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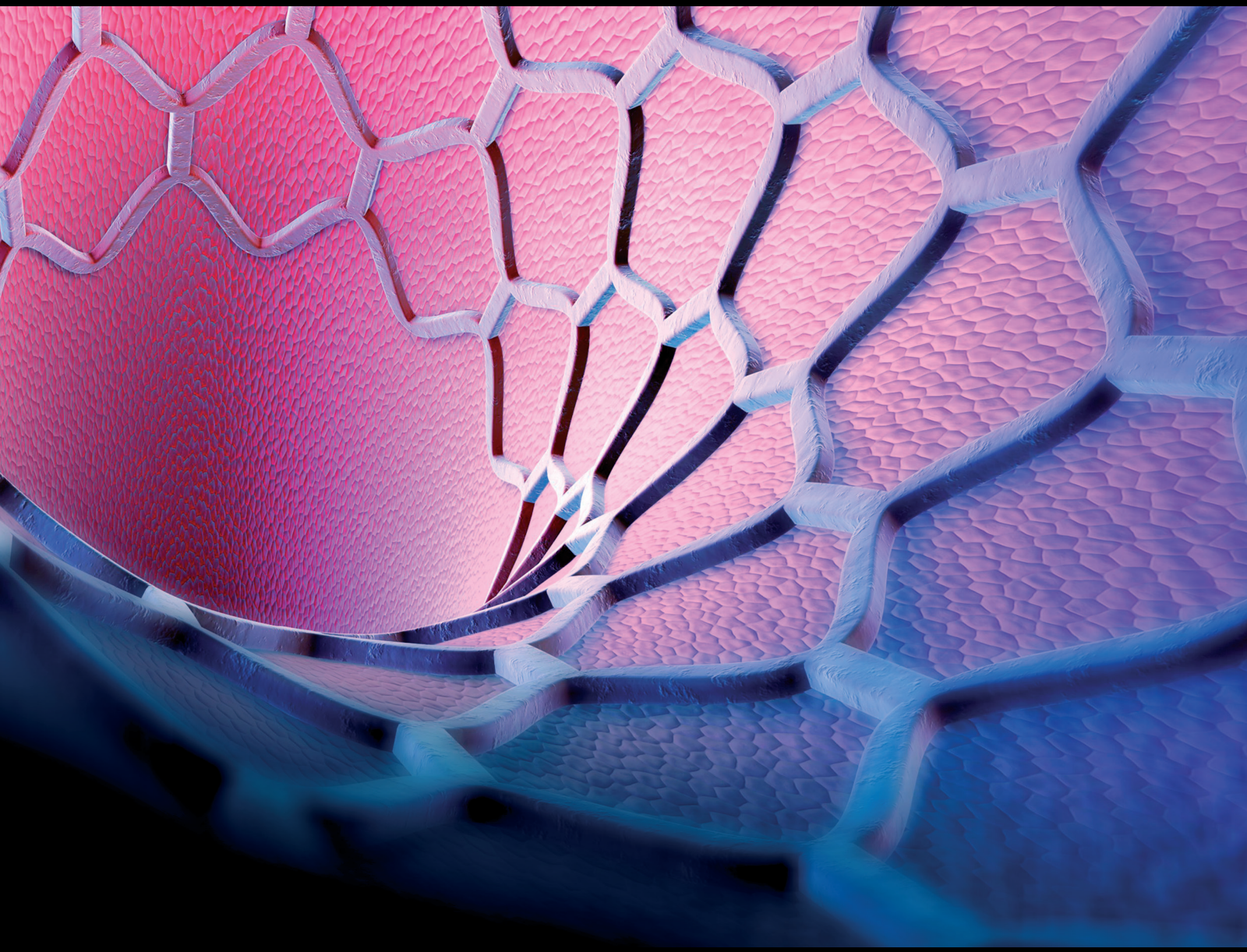

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Review Article

Management of Failed Bioprosthetic Aortic Valves: Mitigating Complications and Optimizing Outcomes

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The use of bioprosthetic prostheses during surgical aortic valve replacements has increased dramatically over the last two decades, accounting for over 85% of surgical implantations. Given limited long-term durability, there has been an increase in aortic valve reoperations and reinterventions. With the advent of new technologies, multiple treatment strategies are available to treat bioprosthetic valve failure, including valve-in-valve (ViV) transcatheter aortic valve replacement (TAVR). However, ViV TAVR has an increased risk of higher gradients and patient prosthesis mismatch (PPM) secondary to placing the new valve within the rigid frame of the prior valve, especially in patients with a small surgical bioprosthesis *in situ*. Bioprosthetic valve fracture allows for placement of a larger transcatheter valve, as well as a fully expanded transcatheter valve, decreasing postoperative gradients and the risk of PPM.

1. Introduction

Treatment of aortic valve pathology has evolved over the past decade with the advent of transcatheter aortic valve replacement (TAVR). In Europe, TAVR first received Conformitè Europèenne (CE) Mark approval in 2007, and the number of patients undergoing TAVR grew exponentially. In the United States (US), clinical trials began in 2007 and TAVR gained Food and Drug Administration (FDA) approval in 2011 for inoperable patients with severe aortic stenosis. Since then, surgical aortic valve replacements (SAVR) have decreased slightly as TAVR approval expanded to patients of all surgical risk profiles in 2019 [1]. However, overall aortic valve replacements, including TAVR and SAVR, have increased [2].

More than 85% of SAVRs are with bioprosthetic valves [3], but one of the major limitations is durability. Bioprosthetic valve dysfunction (BVD) can be categorized as either nonstructural valve deterioration (NSVD)--paravalvular regurgitation, patient-prosthetic mismatch (PPM), malposition, valve embolization, valve thrombosis, or endocarditis, or structural valve deterioration (SVD)--permanent intrinsic changes to the valve [4]. Valve durability is dependent on the valve manufacturer and type of prosthesis. SVD is an irreversible process resulting in hemodynamic and clinical changes similar to native valve aortic stenosis and regurgitation, eventually resulting in the need for reoperation. SVD definitions differ in the literature, leading to varying rates of reported valve failure. In most SAVR series, valve failure has been defined as a need for reintervention, but this is not a true "incidence of failure." Patients can experience significant SVD without undergoing reoperation due to the underdiagnosis of SVD, minimalization of SVD severity, or patients not being considered surgical candidates [5].

The 2021 Valve Academic Research Consortium 3 (VARC-3) guidelines define bioprosthetic valve failure in three stages: (1) any bioprosthetic valve dysfunction with clinically expressive criteria (new-onset or worsening symptoms, left ventricular dilation/hypertrophy/

dysfunction, pulmonary hypertension, or irreversible stage three hemodynamic valve deterioration), (2) aortic valve intervention, and (3) valve-related death [6] (Figure 1). With the increased use of bioprosthetic valves, an increase in reoperations or reinterventions for BVD is predicted. Management strategies continue to evolve and range from traditional redo-sternotomy SAVR, minimally invasive redo-SAVR, and placement of a TAVR valve in a failed SAVR, also known as valve-in-valve (ViV).

2. The Problem

2.1. Risk Factors for Bioprosthetic Valve Failure. Given the increase in bioprosthetic AVR utilization, the identification of predictors of valve failure and the recognition of opportunities to reduce the incidence of SVD are imperative. A variety of factors contribute to valve failure, including patient characteristics and comorbidities, type of implanted valve, and size of implanted valve. In a recent systematic review and meta-analysis, Ochi et al. identified multiple risk factors for BVD including younger age, sex, prosthesis brand, prosthesis size (<19 mm, <21 mm, <23 mm), PPM, absence of anticalcification preparation, concomitant coronary artery bypass graft surgery, subcoronary implantation technique, postoperative pressure gradient, dyslipidemia, smoking, metabolic syndrome, use of lipid lowering medication, elevated body mass index and body surface area, and renal disease. Meta-analysis identified younger age (per 1-year increase in age, HR = 0.91, $p < 0.0001$), increased body surface area (HR = 1.77, $p = 0.03$), smoking (HR = 2.28, $p = 0.0015$), and PPM (HR = 1.95, $p < 0.0001$) as the four significant determinants for SVD [7] (Table 1).

2.2. Patient-Prosthesis Mismatch. Patient-prosthesis mismatch occurs when the effective orifice area (EOA) of the implanted prosthetic valve is too small for the patient's body size [8]. PPM is defined by indexed EOA/body surface area (BSA) and is stratified by severity as follows: none (>0.85 cm^2/m^2), moderate (0.85 to 0.65 cm^2/m^2), and severe (≤0.65 cm^2/m^2). Fallon et al. reported that 65% of patients ≥65 years old with severe aortic stenosis who underwent SAVR had moderate or severe PPM [9]. Those patients with moderate or severe PPM had a significantly increased risk of readmission for heart failure (moderate, HR = 1.15, [95% CI: 1.09, 1.21]; severe, HR = 1.37, [95% CI: 1.26, 1.48]) and redo AVR (moderate, HR = 1.41, [95% CI: 1.13, 1.77]; severe, HR = 2.68, [95% CI; 2.01, 3.56]). Any degree of PPM has been associated with significantly lower survival [9, 10]. Older age, female sex, hypertension, diabetes, renal failure, larger BSA, and larger BMI have been identified as risk factors for PPM [11, 12]. TAVR has been associated with a decreased risk of PPM compared to SAVR, especially in patients with small aortic annuli. Aalaei-Andabili et al. found the incidence of PPM was almost double following SAVR compared to TAVR (54% vs. 29%, $p < 0.001$), especially among patients receiving a valve size ≤23 mm (SAVR, 65% vs. TAVR, 48%, $p = 0.048$) [13]. The average aortic valve size implanted in the US is 22 mm [3], leaving many patients with the risk of PPM, early valve failure, and increased mortality. PPM can be mitigated at the time of initial AVR by implanting an appropriately sized valve.

2.3. Valve Sizing. When selecting a valve, the internal orifice diameter (ID) of the proposed implant should be identified, as the ID differs amongst valve models and manufacturers for the same labeled valve size. The largest valve that can be safely implanted is recommended, but strategies for selecting valve size differ in SAVR vs. TAVR. For SAVR, the valve size is selected by the surgeon at the time of implant based on manufacturer-specific annular valve sizers, while TAVR sizing relies entirely on preoperative computed tomography angiography (CTA). This difference in measurement results in valves with smaller ID being implanted during SAVR [14]. Preoperative CTA analysis defines the aortic annulus and root anatomy, allowing for an appropriately sized implant, SAVR or TAVR, to be selected. If a small aortic prosthesis is predicted, a root enlargement or root replacement can be performed at the time of SAVR. Alternatively, the initial valve that provides the largest EOA and best hemodynamics is often utilized at the time of TAVR. Many structural heart teams will assess every patient with CTA to ensure the most appropriately sized implant is utilized.

Especially in young patients with small annuli, an aortic root enlargement or replacement should be performed when the EOA index is ≤0.65 cm^2/m^2 and may be considered when the EOA index is ≤0.85 cm^2/m^2 [15]. Aortic root enlargement has not been widely adopted and is performed in <10% of SAVRs [3, 16]. Techniques for root enlargement include Nicks [17], Manouguian and Seybold-Epting [18], Konno et al. [19], and the Y-incision [20]. Both the Nicks and Manouguian procedures enlarge the aortic annulus via posterior extension of the aortotomy—the Nicks through the noncoronary sinus and the Manouguian through the left/noncoronary commissure, extending onto the anterior mitral leaflet, then closure with patch augmentation [17, 18]. The annular patch enables the implantation of a valve size 1–2 sizes larger than the native annulus [21]. A Konno, rarely done in adults, is an anterior annular augmentation extending onto the right ventricle [19]. The Y-incision, also a posterior enlargement, undermines the left and noncoronary cusps and enables implantation of a valve 2-3 sizes larger, with reports of up to 5 sizes larger [20, 22, 23]. A posterior aortic root enlargement is not associated with increased risk of mortality or adverse events at expert centers and can facilitate future ViV TAVR but absolutely precludes balloon fracture as the native annulus is unsupported [16, 24].

3. Solutions

Once clinically significant BVD occurs, intervention is indicated. Redo-SAVR may not be appropriate for all patients and a full imaging assessment with CTA and heart team discussion is necessary to determine the best strategy. In Europe, ViV TAVR was first CE Mark approved in 2013 and FDA approved for inoperable and high-risk patients (30-day

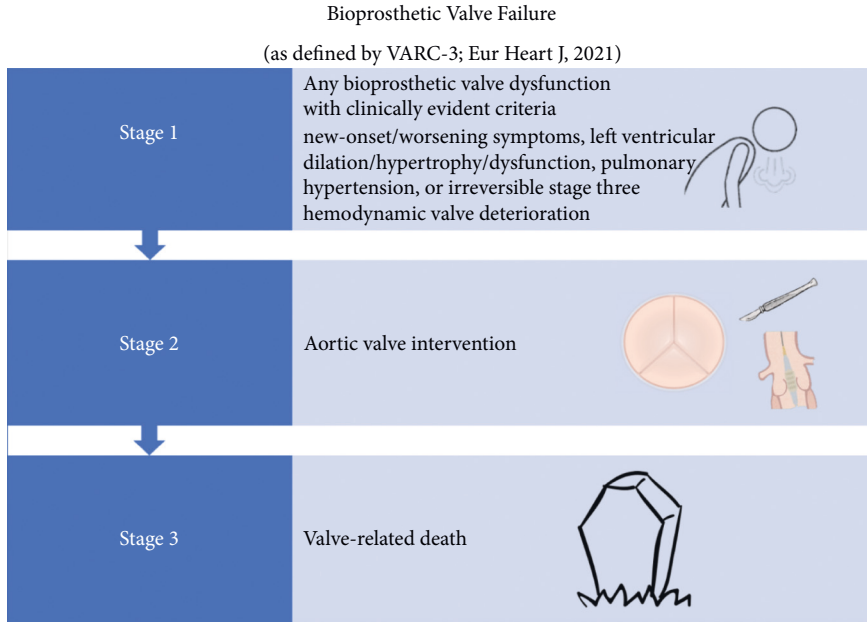


Figure 1: definition of Bioprosthetic Valve Failure. Adapted from VARC-3*. *Varc-3 Writing C, Genereux P, Piazza N, et al. Valve Academic Research Consortium 3: Updated Endpoint definitions for Aortic Valve Clinical Research. J Am Coll Cardiol. 2021; 77 : 2717–2746.

