Catheterization and Cardiovascular Interventions

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REVIEW

What Is the Role for TAVI in Failing Surgical Aortic Valves? A Review on Valve-in-Valve Interventions

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ABSTRACT

Bioprosthetic surgical aortic valve failure represents a significant clinical challenge that necessitates timely and effective intervention to restore valve function and ensure patient well-being. Use of valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) has emerged as a feasible alternative to reoperation surgical aortic valve replacement (SAVR). By providing a less invasive option, this approach offers the opportunity to reduce the potential risks of a reoperation surgery. However, it is important to note that implementing ViV-TAVI requires careful preparation. This review outlines a thorough approach to ViV-TAVI, encompassing preprocedural planning, valve selection, implantation procedure, and its complications. With the availability of updated clinical data supporting long-term outcomes, this particular strategy is an excellent choice for the treatment of failed surgical aortic bioprostheses.

1 | Introduction

Since its introduction in routine clinical practice, the first successful transcatheter aortic valve implantation (TAVI) after surgical aortic valve replacement (SAVR) was performed in 2007 in Germany for an 80-year-old patient with severe regurgitation of a degenerated aortic bioprosthesis using the Corevalve system [1]. Since then, significant progress has been made in this transcatheter procedure, with recent advancements for failing previously operated valves. Patients with a previously implanted surgical valve have two options: to undergo a reoperation, SAVR, or to undergo valve-in-valve transcatheter aortic valve implantation (ViV TAVI). Currently, ViV TAVI constitutes approximately 5% of all TAVI procedures conducted in the United States [2], and has become a feasible alternative to reoperation SAVR for individuals who are at a high risk for surgical procedures [3, 4]. This article provides an up-to-date review and overview of the challenges and future perspectives of ViV TAVI procedures.

2 | A Technical Appraisal of Failed Stentless Versus Stented Bioprosthetic Valves

Biological prosthetic heart valves can either be stented or stentless. Stented valves are typically made of porcine aortic valves or bovine pericardium, which is suspended from a sup-

Abbreviations: BASILICA, bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction during TAVI; BVD, bioprosthetic valve dysfunction; BVF, bioprosthetic valve failure; BVFr, bioprosthetic valve fracture; DW-MRI, diffusion-weighted magnetic resonance imaging; EOA, effective orifice area; ID, internal diameter; MACE, major adverse cardiac events; MDCT, multi-detector computed tomography; PPM, patient-prosthesis mismatch; PVL, paravalvular leakage; SAVR, surgical aortic valve replacement; SHV, surgical heart valve; STJ, sino-tubular junction; SVD, structural valve deterioration; TAVI, transcatheter aortic valve implantation; THV, transcatheter heart valve; VIVID, Valve-in-Valve International Data; VIV-TAVI, valve-in-valve transcatheter aortic valve implantation; VTC, valve to coronary ostium distance.

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port structure consisting of a stent or frame. On the other hand, stentless valves are sutured to the aortic root in the same position as a native valve, removing the support stent/frame to improve hemodynamic performance and durability [5]. Stentless valves present unique challenges for ViV TAVI due to the lack of a frame to anchor the new transcatheter heart valve (THV) and the absence of radiopaque markers for assisting with correct positioning [5].

As compared to mechanical prostheses, bioprostheses are associated with higher rates of reintervention due to bioprosthetic failure [6, 7]. The durability of the bioprosthetic valves is limited due to structural valve deterioration (SVD), which causes significant morbidity and mortality following valve replacement [8].

A bioprosthetic valve dysfunction (BVD) occurs when the normal functioning of a bioprosthetic valve is altered due to structural and nonstructural causes. In contrast, bioprosthetic valve failure (BVF) happens when valve dysfunction from any cause (beyond just structural valve dysfunction) significantly impacts the clinical status of the patients [8, 9].

2.1 | BVD

Permanent changes to the valve, such as bioprosthetic valve leaflets, stents, sewing rings, or struts, are classified as structural BVD. Stage 1 of SVD usually starts with changes which are not associated to a decline in the hemodynamic function of the valve; this stage is followed by stage 2 with moderate hemodynamic valve deterioration, stage 3 with severe hemodynamic impairment, leading to the latter stage of BVF [10]. The primary factors limiting the durability of bioprosthetic valves following aortic valve replacement are SVD caused by leaflet calcification and thrombus or collagen fiber disruption. Early valve fractures and obstructions can occur due to leaflet thrombus (HALT), which can lead to aortic regurgitation (AR) and can worsen over time. This condition requires prompt medical attention to prevent further damage to the valve and surrounding tissue.

In addition to the purely passive degenerative process caused by wear and tear of the valve leaflets, recent studies suggest that active and potentially modifiable mechanisms may also be involved in bioprosthetic SVD. These patient-related mechanisms include lipid infiltration, inflammation, immune rejection, and active mineralization [11, 12].

Any abnormality that is not inherent to the valve device and causes hemodynamic valve dysfunction is referred to as nonstructural BVD. There are two significant causes of nonstructural BVD that do not involve morphologic abnormalities in the bioprosthetic valve leaflets: paravalvular regurgitation and patient-prosthesis mismatch (PPM) [8]. Early (< 5 years) hemodynamic bioprosthetic valve deterioration was linked to diabetes mellitus, active smoking, and renal insufficiency. Instead, late (> 5 years) deterioration was associated with female sex, warfarin use, and type of bioprosthesis in a multicenter study [11].

2.2 | BVF

AR is the major cause of bioprosthetic failure, occurring in 20% of stented and 56% of stentless valves; failing stentless valves had a higher probability of experiencing severe (grade 4) AR ($p < 0.001$). Although there is no difference in 30-day and 1-year results, stentless ViV-TAVI is linked to higher rates of procedural technical challenges such as initial device malpositioning, need for second valve, coronary blockage, and paravalvular leak [13]. Choi et al. compared clinical outcomes and procedural complications in failed stentless versus stented surgical bioprosthetic aortic valve groups performing ViV TAVI. The success rate of the valve in valve (ViV) procedure was 100% ($n = 8/8$) in the stented group and 96.9% ($n = 31/32$) in the stentless group. At both 30-day and 6-month follow-up, the mean aortic gradient was significantly lower in the stentless group compared to the stented group, respectively 12 ± 6 mmHg and 22 ± 8 mmHg, $p < 0.05$ at 30-day, and 9.75 ± 5.07 mmHg and 24 ± 11 mmHg, $p < 0.05$ at 6 months. On the other hand, a second valve was required in 34.4% (11/32) of the stentless group compared with 0% of the stented group. In addition, no significant differences in all-cause mortality at 30 days (6.9%, $n = 2/31$ in the stentless group vs. 0%, $n = 0/8$ in the stented group, $p = 0.33$) and at 1 year (0%, $n = 0/25$ in the stentless group vs. 0%, $n = 0/5$ in the stented group, $p =$ NS) were observed [14].

Given that a ViV implant is selected with a nominal outside diameter that matches or exceeds the reported inside diameter of the failed surgical valve, the mechanism of failure of the original valve deserves particular attention during the phase of procedural planning. Regurgitant valves with ruptured leaflets may have a relatively larger internal diameter (ID), whereas valves with prominent pannus or calcification may have smaller internal dimensions. Thus, the size calculation must take into account the specified ID and the type of valve failure [5]. AR of surgical aortic valve bioprosthesis can lead to rapid degeneration and cardiogenic shock. Valves should be replaced or fixed when moderate AR is present. It is important to note that a "wait and see" approach is not a safe strategy in this case.

Dallan et al. have also studied patients undergoing TAVI in BVF using the Evolut R or Evolut PRO THV in the Society of Thoracic Surgeons and American College of Cardiology Transcatheter Valve Therapy Registry. Transcatheter valve performance was evaluated in 5897 patients, demonstrating excellent clinical outcomes and valve hemodynamics. Thirty-day THV hemodynamic performance was excellent in both groups (mean gradient: Evolut PRO: 13.8 ± 7.5 mmHg; Evolut R: 14.5 ± 8.1 mmHg) with low rates of PVL. Clinical events were also low at 1 year (Evolut PRO: all-cause mortality, 9.2%; any stroke, 3.1%; Evolut R: all-cause mortality, 9.8%; any stroke, 2.9%) [15] (Figure 1).

3 | What to do in Case of BVD: ViV-TAVI Versus Redo SAVR

Currently, there is lack of randomized comparative studies examining the efficacy and safety of ViV-TAVI versus redo SAVR. However, some observational studies showed comparable clinical results.

The most common indications for ViV-TAVI include: (1) failing surgical bioprosthetic aortic valve at high or extreme risk for reoperation; (2) late THV failure caused by structural deterioration of the valve (stenosis, regurgitation or mixed disease); (3) acute aortic valve replacement failure or suboptimal implantation; (4) a combination of structural and nonstructural valve dysfunctions with paravalvular leakage (PVL) and bioprosthesis failure, which may require a combined strategy such as closure of the PVL and implantation of a new prosthesis [16, 17].

On the other hand, elements favoring reoperation SAVR include: (1) low to moderate surgical risk; (2) young age; (3) concomitant disease requiring cardiac surgical intervention; (4) significant paravalvular leak that cannot be closed percutaneously.

Procedural and anatomic features favoring SAVR include: (1) a small surgical valve where PPM cannot be treated; (2) severe PPM where balloon valve fracture is not feasible or at high risk; (3) high risk of coronary obstruction; (4) aortic root injury.

Usually, large surgical valve size without severe PPM, balloon valve fracture feasible and at low risk, favorable coronary anatomy, and calcified aortic root or hostile chest are elements which favor TAVI over reoperation surgery. In any case, patient preference toward one or the other treatment should always be considered [18].

