Chapter

Perspective Chapter: Valve-in-Valve Transcatheter Aortic Valve Replacement (ViV) for Failed Bioprosthetic Valves

Aravdeep Jhand, Vinayak Bapat, Thomas Porter and Poonam Velagapudi

Abstract

Aortic valve disease remains the second most common valvular heart disease worldwide. Surgical aortic valve replacement (SAVR) with mechanical or bioprosthetic valves and transcatheter aortic valve replacement (TAVR) with bioprosthetic valves are both approved therapies for patients with severe aortic stenosis (AS) across all surgical risk categories. On the other hand, SAVR remains the mainstay of treatment for severe aortic regurgitation (AR) with TAVR reserved for selected patients at prohibitive surgical risk. Both surgical and transcatheter bioprosthetic valves are prone to bioprosthetic valve failure (BVF) due to various etiologies, and can lead to restenosis, regurgitation, or a combination of both. BVF can now be addressed by repeat valve replacement whether surgical or valve-in-valve TAVR (ViV). ViV is a desirable option for elderly patients at high surgical risk and requires meticulous planning with pre-operative CT imaging to optimize outcomes and minimize complications.

Keywords: aortic stenosis, aortic regurgitation, bioprosthetic valve failure, structural valve deterioration, transcatheter aortic valve replacement, valve-in-valve

1. Introduction

Aortic valve disease is the second most common valvular heart disease worldwide with calcific aortic disease being the second most common non-rheumatic valvular disorder, increasing in prevalence due to an aging population [1, 2]. Surgical aortic valve replacement (SAVR) with mechanical or bioprosthetic valves and transcatheter aortic valve replacement (TAVR) with bioprosthetic valves are both approved therapies for patients with severe aortic stenosis (AS) across all surgical risk categories while SAVR remains the mainstay of treatment for severe aortic regurgitation (AR) with TAVR reserved for selected patients at prohibitive surgical risk [3–6]. Over the last decade, there has been a steady rise in the number of TAVRs performed in the United States (US) and worldwide while SAVR volumes

have remained fairly constant [7, 8]. A higher proportion of patients undergoing SAVR are being implanted with bioprosthetic valves [9]. This has led to a significant proportion of aortic valve disease patients with an aortic bioprosthesis. Though bioprosthetic aortic valves are beneficial in terms of bleeding risk with no prerequisite for long-term anticoagulation, they have limited durability and are certain to degenerate, resulting in bioprosthetic valve failure (BVF) [10]. BVF can be treated by repeat valve replacement whether surgical or valve-in-valve TAVR (ViV). In this chapter, we discuss various mechanisms and management of BVF with a focus on the evolving field of ViV.

2. Bioprosthetic valve failure

2.1 Mechanisms of bioprosthetic valve dysfunction

The Valve Academic Research Consortium 3 (VARC-3) identifies four major mechanisms of aortic bioprosthetic valve dysfunction as follows: (i) Structural valve deterioration (SVD), caused by intrinsic permanent damage to the prosthetic valve; (ii) Non-structural valve deterioration, caused by any abnormality not intrinsic to the prosthetic valve; (iii) Thrombosis; and (iv) Endocarditis (**Table 1**) [11]. SVD is

Etiology	Mechanism	Examples
SVD	Intrinsic permanent damage of the prosthetic valve	• Wear and tear • Leaflet disruption • Flail leaflet • Leaflet fibrosis or calcification • Strut fracture or deformation
Non-structural valve deterioration	Any abnormality not intrinsic to the prosthetic valve causing valve dysfunction	• PVL • PPM • Pannus formation • Prosthesis malposition
Thrombosis	Thrombus formation on the prosthetic valve, leading to dysfunction with or without thromboembolism	• Subclinical (imaging findings of HALT or RLM without significant hemodynamic compromise and no symptoms) • Clinically significant thromboembolic sequalae or worsening symptoms or worsening hemodynamic changes and confirmatory imaging
Endocarditis	Infection involving any structure of the prosthetic valve	• Peri-valvular Abscess • Pus • Vegetation • Dehiscence

BVF: bioprosthetic valve failure; HALT: hypo-attenuated leaflet thickening; PPM: patient-prosthesis mismatch; PVL: paravalvular degeneration; RLM: reduced leaflet motion; and SVD: structural valve deterioration.