Table 1: Risk /protective factors for SVD.

	Hazard ratio (95% confidence interval)	p value
	Risk factors	
Younger age		
Age per 1 year decrease	1.10 (1.06, 1.12)	<0.0001
Increasing BSA	1.77 (1.04, 3.01)	0.034
PPM	1.95 (1.56, 2.43)	<0.001
Smoking	2.28 (1.37, 3.79)	0.0015
	Protective factor	
Anticalcification preparation	0.41 (0.19, 0.89)	0.025
Older age		
Age >60 years	0.12 (0.06, 0.23]	<0.0001
Age >65 years	0.06 (0.02, 0.21)	<0.0001
Age >70 years	0.06 (0.01, 0.28)	0.0004

BSA = body surface area; PPM = patient prosthesis mismatch. Adapted from Ochi A, Cheng K, Zhao B, Hardikar AA, Negishi K. Patient Risk Factors for Bioprosthetic Aortic Valve Degeneration: A Systematic Review and Meta-Analysis. *Heart Lung Circ.* 2020; 29 : 668–678.

surgical mortality >8% by STS PROM) with the balloon expandable valves [25] and subsequently with self-expandable valves in 2015 [26]. One of the limitations of ViV TAVR is the risk of severe PPM, since the transcatheter valve sits within the surgical valve's true ID. This is especially true in smaller surgical valves and has been associated with higher one-year mortality in the Valve-in-Valve International Data Registry; surgical valves ≤21 mm had significantly higher one-year mortality (25%) compared to valves ≥23 and ≤25 mm (18%), and valves ≥27 mm (7%) ($p = 0.001$) [27]. Surgical prosthesis ≤21 mm (HR = 2.04, [95% CI: 1.14, 3.67], $p = 0.02$) and stenosis as the primary mechanism of failure (vs. regurgitation; HR = 3.07, (95% CI: 1.33, 7.08), $p = 0.008$) were significant risk factors for one-year mortality [27]. To improve the hemodynamic results of ViV TAVR, different techniques can be employed, including implanting the transcatheter valve high within the surgical valve, utilizing a supra-annular transcatheter valve, and bioprosthetic valve fracture (BVF) and bioprosthetic valve remodeling (BVR).

3.1. Bioprosthetic Valve Fracture and Bioprosthetic Valve Remodeling. The bioprosthetic valve fracture was first described by Nielsen-Kudsk et al. in 2015. In small mitroflow bioprostheses, a high-pressure balloon predilatation with an ATLAS Gold balloon fractured the annular stent ring of the SAVR valves and a 20 mm SAPIEN XT was placed in the 19 mm Mitroflow and a SAPIEN 3 23 mm TAVR valve was placed in a 21 mm mitroflow without any complications [28]. The BVF allows for greater expansion of the transcatheter valve and the implantation of a larger, more fully

expanded, transcatheter valve. However, BVF is not an option for all patients. Bioprosthetic valve remodeling (BVR) is similar in concept with the intention of fully expanding the TAVR without fracturing the surgical valve annulus. Although BVR can improve the gradient across the valve and leaflet coaptation of the more fully expanded TAVR leaflets, the annulus diameter is always constrained by the initial surgical valve platform.

3.1.1. Preoperative Assessment. For BVF/BVR, the implanted surgical valve is first identified to determine if it can be fractured or remodeled. Valve fracture is an option for some bioprosthetic valves including Magna, Magna Ease, Perimount 2800, Mitroflow, Mosaic, and Bicor Epic (Table 2) while valve remodeling/stretching is an option for Trifecta, Carpentier-Edwards standard and supraannular, Inspiris, and Perimount 2700 [29] (Table 3). The Medtronic Hancock II and Medtronic Avalus valves cannot be fractured or remodeled [29].

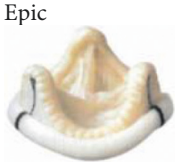
3.1.2. Procedure. The BVF fractures the internal annular ring within the sewing cuff of the surgical valve to allow for maximal expansion of the new valve and results in improved hemodynamics post-ViV TAVR deployment. Following initiation of rapid ventricular pacing, a noncompliant balloon is rapidly filled with dilute contrast and pressurized using an indeflator until fracture occurs [29]. Specific valves fracture at different pressures (Table 2). While fracture can be difficult to confirm, the best indicator is an acute drop in the indeflator pressure near the fracture threshold for the given surgical valve and a vibration or shutter felt through the shaft of the noncompliant balloon [29]. Optimal balloon size should be determined by the ID of the surgical valve, the transcatheter valve used, the anticipated increase in diameter following fracture, the aortic root and left ventricular outflow tract (LVOT) anatomy, and the location of the coronary arteries [29]. A multicenter study by Allen KB et al. found the best hemodynamic result was achieved when BVF was performed after ViV TAVR and with a balloon at least 3 mm larger than the true internal diameter of the surgical valve [30].

3.1.3. Procedural Planning. In a native aortic valve, the ID is measured at the level of the aortic annulus and used to determine the size of the transcatheter valve to be implanted. For ViV TAVR, the size of the *in-situ* valve, particularly the ID, determines the largest transcatheter valve that can be implanted. In both cases, a degree of oversizing is chosen to ensure secure fixation. The ID of the *in-situ* surgical valve can be obtained from the manufacturer; however, the true internal diameter is affected by how the leaflets are secured (internal vs. external); internally mounted leaflets can reduce the true ID by at least 2 mm [31]. The Valve in Valve application (https://apps.apple.com/us/app/valve-in-valve/id655683780) [32] is a useful resource for additional details in selecting the appropriate valve for ViV TAVR. In addition, surgical valve leaflet height should be taken into consideration if implanting a Sapien valve to prevent leaflet overhang.

Cardiac gated multidetector computed tomography (MDCT) is used to determine the inner diameter and area of the failed valve for selection of the appropriate TAVR. Under-sizing can result in paravalvular regurgitation and embolization, but oversizing may result in incomplete expansion, increased gradients, and coronary obstruction [31, 33]. During ViV TAVR, coronary obstruction is more common than in native TAVR due to the supra-annular implantation of most surgical valves. Preoperative CTA is used to predict the risk of coronary occlusion as the SAVR leaflets are pushed toward the coronary ostia during ViV TAVR and create a complete tube of leaflet tissue that can reach the level of the sinotubular junction (STJ). Coronary height, the distance from the coronary ostium to the aortic valve annulus, is one of the important factors to consider when evaluating risk for coronary obstruction [34]. Lower coronary heights are more often seen in patients with *in-situ* surgical valves compared to those with native valves. Therefore, in ViV TAVR planning, the coronary height should be measured from the sewing ring of the basal plane of the prosthesis and not the true native annular plane [35]. On preoperative CTA analysis, crucial factors include identification of the failed leaflets, bioprosthesis angulation in relation to the aortic annulus, coronary ostia height, sinus of Valsalva diameter, STJ height, and SAVR leaflet length. The distance from the surgical valve leaflet to the coronary ostia, the valve to coronary (VTC) distance, predicts the feasibility of ViV TAVR and the risk of coronary obstruction. A VTC of 4 mm or greater is necessary for ViV TAVR (Figure 2). Stentless bioprosthetic valves and stented bioprosthetic valves with externally mounted leaflets have an increased risk of coronary obstruction. Those at highest risk for coronary obstruction are female patients, coronary ostial height <10 mm, sinus of Valsalva (SOV) diameter <30 mm, VTC distance <4 mm, and previous aortic bioprostheses, particularly those with stented valves with externally mounted leaflets or stentless surgical valves (OR 7.67, [95% CI: 3.14, 18.7], $p < 0.0001$) [36]. When BVF is performed, the gain in annular dimension is 3-4 mm; therefore, the VTC distance should be at least 5 mm in order to accommodate valve expansion [37]. Additionally, when evaluating for BVF, the SOV diameter and STJ height must be measured to ensure the sinus is large enough to accommodate the increased valve size without root rupture or sinus sequestration and the STJ height is adequate to accommodate full leaflet excursion without the leaflet reaching the level of the STJ (minimum valve to STJ distance of 2 mm is suggested) [38].

BVF results in an increase in the ID of the surgical valve of 3-4 mm and the selection of transcatheter valve size should be based on this anticipated increased ID. BVF can be performed before or after ViV TAVR. When performed before ViV TAVR, it effectively fractures the surgical valve but does not ensure adequate expansion of the subsequent TAVR. If BVF is performed after ViV TAVR, it fractures the

Table 2: Surgical prosthesis amenable to valve fracture.

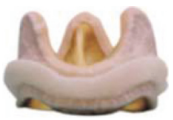
	Make	Stented/Stentless	Leaflets	Fracture threshold (atm)	Valve sizes	ID (mm)	Profile height (mm)
CE magna 	Edwards lifesciences	Stented	Internal	22–24	19	18.0	14.0
					21	20.0	15.0
					23	22.0	16.0
					25	24.0	17.0
					27	26.0	18.0
					29	28.0	19.0
CE magna ease 	Edwards lifesciences	Stented	Internal	18	19	18.0	13.0
					21	20.0	14.0
					23	22.0	15.0
					25	24.0	16.0
					27	26.0	17.0
					29	28.0	18.0
Perimount 2800/2900 	Edwards lifesciences	Stented	Internal	20	19	18.0	14.0
					21	20.0	15.0
					23	22.0	16.0
					25	24.0	17.0
					27	26.0	18.0
					29	28.0	19.0
Mitroflow 	Sorin group	Stented	External	12	19	15.4	11.0
					21	17.3	13.0
					23	19.0	14.0
					25	21.0	15.0
					27	22.9	16.0
Mosaic 	Medtronic	Stented	Internal	10*	19	17.5	13.5
					21	18.5	15.0
					23	20.5	16.0
					25	22.5	17.5
					27	24.0	18.5
					29	26.0	20.0
Epic 	Abbott	Stented	Internal	8	19	18.7	14.0
					21	20.8	15.0
					23	22.6	16.0
					25	24.5	17.0
					27	26.3	19.0

*The Mosaic valve has been manufactured with two different materials and behaves differently during BVF depending on the material used to manufacture the frame. If the frame is made of Derlin, fracture occurs ~10–12 atm. If comprised of the high-performance thermoplastic polyetheretherketone (PEEK) (a small amount in the Mosaic valve) it cannot be fractured but can me remodeled; continue to increase the inflation device pressure beyond 12 atm and at about 18 atm, the valve frame will begin to stretch. Inflate to ~22 atm to achieve maximal expansion. Allen KB, Chhatriwalla AK, Saxon JT, et al. Bioprosthetic valve fracture: Technical insights from a multicenter study. *J Thorac Cardiovasc Surg.* 2019; 158 (5):1317–1328 e1311.

surgical valve and fully expands the transcatheter valve. BVF has been shown as a beneficial strategy to prevent PPM, in particular for small surgical prostheses. Despite patients with larger surgical valves having a lower risk of PPM and high gradients, BVF can still be utilized to promote full transcatheter valve expansion. However, BVF remains understudied in patients with larger surgical valve sizes [39]. BVF results in reduced transvalvular gradients and increased EOA; for optimal results, it is suggested that BVF be performed after ViV TAVR and with a non-compliant balloon at least 3 mm larger than the true ID of the surgical valve being fractured [30] but with a balloon no larger than the waste of the self-expanding valve to avoid damage to the valve leaflets.

3.1.4. Adjunctive Techniques. During SAVR, commissure-to-commissure alignment is maintained, while in TAVR the orientation of the commissures is often random and not consistently achievable. Tang et al. found that the Evolut "hat"

Table 3: Surgical prosthesis amenable to valve remodeling.

	Make	Stented/Stentless	Leaflets	Valve sizes	ID (mm)	Profile height (mm)
Trifecta 	Abbott	Stented	External	19	17	15
				21	19	16
				23	21	17
				25	23	18
				27	25	19
CE standard porcine 	Edwards lifesciences	Stented	Internal	19	17	15
				21	19	16
				23	21	16
				25	23	18
				27	25	18
				29	27	19
				31	29	19
CE supra-annular 	Edwards lifesciences	Stented	Internal	21	19	15
				23	21	16
				25	23	17
				27	25	17
Inspiris resilia  0	Edwards lifesciences	Stented	Internal	19	18	13
				21	20	14
				23	22	15
				25	24	16
				27	26	17
				29	28	19
Perimount 2700  1	Edwards lifesciences	Stented	Internal	19	18	13
				21	20	14
				23	22	15
				25	24	16
				27	26	17
				29	28	18

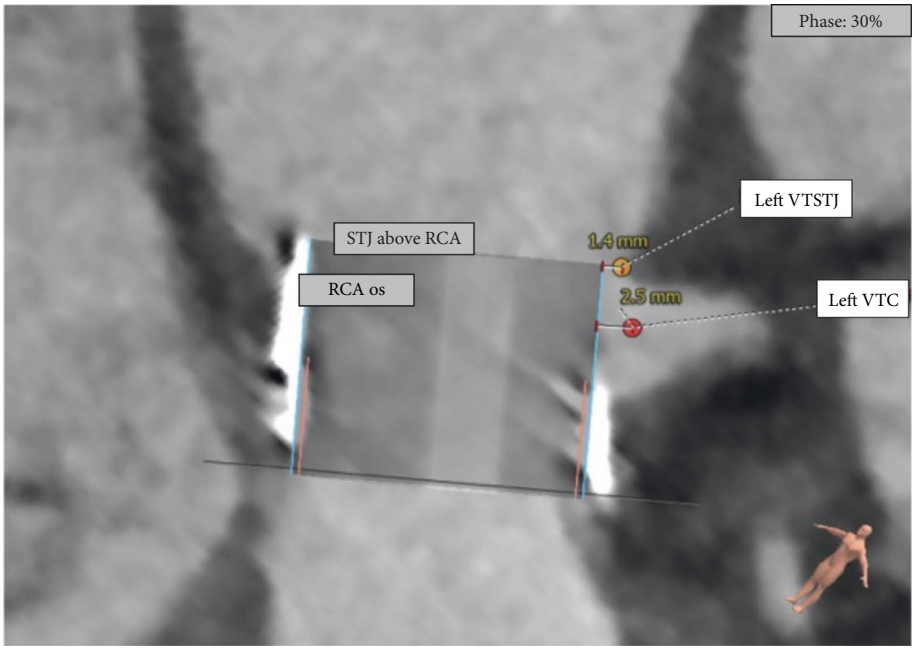


Figure 2: Procedural preplanning with 3D Reconstruction and virtual valve in a failed 21 mm Magna surgical valve. With the smallest sized balloon expandable valve, 20 mm, the valve to coronary (VTC) distance to the left main coronary ostium (2.5 mm) and valve to sinotubluar junction(VTSTJ) (1.4 mm) are not adequate.

marker and the ACURATE-neo commissural post facilitated improved commissural alignment and reduced coronary artery overlap [40]. The crimping of the Sapien 3 valve had no impact on commissural alignment predictability in the study. Commissural alignment facilitates coronary access and future options for transcatheter management if the ViV TAVR fails. This is an area of active investigation as younger and lower-risk patients, with a long life expectancy, receive ViV TAVR.