Patients who received ViV TAVI or reoperation SAVR between 2016 and 2018 were identified in a retrospective cohort research using the Nationwide Readmission Database in Europe. As compared to reoperation SAVR, there was no difference in the incidence of in-hospital stroke, post-procedure pacemaker implantation, major adverse cardiac events (MACE), or death at 30-day and 6 months, indicating that either procedure may be safely conducted in at least a selected population [18, 19]. Majmundar et al. compared the ViV-TAVI approach to reoperation SAVR in a total of 6769 procedures performed on patients with a failed aortic bioprosthesis utilizing the National Discharge Records (NDR) database, a representative database that includes discharge records from 28 states and contains roughly 35 million weighted discharges annually, equivalent to 58.2% of all hospitalizations in the United States. Among 6769 procedures, 55% ($n = 3724$) received ViV-TAVI treatment, while 45% ($n = 3045$) received reoperation SAVR. The rates of in-hospital all-cause mortality was lower in the ViV-TAVI group. On the contrary, the rates of 30-day (HR 1.46, 95% CI: 1.13−1.90, $p = 0.004$) and 6-month all-cause readmissions (HR 1.54, 95% CI: 1.14−2.10, $p = 0.006$) were higher in the ViV-TAVI arm compared with reoperation SAVR [19].

A recent study also assessed the clinical outcomes of ViV-TAVI ($n = 198$) in comparison to reoperation SAVR ($n = 147$) in patients with failed surgical aortic valve implants. The reoperation SAVR group was associated with higher transfusions and need for reoperation because of bleeding, new-onset renal failure requiring dialysis, and need for a permanent pacemaker implantation compared to the ViV-TAVI group. Furthermore, the mean gradient at 30-day and 1-year follow-up was significantly lower in the reoperation SAVR group compared to the ViV-TAVI group [20].

A meta-analysis evaluated the clinical outcomes of patients with failed surgical aortic valves who underwent either TAVI ViV or reoperation SAVR in 12 observational studies with a total of 8,430 patients and a median weighted follow-up period of 1.74 years. In the ViV-TAVI arm, the rate of procedural mortality (OR 0.41; 95% CI 0.18 to 0.96, $p = 0.04$), 30-day mortality (OR 0.58; 95% CI 0.45 to 0.74, $p < 0.0001$), major bleeding (OR 0.36; 95% CI 0.16 to 0.83, $p = 0.02$), and stroke (OR 0.65; 95% CI 0.52 to 0.81, $p = 0.0001$) were significantly lower compared to the reoperation SAVR group, despite a significantly higher mean transvalvular pressure gradient post-implantation in the ViV-TAVI group (mean difference 3.92 mmHg; 95% CI 1.97 to 5.88, $p < 0.0001$) [21].

4 | Valve Selection for ViV TAVI

So far, many devices have been widely used for ViV-TAVI. The most used ones are: (1) Edwards SAPIEN valve (Edwards Lifesciences Corporation, Irvine, CA, USA) is a balloon expandable valve and consists of a metal stent frame with bovine pericardial leaflets pressed onto a balloon catheter. The SAPIEN 3 valve is currently being used in the United States and is also currently available with expanded outer diameters of 20, 23, 26, and 29 mm and enables the treatment of failed bioprostheses in all positions; (2) Evolut system (Medtronic Inc, Minneapolis, MN, USA) consists of a self-expanding nitinol multilevel frame and porcine pericardial leaflets. These valves are available in external diameters of 23, 26, 29, and 34 mm; (3) the ACURATE neo2 valve (Boston Scientific, Marlborough, MA, USA) consists of a porcine pericardial tissue bioprosthesis stitched into a self-expanding Nitinol stent with supra-annular leaflet position. These valves are available in external diameters of 23, 25, and 27 mm [22]; (4) the Abbott Portico/Navitor System (Abbott Inc, Santa Monica, CA, USA) consists of a porcine bioprosthetic valve with intra-annular leaflet position in a self-expanding nitinol valve. These valves are available in external diameters of 23, 25, 27, 29, and 35 mm [23]. Devices by other manufacturers have been used for this intervention, but less often or in an off-label fashion [24].

The concept of "True ID": The selection of the appropriate THV size for a ViV-TAVI is determined by the ID of the surgical heart valve [5, 25, 26]. In most SHV, the stent ID may be reduced due to design factors. Before VIV intervention, it is crucial to determine the SHV design to account for this decrease while selecting the suitable THV [27]. The true ID of the porcine valve leaflets is usually 2 mm smaller than the stent ID, and they are always sutured inside the stent frame. Pericardial SHV with leaflets sutured inside the stent demonstrated a 1 mm difference between true ID and stent ID, with the pericardial leaflets having a lesser effect than the porcine leaflets. SHV involving the pericardial leaflets sutured external to the stent have similar stent ID and real ID.

Choosing the appropriate THV type requires careful and thorough deliberation. A direct comparison between the various transcatheter devices used in ViV operations is still lacking. For example, we will categorize the valves into supra-annular valves, defined by the presence of leaflets that are functionally

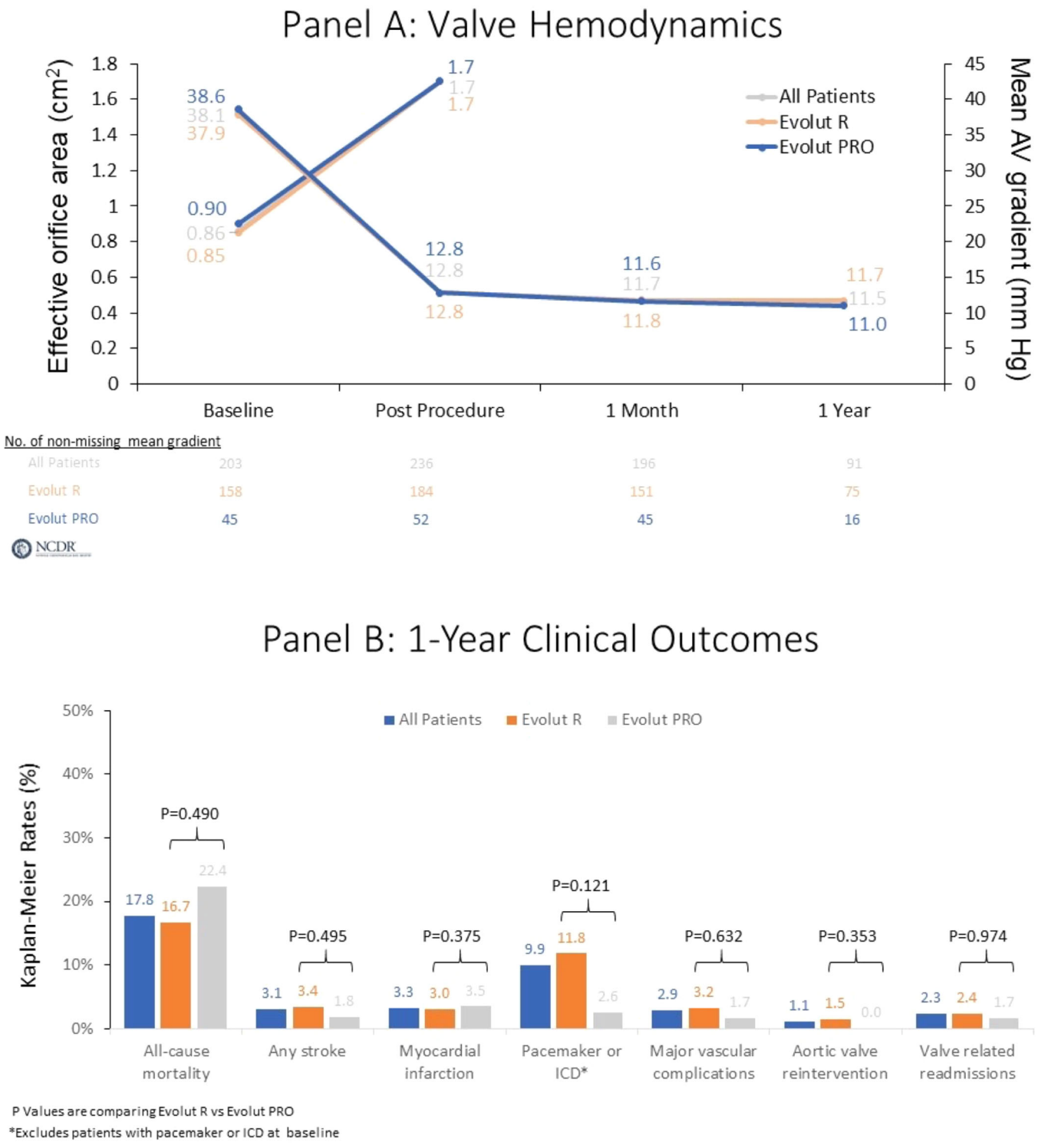


FIGURE 1 | Procedural and clinical outcomes for ViV-TAVI using self-expandable supra-annular valves Evolut R and Evolut PRO. (A) Valve hemodynamics variation after ViV-TAVI, showing a significant increase in effective orifice area and a significant reduction in the mean AV gradient for both valves. (B) Excellent 1-year clinical outcomes post-ViV-TAVI for both valves (MOD: Dallan et al. 15). AV = aortic valve, ICD = implantable cardioverter defibrillator. [Color figure can be viewed at wileyonlinelibrary.com]

positioned above the aortic annulus, and intra-annular valves, where leaflets are located inside the aortic annulus.

Which is the best device for ViV TAVI? As the VIV TAVI opportunity expands to younger patients with longer life expectancy, the challenge shifts to managing the lifelong strategy for patients with aortic stenosis, making the initial choice of intervention critical in shaping future therapeutic decisions. The selection of the device should be individualized, once all the bioprosthetic valves have their inherent pros and cons. For example, VIV TAVI using self-expandable supra-annular valves has better hemodynamic features and lower rated of PPM.