Table 1.
Mechanisms of BVF [11].

Stage 1	Morphological valve deterioration	Evidence of SVD, non-structural valve dysfunction, thrombosis, or endocarditis without any significant hemodynamic changes
Stage 2	Moderate hemodynamic valve deterioration	i. Increase in MG ≥ 10mm Hg leading to • MG ≥ 20mm Hg + decrease in EOA ≥ 0.3 cm^2 or ≥ 25% and/or • decrease in DVI ≥ 0.1 or ≥ 20% compared with echocardiographic assessment performed 1–3 m post procedure OR ii. New occurrence or increase of ≥ 1 grade of intraprosthetic AR resulting in ≥ moderate AR
Stage 3	Severe hemodynamic valve deterioration	i. Increase in MG ≥ 20mm Hg leading to • MG ≥ 30mm Hg + decrease in EOA ≥ 0.6 cm^2 or ≥ 50% and/or • decrease in DVI ≥ 0.2 or ≥ 40% compared with echocardiographic assessment performed 1–3 m post procedure OR ii. New occurrence or increase of ≥ 2 grades of intraprosthetic AR resulting in severe AR

AR: aortic regurgitation; DVI: Doppler velocity index; EOA: effective orifice area; m: months; MG: mean gradient; and SVD: structural valve deterioration.

Table 2.
Stages of SVD [11].

further classified into three stages: Stage 1: morphological valve deterioration without any hemodynamic compromise; Stage 2 and Stage 3: moderate and severe hemodynamic valve deterioration, respectively (**Table 2**).

BVF is defined as any mode of bioprosthetic valve dysfunction, which is associated with clinical consequences (new onset or worsening symptoms, LV dilation/dysfunction/hypertrophy, or pulmonary hypertension), stage 3 irreversible SVD, or any aortic valve reintervention or valve-related death [12].

2.2 Risk factors for structural valve deterioration

Development of SVD is influenced by various patient and prosthesis-related risk factors (**Table 3**) [13, 14]. Young age is an independent risk factor for SVD possibly due to a higher physiological demand. Some of the other patient-related risk factors are similar to risk factors associated with atherosclerosis and calcific AS, including diabetes mellitus, hyperlipidemia, metabolic syndrome, hypertension, renal disease, and smoking. This suggests a potential lipid mediated inflammatory pathway in the pathogenesis of SVD [15].

Prosthesis-related risk factors include smaller prosthesis size and annular implantation of prosthesis. The effect of type of tissue (bovine versus porcine) on development of SVD remains unclear. Calcification of the bioprosthesis has been identified as the predominant mechanism behind SVD. Calcifications tend to occur along commissural and basal regions of valve leaflets and can manifest as stenosis (**Figure 1A**), valve insufficiency, or both. Other mechanisms postulated for SVD include degradation of extracellular matrix, shear stress leading to mechanical degeneration and adaptive immune responses to a foreign body (prosthetic valve) [15].

Patient-related factors	Prosthesis-related factors
Young age	Smaller prosthesis
HLD	Annular implantation
HTN	Under expanded bioprosthesis
CKD	Over expanded bioprosthesis
Metabolic syndrome	
Smoking	
Hyperparathyroidism	

CKD: chronic kidney disease; HLD: hyperlipidemia; HTN: hypertension; and SVD: structural valve deterioration.

Table 3.
Risk factors for development of SVD.