Bioprosthetic or native Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery Obstruction (BASILICA) is an electrosurgical leaflet modification technique which is effective in preventing coronary obstruction in native and bioprosthetic valves. In patients at high risk of coronary obstruction due to a VTC distance <4 mm, or at risk of sinus sequestration due to a narrow SOV, short STJ height, and/or long bioprosthetic valve leaflets, using an electrified wire, the nadir of the bioprosthetic leaflet is crossed and leaflet lacerated to create a *V* shaped opening (leaflet splay) to increase blood flow and access to the coronary artery at risk. In a series of 30 patients in the initial BASILICA feasibility study, freedom from coronary obstruction was 95% and no patient required reintervention [41]. Patients in whom BASILICA is predicted to result in inadequate "splay" (particularly problematic for failed TAVR valves and the feasibility of TAVR-in-TAVR), balloon-assisted BASILICA can be utilized to expand the traversal point outward by balloon inflation prior to laceration [42].

3.2. Surgical Techniques. In addition to ViV TAVR, redo-SAVR is another option. Although redo-SAVR has traditionally been considered a higher-risk operation compared to primary AVR, the mortality of redo SAVR is 1–5% with appropriate patient selection [43, 44]. Comparing ViV TAVR and redo-SAVR in a single center series, those undergoing ViV TAVR were older and had more comorbidities including peripheral arterial disease, congestive heart failure with NYHA class III or IV symptoms, hypertension, prior myocardial infarction (MI), and history of atrial fibrillation; however, postoperative outcomes were similar. The ViV-TAVR group had shorter lengths of stay while the redo-SAVR group had improved hemodynamics [44]. In a meta-analysis comparing ViV TAVR and redo-SAVR with degenerated bioprosthetic valves, all cause 30-day mortality was higher in the redo-SAVR group and there was no significant difference in stroke, MI, or permanent pacemaker at mid-term follow-up of up to 5 years. However, ViV TAVR was associated with a higher risk of PPM and greater transvalvular pressure gradients postimplantation [45]. Both ViV TAVR and redo-SAVR are viable options and patient selection is key to success; higher-risk patients and patients with larger valves benefit more from ViV TAVR while younger patients and patients with smaller valves benefit more from redo-SAVR.

4. Conclusion

Due to the increase in bioprosthetic valve utilization for the treatment of aortic valve disease and patients with longer life expectancy, bioprosthetic valve failure is becoming a significant problem requiring innovative treatment strategies. Redo-SAVR has traditionally been the only treatment modality for failed biologic valves, but many elderly patients are not candidates for a second operation or do not wish to undergo a redo-sternotomy. Valve fracture provides one strategy to achieve optimal hemodynamics by increasing the size of the annulus for ViV TAVR. BVF is especially useful in patients with small surgical valves to decrease the risk of PPM by removing the constraints of placing a transcatheter valve within a rigid surgical bioprostheses and when performed after ViV-TAVR facilitates expansion of the transcatheter valve. Although in the US ViV TAVR is reserved for high-risk patients, risk drift is expected with this technology. Not only do we need to provide a solution to the initial failed surgical valve, but planning for a third valve when the VIV TAVR fails must be considered in the lifetime management of aortic valve disease. It may be that all patients, not just those with small annuli, benefit long-term from valve fracture and additional study is needed.

Abbreviations

AVR: Aortic valve replacement
BASILICA: Bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction
BSA: Body surface area
BVD: Bioprosthetic valve dysfunction
BVF: Bioprosthetic valve fracture
BVR: Bioprosthetic valve remodeling
CE: Conformitè europèenne
CTA: Computed tomography angiography
EOA: Effective orifice area
FDA: Food and drug administration
HR: Hazard ratio
ID: Internal diameter
LVOT: Left ventricular outflow tract
MDCT: Multidetector computed tomography
MI: Myocardial infarction
NSVD: Nonstructural valve deterioration
NYHA: New York heart association
PPM: Patient-prosthesis mismatch
SAVR: Surgical aortic valve replacement
SVD: structural valve deterioration
TAVR: Transcatheter aortic valve replacement
US: United states
VARC-3: Valve academic research consortium 3
ViV: Valve-in-valve.

Data Availability

This is a review article; data can be found on Pubmed as per the list of references.

Conflicts of Interest

The authors declare that there are no conflicts of interest. AG is a proctor for Edwards Lifesciences and Abbott Vascular;

KG is a consultant for or receives an honorarium from Medtronic, Edwards, Boston Scientific, Abbott, Gore, Ancora, HLT Inc, OpSens Medical, and 4C Medical.

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Review Article

Balloon Fracturing Valve-in-Valve: How to Do It and a Case Report of TAVR in a Rapid Deployment Prosthesis

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Transcatheter aortic valve replacement (TAVR) to treat degeneration of bioprosthetic heart valves (BHVs), called as valve-in-valve (ViV), is becoming a key feature since the number of BHVs requiring intervention is increasing and many patients are at high risk for a redo cardiac surgery. However, a TAVR inside a small previous cardiac valve may lead to prosthesis-patient mismatch (PPM) and not be as effective as we hoped for. An effective option to decrease the chance of PPM is to fracture the previous heart valve implanted using a high-pressure balloon. By performing a valve fracture, the inner valve ring of small BHVs can be opened up by a single fracture line, allowing subsequent implantation of a properly sized transcatheter heart valve, without increasing substantially the procedure risk. In this article, we provide a step-by-step procedure on how to safely and properly fracture a BHV and report a case of a TAVR in a degenerated rapid deployment valve.

1. Introduction

Degeneration of bioprosthetic heart valves (BHVs) requiring a new implant is a featured topic since the use of BHVs is becoming increasingly frequent, overcoming the number of mechanical ones [1–3]. Considering that many patients with degenerated BHVs are at high risk for redo open cardiac surgery, the need for a less-invasive intervention has become a reality and the valve-in-valve (ViV) transcatheter aortic valve replacement (TAVR) has emerged as an effective alternative to redo aortic valve replacement. However, the presence of a smaller-sized surgical BHV may preclude a successful ViV procedure, unless combined approaches, such as balloon valve fracture (BVF), are performed. How to perform a BVF, which are the recommended balloon sizes and balloon pressures required to fracture the frame, and when is the best moment to perform it, if before or after ViV TAVR, are some of the current questions related to this issue. This article aims to provide an updated review of BVF and report an unusual case of TAVR in a previous degenerated rapid deployment prosthesis using the balloon cracking technique.

2. Structural Valve Deterioration

The concept of structural valve deterioration (SVD) resulting in severe BHV failure was well defined in the recent published VARC-3 consensus. According to this document, severe hemodynamic valve deterioration means an "increase in mean transvalvular gradient ≥20 mmHg resulting in mean

gradient ≥30 mmHg with concomitant decrease in effective orifice area (EOA) ≥0.6 cm^2 or ≥50% and/or decrease in Doppler velocity index ≥0.2 or ≥40% compared with echocardiographic assessment performed 1–3 months post-procedure, or an increase, or new occurrence, of ≥2 grades, of intraprosthetic aortic regurgitation causing in severe aortic regurgitation" [4].

The options to manage severe SVD are optimized medical therapy (for patients with a low life expectancy for whom any intervention is deemed futile), redo open cardiac surgery, or a transcatheter intervention (ViV TAVR). In the case of the latter, one of the first requirements is to evaluate if the BHV effective orifice has enough size to accommodate a new bioprosthesis implant, or if it is too narrow, which could cause prosthesis-patient mismatch (PPM) [5]. Concerns about final effective orifice area are especially relevant since previous studies have demonstrated that ViV TAVR in patients with small surgical bioprostheses or with pre-existing PPM can result in high residual transvalvular gradients and, consequently, poor clinical outcomes and reduced 1-year survival [6–9]. According to Pibarot et al., PPM occurs when the indexed EOA is <0.85 cm^2/m^2 and can be classified as moderate (indexed EOA 0.66–0.85 cm2/m2) or severe (indexed EOA <0.65 cm^2/m^2) [10].

Aiming to avoid PPM following ViV TAVR, several strategies have been developed. One possible alternative is to use a transcatheter heart valve (THV) with supra-annular leaflets (e.g., CoreValve Evolut; Medtronic, Minneapolis, MN, USA), which may result in a larger EOA. Another is to deploy the THV in a higher implant depth to improve inflow dynamics and increase the EOA. Additionally, in the presence of a smaller-sized BHV, an effective option is to fracture the previous BHV frame by using a high-pressure balloon [5].

3. Preprocedural Planning

Planning a ViV TAVR involves 3 important steps [11]:

(1) Careful preprocedural examination of the existing BHV

(2) Choice of the new transcatheter heart valve (THV) size and type to be used

(3) Assessment if balloon valve fracture is indicated and how to do it

In this line, the size of the degenerate BHV, its model, and true inner diameter (ID) should be checked by analyzing the previous surgical description and the preoperative computed tomography (CT) and confirmed by the intra-procedural fluoroscopic images. With this information, THV selection for ViV TAVR is guided by the true ID of the BHV rather than the labeled surgical valve size. The true ID can be obtained from the manufacturer or from the "ViV Aortic" phone application developed by UBQO Ltd. and Dr. Vinayak Bapat (Figure 1). It is known that for all porcine valves, the true ID is 2 mm smaller than the listed size (i.e., the stented ID), while for pericardial valves, the true ID is 1 mm smaller than the stented ID if the leaflets are mounted inside the stent and equal to the stented ID if the leaflets are mounted outside the stent [12].

4. Balloon Valve Fracture

BVF is a technique that utilizes high-pressure and non-compliant balloon inflation to fracture a previously implanted surgical valve sewing ring, thus allowing further expansion of the BHV and increasing the maximum EOA (Figure 2) [13]. Therefore, by performing a valve fracture, the inner valve ring of a small BHV could be opened up by a single fracture line enabling a subsequent properly sized THV implantation [14].

In 2017, Allen et al., in a bench testing study, demonstrated that the frame of most, but not all, BHVs can be fractured using high-pressure balloons. According to their tests, Mitroflow, Magna, Magna Ease, Mosaic, and Biocor Epic surgical valves could be successfully fractured using a high-pressure balloon 1 mm larger than the labeled valve size, whereas Trifecta and Hancock II could not be fractured [15]. In this same line, Chhatriwalla and Sorajja showed that some BHVs can be fractured (Biocor Epic, Magna Ease, Mosaic, Mitroflow, Perimount newer generation), others can be significantly remodeled (Inspiris, Carpentier-Edwards Standard, Carpentier-Edwards supra-annular, Perimount old generation, Trifecta), but some prostheses cannot be fractured or remodeled (Avalus and Hancock II) [16].

5. Balloon Type, Size, and Pressure

The most frequently used balloons are the noncompliant True Dilatation and Atlas Gold (Bard Peripheral Vascular, Inc., Tempe, AZ, USA).

Traditionally, the balloon is sized 1 mm larger than the true ID; however, as published by Allen et al., successful BVF has been consistently achieved using balloons 1 mm larger than the labeled valve size, which, for most surgical valves, equates to a balloon 3–4 mm larger than the true ID (i.e., a 21 mm valve is fractured with a 22 mm balloon) [13]. These same authors described that balloon pressure required to fracture a stent frame varies from 8 to 24 atmospheres (atm) depending on the type of BHV (Table 1) [15].

Similarly, Johansen et al. have studied an in vitro model, which BHV can be fractured by a high-pressure balloon and what is the pressure required to induce the fracture. The authors observed that valves with a polymer frame were fractured at lower pressures (8–10 atm) than those with a metal stent (19–26 atm). Fracture pressures for the Mosaic valves (19 mm and 21 mm) and the Mitroflow 21 mm valve were in a similar range (8–10 atm). On the other hand, it was not possible to fracture the Trifecta 19 mm, even though the metal frame experienced notable. The Trifecta 21 mm did fracture but at a high pressure of 26 atm. The Magna Ease 19 mm and 21 mm valves, both having metal frames, were considered fracturable [5].

