Transcatheter aortic valve implantation for failed surgical and transcatheter prostheses. Expert opinion of the Association of Percutaneous Cardiovascular Interventions of the Polish Cardiac Society

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ABSTRACT

Over 15 years of clinical experience and multiple large-scale observational studies followed by guidelines show good safety and efficacy of valve-in-valve transcatheter aortic valve implantation TAVI (ViV-TAVI), which reduces the need for re-do surgical aortic valve replacement (SAVR) in high-risk patients. The number of procedures in Poland, estimated as ca. 2% of all TAVIs in 2020, is expected to rise. This article aims to review specific challenges of the ViV-TAVI procedure including proper pre-procedural planning to achieve best possible hemodynamic results and mitigate coronary occlusion risk. It also provides a preliminary review and guidelines on repeat TAVI (re-do TAVI) in patients presenting with a failed transcatheter aortic bioprosthesis.

Key words: aortic bioprosthesis, coronary occlusion, degeneration, valve-in-valve

INTRODUCTION AND ViV-TAVI EXPERIENCE IN POLAND

Transcatheter aortic valve implantation (TAVI) in native severe aortic stenosis (AS) is currently considered as standard treatment for patients older than 75 years of age [1, 2]. Nevertheless, surgical aortic valve replacement (SAVR) is the standard method of treatment especially in low-risk, younger populations and accounts for as many as >20% of all heart surgery procedures in Poland [3]. Interestingly, with SAVR, diseased valves are more often replaced by bioprostheses rather than mechanical prostheses. To that end, considering the young age at the index procedure coupled with increasing lifespan, one can predict a growing need for re-intervention in the future due to expected bioprosthetic failure (mainly structural valve deterioration). Alongside TAVI in native aortic stenosis, first transcatheter valve-in-valve TAVI (ViV-TAVI) procedures were introduced and showed to be a feasible alternative to re-do surgery in symptomatic patients [4]. Most of the available data concerning ViV-TAVI safety, efficacy, and specific underlying issues come from the largest international VIVID registry (Valve in Valve International Data) [5]. Information acquired in VIVID demonstrated 95% technical success while systematic reviews showed at least non-inferiority in survival with fewer bleeding and stroke complications or the need for a pacemaker or dialysis after ViV-TAVI as compared to re-do surgery. These results secured a viable IIA indication class for inoperable or high-risk patients with failed surgical aortic valves (SAVs), both in recent 2021 European Society of Cardiology (ESC)/European Association of Cardio-Thoracic Surgery (EACTAS) and 2020 American College of Cardiology (ACC) /American Heart Association (AHA) valvular guidelines [1, 2, 6, 7]. Moreover, data from a large TVT registry (Transcatheter Valve Therapy) show that ViV-TAVI accounts nowadays for as many as 5% of all TAVI procedures in North America [8].

At the beginning of the TAVI program in Poland, the experience with ViV-TAVI was sparse and only small, single-center reports were available in the literature [9]. Recently, to change that, the Polish Transcatheter Aortic Valve-in-Valve Implantation (ViV-TAVI) Registry (ClinicalTrials.gov identifier, NCT03361046) was established, and both clinical and procedural data were obtained from each TAVI center in Poland that performed at least 1 ViV-TAVI procedure. This effort led to the first comprehensive overview of the frequency, characteristics, and outcomes of ViV-TAVI [10]. From 2008 until database lock (mid 2020), there were 130 ViV-TAVI procedures performed, which constituted almost 2% of all TAVI procedures in that period. It is worth noting that almost half of ViV-TAVI cases were performed in the last 2 years (since 2018) suggesting rapidly increasing frequency. When analyzing the treated SAVS, failed Hancock II, Freestyle and homografts were most often referred for ViV-TAVI, interestingly with 45% of all SAVS’ design being stentless or homografts. On the other end, the most frequently used (three-thirds of all) transcatheter aortic valves (TAVs) were self-expanding, supra-annular bioprostheses, namely CoreValve/Evolut R/Pro followed by balloon-expandable Sapien XT/3 in 15%. Immediate echocardiographic improvements were noted across the whole cohort; however, residual mean gradients remained elevated (>20 mm Hg) in one-fifth of all patients. At 1-year, overall mortality was 10.8% with cardiovascular mortality being higher in the first part of the registry when 1st generation TAVs were used as compared with 2nd generation (17.2% vs. 5%) [10].

Considering the current and expected further future increase in the need for transcatheter treatment of failed SAVs in Poland, this document aims to review specific challenges of the ViV-TAVI procedure including proper pre-procedural planning to achieve the best possible hemodynamic results and mitigate coronary occlusion risk. It also provides preliminary review and guidelines on repeat TAVI (re-do TAVI) in patients presenting with a failed TAV.