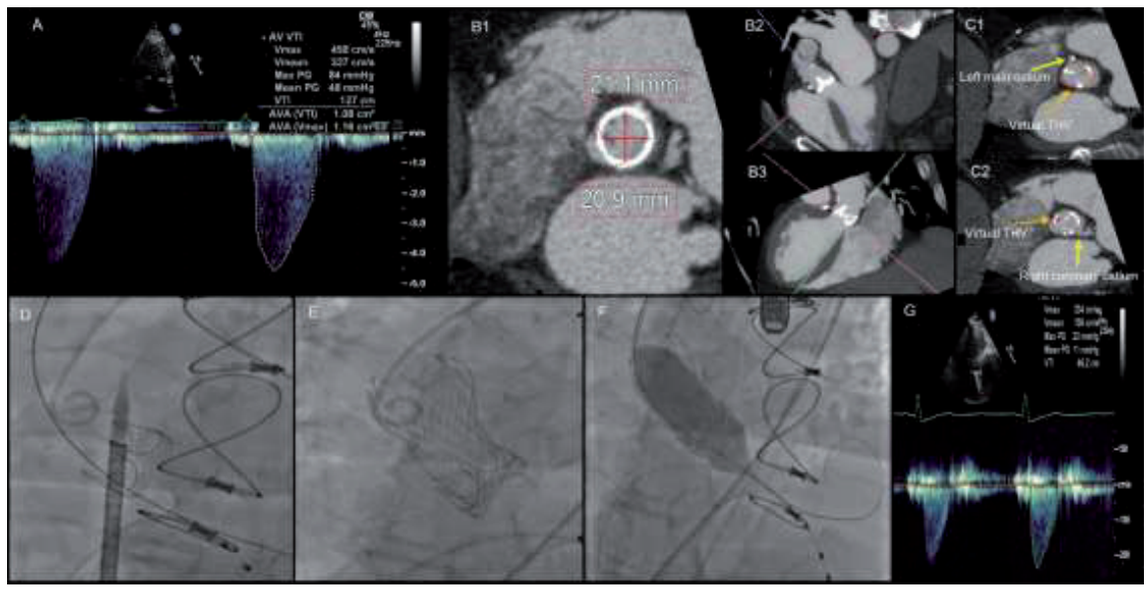

Figure 1.
A case of ViV in a 72-year-old male with SVD of a 23 mm Carpentier-Edwards Perimount Magna Ease aortic prosthesis. Figure A: TTE demonstrating a MG of 48 mm Hg across the aortic valve consistent with severe prosthetic stenosis; Figures B1–B3: CT showing a true ID of 21 mm. The stent ID reported by the manufacturer is 22 mm; Figures C1 and C2: demonstrating the use of CT in assessing risk of coronary obstruction. Virtual THV of the planned size is simulated and distance from the coronary ostia is measured. In this case VTC was <4 mm for both coronary ostia; Figure D: failed bioprosthetic valve under fluoroscopy; Figure E: A 26 mm Evolut R valve is implanted in a supra-annular position. A gradient of 17 mm Hg was noted across the aortic valve post deployment; and Figure F: BVF with a 24 mm TRUE balloon was performed with decrease in gradient to 11 mm Hg post BVF. BVF: bioprosthetic valve fracture; CT: computed tomography angiography; ID: internal diameter; MG: mean gradient; SVD: structural valve deterioration; THV: transcatheter heart valve; TTE: transthoracic echocardiogram; and ViV: valve in valve transcatheter aortic valve replacement.

2.3 Durability of bioprosthetic aortic valves

The aim of aortic valve replacement is to outlast the life expectancy of the patient. Surgical bioprosthetic valves have lower long-term durability compared with mechanical valves [10]. However, numerous observational studies have shown rates of freedom from SVD of more than 85% at 10 years post implantation of surgical bioprosthetic valves [16]. Freedom from SVD has been reported as high as 93% at 8 years with use of contemporary bovine pericardial prosthetic devices [17]. Nonetheless,

SVD may potentially be a problem in younger patients (<65 years) and those with longer life expectancy where reintervention at an older age more than two decades after implantation may be necessary.