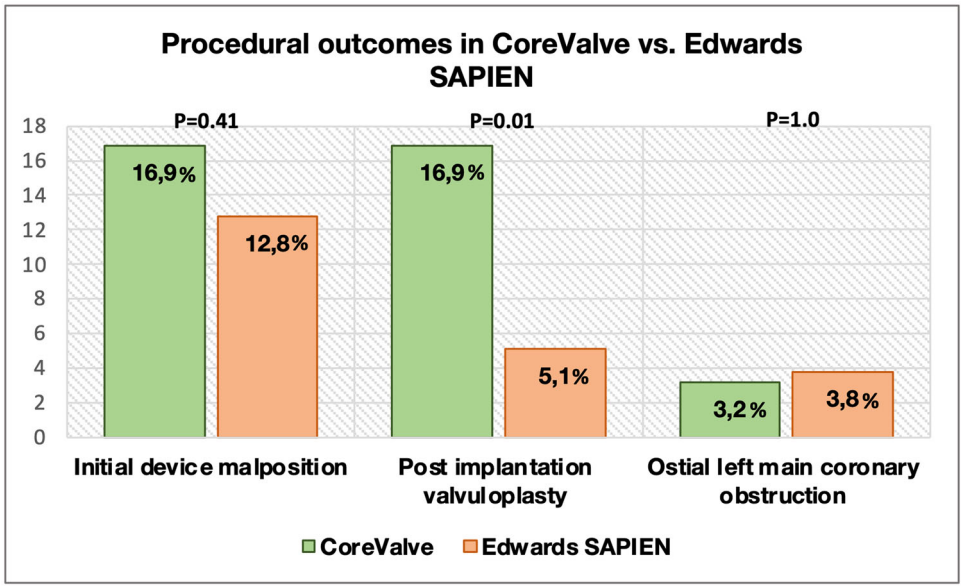


FIGURE 2 | A procedural comparison between CoreValve and Edwards SAPIEN (MOD = Dvir et al. [28]). [Color figure can be viewed at wileyonlinelibrary.com]

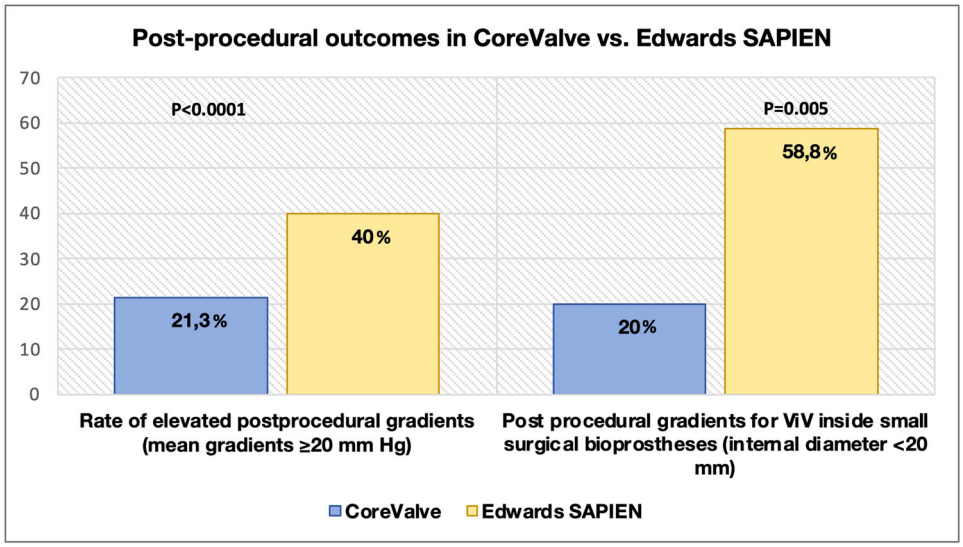


FIGURE 3 | A postprocedural comparison between CoreValve and Edwards SAPIEN (MOD = Dvir et al. [28]). ViV = valve in valve. [Color figure can be viewed at wileyonlinelibrary.com]

However, they might have also increased rates of need for permanent pacemaker implantation compared to balloon-expandable valves [28–30].

In the Global Valve-in-Valve Registry, a total of 202 patients (mean age 77.7 ± 10.4 years; 52.5% men) from 38 heart centers with degenerated bioprosthetic valves were included, of whom 124 were assigned to the CoreValve arm and 78 to the Edwards SAPIEN arm. Initial device malpositioning occurred in 31 cases (16.9% with CoreValve vs. 12.8% with SAPIEN; $p = 0.41$). In addition, the SAPIEN group underwent fewer post-implantation valvuloplasty procedures (5.1% vs. 16.9%; $p = 0.01$) than the CoreValve group (Figure 2). Edwards SAPIEN and CoreValve groups had comparable rates of left main ostial coronary obstruction (3.8% and 3.2%, respectively; $p = 1.0$). The rate of elevated postprocedural gradients (mean gradients ≥ 20 mmHg) was higher after Edwards SAPIEN than after CoreValve implantations (40% vs. 21.3%, respectively; $p < 0.0001$) (Figure 3). There was a significant difference in the rate of high postprocedural gradients (inside small surgical bioprostheses of ID < 20 mm) between the Edwards SAPIEN and the CoreValve groups for VIV procedures performed inside small surgical bioprostheses (ID < 20 mm): 58.8% versus 20%, respectively ($p = 0.005$) (Figure 3) [28]. However, there was no significant difference in 30 day mortality between the two groups (7.3% vs. 10.3%, $p = 0.45$) which was comparable to other TAVI cohorts [28, 29].

In two propensity-matched comparisons, the CoreValve device was found to have a larger effective orifice area (EOA) (1.67 vs. 1.31 cm^2; $p = 0.001$), lower mean gradients (14 ± 7.5 vs. 17 ± 7.5 mmHg; $p = 0.02$), a lower incidence of moderate to severe AR (4.2% vs. 13.7%; $p = 0.04$), and a lower mortality rate

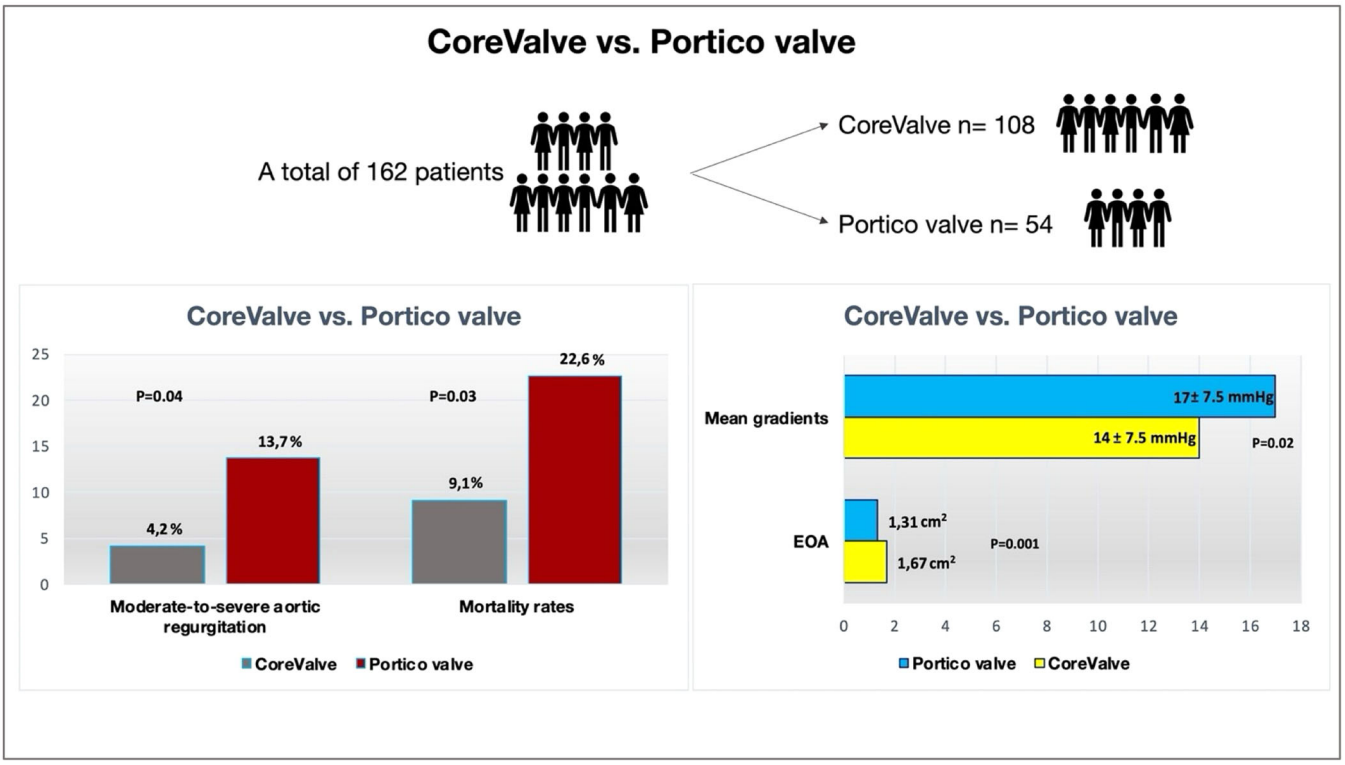


FIGURE 4 | A comparison between CoreValve and Portico valve (MOD: Alnasser et al. [31]). EOA = effective orifice area. [Color figure can be viewed at wileyonlinelibrary.com]