More recently, Allen et al. caught the attention to the fact that it is crucial to have an understanding of THV anatomy, particularly when performing BVF after implanting a self-

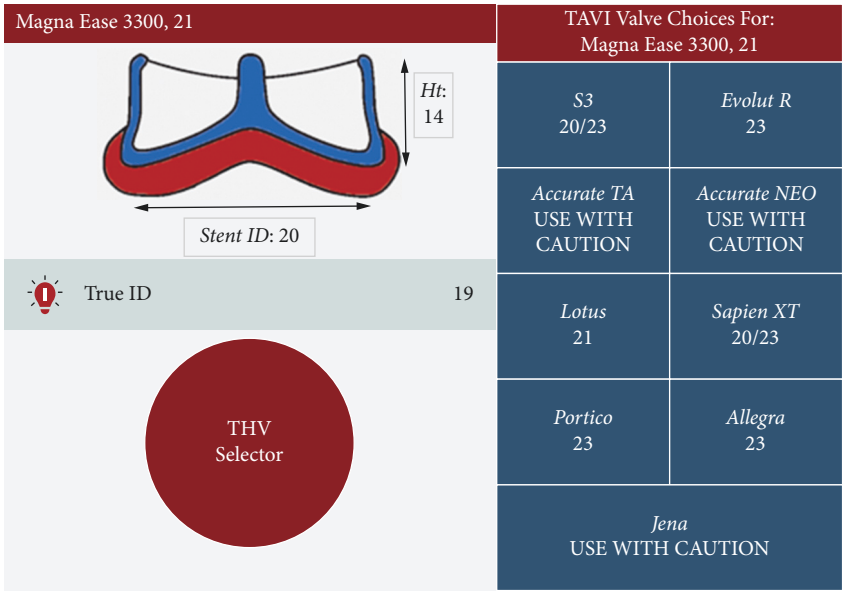


Figure 1: Example of some information obtained in the ViV Aortic App. In this simulation, the true ID for a Magna Ease 21 mm bioprosthesis is 19 mm, and a TAVR using an Evolut R 23 mm self-expanding or a Sapien 3 20/23 mm balloon-expandable would be recommended.

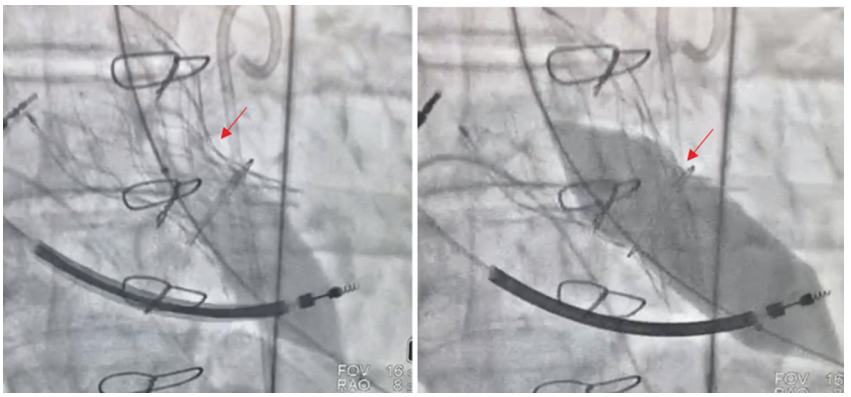


Figure 2: Example of a balloon valve frame fracture using a noncompliant balloon and high-pressure inflation. Observe the prosthesis waist before (first image) and after (second image) the balloon inflation.

expanding THV. Since the Medtronic self-expanding valve has a narrowed area where the commissures are attached to the nitinol frame, known as the "constrained area," when using a high-pressure balloon larger than the diameter of the constrained area, operators should be careful to avoid THV trauma, which could lead to severe insufficiency. Thus, according to these authors, when doing BVF with CoreValve/Evolut, a balloon that is no larger than 2 mm of the constrained area is recommended (the waist is 20, 22, 23, and 24 mm, respectively, for CoreValve Evolut Pro/R 23, 26, 29, and 34 mm THV). Furthermore, ideally, the proximal shoulder of the balloon should be placed distal to the CoreValve (Figure 3). Exemplifying, the 21 mm Magna valve should be fractured with 22 mm balloon if a 23 mm CoreValve is used [15]. On the other hand, when using a balloon-expandable valve, the goal is to size the balloon considering the perfect THV expansion; therefore, a 23 mm Sapien valve should be fractured using a 23 mm balloon [17]. Left ventricular outflow tract, coronary sinuses, and sinotubular junction sizes and calcification should also be carefully assessed when evaluating BVF suitability.

As commented above, initial *in vitro* testing has demonstrated that BVF results in an increase of 3–4 mm in the ID of surgical valves with labeled valve sizes of 19 and 21 mm, respectively. Moreover, according to a recent publication from Allen et al., additional bench testing has shown that an expansion of 5 mm can be achieved in larger labeled valve sizes (23 and 25 mm), and clinical experience suggests that even a 6 mm increase in diameter can be obtained following BVF in larger (≥27 mm) surgical valves [17].

Table 1: Balloon fracture pressures according to Allen et al., 2017 [15]. In this study, the balloon was sized 1 mm larger than the valve size. atm, atmospheres.

Valve type	TRUE balloon Fracture pressure	Atlas Gold balloon Fracture pressure
St. Jude Trifecta		
19 mm	No	No
21 mm	No	No
St. Jude Biocor Epic		
21 mm	8 atm	8 atm
Medtronic Mosaic		
19 mm	10 atm	10 atm
21 mm	10 atm	10 atm
Medtronic Hancock II		
21 mm	No	No
Sorin Mitroflow		
19 mm	12 atm	12 atm
21 mm	12 atm	12 atm
Edwards Magna		
19 mm	24 atm	24 atm
21 mm	24 atm	24 atm
Edwards Magna Ease		
19 mm	18 atm	18 atm
21 mm	18 atm	18 atm

6. Inflation Technique

The setup for high-pressure balloon inflation includes the following:

(a) Noncompliant balloon

(b) 60 mL Luer-Lok syringe filled with dilute contrast

(c) Inflation device

(d) High-pressure stopcock

The technique consists of placing the noncompliant balloon within the surgical prosthesis, and then, during rapid ventricular pacing, the balloon is inflated by hand using the 60 mL syringe with diluted contrast. The stopcock is opened to the inflation device, and the balloon pressure is increased to the fracture threshold. BVF is noted by a sudden drop in the inflation pressure on the inflation device gauge and a visible release of the balloon waist, which is frequently accompanied by an audible "click," visual and haptic feedback. Successful BVF is noted fluoroscopically as a release of the balloon waist, but this is not always obvious. The valve is then echocardiographically assessed, and repeat hemodynamic measurements are obtained to ensure optimal expansion and satisfactory drop in transvalvular gradients. If the mean gradient is still elevated and the valve was not fractured, the maneuver can be carefully repeated. If gradients remain elevated after successful BVF, postdilation may be performed by inflation of a slightly larger balloon [19].

Taking into consideration that prolonged rapid pacing is required during BVF, it may be advisable to perform the procedure under general anesthesia. In addition, general anesthesia provides a more controlled environment during the procedure and eventful complications management. Transesophageal echocardiography guidance has been also recommended since it can be used to evaluate adequate THV expansion and leaflet excursion and detect potential complications early [20].

7. Time to Perform Balloon Fracture

BVF can be performed before or after THV deployment. The choice involves a balance between the potential risk of inducing a catastrophic valve insufficiency versus the unknown influence of high-pressure balloon inflation on the THV leaflets' structural integrity and, consequently, its long-term durability. Besides, BVF before may be effective to fracture the surgical valve but not to ensure adequate THV expansion. This is particularly true with balloon-expandable valves, whose compliant delivery balloon does not generate sufficient pressure to fully expand the THV in a fractured surgical valve [15]. In this same line, in vivo tests showed that degenerated surgical valves may impede even self-expanding THVs from fully expanding when using the BVF-first strategy. Therefore, to maximize the increase in diameter achieved with BVF, the THV itself needs to be dilated with high-pressure balloon inflation (as occurs with BVF after TAVR) [13]. A crucial point when performing BVF before is to assure that the THV is ready for prompt use if acute regurgitation occurs.

In 2019, Allen et al. evaluated the results of 75 patients who underwent BVF at 21 centers. BVF was performed successfully in 100% of them, with an in-hospital and/or 30-day mortality of 2.7% (2 out of 75) and no case of annular/aortic root rupture, coronary occlusion, or new pacemaker implant. The final mean transvalvular gradient was 9.2 ± 6.3 mmHg and was significantly lower when BVF was performed after compared with BFV before TAVR (8.1 ± 4.8 mmHg vs 16.9 ± 10.1 mmHg; $p < 0.001$). In a hierarchical multiple linear regression analysis, performing BVF after ViV TAVR ($p < 0.001$) and performing BVF with a balloon that was at least 3 mm larger than the true ID of the surgical valve ($p = 0.038$) were the only procedural factors associated with a lower final mean gradient. Therefore, the authors concluded that BVF performed after ViV TAVR and using larger balloons contributed to achieving the best hemodynamic results [13]. Following this study, many centers have adopted the technique of performing BVF after ViV TAVR.

8. THV Selection

Selection of THV size is not always straightforward when BVF is performed because the size of the THV should be based on the anticipated increase in the true ID of the surgical valve. The question remains whether to use a THV that can be optimally expanded after BVF or to upsize to a larger THV, anticipating achieving a larger EOA and superior hemodynamic results. Bench testing has suggested that a larger prosthesis, even if expanded to a less than nominal diameter, may result in a more favorable transvalvular gradient. On the other hand, Allen et al. have shown that upsizing the THV did not result in a difference in the final mean gradient or EOA after BVF. These findings

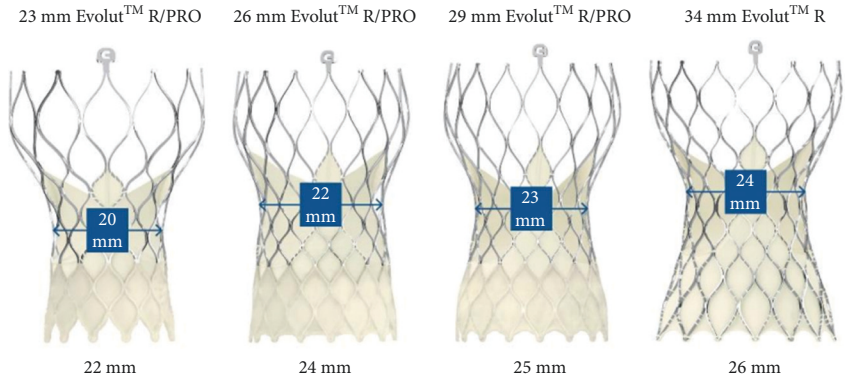


Figure 3: Maximum recommended balloon size for self-expanding CoreValve/Evolut valves (adapted from Chhatriwalla [18]).

suggest that if there is any hemodynamic downside to using intra-annular THVs during ViV TAVR, it may be overcome by performing BVF and optimally expanding the THV [13].

Another uncertainty point is the decision between self-expanding or balloon-expandable THV, with some data suggesting that self-expanding THVs could result in superior procedural hemodynamics and increased EOA compared with the balloon-expandable one [21, 22].

9. Indications

The indications to perform the BVF technique are not fully defined. The majority of patients, in particular those with large surgical valves, are likely to achieve adequate hemodynamic results after a standard ViV TAVR, and patients without PPM have an excellent 1-year survival. Therefore, patients who stand to benefit the most from BVF are those who are predisposed to PPM and high residual transvalvular gradients, including those with small BHVs (labeled valve size ≤21 mm) and/or stenosis as the BHV failure mechanism. Whether patients with large BHVs (>21 mm labeled valve size) or intermediate transvalvular gradients (10–20 mmHg) stand to benefit from BVF is still not known [20]. Besides this classical BVF indication (increase final valve diameter and decrease residual transvalvular gradient), the procedure has been also considered to optimize THV expansion, manage perivalvular leak (PVL), prevent the constrained THV from pinwheeling, and potentially improve THV durability.

10. Concerns

It is important to acknowledge that the clinical experience with BVF is still early [20] and there are some theoretical risks associated with BVF such as acute severe aortic regurgitation causing hemodynamic collapse, THV migration, coronary obstruction, aortic root injury, and THV failure due to balloon injury to the leaflets [23].

Saxon et al. highlighted that with BVF the architecture of the BHV is altered such that the final position of the BHV leaflets is less certain. These authors also commented that the additional space in the coronary sinuses necessary to accommodate BVF is not fully understood. Extrapolating from the recommended safety margins of ViV TAVR, it is reasonable to estimate that a BHV to coronary distance of less than 5 mm could be considered to place a patient at high risk for coronary occlusion when BVF is performed [20].

Furthermore, it should be highlighted that BVF does not completely extinguish the risk of PPM. While BVF has been shown to enlarge the neoannulus by approximately 3 mm, "shoehorning" a larger THV into the annulus may even distort the valve [13].

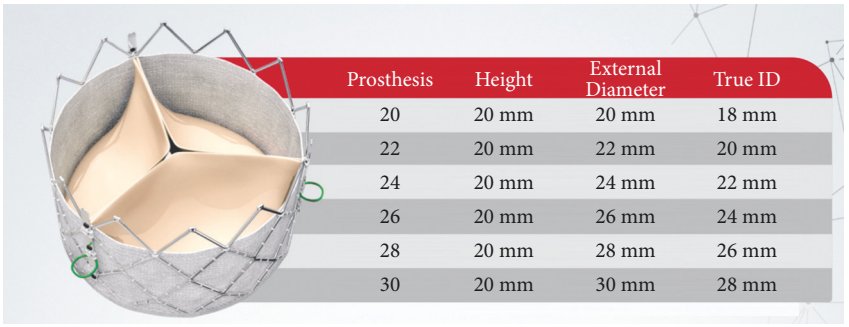
11. Case Report—TAVR in a Rapid Deployment Valve

Although TAVR is a well-established treatment option for severe symptomatic native aortic valve stenosis, BHV failure [24], and even for TAVR failure [25], there is almost no data supporting TAVR in degenerated rapid deployment valves. Here, we describe a case of rapid deployment valve failure that was treated with TAVR and balloon cracking.

A 79-year-old female patient with 85 kg (body surface are = 2 cm^2) had a rapid deployment aortic valve (Inovare® Alpha 22 mm; Braile Biomédica, Brazil) implanted 7 years ago (Figure 4). Three years after the first surgery, she was submitted to a percutaneous balloon dilatation aiming to treat a moderate aortic regurgitation (AR) due to PVL. The mean aortic valve gradient at the index procedure was around 20 mmHg.