DESIGN, CHARACTERISTICS, AND SURGICAL IMPLANTATION TECHNIQUES OF SAVS

According to the current ACC/AHA and ESC/EACTAS guidelines, SAVR is the preferred method of treating severe aortic stenosis in low-risk patients under 65 and 75 years of age, respectively [1, 2]. A biological prosthesis is recommended in the presence of contraindications or a low probability of adequate anticoagulation. These may be related to the
The surgical bioprostheses can be divided into 2 groups according to the type of leaflet tissue used – homografts and heterografts (xenografts). Homografts are made of human tissues and include autografts (own pulmonary valve used in Ross’s procedure) and allografts (cadaver valves). In xenografts, the valve leaflets are made of porcine or bovine pericardial tissues. Based on stent construction and the tissue from which the valve leaflets are made, we distinguish the following types of bioprostheses: porcine stented (Medtronic Hancock II, Medtronic Mosaic, Carpentier-Edwards aortic porcine bioprosthesis, Abbott Biocor, Abbott Epic, Vascutec Aspire), pericardial stented (Carpentier-Edwards Perimount, Carpentier-Edwards Perimount Magna, Abbott Trifecta, Sorin Mitroflow, Sorin Soprano), stentless porcine (Edwards Lifesciences Prima root, Medtronic Freestyle root, St. Jude Medical Toronto SPV root), and stentless pericardial (Sorin Solo Smart) valves (Figure 1). All prostheses have 3 leaflets attached to the stent frame and a suturing ring positioned below the stent frame. The leaflets are mounted internally within the stent frame in most stented valves; however, some valves have leaflets attached to the outside of the stent, which increases the effective opening area of the valve, e.g. Trifecta, Mitroflow, and Dokimos (Figure 1). Stentless prostheses do not have a stent frame or the ring at their base. In stentless valves, the valve leaflets are located inside the native aortic root and form a natural anatomic complex. The idea behind the design of a stentless prosthesis was to increase the effective area of the aortic opening, achieve the physiological pattern of the flow, improve hemodynamics, and
reduce the transvalvular gradient. Consequently, this was supposed to lead to the regression of left ventricular mass and improvement of survival, but the evidence for this is inconclusive [11–13].

After resection of the stenotic aortic valve leaflets and decalcification of the aortic annulus, sutures with patches are placed around the entire circumference of the annulus. The sutures can be put in two ways. Placing the patches below the annulus (from the left ventricular outflow tract side) allows for supra-annular implantation of the prosthesis. In the intra-annular technique, suture patches are placed above the ring on the aortic side of the annulus. The advantage of the supra-annular technique is the possibility of implanting larger prostheses. The intra-annular technique is easier and safer as it reduces the risk of the patch dislocation into the left ventricle if the suture breaks during binding. Some bioprostheses are manufactured in two versions: for supra-annular (Epic Supra, Perimount Magna) or intra-annular implantation (Epic, Perimount). In supra-annular valves, the suturing ring is positioned at the lower edge of the stent frame, while in intra-annular valves about 3 to 5 mm below it [14]. Another surgical technique is the use of several continuous sutures. Stentless valves, depending on the construction, can be implanted using the subcoronary technique (Freedom), inclusion root technique (miniroot), and root replacement technique (full root, Freestyle). The subcoronary technique can be used in patients with a narrow ring and a non-dilated symmetrical aortic root. The miniroot technique allows obtaining the correct geometry in the native aorta. The full root technique allows the replacement of the entire aortic root in the case of small annulus size, root dilatation, or in infective endocarditis. It is a longer and more technically advanced procedure than the subcoronary technique, but it leads to smaller transvalvular gradients and, less frequent, regurgitation [11, 15, 16].

**SAV DYSFUNCTION AND FAILURE DEFINITIONS**

For many decades, SAVR was the only treatment of choice for symptomatic AS patients, with the first procedure being performed as early as 1960. Thus, there is an abundance of publications reporting on the performance of different SAVs [17, 18]. However, it is still difficult to draw meaningful conclusions on the durability of SAVs due to inconsistency in reporting results, variable observation periods, frequent lack of echocardiographic follow-up, core lab data adjudication, and above all heterogeneity in defining valve dysfunction across individual studies (11 definitions in a recent large systematic review, mostly based only on the rates of reoperation) [19]. In one representative study with 10-year follow-up, 7.3% of patients had reintervention and further 6.6% had elevated mean gradients >20 mm Hg or more than moderate regurgitation, and implantation of Mitroflow prosthesis and body mass index were independent predictors of valve dysfunction [20]. More recently, in the randomized NOTION trial, with a smaller cohort and shorter follow-up time of 6 years, valve deterioration (gradient >20 mmHg or increase>10 mmHg or, at least, moderate aortic regurgitation) was found in almost one quarter (24%) of the SAVR arm population [21].