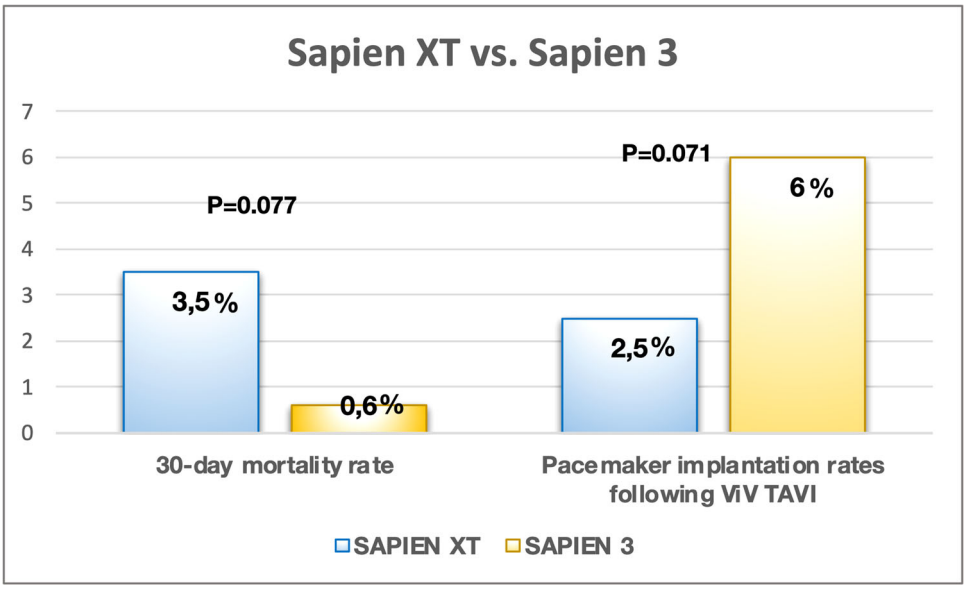


FIGURE 5 | A comparison between Sapien XT and Sapien 3 (MOD: Seiffert et al. [32]). ViV TAVI = valve-in-valve transcatheter aortic valve implantation. [Color figure can be viewed at wileyonlinelibrary.com]

(9.1% vs. 22.6%; $p = 0.03$) compared with the Portico valve [31] (Figure 4). In addition, when comparing patients receiving SAPIEN XT and SAPIEN 3 valves, the SAPIEN 3 group was found to have a lower 30-day mortality (0.6% vs. 3.5% $p = 0.077$) (Figure 5). However, it should be mentioned that patients who received the SAPIEN 3 valve, because of its distinct profile, had a higher likelihood of requiring pacemaker implantation (6% vs. 2.5%, $p = 0.07$) [17] (Figure 5). This finding may have been influenced by the longer device frame of SAPIEN 3, since it was shown that the rate of pacemaker is influenced by implantation depth. A cut-off of implantation deeper than 5 mm was found to be linked to an increased risk for pacemaker implantation (depth ≤ 5 mm 4% vs. depth > 5 mm 22.2%; $p = 0.01$) [32].

The "Valve-in-Valve" application, which was jointly created by UBQO, a technology enterprise, is clearly an essential tool for

the effective planning of the ViV TAVI procedures [33]. It helps in the preprocedural planning by providing detailed information on various bioprosthetic valves that have been implanted in patients previously. This includes dimensions, suggested THV sizes, and other technical specifications essential for selecting the appropriate valve for the valve-in-valve procedure.

VIV TAVI in small aortic annuli (SSA): VIV TAVI has been proven to be a successful treatment option for patients with SSA and those with small failing aortic bioprothesis. Studies have shown that VIV TAVI can greatly improve the prognosis, particularly for patients with small failing aortic bioprothesis, making it a valuable and effective treatment option in this setting.

A prospective multicenter randomized trial further compared hemodynamic and clinical outcomes between TAVI ($n = 77$) and SAVR ($n = 74$) in patients with a small aortic annulus. The incidence of severe PPM was not significantly different between the TAVI and SAVR groups (5.6% vs. 10.3%, $p = 0.30$), with no cases of moderate to severe AR in either group. Additionally, 30-day follow-up data showed similar mortality (1.3% TAVI vs. 1.4% SAVR, $p = 1.00$) and stroke rates (0% TAVI vs. 2.7% SAVR, $p = 0.24$). Over a 2-year follow-up, mortality, stroke, and cardiac hospitalization rates remained comparable (9.1% vs. 8.1%, $p = 0.89$ for mortality, 3.9% vs. 4.1%, $p = 0.95$ for stroke, and 19.5% vs. 20.3%, $p = 0.80$ for hospitalizations). These findings suggest TAVI and SAVR provide equivalent outcomes for severe aortic stenosis patients with SSA (mean diameter < 23 mm) in terms of valve function and major clinical outcomes [34].

In patients with small failing aortic bioprostheses, echocardiographic evaluation of valve hemodynamics revealed that ViV-TAVI with a self-expanding valve as compared to the balloon-expandable one exhibited lower mean and maximal transvalvular gradients (15 ± 8 vs. 23 ± 8 mmHg; $p < 0.001$; 28 ± 16 vs. 40 ± 13 mmHg, $p < 0.001$), and a tendency toward a lower rate of severe PPM (44% vs. 64%; $p = 0.07$). However, intraprocedural invasive hemodynamics and 30-day clinical outcomes showed no significant differences between the groups [35].

Despite these results, suboptimal expansion of the TH is not uncommon. To address this issue, bioprosthetic valve fracture (BVFr) techniques have been developed to optimize the expansion of the THV and reduce residual transvalvular gradients. This technique consists in using high-pressure inflation with a noncompliant balloon to either fracture or stretch the surgical valve ring, allowing for a better fit and improved outcomes for patients undergoing VIV TAVR [36].

5 | Risks of ViV Interventions

5.1 | Coronary Occlusion

With the increased number of implanted bioprosthesis, catheter-based VIV interventions have become a viable treatment option for patients. However, coronary obstruction is a potentially serious complication that occurs more frequently in aortic VIV cases than in transcatheter aortic valve replacement (TAVR) of a native valve. Externally mounted leaflet valves, like the Mitroflow (Sorin Group, Milano, Italy) and the Trifecta aortic valve (St. Jude Medical, St. Paul, MN, USA), may theoretically pose an increased risk of coronary artery obstruction [5, 37, 38]. The unique design features of these bioprosthesis include that their bovine pericardial leaflets are attached to the exterior of the valve stent and have a slightly higher stent profile and their ability to ensure a lower final gradient and reduce the risk of severe PPM [13, 39]. These features contribute to their excellent hemodynamic with low transvalvular gradient which is beneficial in smaller anatomical structures. However, due to their wider and longer stance, they may be more susceptible to coronary compromise at the time of VIV-TAVI. Therefore, stented bioprosthesis with externally mounted leaflets or stentless bioprosthesis valves pose the highest risk for coronary obstruction compared to in-stented bioprosthesis with internally mounted leaflets in ViV procedures (6.1% vs. 3.7% vs. 0.8%, respectively, in the VIVID study; $p < 0.001$). Furthermore, coronary occlusion was associated with a higher mortality rate at 30-day follow-up (52.9% vs. 3.9%; $p < 0.001$) [39].

Based on preprocedural multi-detector computed tomography (MDCT), the VIVID registry suggested a simpler categorization to evaluate the risk of coronary obstruction during ViV-TAVI.

- Type II: The failed bioprosthetic leaflets extend from the coronary ostium to the STJ. The Type II anatomy was categorized into type IIA (valve to coronary ostium distance [VTC] ≥ 4 mm) or type IIB (VTC < 4 mm) depending on the VTC distance.
- Type III: The malfunctioning bioprosthetic leaflets protrude beyond the STJ level. Type III anatomy was subdivided into type IIIA (VTC ≥ 4 mm and VTSTJ ≥ 3.5 mm), type IIIB (VTC < 4 mm), and type IIIC (VTC ≥ 4 mm but VTSTJ < 3.5 mm) according to VTC and VTSTJ distances.
- Type I: The failed bioprosthetic leaflets protrude beneath the level of the coronary ostia plane.

High-risk anatomies prone to coronary obstruction, such as Types IIB, IIIB, and IIIC, may benefit from utilizing the BASILICA procedure to lower the risk.

However, more refined techniques are needed to estimate the risk of coronary obstruction, especially for patients with stentless valves [29]. The virtual transcatheter VTC in the VIV-TAVI method is another crucial factor in predicting coronary occlusion. Patients who have undergone SAVR frequently experience a reduction in coronary height due to the placement of surgical bioprostheses in a supra-annular orientation. By superimposing THV implantation simulation onto CT data, the "virtual ring to coronary ostial distance" can be quantified by a reviewer [40]. Thus, coronary occlusion can be predicted by a shorter VTC distance, with an ideal cut-off level of 4 mm [41]. Rarely, delayed coronary blockage occurs, which is more common in ViV-TAVI after self-expanding valve implantation. Endothelialization of natural or surgical bioprosthetic leaflets or thrombus embolization in the TAVI valve or sinus of Valsalva may lead to late obstruction [42]. Furthermore, a low sinotubular distance may lead to coronary sequestration when the SAV leaflets are open. This risk can be anticipated with adequate CT planning.

TABLE 1 | Potential complications of VIV-TAVI procedure [41–46].