Currently, she presented with heart failure due to nonstructural and structural valve degeneration (severe PVL, severe central aortic regurgitation, and severe stenosis with a mean gradient of 46 mmHg). Angio CT showed a true ID of 18 mm and thickened leaflets. Left coronary artery height was 8 mm, and the VTC was 5 mm. Femoral accesses are judged adequate.

The patient was considered at high surgical risk for a redo surgery, and thus a TAVR was indicated. The procedure was performed throughout percutaneous transfemoral access, and an Evolut R 23 mm THV (Medtronic, USA) was deployed using the balloon cracking technique to optimize the THV expansion and reduce final gradients (Figures 5–7).



Prosthesis	Height	External Diameter	True ID
20	20 mm	20 mm	18 mm
22	20 mm	22 mm	20 mm
24	20 mm	24 mm	22 mm
26	20 mm	26 mm	24 mm
28	20 mm	28 mm	26 mm
30	20 mm	30 mm	28 mm

Figure 4: Chart of Inovare® Alpha sizes.

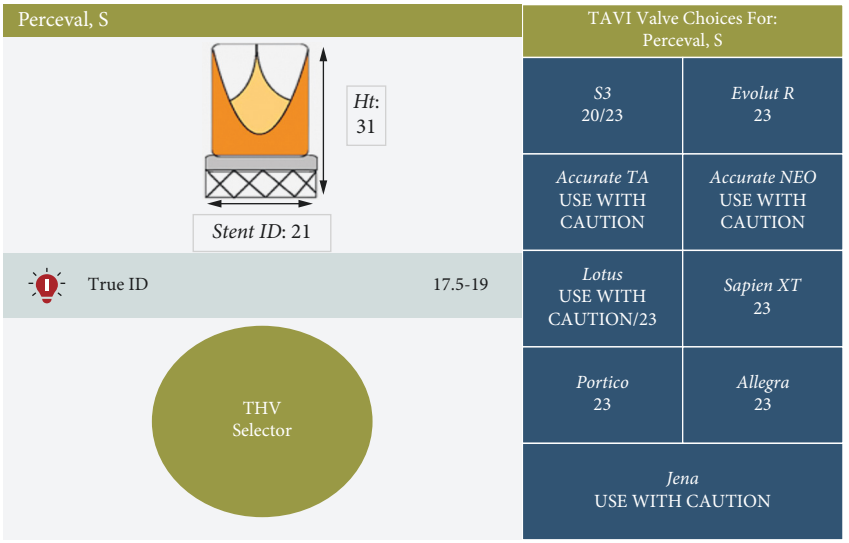


Figure 5: As Inovare® Alpha is not present in the ViV App, we looked at the Perceval valve, which has a similar true ID. In a true ID of 17.5–19 mm, an Evolut R 23 mm is suggested.

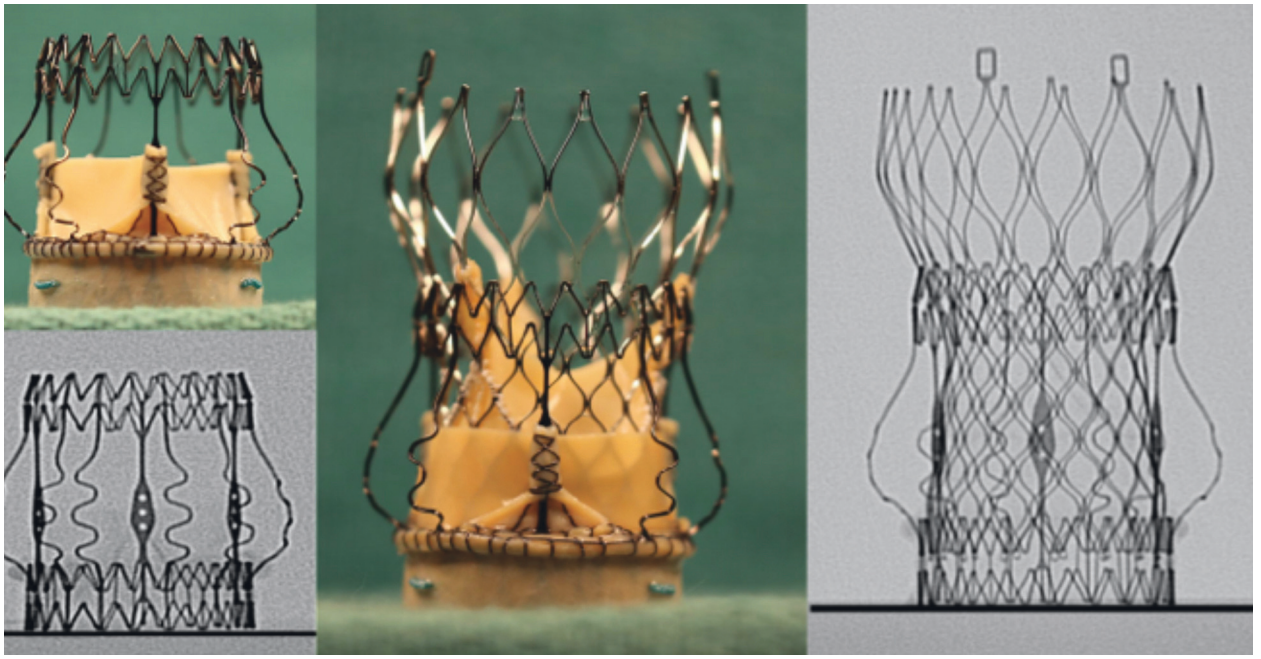
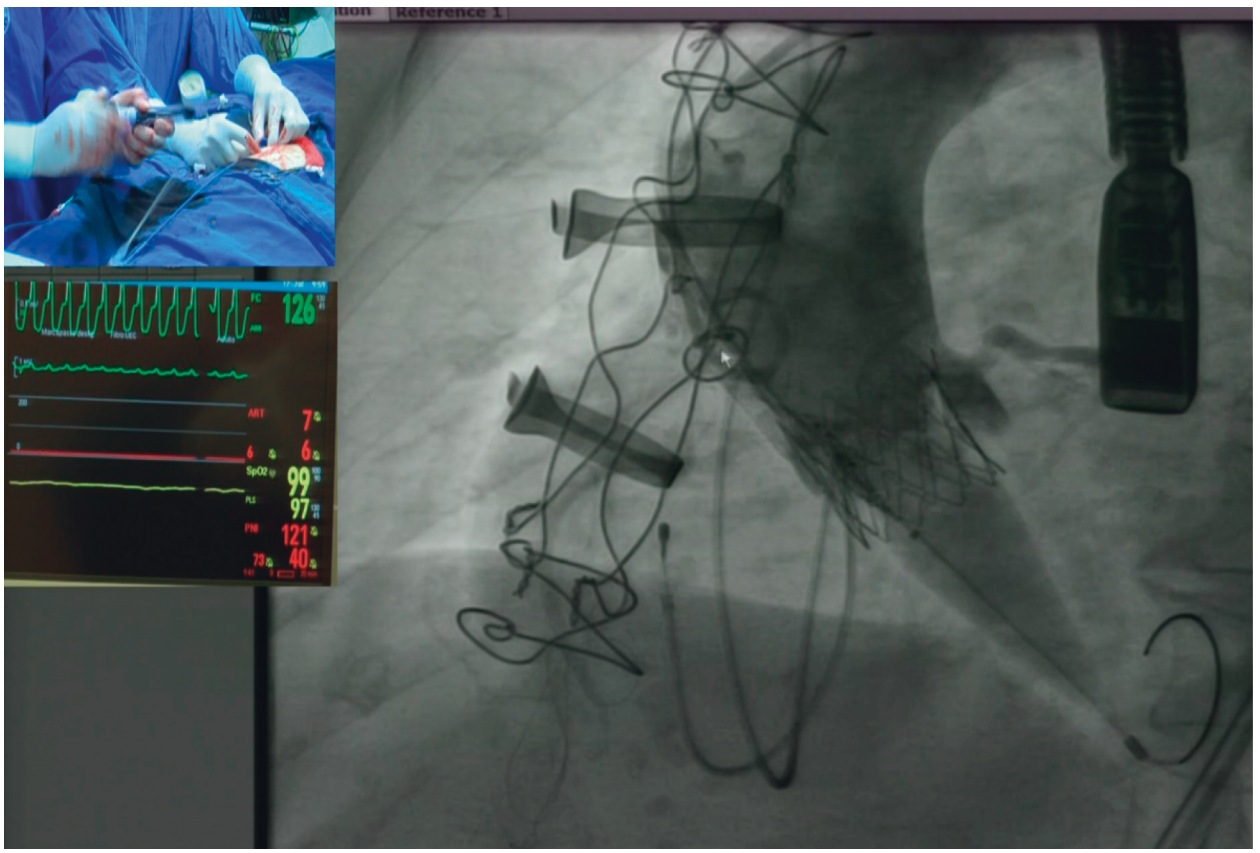
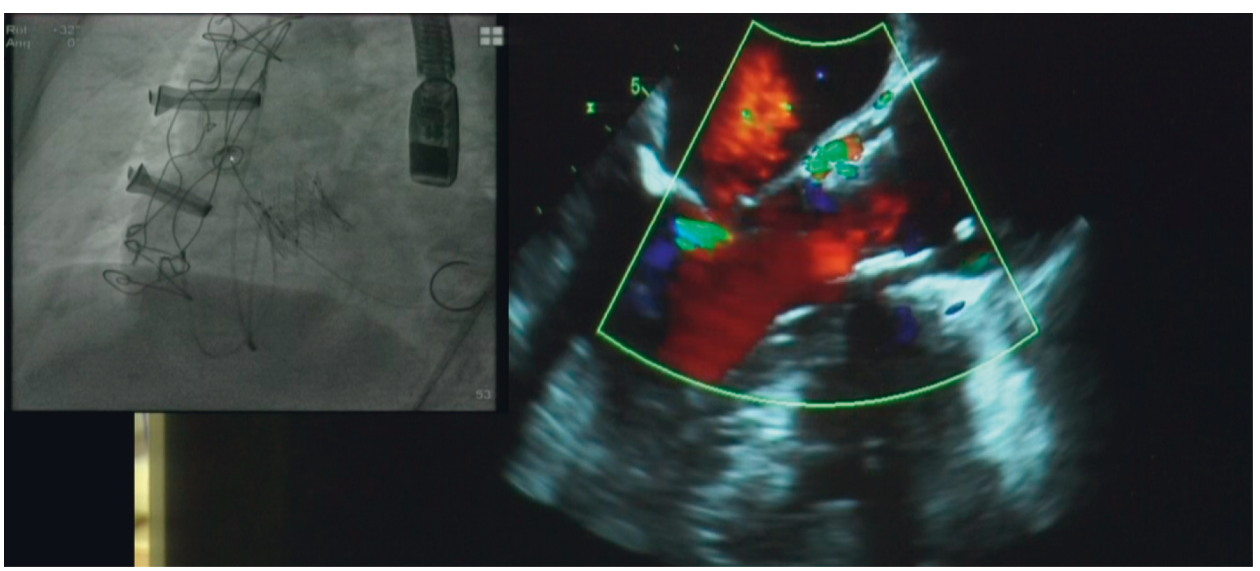


Figure 6: ViV App suggestion of depth of implantation of an Evolut R 23 mm in a Perceval valve.

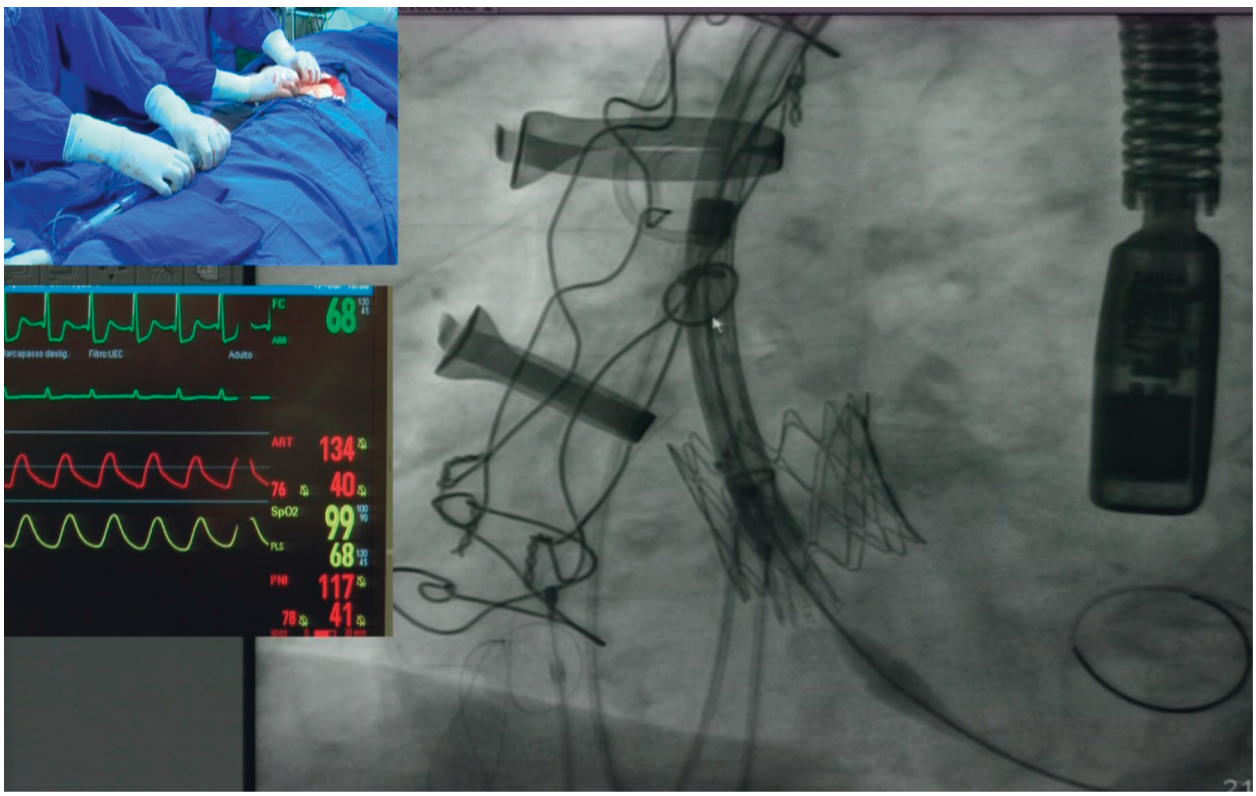


(a)

