[d]	1.5[d]	1.83 [0.74, 4.55][d]	3.8	3.5	0.3 [-1.8 , 2.4]
Disabling Stroke	0.8	1.1	0.71 [0.19, 2.63]	1.5	2.7	-1.2 [-2.8, 0.4]
Death (all cause)	2.5	3.2	0.75 [0.35, 1.63]	3.5	4.4	-0.9 [-3.0, 1.2]
Coronary occlusion	0.2	0.7	p-value: 0.28[c]	0.9[d]	0.4[d]	0.5 [0.3, 1.4][d]

[a]Sapien3 Valve. [b]CoreValve-Evolut R-PRO. Table Data is expressed as % with Kaplan-Meier rates with 95% CI, unless marked as p-value[c] where it mirrors original publication data available. [d]Incidence at 1-year, not 2-years.

CI = confidence interval; SAVR = surgical aortic valve replacement; STS = Society of Thoracic Surgeons; TAVI = transcatheter aortic valve replacement.

Conduction Disorders

The incidence of pacemaker implantation post-TAVI is variable across different valve manufacturers and implantation techniques (**Figure 1**). In addition, there is an incidence of >20% of newly diagnosed left bundle branch block (LBBB) (3). Post-TAVI, both pacemaker implantation and intraventricular conduction delay are associated with reduced left ventricular function, reduced morbidity, and increased mortality (7). The risk factors predicting the need for pacemaker implantation appear to be pre-existing conduction disorder, procedural factors such as valve manufacturer, valve diameter and depth of valve implantation (8). Techniques such as a higher level of implantation - 'cusp-overlap technique' - have been proposed to reduce the permanent pacemaker requirement (9).

Paravalvular Aortic Regurgitation

Over time and with advances in manufacturers' technology, the proportion of patients who experience aortic regurgitation (AR) post TAVI has decreased (**Figure 1**). This improvement in prevalence is noteworthy, but it remains important to consider that AR may have little impact on elderly patients and greater long-term impact on younger patients. In addition, the incidence of no-more-than mild aortic regurgitation was significantly higher in the TAVI population (29% PARTNER-3 (3), 33.1% Evolut Low Risk (4)) compared to SAVR, posing the same clinical concern of cumulative long-term impact with implantation in younger patients.

Future Coronary Artery Intervention

During TAVI pre-procedural planning, precise measurements of the aorta and aortic valve are crucial to accurately determine the valve diameter and assess the coronary fundus heights. This is particularly significant in younger patients who are at risk of developing future coronary artery disease, as some TAVI valves can interfere with the selective engagement of coronary arteries during catheterization procedures (**Figure 1**). Such interference can result from the TAVI valve leaflets or struts rising above the coronary ostia, displacement of native valves or commissural misalignment. Further limitations to coronary intervention may arise during future repeat TAVI procedures or if centres implement techniques discussed above to reduce the incidence of post-implant conduction disorders. Notably, a recent CT-scan simulation study reported a high risk of coronary obstruction following redo-TAVI in at least 27% of patients, regardless of valve manufacturer (18). Therefore, a higher placed implant may increase the risk for difficult coronary access, while a lower implant may increase the risk of conduction disorders and pacemaker implantation as discussed above.