Potential complications of VIV-TAVI	Prevention of complications
Coronary artery occlusion	• Careful assessment of multi-detector computed tomography • Measure of virtual transcatheter valve to coronary ostium distance • Superimposure of THV implantation simulation onto CT data • Performance of some procedural techniques: ○ Intentional implantation of a smaller diameter THV ○ lower depth THV implantation within the bioprosthesis ○ valves that directly engage with bioprosthetic valve leaflets • BASILICA procedure • Coronary wire protection • Chimney/snorkel stent technique
Cerebral embolization	Using cerebral protection during ViV TAVI operations, and particularly when using BASILICA-assisted ViV-TAVI
Elevated postprocedural gradients	• Supra-annular valve and high THV device • Pursuing a bioprosthetic valve ring fracture with high-pressure balloon valvuloplasty inflation • Inducing high implantation depth within the falling bioprosthesis • Performing BVFr after VIV TAVI

Abbreviations: BASILICA = bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction during TAVI, BVFr = bioprosthetic valve fracture, CT = computerized tomography, THV = transcatheter heart valve, ViV-TAVI = valve-in-valve transcatheter aortic valve implantation.

Some procedural approaches might be taken into account to reduce the risk of coronary obstruction (Table 1). The intentional implantation of a smaller diameter THV or underfilling and hence under expansion of a balloon expandable THV decreases lateral displacement of surgical valve leaflets. In comparison to a high-depth implantation, a low-depth THV implantation within the bioprosthesis causes less outward displacement of the surgical valve posts and leaflets [47, 48].

Valve leaflet displacement can range from mild to severe depending on the THV utilized for ViV-TAVI. In situations where there is a high risk of coronary occlusion, valves that directly engage with bioprosthetic valve leaflets (intra-annular valves) may provide an advantage [41].

The optimal coronary alignment occurs when one of the neocommissures is positioned at the bisector angle between the coronary artery ostia. The positioning for implanting a bioprosthesis post can be determined in the preprocedural computed tomography angiogram (CTA) by aligning both coronary ostia on the right side of the image with the C-arm projection, ensuring that only one post is placed and avoiding overlap with the two posts on the left side, regardless of coronary anatomy. This reduces the risk of moderate-to-severe CO significantly, from 32% to 5% [49].

5.1.1 | Strategies to Prevent Coronary Artery Obstruction After TAVI

5.1.1.1 | Coronary Wire Protection. This is the simplest protection technique in the high-risk TAVR setting and one of the first reported protection strategies. This technique involves passing a 0.014-inch coronary guidewire through the aortic valve and inserting it through a guide catheter into one or both arteries. Depending on the surgeon's preference, an angioplasty balloon with a diameter of 2.5 to 3.5 mm is then advanced over the coronary wire to prepare for potential expansion in the event of sudden obstruction. If acute CO occurs, the coronary wire can be used for ostial angioplasty with a balloon or for implanting a stent to restore coronary blood flow [50, 51].

5.1.1.2 | BASILICA Technique. The BASILICA (bioprosthetic or native aortic scallop) technique aims at reducing the risk of coronary artery occlusion during TAVI [43]. The main objective of the BASILICA procedure is to carefully create a controlled split in the native or bioprosthetic leaflets to prevent critical coronary obstruction using catheter electrosurgery. Thus, BASILICA directly addresses the pathophysiology of coronary artery obstruction by lacerating the leaflet in front of a threatened coronary artery. During this procedure, an electrified wire is positioned near the leaflet, and radiofrequency energy is used to intentionally slice through the leaflet of the bioprosthetic valve [39]. This strategic laceration and subsequent formation of the triangle of flow are critical for ensuring that blood can freely flow toward the sinus of Valsalva and from there into the coronary artery [52]. To determine whether the BASILICA procedure is necessary, the anatomical classification of the aortic root and valve leaflet location results in the identification of three patient types:

- Type I, with valve leaflets below the coronary ostium;
- Type II, with leaflets above the ostium in the presence of wide (IIA) or effaced sinuses (IIb);

- Type III, with leaflets above or very close to the sinotubular junction (STJ) with wide STJ/sinuses (IIIA), narrow STJ (IIIC), and effaced sinuses (IIIB). Based on this methodology, if the VTC is less than 4 mm, as it is in Types IIB, IIIB, and IIIC, the BASILICA technique should be taken into consideration [53].

Kitamura et al. demonstrated the feasibility, efficacy, and relative safety of the BASILICA technique in patients at high risk of coronary occlusion. BASILICA was feasible in 95% of the cases studied and resulted in effective coronary occlusion prevention in 90% of them. Complication rates were low, with no major vascular complications, mechanical circulatory support, stroke, or death reported after 30 days [54].

A prospective, multicenter, single-arm BASILICA trial with 30 participants assessed the safety and feasibility of BASILICA in both failed native (43%) and bioprosthetic valves (57%). The primary endpoints of procedure success and early safety were achieved in 93% and 70% of subjects, respectively. Leaflet traversal and laceration were successful in 35 out of 37 (95%) attempted leaflets. There were no cases of coronary obstruction, and no cases requiring additional reintervention or surgery [55]. Similarly, according to the recently published results of the BASILICA trial, the 30-day success rate after 1 year of follow-up was 93.3%, with a stroke rate of 10% and one death. There were no further strokes, myocardial infarctions, or deaths between 30 days and a year. Furthermore, none of the patients required additional surgery for the aortic valve or coronary disease [56].

5.1.1.3 | Chimney/Snorkel Stent Technique. The chimney stent method involves inserting a coronary guidewire with an undeployed stent in one or both coronary arteries. The stent is implanted if CO happens, extending above the coronary ostium like a "chimney" or a "snorkel." Initially utilized by Chakravarty et al. [57], this approach was first employed for the management of acute coronary occlusion of the left main artery in a patient with a degenerative bioresorbable scaffold. Numerous case studies have demonstrated its efficacy and safety [58].

5.2 | Cerebral Embolization

The discovery of brain lesions is common in diffusion-weighted magnetic resonance imaging (DW-MRI) scans taken after native valve TAVI. In the high-risk subgroup of patients in the PARTNER trial, the rate of major stroke was 3.8% in the native valve TAVI group and 2.1% in the surgical valve replacement group at 30 days ($p = 0.20$) and 5.1% and 2.4%, respectively, at 1 year ($p = 0.07$) [59].

However, the ViV-TAVI procedure showed a lower incidence of DW-MRI brain lesions 3−5 days after the procedure (51.2% vs. 73.2%, $p = 0.005$) and a lower number of brain lesions (1.0 ± 1.4 vs. 2.8 ± 3.2, $p < 0.001$) as compared to TAVI for native valve stenosis; this may be explained by the younger age of the patients (mean 82.3 vs. 74.7 years, $p < 0.001$) and the lower rate of post dilatation (7% vs. 17%, $p = 0.110$) (Figure 6) [60]. The incidence of procedural major stroke was 1.7%, according to the VIVID registry [61].

The TAVI procedure carries inherent risks of cerebral embolism and bleeding. Despite efforts to reduce thrombotic complications from TAVI, concerns about issues such as valve thrombosis and cerebral ischemic events persist. The mechanisms underlying TAVI-associated thrombosis are likely multifactorial. Several possible factors that may explain the thrombotic risk associated with TAVI have been suggested. These include: (1) disruptions in flow associated with the implantation of prosthetic valves, (2) the introduction of a metallic prothrombotic frame, and (3) coexisting prothrombotic tendencies in an elderly comorbidity population [62].

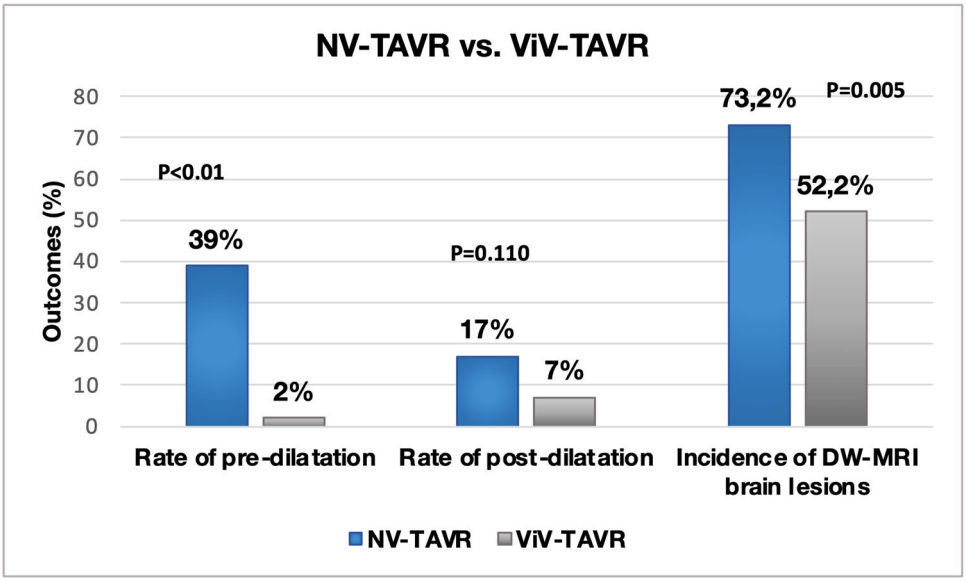


FIGURE 6 | Pre- and postprocedural outcomes, particularly risk of symptomatic or asymptomatic cerebral emboli: a comparison between NV-TAVI versus ViV-TAVI procedures (MOD = Eitan et al. [60]). Both pre- and post-dilatations were performed in all the patients. DW-MRI = diffusion-weighted magnetic resonance imaging, NV-TAVI = native valve transcatheter aortic valve implantation, ViV-TAVI = valve-in-valve transcatheter aortic valve implantation. [Color figure can be viewed at wileyonlinelibrary.com]

Recent evidence indicates that hemodynamic impairments occurring at the valve implantation site play a crucial role in thrombus formation. Clinical data suggest that most thrombi formed around TAVI occur on the aortic side of the implanted valve, between the valve leaflets and the stent. This is important because the placement of stents and bioprostheses displaces the native valve, creating a so-called neosinus and a smaller native sinus [62, 63].