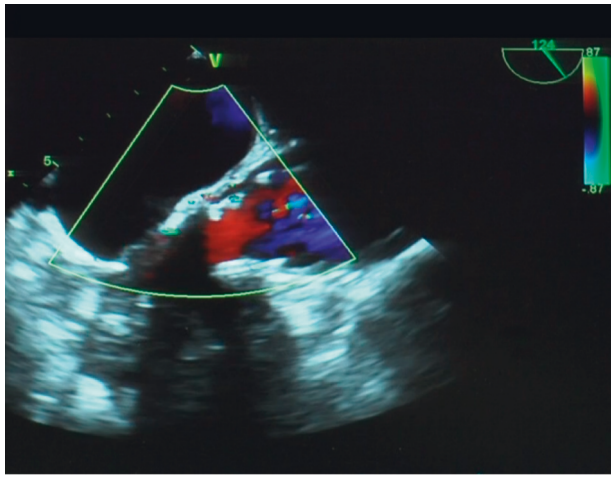


(b)

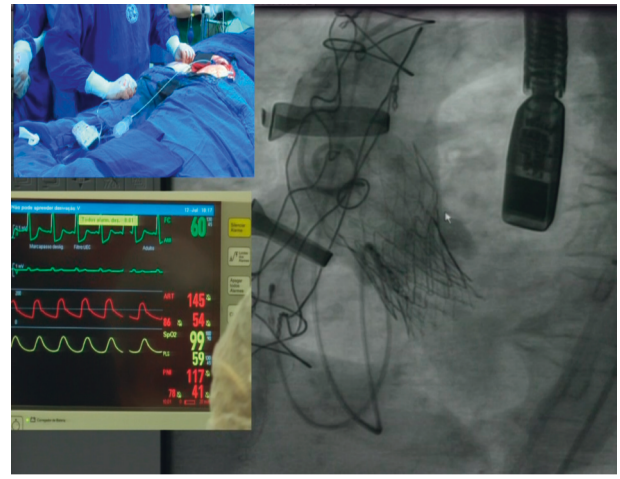
Figure 7: Continued.



(c)



(d)



(e)

Figure 7: Step-by-step procedure. (a) Predilatation and valve cracking using an Atlas 20 mm noncompliant balloon while injecting contrast in the ascending aorta to simultaneously evaluate the left coronary artery flow. (b) Immediate prosthesis cracking and expansion with mean gradient reduction and PVL resolution. (c) Slow Evolut R 23 deployment immediately below the previously implanted rapid deployment valve. (d) Aortic regurgitation reduction on TEE and expansion of the previously implanted rapid deployment valve. (e) Final aortogram showing no aortic regurgitation and both prostheses proper expansion with a mean gradient of 8 mmHg.

12. Step-by-Step Procedure

(1) The procedure was carried out under general anesthesia and transesophageal echocardiogram (TEE) guidance

(2) A Lunderquist double curve guidewire was placed in the left ventricle

(3) We decided to predilate the previous rapid deployment Inovare® Alpha prosthesis and crack it with a noncompliant 20 mm Atlas balloon with simultaneous injection of contrast in the ascending aorta. After this maneuver, echocardiogram and invasive measurements showed an excellent result, with elimination of the aortic regurgitation.

(4) An Evolut R 23 mm was implanted, and a mean gradient of 8 mmHg was measured at the end of the procedure.

Implantation of a TAVR within a rapid deployment prosthesis is a new procedure and poses several challenges. This patient had multifactorial problems such as small prosthesis with some degree of PPM, valve regurgitation and stenosis (structural and nonstructural), and PVL. Predilatation using a noncompliant Atlas balloon was crucial to reduce the aortic regurgitation, and fracture the previous rapid deployment valve resulted in a significant final mean gradient reduction. As mentioned by Tarantini et al., sutureless and stentless surgical aortic valves cannot undergo BVF; however, sutureless valves can potentially be remodeled by overexpansion [23].

13. Conclusion

BVF of a previously implanted stented bioprosthetic valve is an important tool to reduce the aortic valve gradient and the risk of PPM. We presented a case in which a TAVR was deployed in a small and degenerated rapid deployment prosthesis using the balloon cracking technique. The employment of the balloon cracking technique in the setting was really useful to reduce aortic regurgitation and final gradients. Further studies are necessary to confirm this anecdotal initial result.

Disclosure

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Conflicts of Interest

The authors declare that they have no conflicts of interest.

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Review Article

Practical Approach to Transcatheter Aortic Valve Implantation and Bioprosthetic Valve Fracture in a Failed Bioprosthetic Surgical Valve

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Bioprosthetic surgical aortic valve failure requiring reintervention is a frequent clinical problem with event rates up to 20% at 10 years after surgery. Transcatheter aortic valve-in-valve implantation (ViV-TAVI) has become a valuable treatment option for these patients, although it requires careful procedural planning. We here describe and illustrate a stepwise approach to plan and perform ViV-TAVI and discuss preprocedural computerized tomography planning, transcatheter heart valve selection, and implantation techniques. Particular attention is paid to coronary artery protection and the possible need for bioprosthetic valve fracture since patients with small surgical aortic bioprostheses are at a risk of high residual gradients after ViV-TAVI. Considering updated clinical data on long-term outcomes following ViV-TAVI, this approach may become the default treatment strategy for patients with a failing surgical aortic bioprosthesis.

1. Introduction

Surgical implantation of a bioprosthetic aortic valve (aortic valve replacement, AVR) has been the treatment of choice for many patients with aortic valve stenosis (AS) or regurgitation. Current guidelines of the ACC/AHA (American College of Cardiology/American Heart Association) and ESC/EACTS (European Society of Cardiology/European Association for Cardio-Thoracic Surgery) recommend surgical AVR for patients below, respectively, 65 or 75 years of age, who have symptomatic AS or severe asymptomatic AS, provided they have a long life expectancy [1, 2]. However, bioprosthetic aortic valve failure is frequent, with event rates ranging from 5% up to 20% at 10-year follow-up, depending on the valve type [3, 4]. Bioprosthetic valve failure is defined as prosthetic dysfunction which leads to valve-related death, repeat intervention, or severe hemodynamic structural valve degeneration (a mean gradient of 40 mmHg or more or a 20 mmHg increase compared to immediately after implantation) [5].

In the recently updated ESC guidelines (2021), redo cardiac surgery is a class I, level of evidence C indication for symptomatic patients with bioprosthetic valve failure (after excluding thrombosis and endocarditis) and class IIa (C) indication for asymptomatic patients with low surgical risk [1]. However, transcatheter aortic valve-in-valve implantation (ViV-TAVI) has gained much attention in recent years because of the high procedural success rates of more than 90%. ViV-TAVI has been upgraded from a class IIa (C) in the 2017 ESC guidelines to class IIa (B) recommendation in the 2021 ESC guidelines and should be considered based on anatomical characteristics and features of the surgical prosthesis and in patients at high surgical risk. These recommendations are based on registry data and propensity-matched registry studies, showing better short- and long-term

outcomes with ViV-TAVI vs. redo surgery [6–8]. Considering these data and new insights, ViV-TAVI may become the preferred treatment for bioprosthetic valve failure, irrespective of the surgical risk category of the patient.

However, ViV-TAVI requires meticulous planning of the procedure and selection of the approach to minimize the risk of coronary obstruction, device malposition, and high residual gradients [9]. While multiple studies have shown that patients with bioprosthetic valves with small dimensions (21 mm or lower) or with high gradients (patient-prosthesis mismatch, PPM) are at an increased risk of early degeneration, these patients are also at risk for high residual gradients after ViV-TAVI [10].

We here systematically describe the approach to plan and perform a ViV-TAVI (Figure 1), carefully addressing the issues mentioned above, with particular attention to coronary artery protection strategies and bioprosthetic valve fracture (BVF) to avoid high residual gradients in case of small aortic bioprostheses.

2. Surgical Aortic Bioprosthetic Valve Types

When assessing a potential candidate for ViV-TAVI, the first step is to identify the type and size of the surgical bioprosthesis as this may identify procedural risks (e.g., coronary occlusion because of externally mounted leaflets) and influence the approach (e.g., bioprosthetic valve fracture). Surgical bioprostheses can be classified into stented, stentless, or sutureless valves (Table 1). Stented valves may have internally mounted leaflets, resulting in a true inner diameter (ID) that is smaller than the labeled valve size. To maximize effective orifice area (EOA), surgical bioprostheses with externally mounted leaflets (e.g., St. Jude Trifecta and Sorin Mitroflow) and stentless valves have been designed.

In the Valve-in-Valve International Data (VIVID) registry, reporting on the outcomes in 1600 ViV-TAVI procedures, the main challenge in stented valves was reported to be a high residual gradient or PPM [12]. In contrast, stentless valves are more challenging because of the lack of fluoroscopic markers, an increased risk of device malposition (10.3% versus 6.2% in stented valves, $p = 0.014$), coronary obstruction (6.0% vs. 1.5%, $p < 0.001$), and paravalvular leak (PVL, 11% vs. 4.5%, $p < 0.001$). Coronary obstruction following ViV-TAVI is also a major concern in patients with stented valves with externally mounted leaflets [13].

Once the surgical valve has been identified, the "valve-in-valve aortic" app (by UBQO and Dr. Vinayak Bapat) can be used to identify which THV types can be used for ViV-TAVI. The aortic ViV app also provides information on the true internal diameter, fluoroscopic landmarks to correctly position the THV, and the possibility of valve fracturing. Ex vivo images of the transcatheter heart valves (THVs) mounted inside surgical bioprostheses, obtained from the aortic ViV app, are shown in Figure 2 (internally mounted leaflets in Figures 2(a), 2(b), and 2(d) and externally mounted leaflets in Figure 2(c)).

3. Preprocedural Computerized Tomography Planning

Preprocedural computerized tomography (CT) planning is the key when performing ViV-TAVI (Figure 3). The stent diameter of the valve and true ID can be measured and should be in line with the expected values based on the surgical valve type. In case of internally mounted leaflets, the true ID can be smaller than the stent diameter. The upper stent posts of the surgical valve can be marked with three generic markers which can then be used to determine the optimal fluoroscopic views (i.e., three-cusp coplanar view and left/right coronary (LCC/RCC) cusp-overlap).

Next, it is important to identify anatomical factors which may lead to coronary obstruction. When implanting a THV in a surgical bioprosthesis, the leaflets are displaced outward and may occlude the coronary ostia. The implanted THV is not necessarily restricted by the surgical valve, especially not at the level of the coronary ostia since the surgical valve commissures are most often aligned with the native valve [13, 14]. This is also the reason why surgical bioprostheses with externally mounted leaflets or stentless valves have a higher risk of coronary occlusion. The sinuses can even be completely sealed off when the displaced leaflets extend to the sinotubular junction (sinus sequestration), which is more likely in the case of a narrow sinotubular junction or TAVI-in-TAVI [15]. The risk for coronary obstruction can be assessed by measuring the virtual transcatheter valve-to-coronary (VTC) ostium distance and the valve-to-sinotubular junction distance. The VTC distance is measured from the ostium of the coronaries to a virtual cylinder, aligned at the base of the surgical valve, extending up to the coronary ostia and with a diameter equal to the planned THV or its waist at that level (Figure 3). It has been shown that patients with a VTC distance ≤4 mm are at an increased risk of coronary obstruction, and a cutoff of ≤3 mm is considered high risk [13, 14].

4. Choice of the Transcatheter Heart Valve

The US Food and Drug Administration (FDA) has approved the balloon-expandable (BEV) Sapien XT and Sapien 3 (Ultra) valve (Edwards Lifesciences) with intra-annular leaflet position and the self-expanding (SEV) Evolut platform (Medtronic) with supra-annular leaflet position for ViV-TAVI. Other platforms can be used off-label (Figure 2). Differences in valve stent frame design, leaflet position, and THV expansion/implantation may potentially be beneficial in specific situations.