On the other hand, data on long-term durability of TAVR valves are scarce given the contemporary nature of this field and evolving technology. Barbanti et al reported data on incidence of BVF among 288 patients with a mean age of 81 years who underwent TAVR with first-generation balloon expandable (BE) and self-expandable (SE) bioprosthesis [18]. Survival at 8 years was only 29.8% reflecting an elderly population with multiple comorbidities. Despite low survival, the cumulative incidence of severe SVD and BVF was only 2.39 and 4.51%, respectively. When compared with surgical bioprosthetic valves, data on durability of transcatheter heart valves (THV) in TAVR trials have been encouraging. Follow-up data from NOTION trial, which randomized low-risk patients with symptomatic severe AS to TAVR with first-generation SE bioprosthesis versus SAVR, showed a lower incidence of severe SVD in TAVR group as compared with SAVR at 8 years (2.2 vs 6.8%, $p = 0.068$) [19]. There was no difference in cumulative incidence of BVF between groups (8.7% in TAVR vs 10.5% in SAVR, $p = 0.61$).

3. Management of bioprosthetic valve failure

Careful diagnosis of BVF should be made based on clinical presentation and assessment of data from transthoracic echocardiogram (TTE). Whenever necessary, ancillary imaging techniques such as transesophageal echocardiogram (TEE), computed tomography (CT) scan, and magnetic resonance imaging (MRI) can be performed to understand the mechanism of BVF. There are no randomized controlled trials currently comparing redo SAVR with ViV for BVF. A heart team discussion should be facilitated to individualize the management based on patient and prosthetic characteristics. Both American and European valvular heart disease guidelines give ViV a class IIa recommendation for inoperable and high-risk patients with BVF (stenosis or regurgitation) [3, 20]. Redo SAVR should be favored over ViV in younger patients where valve durability is important and in patients at high risk of coronary obstruction or aortic root injury. Patients with severe patient-prosthetic mismatch (PPM) usually do not benefit from ViV given smaller annular areas unless adjunctive procedures such as balloon valve fracture are performed.

4. Preprocedural considerations for ViV

4.1 Determining type and size of failed bioprosthetic valve

Information on manufacturer, model, and size of the failed bioprosthetic valve should be obtained from the operative report or implant card. This will also help in determining the type of failed valve. There are three different types of aortic bioprosthetic valves: stented, stentless, and sutureless. Xenograft leaflets used in stented and stentless valves are usually composed of either bovine pericardium or porcine valve tissue. Stent internal diameter (stent ID) is defined as diameter of the stent frame when covered with fabric or pericardium but without the leaflets, whereas the true internal diameter (true ID) is the diameter of the inflow of the bioprosthetic valve. It should be noted that the true ID in stented bioprosthetic valves is smaller than the stent ID. The stent ID is usually reported by the

manufacturer [21]. The true ID is about 2mm and 1mm less than the stent ID for porcine and bovine pericardial valves, respectively [21]. The true ID of the failed valve should be used to determine the size of valve being considered for ViV. Slight upsizing is considered to achieve adequate hemodynamic result. True ID can also be measured with CT imaging (**Figure 1B**).

4.2 Determining the risk of coronary occlusion

Risk of coronary obstruction following ViV is greater than threefold compared with native valve TAVR (NV-TAVR) and is associated with a very high mortality rate (30-day mortality of 53%) [22]. When a THV is implanted in a stented bioprosthetic valve, it holds the bioprosthetic leaflets open, forming a covered cylinder with the THV frame and the overlying bioprosthetic leaflets. This may lead to coronary obstruction if the aortic root is small or if the bioprosthetic valve was implanted in a canted fashion along the long axis of the aortic root, despite the latter being normal or large in size [23]. Furthermore, stentless valves are usually implanted in a supra-annular position and thus may result in short distances between leaflets and coronary ostia once THV is implanted risking coronary obstruction [22].