Using cerebral protection during ViV TAVI operations, and particularly when using BASILICA assisted ViV-TAVI, may be prudent due to the potentially increased risk of embolic stroke or debris [44] (Table 1).

A recent cohort study aimed at comparing patients who received VIV-TAVR ($n = 198$) and those who underwent native valve TAVR ($n = 3.334$), from 2013 to 2022. The VIV-TAVR group experienced greater major vascular complications (2.5% vs. 0.8%, $p = 0.008$) but fewer permanent pacemaker placements (2.5% vs. 8.1%, $p = 0.004$). Both groups had a comparable stroke rate (VIV-TAVR 2.5% vs. native TAVR 2.4%, $p = 0.911$). Thirty-day readmission rates (VIV-TAVR 7.1% vs. native TAVR 9%, $p = 0.348$), in-hospital mortality (VIV-TAVR 2% vs. native TAVR 1.4%, $p = 0.46$), and total mortality (VIV-TAVR 26.3% vs. native TAVR 30.8%, $p = 0.18$) were similar in both groups during a median follow-up of 1.8 years. Furthermore, the survival rates were comparable between the two groups ($p = 0.27$) [64] (Figure 7).

5.3 | Elevated Postprocedural Gradients

In the STS/ACC TVT and VIVID registries, the ViV TAVI procedure was an important predictor of PPM. At 1 year, there was an increased risk of death and HF rehospitalization linked with severe but not with moderate prosthesis-patient mismatch following TAVI [61, 65]. A large study that included only ViV-TAVI patients showed that severe postprocedural PPM occurred in a quarter of procedures but was not associated with 1-year mortality [66]. According to the Valve Academic Research Consortium-VARC-3-specified outcomes, stentless bioprostheses and stented bioprosthetic valves both resulted in identical short-term results and similar death rates up to 5 years of follow-up after ViV-TAVI [67]. Different steps can be taken to lower the risk of having a high gradient after surgery. For example, a supra-annular valve and a high THV implant can be opted to reduce this risk (Table 1). Another method to improve hemodynamic outcomes for patients with small failing bioprosthetic valves is to pursue BVFr with high-pressure balloon inflation [45].

High implantation depth within the failing bioprosthesis has been shown to be an independent predictor of lower postprocedural gradients in both self- and balloon-expandable transcatheter valves in a study of 292 consecutive patients. This study found that the ideal implantation depth for the CoreValve Evolut was between 0 and 5 mm, whereas for the Sapien XT, it was between 0 and 2 mm (0%–10% of the frame height) [68]. Distinct types of SAVs exhibit different fracture thresholds dependent on elements of their construc-

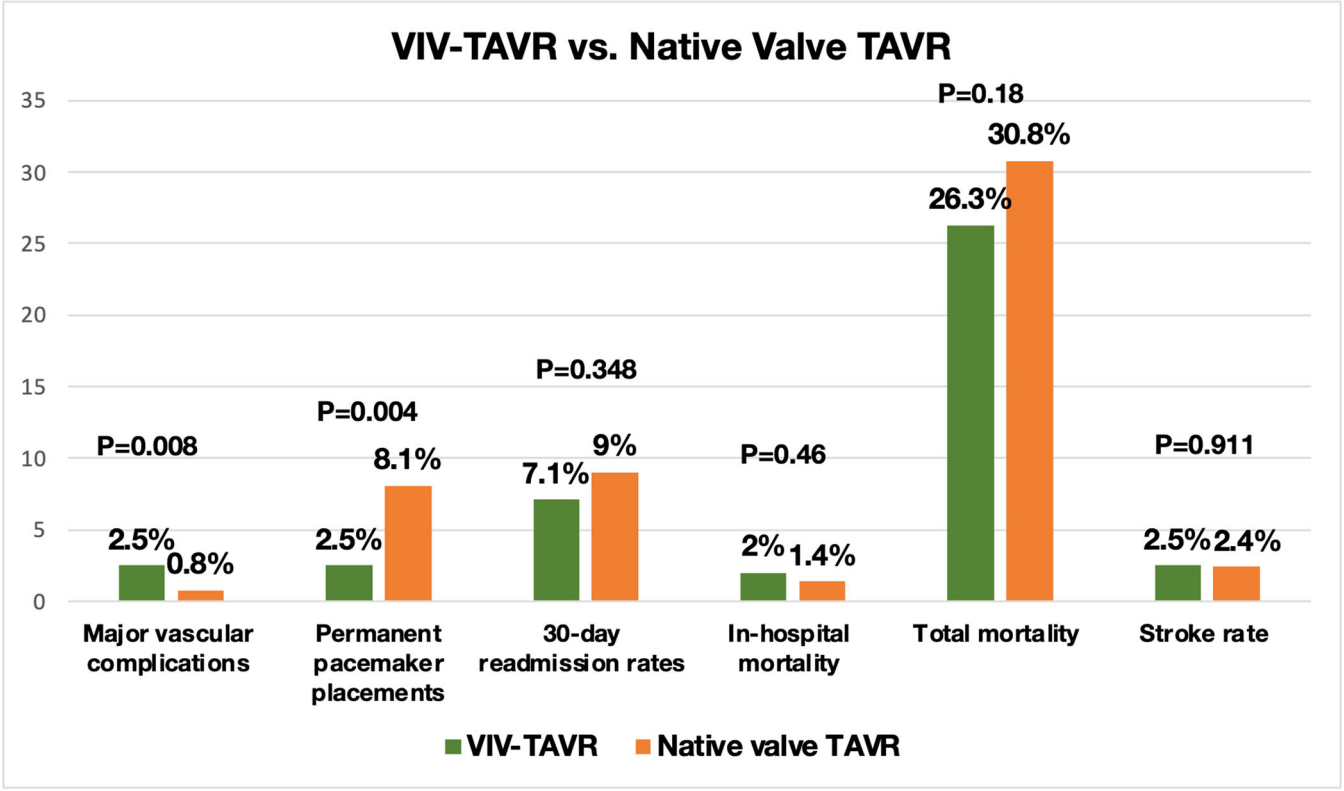


FIGURE 7 | Clinical outcomes of patients receiving VIV TAVI compared to native valve TAVI (MOD = Ahmad et al. [64]). ViV-TAVI = valve-in-valve transcatheter aortic valve implantation. [Color figure can be viewed at wileyonlinelibrary.com]

tion, leading to slightly different inflation pressure requirements before the valve ring fractures. In particular, the fracture threshold (18–24 atm) is greater in SHV with a metal ribbon ring (i.e., Magna and Magna Ease) than in SHV with a polymer ring (i.e., Biocor Epic, Mosaic, Mitroflow; 8–12 atm) [46].

6 | BVFr During VIV TAVI

It is crucial to exercise careful consideration while selecting the appropriate dimensions and positioning of the balloon during VIV TAVI. Currently, the indications for performing BVFr to facilitate VIV TAVI are not fully defined. Patients who are predisposed to PPM and high residual transvalvular gradients after VIV TAVI, including those with small BPV (labeled valve size ≤ 21 mm) and/or stenosis as a consequence of BPV failure, are most likely to benefit from BVFr [61, 69].

Similar to VIV TAVI, one of the main concerns with BVFr is the possibility of coronary artery occlusion. The most important factor in VIV TAVI is the expected distance between the coronary ostia and the final position of the BPV leaflets. Preprocedural coronary angiography, computed tomography, and "virtual THV" superimposed on CT images can be used to assess the relationship between the coronary arteries and the BPV sheets. A patient can be considered to be at high risk for coronary occlusion if their THV virtual coronary distance is less than 4 mm [70].

A recent study evaluated the safety and effectiveness of VIV TAVI using SAPIEN 3 and SAPIEN 3 Ultra valves with or without BVFr. A total of 2975 patients were included, of whom 619 (21%) received BVFr before implantation. After adjustment for the variables, BVFr was associated with a modest reduction in echocardiographic final mean gradient (16.3 vs. 19.2 mmHg, $p < 0.01$) but higher in-hospital all-cause mortality (2.26% vs. 0.91%, $p < 0.01$) and life-threatening bleedings (3.39% vs. 1.36%, $p < 0.01$) in comparison to VIV TAVI without BVFr [71] (Figure 8).

It is important to correctly identify the surgical valve and assess if it can be fractured or remodeled when planning BVFr. Aortic surgical valves prone to fracturing, along with their fracture thresholds, consist of the Magna (22–24 atm, Edwards Lifesciences), Magna Ease (18 atm, Edwards Lifesciences), Perimount 2800 (20 atm, Edwards Lifesciences), Mitroflow (12 atm, Sorin Group), Mosaic (10 atm, Medtronic), and Biocor Epic (8 atm, Abbott) [36]. Valves that can be adjusted or expanded during surgery, without fracturing, are Trifecta (Abbott), Carpentier-Edwards standard and supra-annular (Edwards Lifesciences), Inspiris (Edwards Lifesciences), and Perimount 2700 (Edwards Lifesciences) [72]. The Hancock II (Medtronic) and Avalus (Medtronic) surgical valves are examples of surgical valves that cannot be fractured or remodeled [36].