To prevent high gradients after ViV-TAVI, a THV with supra-annular leaflet position may theoretically be preferred to maximize the EOA. Especially, patients with small annuli, stented bioprostheses, and a small EOA are at risk for high transvalvular gradients after ViV-TAVI. In the VIVID registry, the use of the Sapien device was an independent predictor for increased gradient after ViV-TAVI (mean gradient >20 mmHg, odds ratio: 2.3) [9]. These higher postprocedural gradients with Sapien were especially observed in patients with small annuli (<20 mm) (43% for Sapien versus 24% for the

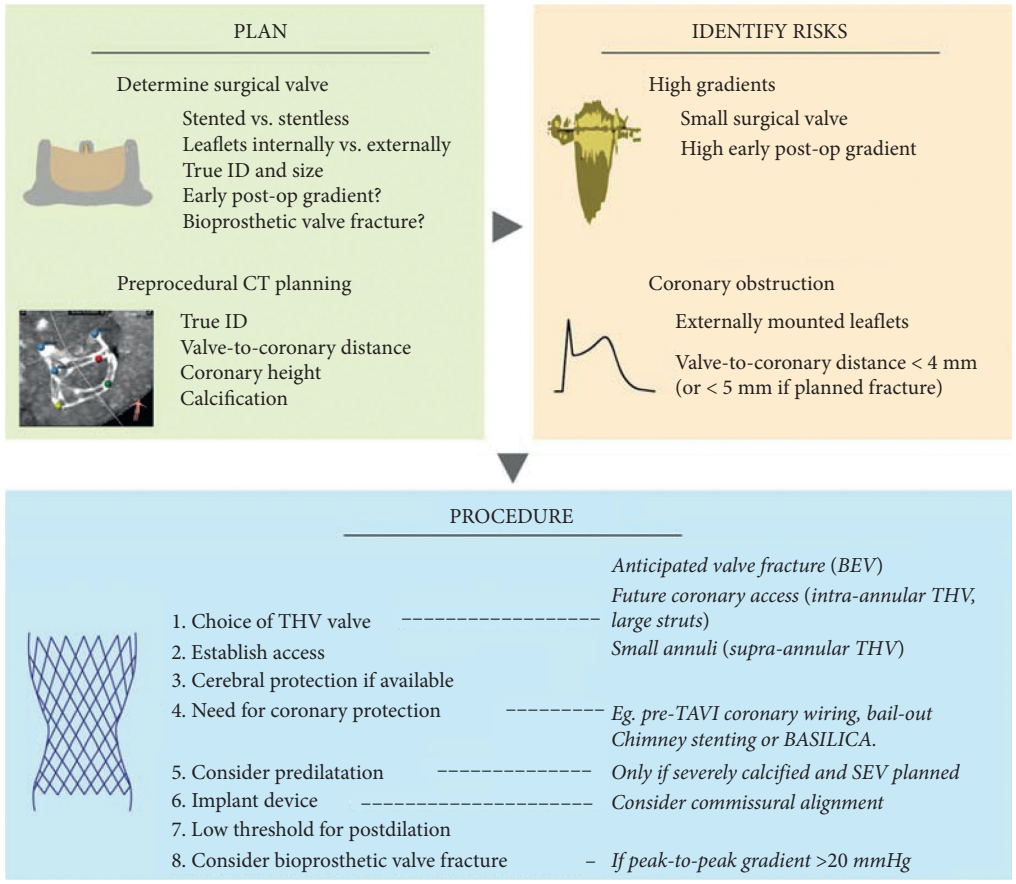
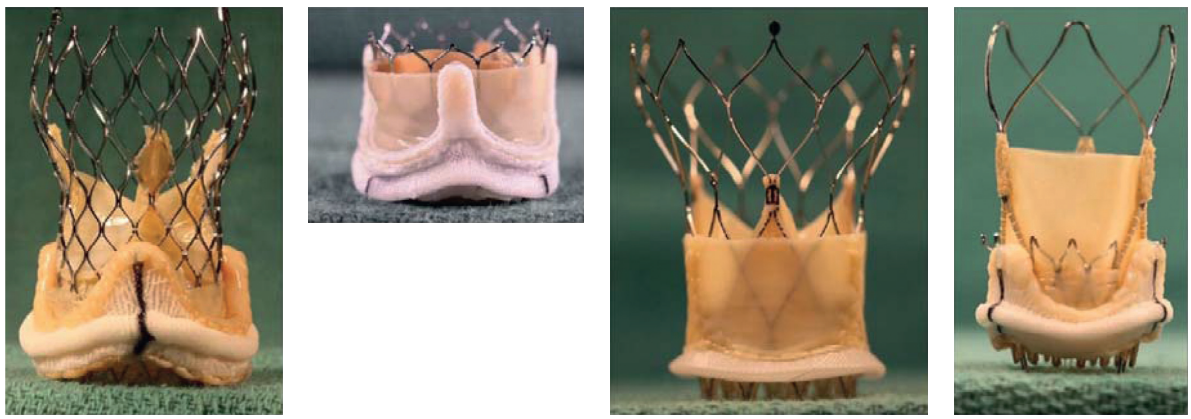


Figure 1: Practical approach to ViV-TAVI, with preprocedural planning to identify and address coronary occlusion or high residual gradients after TAVI. BEV: balloon-expandable valve; SEV: self-expandable valve; THV: transcatheter heart valve; TAVI: transcatheter aortic valve implantation; ID: internal diameter; BASILICA: bioprosthetic aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction.

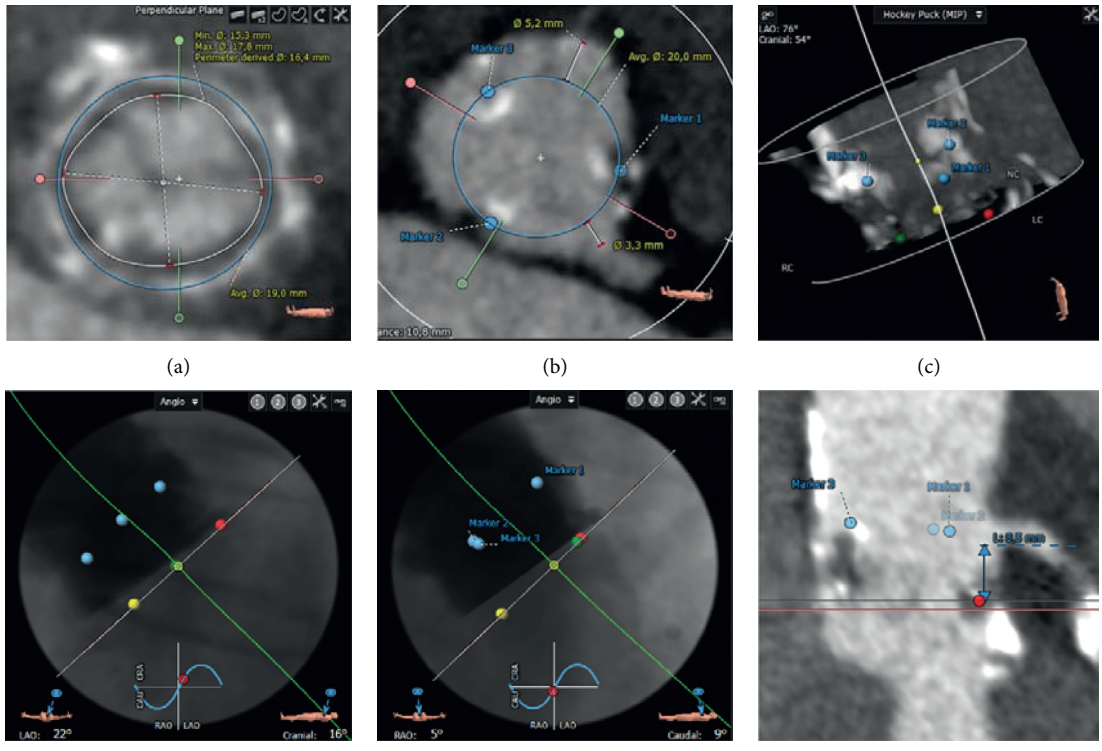
Table 1: Design, characteristics, and challenges of commonly used surgical aortic valves.

	Leaflets mounted	Fracture potential [11]	Challenges
Stented valves			
Sorin Mitroflow	Externally	Yes (19–21 mm)	(i) Higher postprocedural gradients (ii) Coronary obstruction (externally mounted leaflets)
St. Jude Trifecta	Externally	No	
St. Jude Biocor Epic	Internally	Yes (21 mm)	
Medtronic Mosaic	Internally	Yes (19–21 mm)	
Medtronic Hancock II	Internally	No	
Edwards Magna Ease	Internally	Yes (19–21 mm)	
Edwards Magna	Internally	Yes (19–21 mm)	
Edwards Perimount 2700	Internally	No, but expandable	
Edwards Perimount 2800	Internally	Yes	
Labcor Porcine	Internally	Yes	
Stentless valves			(i) Lack of fluoroscopic markers (ii) Device malposition (iii) Coronary obstruction (iv) Paravalvular leak
Sorin Freedom			
St. Jude Toronto			
Medtronic Freestyle	Extended full porcine root		
Edwards Prima Plus	Extended full porcine root		
Sutureless			
Sorin Perceval	Internally		
Edwards Intuity	Internally		
Medtronic Enable	Internally		



(a) (b) (c) (d)

Figure 2: Ex vivo examples of THVs mounted in surgical bioprostheses. (a) Evolut R 23 mm THV in an Epic 21 mm surgical valve. (b) Sapien 23 mm THV mounted in a Perimount Magna Ease 21 mm surgical valve. (c) Portico 23 mm THV mounted in a Trifecta 21 mm valve with externally mounted leaflets. (d) ACURATE neo S mounted in Epic 25 mm. Images were obtained from the valve-in-valve aortic app (by UBQO and Dr. Vinayak Bapat), reproduced with permission.



(a) (b) (c)

(d) (e) (f)

Figure 3: Preprocedural CT planning in a 91-year-old female patient with high-grade aortic stenosis (peak gradient 64 mmHg and mean gradient 35 mmHg) that underwent ViV-TAVI in a failed 21 mm Epic bioprosthesis. (a) The basal ring of the Epic valve is marked at the center of the cusps (red, blue, and green dots). The stent diameter is 19 mm, and true internal diameter is 16.4 mm (17 mm according to the aortic ViV app, with internally mounted leaflets). (b) The posts of the stent of the Epic valve are marked with generic markers (blue). The blue circle is centered on the surgical valve and represents the waist of the planned 23 mm Evolut valve. The distance between the virtual 23 mm valve (with the waist of 20 mm) and the left coronary (virtual transcatheter valve-to-coronary ostium distance, VTC) is low (3.3 mm). (c) Hockey puck view showing the generic blue markers on the top posts, while the colored markers are in the middle of the cusps at the base of the surgical valve. (d) Coplanar view with the left coronary cusp at the right side (red marker). (e) Cusp-overlap view with overlapping left and right coronary cusps (red and green markers). (f) Low left coronary height (8.5 mm) with shallow sinuses of Valsalva.

CoreValve/Evolut platform) [16]. No significant difference in postprocedural gradients was reported for patients with larger annuli (23 mm or more), with rates of 21% in both groups. Importantly, at longer-term follow-up, the use of Sapien was associated with higher reintervention rates, caused by higher postprocedural gradients [17].

While a SEV with supra-annular leaflet position may be preferred to maximize the EOA, device malposition is more common when using the SEV as compared to BEV [12]. However, with increasing operator experience and the introduction of repositionable SEV, the rates of device malposition have markedly dropped from 15% in 2012 to 6.5%, and this number can be expected to further decrease [9, 17]. The reported rates of PVL have also been higher for the SEV as compared to BEV, although again, the rate of PVL was reported to be reduced with newer generation devices [12]. No difference in all-cause mortality has been reported for BEV versus SEV in ViV-TAVI procedures [16].

Finally, the need for future coronary access and the need for a possible future re-ViV-TAVI can also guide the THV type selection [18]. A lower stent frame or intra-annular design (Sapien platform) or bigger stent struts are preferred when the possibility of future coronary access needs to be optimized. An intra-annular valve design with low stent height (Sapien platform) may also facilitate future re-ViV-TAVI.

5. Implantation Techniques

In contrast to native valve TAVI, the THV in ViV-TAVI is positioned relative to the fluoroscopic landmarks of the surgical aortic bioprosthesis (usually 2–4 mm below the surgical valve) and not to the annular plane (Figure 4(a)). The optimal implantation depth is also provided by the aortic ViV app. A radiopaque ring at the inflow part of the surgical aortic bioprosthesis may facilitate this, while it is more difficult when there are only radiopaque markers of the surgical valve posts (e.g., Mosaic) or no radiopaque markers at all (e.g., stentless valves). When severe calcification is observed on the preprocedural CT scan, predilatation should be considered to avoid severe underexpansion of a self-expanding THV. However, there is no indication for routine predilatation. Patient-specific commissural alignment can be obtained by aligning the THV with the surgical valve, using the predefined fluoroscopic views and generic markers outlined above [19]. For Evolut, the hat marker should be at the center front during implantation, and the C-tab should be on the inner curve after valve deployment in the R/L cusp-overlap view. No implantation techniques are currently available to provide patient-specific commissural alignment when using Sapien, although this is less critical because of the lower profile of the valve. Standard pacing approaches are used during implantation of the BEV, i.e., 180/min or up to 200–220/min if slower rates do not provide enough pressure decrease. In case of implantation of the SEV in surgical aortic bioprostheses, it is typically best to use intermediate rate pacing, starting at 120–130/min but often transiently increasing the pacing rate to 160/min for a few seconds during valve expansion. Often, postdilatation is performed to optimize the hemodynamic result. The risk of inducing conduction disorders and permanent pacemaker implantation is low (typically <5%) [16]. For Evolut valves, it is recommended to size the postdilatation balloon to the true ID of the surgical valve or 1 mm smaller. For the Sapien platform, the valve is usually oversized minimally 1 mm based on the true ID [20].

6. Bioprosthetic Valve Fracture

Routine postdilatation of the SEV should be considered as high residual transvalvular gradients have consistently been shown to be associated with increased mortality [17, 21]. When residual invasive peak-to-peak gradients of 20 mmHg or more are measured after the ViV-TAVI procedure, bioprosthetic valve fracture (BVF) can be considered (Figures 4(b)–4(f)). BVF will be more likely necessary if the immediate postoperative gradients after SAVR were already high (PPM). BVF also reduces pinwheeling, especially in the case of Sapien valves. While this maneuver may be considered to be relatively aggressive, BVF was shown to be safe in a multicenter registry [22]. Whether BVF should be performed just before or after the THV implantation is still a matter of debate among experts; solid real-world data on this topic are still missing.

An indication on which surgical valves can be fractured is shown in Table 1. In general, sutureless and stentless valves cannot be fractured, but they can potentially be overexpanded. To perform BVF, a 50 cc syringe is used, connected with a 3-way stopcock to a noncompliant (NC) high-pressure balloon (True or Atlas Gold balloon (Becton, Dickinson and Company, New Jersey, US)) and an indeflator. It is recommended to fill the 50 cc syringe and indeflator with a 20% contrast-80% saline mixture. After positioning the balloon at the level of the valve, rapid pacing (180–220/min) is initiated. The balloon is quickly inflated with the 50 cc syringe (volume phase, which takes 3–5 seconds) after which the 3-way stopcock is opened to the indeflator to allow pressures up to 14 atm (pressure phase, which can take up to 15–20 seconds). Fracturing of the frame is confirmed visually on fluoroscopy or when a pressure drop is observed on the indeflator (Figures 4(e) and 4(f) and video 1). The indeflator is then released, the balloon is deflated, and the invasive gradients can be measured again.