CT imaging is crucial in assessing the risk of coronary obstruction following ViV [24]. A shallow height of coronary ostium (≤ 10 mm) from the level of valve plane and narrow sinus of valsalva measurements (≤ 30 mm) are both high-risk features for coronary obstruction. Furthermore, the risk of coronary obstruction is high when the tip of stent posts extends above the level of coronary ostia as seen with stented bioprosthetic valves. In these scenarios, a virtual THV to coronary ostium distance (VTC) can be measured with the help of CT images (**Figure 1C**) [25]. A virtual cylinder with dimensions (height and area) similar to the THV being considered is simulated at the anticipated position of THV, and distance from the edge of cylinder to both coronary ostia is measured. A distance of ≤ 4 mm is considered high risk for procedure-related coronary obstruction [22]. In higher-risk cases, upfront coronary protection with a guidewire and undeployed stent can be considered [26]. The stent can be deployed rapidly at the ostium of coronary artery in case coronary obstruction occurs post ViV in a maneuver referred to as chimney stenting technique [27]. Alternatively, a novel procedure referred to as bioprosthetic scallop intentional laceration to prevent coronary artery obstruction (BASILICA) might be considered [28]. Herein, laceration of failed bioprosthetic valve leaflet posing risk of coronary obstruction is performed using an electrified guidewire by puncturing and snaring the leaflet.

5. Procedural considerations for ViV

5.1 Determining optimum type of THV

Currently, SE CoreValve system (Medtronic, Minneapolis, MN) and BE Sapien-3 and Sapien XT valves (Edwards Lifesciences, Irvine, CA) have the US Food and Drug Administration (FDA) approval in the United States for ViV in patients at high or extreme risk of complications from conventional surgical replacement [29, 30].

Choice of THV for a failed bioprosthetic valve depends on the size of failed valve and anticipated need for coronary access in the future [31]. Failed valves with a smaller size (true ID ≤ 23 mm) may benefit from implantation of an SE bioprosthesis given supra-annular design with favorable hemodynamic results (**Figure 1D–E**) [32]. On contrary, these THV should be avoided if coronary access post ViV is anticipated given technical challenges with coronary engagement [33].

5.2 Determining optimum implantation depth of THV

For a failed stented bioprosthesis, the optimum depth for implantation of THV has been recommended to achieve adequate hemodynamic results. Thus, "Supra-Annular" positioning has been proposed as the implanted THV works above native valve annulus and is not constrained by the sewing ring of failed valve [34]. Implantation depth of 0–5 mm for Evolut Valve (Medtronic, Minneapolis, MN), 0–2 mm for Sapien XT (Edwards Lifesciences, Irvine, CA), and a depth of ≤ 20% of total height of THV for Sapien 3 (Edwards Lifesciences, Irvine, CA) have correlated with lower post procedural gradients (**Figure 2**) [34, 35]. For failed stentless valves, implantation depth should be similar to TAVR in native valves [36].

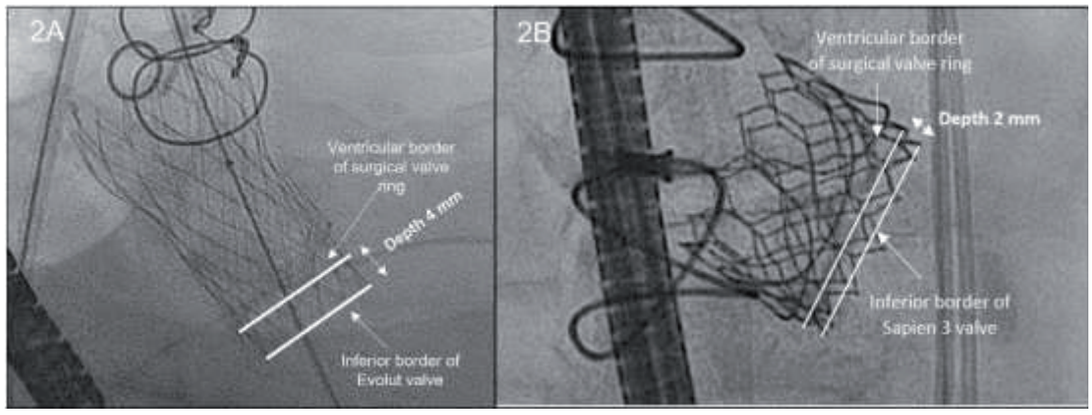

Figure 2.
Optimum depth of implantation below the ventricular border of surgical valve ring is 0–5mm for Evolut valve (2A) and <20% of height of Sapien 3 valve (2B – the height of 26mm Sapien 3 valve used is 20mm).