Differences in fracture thresholds of surgical valves are determined by the material used in the surgical valve frame. For instance, the Mosaic valve has been recently produced with two different frame materials, resulting in varying behaviors during BVFr. During the first bench test, the Mosaic valve frame was constructed using Delrin (acetal homopolymer resin), prone to fracturing at around 10–12 atm. Polyetheretherketone (PEEK) in Medtronic's Avalus valve shows resistance to fractures when used in large amounts. However, the smaller amount of material used in the Mosaic valve prevents it from breaking while

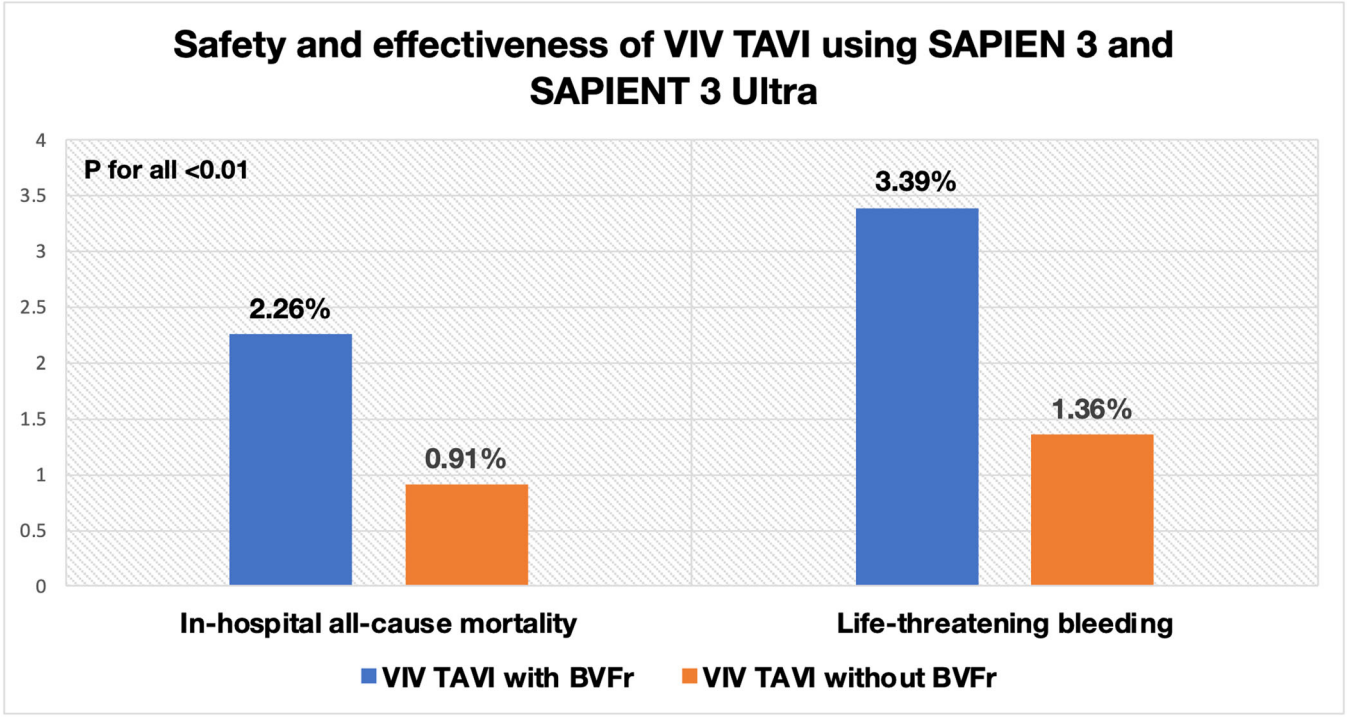


FIGURE 8 | Safety and effectiveness of VIV TAVI using SAPIEN 3 and SAPIEN 3 Ultra valves with or without BVFr (MOD = Chhatriwalla et al. [71]). BVF = bioprosthetic valve fracture, ViV-TAVI = valve-in-valve transcatheter aortic valve implantation. [Color figure can be viewed at wileyonlinelibrary.com]

allowing it to be stretched. Therefore, if the BVFr is being performed on a Mosaic valve and the pressure reaches around 10–12 atm without any issues, it may indicate that the frame is constructed from PEEK material [36].

6.1 | BVFr Timing and Safety Results

BVFr performance was analyzed based on the time when it was performed (before or after VIV TAVI vs. no fracture). In case of BVFr performed before TAVI versus no fracture, in-hospital all-cause mortality (OR: 2.9; 95% CI: 1.21–6.94), cardiac death (OR: 3.42; 95% CI: 1.25–9.37), new onset of atrial fibrillation (OR: 3.84; 95% CI: 1.07–13.83), and major vascular complications (OR: 4.09; 95% CI: 1.37–12.20) were higher. In contrast, in case BVFr was performed after TAVI versus no BVF, in-hospital all-cause mortality (OR: 2.1; 95% CI: 0.8–5.1), cardiac death (OR: 1.91; 95% CI: 0.68–5.40), new-onset atrial fibrillation (OR: 1.73; 95% CI: 0.55–5.39), and major vascular complications (OR: 1.29; 95% CI: 0.48–3.53) were not significantly different [71]. This analysis, based on the timing of BVFr (before vs. after VIV TAVI), suggests that performing BVFr after VIV TAVI can be associated with improved hemodynamics maintaining similar clinical outcome [71].

6.2 | ViV TAVI Procedure—A Stepwise Approach

The first step in the VIV-TAVI procedure is to identify the failing surgical valve. This takes into account whether the valve is provided with or without a stent, as well as the orientation of the valve leaflets, regardless of whether they are placed internally or externally. It is also crucial to determine the precise ID and dimensions of the valve. Preprocedural imaging, particularly computed tomography scans, plays a critical role in accurately measuring valve size, assessing its position in relation to the coronary arteries, determining the height of the coronary arteries, the VTC, and assessing the presence and extent of calcifications. Following this step, the choice of THV is made, along with deciding on coronary access. Next step is to plan any additional necessary procedures including brain protection, coronary protection, and the BASILICA procedure as needed [24]. While routine pre-dilatation is not indicated in all ViV procedures, it may be performed in situations where there is extensive calcification to prevent under-expansion of self-expanding valves. Patient-specific commissural alignment of the THV is crucial for optimizing the valve's function and reducing the risk of complications. Commonly, post-dilatation is carried out to enhance the hemodynamic performance [24, 73] (Figure 9).

In ViV-TAVI, the reference point for valve implantation changes from the annular plane to the fluoroscopic landmarks of the pre-existing surgical aortic bioprosthesis. The presence of a radiopaque ring located at the inflow portion of the surgical aortic bioprosthesis is advantageous as it provides a reference point. However, the situation becomes more challenging with stentless valves or those without any radiopaque markers [24].

The UNICORN (Undermining Iatrogenic Coronary Obstruction with Radiofrequency Needle) procedure represents an innovative

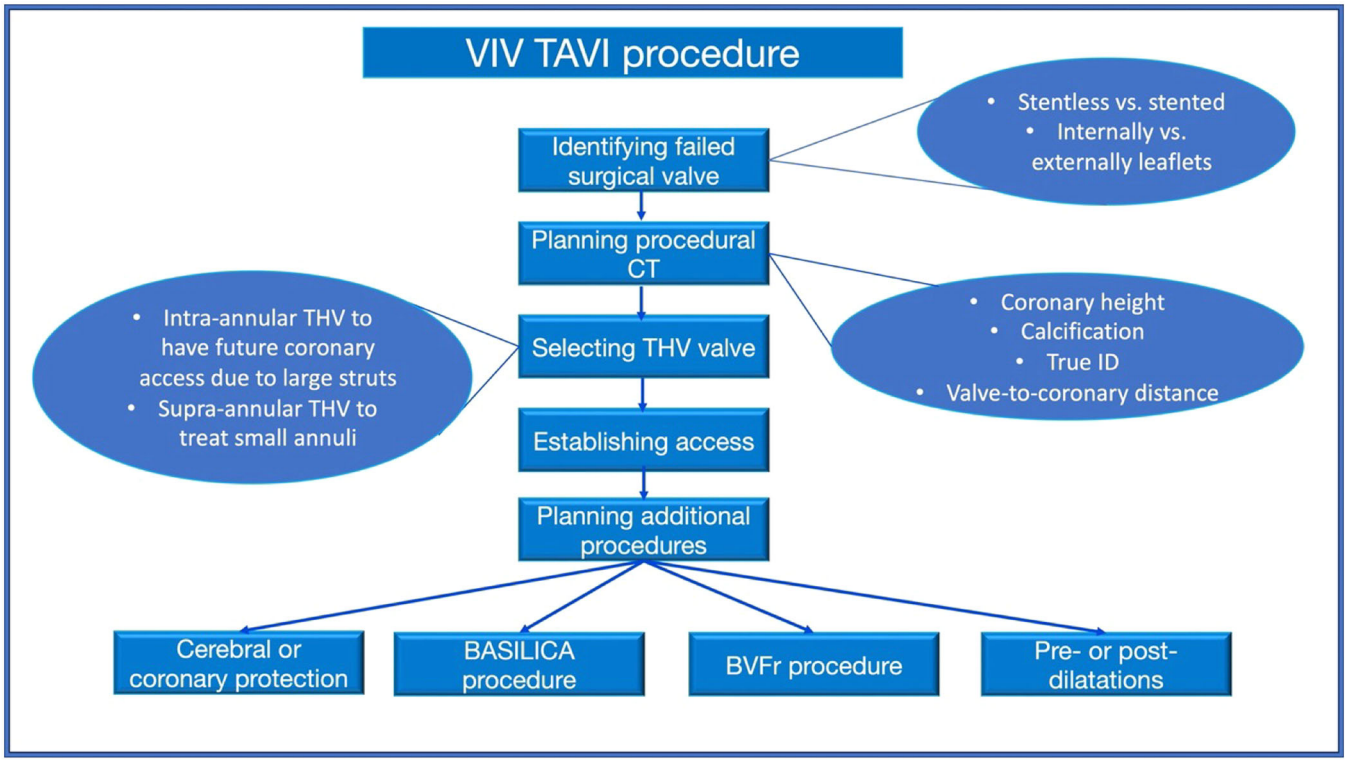


FIGURE 9 | Summary of VIV TAVI procedure (MOD = Vanhaverbeke et al. [24], Bieliauskas et al. [73]). BASILICA = bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction during TAVI, BVFr = bioprosthetic valve fracture, ID = internal diameter, THV = transcatheter heart valve, VIV-TAVI = valve-in-valve transcatheter aortic valve implantation. [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 2 | Ongoing clinical trials on VIV-TAVI.