Typically, the size of the balloon is 1 mm larger than the labeled valve size or 1–3 mm larger than the true ID [11, 23, 24]. Postdilatation balloon sizes have to be carefully chosen in case of the Evolut valve to avoid trauma to the Evolut leaflets. Medtronic recommends that the NC postdilatation balloon does not exceed 1 mm more than the THV waist diameter (i.e., a 20 mm waist in a 23 mm Evolut valve). Intraventricular balloon positioning can be performed if postdilatation with a larger NC balloon is needed. BVF can increase the surgical frame diameter by 2–4 mm. As a consequence, it is also reasonable to use a safety margin when measuring the VTC distance (e.g., 5 mm instead of 3-4 mm).

Achieving a good hemodynamic result after BVF is important since a high residual gradient results in a poor clinical outcome, as illustrated in the two examples in Figure 4. Nevertheless, it can often be difficult to observe geometric changes in the stent frame. Moreover, there can

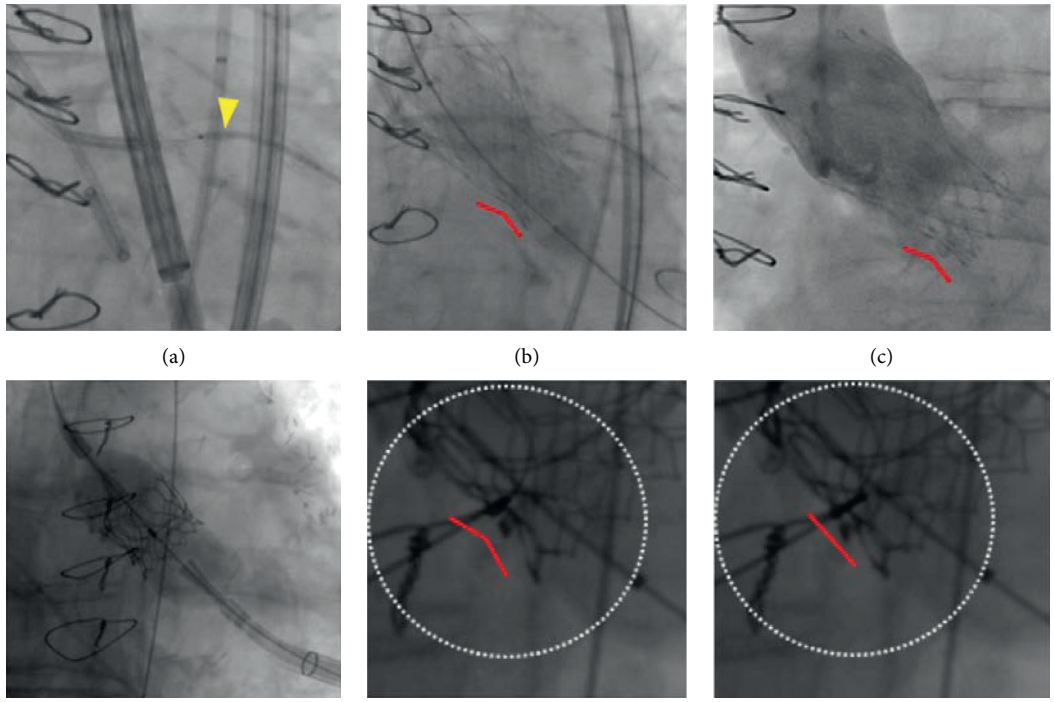


Figure 4: ViV-TAVI with bioprosthetic valve fracture and suboptimal result in a transfemoral (a–c) and good result in a transapical (d–f) approach. (a) In the 91-year-old female patient from Figure 3, because of low coronary height, anticipated bioprosthetic valve fracture, and shallow sinuses, coronary protection was obtained using a 6 F guiding catheter, 6 F GuideLiner, and undeployed stent standby (yellow arrowhead). A 23 mm Evolut R valve was implanted 4 mm under the fluoroscopic ring of the Epic valve as a reference. (b) Invasive gradient after valve implantation was 26 mmHg. BVF was attempted using an 18 mm True balloon at 14 atm. (c) No change in surgical ring geometry or pressure drop on the indeflator was noticed, but the invasive gradient at the end of the procedure was only 3 mmHg. However, the noninvasive peak transvalvular gradient increased to 60 mmHg at 3 months after TAVI, and the patient was rehospitalized with heart failure. Potentially, the 18 mm balloon (true ID + 1 mm) was slightly undersized to achieve fracturing. (d) In contrast, an 85-year-old patient with extensive peripheral vascular disease and a degenerated Perimount Magna Ease 21 mm valve (true ID: 19 mm) underwent transapical implantation of a 23 mm Sapien 3 valve. Postimplantation invasive gradient was 25 mmHg. (e) Postdilatation with Atlas Gold 22 mm balloon. (f) Sudden geometric expansion of the valve at the end of the inflation and a pressure drop on the indeflator, with a reduction of the gradient to 9 mmHg (circles in (e) and (f) denote the similar region in video 1).

be a discrepancy between invasively measured gradients after BVF and the final result measured noninvasively days to weeks after the implantation [25].

7. Coronary Protection Strategies

Coronary obstruction is a rare but devastating complication of ViV-TAVI, with rates of approximately 3% [13]. Meticulous preprocedural cardiac CT analysis can identify risk factors for coronary obstruction, as previously discussed. In a multivariable model, VTC distance and the use of stented bioprostheses with externally mounted leaflets or stentless bioprostheses were independent risk factors for coronary obstruction [13]. BVF may also increase the risk of coronary obstruction. To mitigate this risk, a THV with a lower stent frame height may sometimes be preferred.

In elderly patients at the risk of coronary obstruction, protection with a coronary guidewire, with or without undeployed stent standby in the coronary artery, is a reasonable strategy. In case of obstruction or anticipated very high risk of obstruction (e.g., Figures 5(a)–5(c), bail-out TAVI-in-TAVI in a patient already at a high risk of coronary obstruction), chimney stenting can be performed. In younger patients, in whom the need for future coronary access is important, a preemptive intervention to safeguard coronary access should be considered. In the recently described BASILICA technique (Bioprosthetic Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstruction), the bioprosthetic leaflet is punctured from the side of the sinus, snaring a wire in the left ventricular outflow tract, externalizing it, and then lacerating the leaflet using electrocauterization (Figure 5(d)) [26–29]. By lacerating the leaflet and creating a V-shaped surgical valve leaflet, the risk of coronary occlusion by the bioprosthetic leaflet is reduced when it is pushed to the side by the THV. Although there is a substantial learning curve, the safety and feasibility of this technique have been documented in a prospective cohort study [30]. To assess whether the coronary ostium is patent at the end of the ViV-TAVI procedure, an aortogram in an isolated RCC or LCC cusp view can be performed. In case of doubt, IVUS can also be helpful (Figures 5(e) and 5(f)).

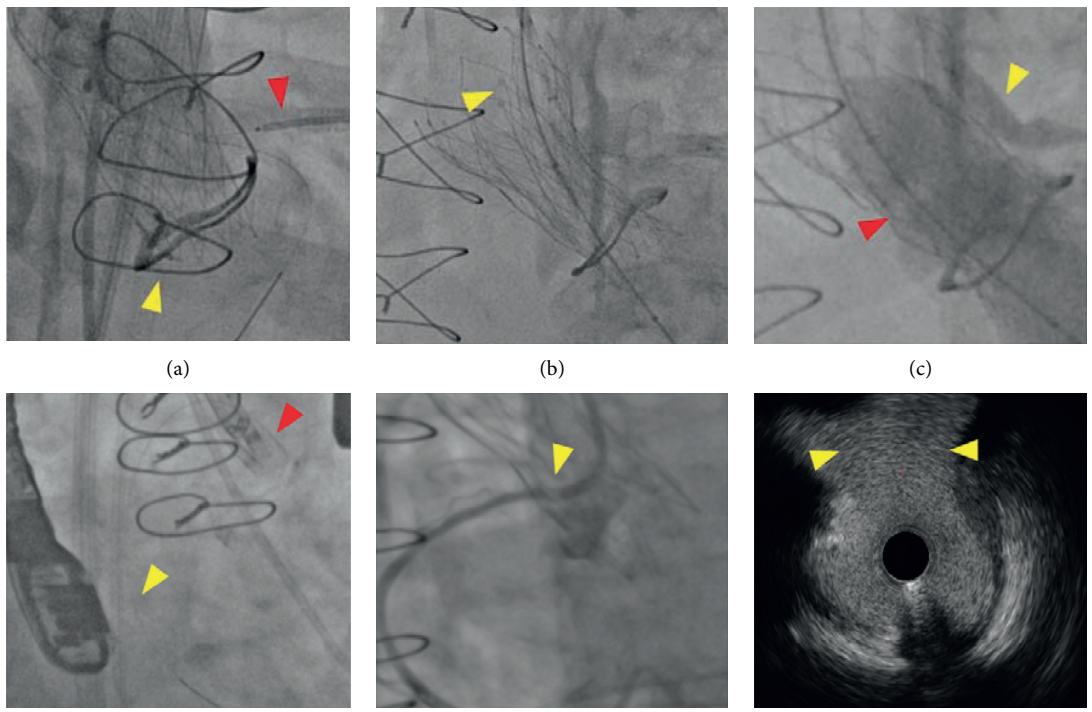


Figure 5: Coronary protection using chimney stenting (a–c) or BASILICA (d, e). (a) An 83-year-old male patient underwent transfemoral ViV-TAVI because of severe aortic regurgitation in a bioprosthetic valve of unknown type. Because of low coronary height, shallow sinuses, VTC 1 mm, and advanced age, coronary protection was obtained with a wire, 6 F GuideLiner, and unexpanded stent in the LAD (red arrowhead). Device malposition of a 25 mm Navitor valve occurred, resulting in severe aortic regurgitation (yellow arrowhead). (b) A second Navitor 25 mm valve was implanted with a good result (double layer of markers of the Navitor valve, yellow arrowhead). (c) Chimney stenting was performed using a Synergy Megatron 4.0 × 20 mm DES with kissing balloon inflation with 6.0 × 20 mm Emerge NC (yellow arrowhead) and 22 mm True balloon (red arrowhead). (d) A 63-year-old female patient underwent transfemoral ViV-TAVI in a 21 mm Trifecta valve. Because of low right coronary ostium (10 mm), VTC of 3 mm, shallow sinuses, and externally mounted leaflets, the right coronary was protected with a wire (yellow arrowhead) and 6 F GuideLiner (temporarily retracted in the 6 F guiding catheter). Because of the young age, a BASILICA procedure was performed upfront (red arrowhead, set up before leaflet laceration with an 8 F traversal MP1 guiding catheter with Astato XS 20 wire inside the PiggyBack wire converter and snared Astato wire inside a 6 F MP guiding catheter). (e) Haziness at the right coronary ostium after successful implantation of a Navitor 23 mm valve 4 mm below the fluoroscopic ring. (f) IVUS showing a nice opening at the level of the right coronary ostium towards the aorta (yellow arrowheads) BASILICA: bioprosthetic aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction; IVUS: intracoronary vascular ultrasound; DES: drug-eluting stent; VTC: virtual transcatheter to coronary distance.

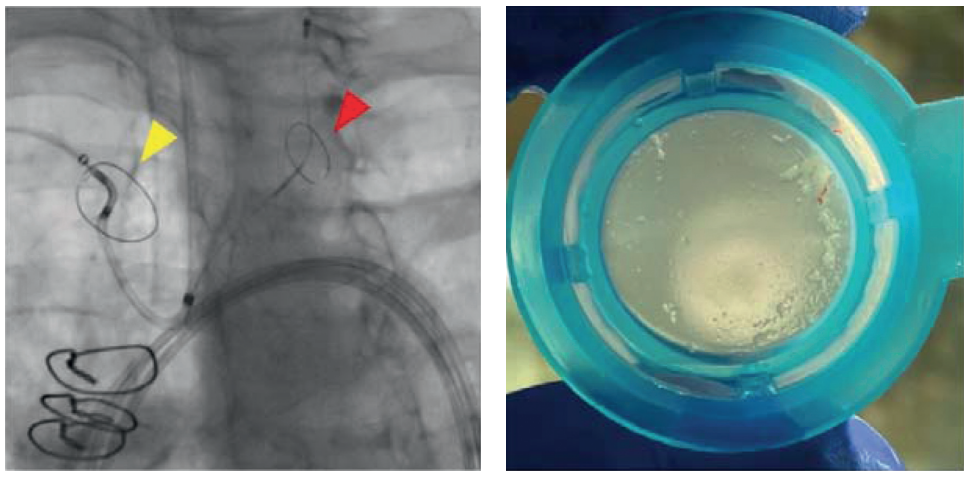


Figure 6: Cerebral protection in ViV-TAVI. (a) Sentinel® cerebral protection device, implanted with filters in the brachiocephalic trunk and left common carotid artery. (b) Filter from the Sentinel cerebral protection device from a valve-in-valve case showing debris.

8. Cerebral Protection

Ischemic stroke risk after ViV-TAVI has been reported to be approximately 2%, but no information on the use of cerebral protection is available in these reports [12, 17]. As the risk for embolic stroke or debris may theoretically be higher in ViV-TAVI, it may be advisable to use cerebral protection during these procedures, especially when performing BASILICA-assisted ViV-TAVI (Figure 6).

9. Conclusion

ViV-TAVI is a safe and valuable treatment option to treat failed surgical aortic bioprostheses, provided that the procedure is carefully planned and performed. Besides newer THV generations with better implantation results, also newer techniques for coronary protection and cerebral protection are now available to mitigate the major risks of ViV-TAVI. Achieving good hemodynamic results with low gradients after implantation is the key to ascertain good long-term outcome.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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