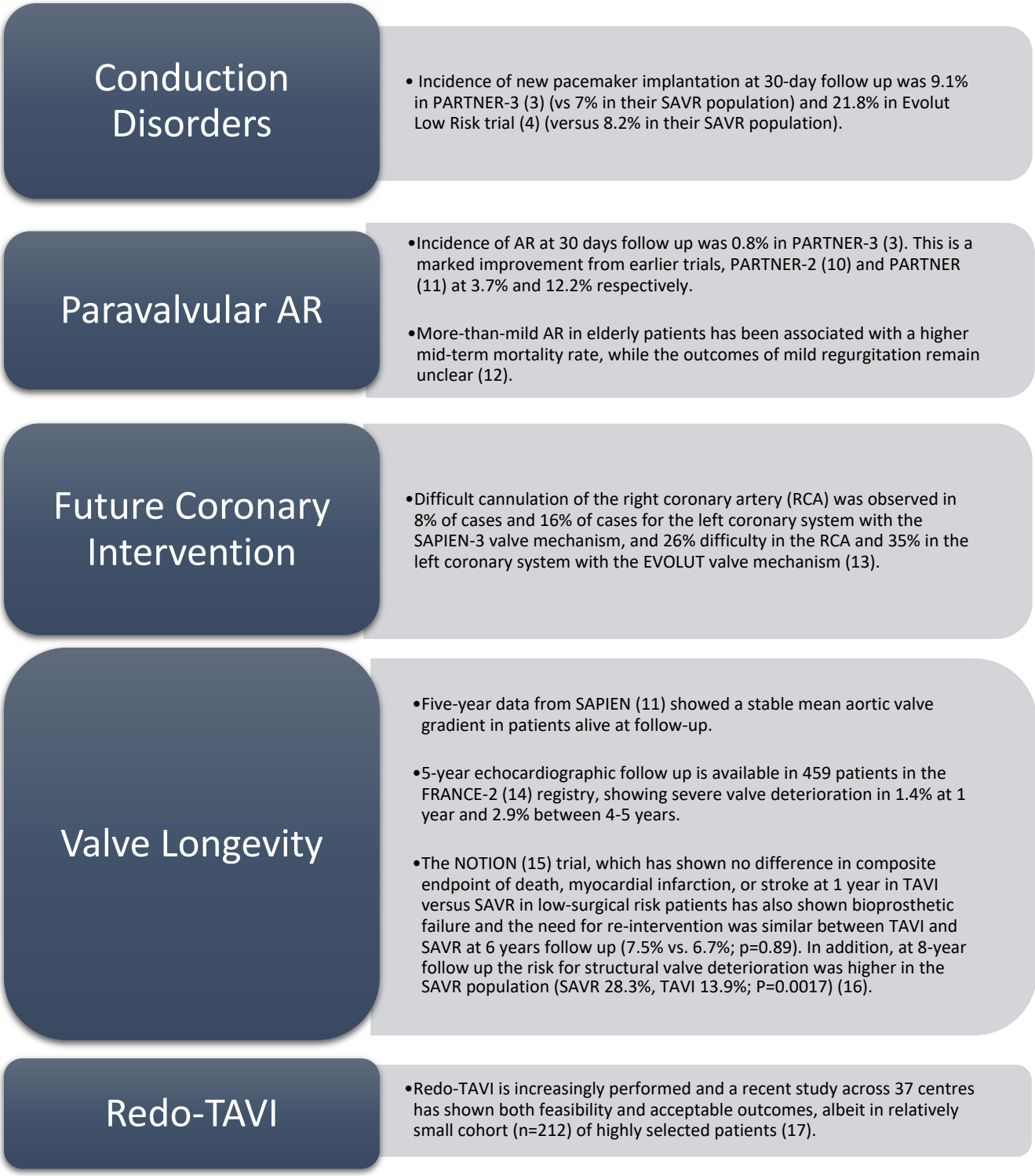

***Figure 1**. Graphical representation of the main findings and areas of consideration for TAVI in low-surgical risk patients.*

Valve Longevity

All bioprosthetic valves, including TAVI, can fail over time. While both surgical and TAVI valves undergo similar production methods and anti-calcification treatment, their handling differs. The crimping and post-dilation of TAVI valves may cause leaflet damage more frequently than the no-touch approach used for surgical valves (19). Several studies have reported longevity (Figure 1). In addition, at 8-year follow up the risk for structural valve deterioration was higher in the SAVR population (SAVR 28.3%, TAVI 13.9%; P=0.0017) (16). Although recent bench-studies simulating 25 years of use (1 billion cardiac cycles) demonstrate favourable haemodynamic markers (20), real-world factors such as patient-prosthesis mismatch and valve under-expansion have not yet been studied.

Redo-TAVI

Here the key focus remains not only on the potential need for future intervention, but also on the suitability and feasibility of different combinations of aortic valve intervention. The prevalence of patients with late TAVI valve degeneration will inevitably increase in the future, and given that valve explant may be challenging, the discussion is centred on the repeatability of TAVI (**Figure 1**). However, it is important to note that redo-TAVI is not the only possible approach for patients requiring future aortic valve intervention. In younger patients, a hybrid approach involving a combination of SAVR and TAVI in varying orders (SAVR-TAVI, TAVI-SAVR) may present opportunities for improved quality of life. However, this approach will require long-term tailored patient care, as several factors such as patient co-morbidities, anatomy, and possible valve incompatibility for repeat procedures, including risks of coronary artery access and coronary sinus sequestration (21), will need to be carefully considered in planning for any possible future intervention.

Conclusions

The increasing use of TAVI in younger patients highlights the need for tailored approaches and rigorous patient selection in the lifetime management of AS and valve intervention. However, it is almost certain that this population will require more than one procedure in their lifetime, and while redo-TAVI and hybrid approaches combining SAVR and TAVI have been proposed there is limited longevity data available. Furthermore, complications from TAVI procedures discussed in this review are even less studied in redo procedures. The prevalence of bicuspid aortic valves in a younger population also necessitates further investigation into the long-term effects of mild paravalvular leak and the impact of repeat aortic valve interventions. Although there is favourable 8-year TAVI follow-up data, it provides little reassurance to patients in their sixth or seventh decade. TAVI has transformed the management of aortic stenosis over the past two decades, and its success has expanded the patient pool to include younger individuals. However, the available longevity data does not address all areas of concern, and in the future Heart Teams will need to consider not only the immediate patient care but also anticipate future developments and challenges to ensure optimal outcomes for their patients.

Declarations

None

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