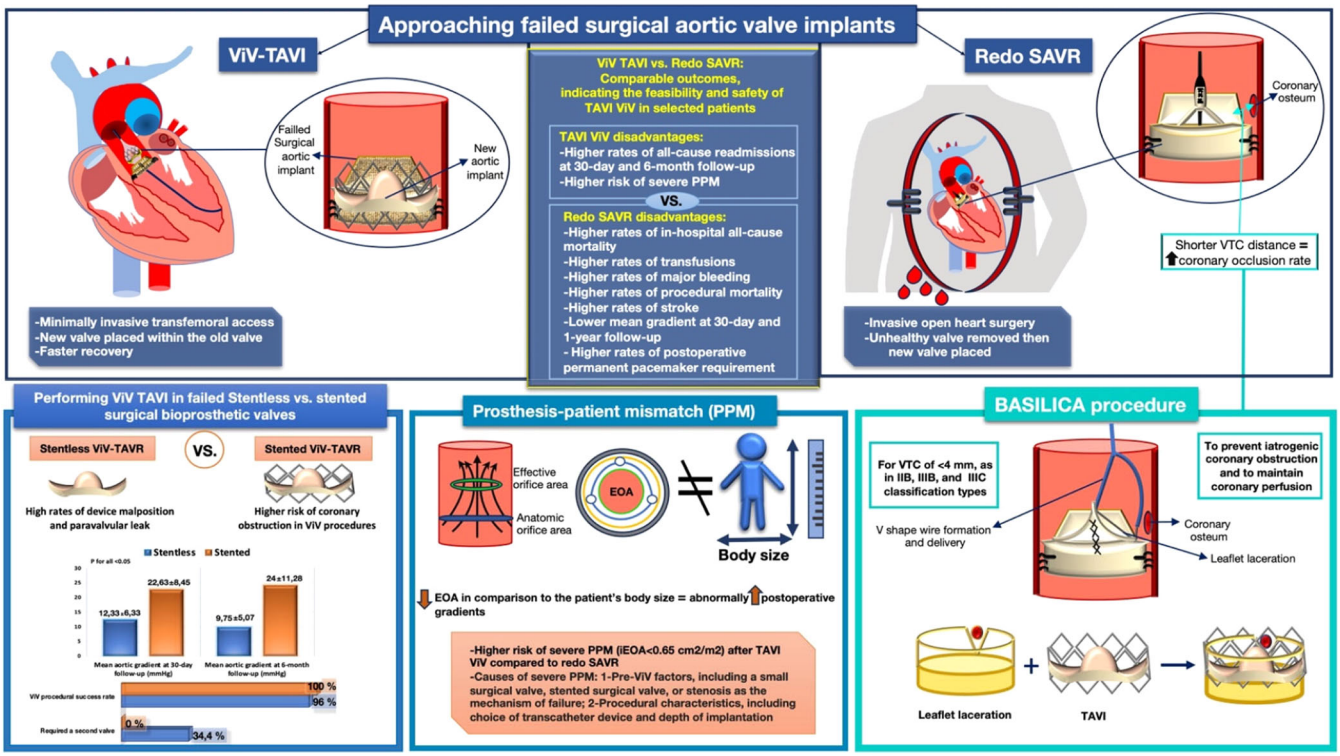
Identifier	Status	Study title	Study design	Arms	Population	Inclusion criteria	Exclusion criteria	Primary outcome	Secondary outcomes
NCT05093764	Recruiting	Quantification of debris captured using transcatheter cerebral embolic protection (TCEP) during valve in valve transcatheter aortic valve replacement (VIV TAVI) with bioprosthetic valvular fracture (BVFr)	Prospective, single-center, single-arm, unblinded pilot trial	VIV TAVI with BVFr using TCEP	20	-Men and Women ≥ 18 years of age -Severe bioprosthetic aortic valve degeneration -Presence of a bioprosthetic valve that can be fractured with high-pressure balloon inflation -High mortality risk following surgical aortic valve replacement	-Low or moderate mortality risk of surgical aortic valve replacement -Presence of ioprosthetic valves that cannot be fractured with standard noncompliant valvuloplasty balloons -Significant carotid artery stenosis -Right subclavian/ brachiocephalic artery stenosis -Prohibitive aortic arch anomalies for SENTINEL device implantation -Presence of right arm/forearm dialysis fistula or graft -History of cerebrovascular event (CVA) within 6 months	-Amount of debris captured by the SENTINEL TCEP device in VIV TAVI with BVFr -Complication rate: In-hospital stroke, device embolization rate, procedure-related major bleeding	-Death from all causes -Major adverse cardiac and cerebrovascular events
NCT05459233	Recruiting	Valve hemodynamic optimization based on Doppler-echocardiography versus catheterization measurements following valve-in-valve TAVI: A	Prospective, multicenter, randomized, single-blinded design trial	SAPIEN 3 Ultra VIV TAVI in	310	-Surgical aortic bioprosthetic valve failure -Surgical stented bioprosthetic valve (label size ≤ 25 mm)	-Stentless or sutureless surgical valves -Trifecta bioprosthesis -Hancock II bioprosthesis	-Changes in quality of life (Efficacy) -Periprocedural complications including in-hospital mortality, stroke, annular rupture, coronary	-Residual (maximal and mean) transvalvular gradient -Moderate or severe prosthesis-patient mismatch and/or

(Continues)

TABLE 2 | (Continued)

Identifier	Status	Study title	Study design	Arms	Population	Inclusion criteria	Exclusion criteria	Primary outcome	Secondary outcomes
		prospective randomized trial				-TAVI with the SAPIEN 3 Ultra valve	-High risk of coronary obstruction	obstruction, new-onset left bundle branch block, need for permanent pacemaker implantation, and conversion to open heart surgery	moderate or severe aortic regurgitation -Heart failure -Exercise capacity -Changes in quality of life -Death, stroke, major lifethreatening bleeding, pacemaker implantation, myocardial infarction -Need for rehospitalization -Wear and tear deterioration -Leaflet disruption -leaflet fibrosis and/or calcification -Strut fracture or deformation -Valve reintervention

Abbreviations: BVFr = bioprosthetic valve fracture, ViV-TAVI = valve-in-valve transcatheter aortic valve implantation.



CENTRAL FIGURE 1 | A snapshot of the entire manuscript demonstrating the feasibility and safety of TAVI ViV in comparison to redo SAVR in failed stentless and stented surgical aortic valve implants, along with the visual demonstration of the PPM and Basilica procedure. (MOD: Majmundar et al. [19]; Choi et al. [14]; Yousef et al. [20]; Al-Abcha et al. [21]; Khan et al. [43]; Tang et al. [53]; Sa et al. [77]; Bleiziffer et al. [66]). BASILICA = bioprosthetic or native aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction during TAVI, EOA = effective orifice area, SAVR = surgical aortic valve replacement, ViV-TAVI = valve-in-valve transcatheter aortic valve implantation, VTC = valve to coronary ostium distance. [Color figure can be viewed at wileyonlinelibrary.com]

intervention designed to alleviate the risk of coronary artery obstruction during TAVR procedures, particularly in valve-in-valve scenarios. This technique utilizes a radiofrequency needle to induce controlled laceration of the pre-existing valve leaflet, thereby preventing obstruction of the coronary ostia upon the deployment of a new valve. The first successful application of the UNICORN procedure was reported by a clinical team in Hong Kong, performed on a high-risk patient [74]. Initially, the UNICORN technique was limited to balloon-expandable valves due to their superior radial strength, which facilitated the effective laceration of the valve leaflet. However, more recent developments have demonstrated the feasibility of employing self-expanding valves in conjunction with the UNICORN procedure [75].

The LLAMACORN (Leaflet Laceration with Balloon Mediated Annihilation to Prevent Coronary Obstruction with Radiofrequency Needle) technique is an advanced iteration designed to further enhance the efficacy and safety of TAVR, particularly in high-risk contexts such as valve-in-valve procedures. This method involves the precise laceration of the aortic valve leaflets using a radiofrequency needle, followed by sequential balloon-mediated perforation to mitigate the risk of coronary artery obstruction. Preliminary clinical data from a case series involving five high-risk patients indicate favorable outcomes, with no instances of coronary obstruction or significant procedural complications during follow-up [76, 77]. LLAMACORN expands on the foundational concepts established by earlier techniques, such as BASILICA and UNICORN, by facilitating the use of self-expanding valves while addressing critical limitations, including leaflet overhang and the requisite radial force for effective laceration. While these initial results are promising, further rigorous investigation is necessary to confirm the broader applicability and long-term safety of the LLAMACORN technique (Table 2).

7 | Conclusions

ViV TAVI is a safe and effective treatment for failed surgical bioprostheses, particularly in high-risk patients. Nevertheless, this intervention remains technically demanding, requiring careful planning, experienced operators, possibly at high-volume centers, to reduce complications and ensure optimal hemodynamics persisting for years. Device selection should be individualized, as each valve type has distinct advantages and limitations. Techniques such as BASILICA and valve fracture may further enhance safety and outcomes. As ViV TAVI extends to younger patients with longer life expectancy, long-term management becomes crucial, making the initial choice of intervention pivotal for future therapeutic planning (Central Figure 1).

Conflicts of Interest

Dr. Guilherme F. Attizzani is a consultant for Medtronic. The other authors declare no conflicts of interest.

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