Procedural complications
Stroke
Myocardial Infarction
Coronary obstruction
Major bleeding
Vascular complications
Conduction abnormalities requiring permanent pacemaker implantation
Device embolization
Annular rupture

Table 4.
Procedural complications that may occur during ViV.

5.3 Procedure-related complications

Procedural complications such as major bleeding and major vascular complications tend to occur at lower rates following ViV when compared with NV-TAVR [37, 38]. Rates of permanent pacemaker implantation have been substantially lower following ViV since THV is placed within framework of failed bioprosthetic valve and thus has limited contact with myocardium and the conduction system. Other mechanical complications such as annular rupture and paravalvular leak are uncommon following ViV in stented bioprosthetic valves. Coronary obstruction is an infrequent but potentially fatal complication following ViV [39]. Its incidence is reported to be 0.7–3.5% post ViV in the literature and is more common after ViV when compared with NV-TAVR. The left main ostium is more frequently involved and incidence is about four times higher following ViV of stentless bioprosthetic valves when compared with stented valves (**Table 4**).

6. Post-procedural considerations After ViV

6.1 Elevated gradients post-procedure

Pre-procedural severe PPM, small size valve, and stented bioprosthesis have been identified as risk factors for elevated gradients post procedure [40]. Furthermore, analysis from Valve-in-Valve international data (VIVID) registry showed that higher post-procedural gradients (MG ≥20 mm of Hg) were seen more frequently after implantation of BE bioprosthesis [Sapien valve (Edwards Lifesciences, Irvine, CA)] compared with SE bioprosthesis [CoreValve (Medtronic, Minneapolis, MN)] (40 vs. 21.3%, $p<0.0001$) [41]. These elevated gradients may impact long-term durability of the valve and mortality. Strategies to minimize elevated gradients post procedurally include careful selection of THV (SE bioprosthesis preferred for small size valves), optimum positioning of the THV, and finally consideration of bioprosthetic valve fracture. This involves the use of noncompliant balloons to fracture the ring in stented bioprosthetic valves allowing a larger size THV to be implanted and thus optimizing hemodynamics (**Figure 1F-G**) [42].

6.2 Antithrombotic regimen

Antithrombotic regimen post ViV should be individualized after weighing thromboembolic and bleeding risks. For patients without recent percutaneous coronary intervention and no concurrent indication for anticoagulation, lifelong single antiplatelet with low-dose aspirin is deemed sufficient [3]. In patients with low bleeding risk, dual antiplatelet therapy with Aspirin and Clopidogrel may be considered for initial 3–6 months followed by lifelong Aspirin therapy. Use of oral anticoagulants should be driven by other indications for anticoagulation therapy such as atrial fibrillation [43].

6.3 Follow-up

Post ViV, transthoracic echocardiogram should be performed prior to hospital discharge, at 6 month and 1 year, and annually thereafter [3]. Thorough examination should include: (i) assessment of valve position, valve thickness, and leaflet mobility; (ii) hemodynamic review of mean gradient, peak velocity, effective orifice area,

regurgitation, and paravalvular leak (if any); and (iii) assessment of nearby cardiac function and nearby structures (mitral valve, aorta etc.) [44].

7. Outcomes

Overall, clinical outcomes following ViV are comparable or even better than redo-SAVR and TAVR in native valves [37, 45]. Furthermore, ViV is associated with a high procedural success rate owing to an improvement in designs of THV and increasing operator experience. A meta-analysis comprising 5294 patients from a total of 22 studies reported a procedural success rate of 97% [46]. Incidence of all-cause mortality at 30 days, 1 year, and 3 years was reported to be 5, 12, and 29%, respectively. One-year survival rate reported in the VIVID registry was 83.2% following ViV [47]. Baseline stenosis of surgical bioprosthetic valve and a small valve size ($\leq$ 21 mm) were associated with an increased risk of mortality. No significant difference in 1-year mortality was observed between use of SE and BE THV [47]. Additionally, type of bioprosthetic valve (stented vs stentless) being replaced had no significant impact on 1-year mortality [38]. An interesting finding was reported in a propensity-matched analysis of the Transcatheter Valve Therapy registry where patients who underwent ViV were found to have lower 30-day mortality, 1-year mortality, and hospitalization for heart failure as compared with matched cohort of patients undergoing NV-TAVR [37].

In the absence of any prospective randomized trial, multiple observational studies have compared clinical outcomes of ViV and redo SAVR. Thandra et al conducted a meta-analysis reporting short-term and mid-term (1–5 years) outcomes from a total of nine studies [45]. ViV was associated with a 35% reduction in 30-day all-cause mortality. No statistically significant difference was reported in mid-term and 1-year mortality. With widespread use of newer generation THV and more patients being considered for ViV, data on long-term clinical outcomes and durability of THV will continue to emerge.

8. Conclusions

Treatment with ViV is safe and effective in carefully selected patients with BVF. Though overall complication rates are lower than NV-TAVR, adverse events such as coronary obstruction and elevated post-procedural gradients may occur. Thus, meticulous pre-procedural planning with CT imaging, selection of optimum type of THV, and adequate positioning of THV within failed bioprosthetic valve are all critical steps to ensure a successful procedure and prevent complications. As the number of patients with surgical and transcatheter bioprosthetic valves increase and inevitably age, the need for ViV is also expected to increase, thus necessitating continuous technological advancements to allow ViV to evolve further. Future research should focus on prevention of coronary obstruction, optimization of THV hemodynamics and design to ensure long-term durability of valves used for ViV.

Conflict of interest

Aravdeep Jhand: None. Vinayak Bapat: Consultant – Edwards Lifesciences, Medtronic, Boston Scientific and Abbott Laboratories. Thomas Porter: Industry grant from Lantheus Medical Imaging, equipment support from Philips Healthcare. Poonam

Velagapudi: Speakers bureau – Abiomed, Opsens; Advisory board – Abiomed, Sanofi; Travel/meals – Abiomed, Boston Scientific, Cheisi, Medtronic, Phillips.

Abbreviations

AS	Aortic stenosis
AR	Aortic regurgitation
BASILICA	Bioprosthetic scallop intentional laceration to prevent coronary artery obstruction (BASILICA)
BE	Balloon expandable
BVF	Bioprosthetic valve failure
CKD	chronic kidney disease
CT	Computed tomography
DVI	Doppler velocity index
EOA	Effective orifice area
FDA	United States Food and Drug Administration
HALT	Hypo-attenuated leaflet thickening
HLD	hyperlipidemia
HTN	hypertension
ID	Internal diameter
MG	Mean gradient
MRI	Magnetic resonance imaging
NV-TAVR	Native valve transcatheter aortic valve replacement
PPM	Patient-prosthesis mismatch
RLM	Reduced leaflet motion.
SAVR	Surgical aortic valve replacement
SE	Self expandable
SVD	Structural valve deterioration
TAVR	Transcatheter aortic valve replacement
THV	Transcatheter heart valve
TTE	Transthoracic echocardiogram
TEE	Transesophageal echocardiogram
VARC 3	Valve Academic Research Consortium 3
ViV	Valve-in-Valve transcatheter aortic valve replacement
VIVID	Valve-in-valve international data
VTC	Virtual THV to coronary ostium distance
US	United States

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