Recently a novel classification of bioprosthetic valve dysfunction (BVD) was proposed and defined in several position papers [22, 23]. Unlike artificial mechanical prostheses, mostly bioprosthetic SAVs are uniquely prone to structural deterioration (SVD, structural valve deterioration) over time, with SVD being a result of permanent intrinsic changes. They are multifactorial and may result from wear and tear, leaflet disruption or flail leaflet, fibrosis, and/or calcification and suture line disruption. Furthermore, different mechanisms of BVD consist of non-structural valve dysfunction (e.g. para- and periprosthetic regurgitation, prosthesis-patient mismatch [PPM], dilatation of the aortic root, etc.), thrombosis, and endocarditis. Echocardiography remains the primary imaging modality to assess BVD. Recently, cardiac computed tomography (CT) proved to be very useful in understanding the underlying mechanism behind BVD, e.g. thrombosis.

Consequently, SVD together with remaining types of BVD may or may not induce hemodynamic changes in individual patients. These are best described and diagnosed using echocardiographic examinations with mandatory baseline status recorded up to 1-3 months after index SAVR and serial follow-up check-ups (especially important with suspicion of PPM and potentially reversible changes with valve thrombosis and/or endocarditis). If no or mild hemodynamic changes are noted, it is defined as only morphological valve deterioration. However, usually hemodynamics is impacted at some point, and 2 major stages of hemodynamic valve deterioration (HVD) are possible: moderate or severe (Table 1). For stenosis, it depends on the change from baseline of (1) mean transvalvular

| Table 1. Hemodynamic valve deterioration definitions. Based on [22, 23] |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| Stenosis                        | Mean PG, mm Hg  | EOA, cm²        | DVI              | Regurgitation    |
| Moderate HVD (stage 2)          | ≥10 (to at least 20)* | ≥0.3 or ≥25%    | ≥0.1 or ≥20%     | Moderate*       |
| Severe HVD (stage 3)            | ≥20 (to at least 30)* | ≥0.6 or ≥50%    | ≥0.2 or ≥40%     | Severe*         |

All changes compared to the baseline evaluation (1-3 months after index SAVR).

*Together with EOA and/or DVI (at least 2 parameters needed including PG).

*New onset or increase of ≥1 grade (moderate) or ≥2 grades (severe).

Abbreviations: DVI, Doppler velocity index; EOA, effective orifice area; HVD, hemodynamic valve deterioration; PG, pressure gradient (transvalvular).
gradients, (2) effective orifice areas (EOA), and (3) Doppler velocity index (DVI). In the latest VARC-3 (Valve Academic Research) guidelines, in contrast to prior definitions, it is stressed that due to the inherent variability in echocardiographic assessment and periodical differences in blood flow, a single parameter is not sufficient and at least 2 of 3 should be present to qualify a patient for respective stages. For regurgitation, the respective staging is based on the 3-class grading scheme (mild/moderate/severe) (Table 1). It is believed that the initial echocardiographic presentation of HVD is of importance when predicting a patient’s prognosis before ViV-TAVI. It has been demonstrated in one of VIVID analyses on a group of 459 patients that in terms of 1-year mortality, the population of patients presenting with predominant stenosis has the worst outcome after ViV-TAVI (23.4%) when compared to cohorts with mixed presentation (stenosis and regurgitation, 16.1%) and most notably with sole regurgitation (8.8%) [24].

Clinical consequences arising from any BVD and manifesting itself as new onset or worsening of heart failure due to left ventricular dysfunction or irreversible severe SVD itself are defined as stage 1 bioprosthetic valve failure (BVF). Further 2 stages are defined as the need for aortic reintervention (either re-do surgery or ViV-TAVI) — stage 2, and valve-related death — stage 3.

**PRE-PROCEDURAL PLANNING SPECIFIC TO ViV-TAVI**

**Identifying the type and size of SAV**

Pre-procedural preparation and planning differ somewhat from routine workup before the native TAVI procedure. For ViV-TAVI, the process should start with identifying the type and size of the failed SAV. Patient discharge records are usually valuable sources of information for that. If unavailable or the information is indefinite, the type of most stented SAVs can be quite easily identified by its specific fluoroscopic appearance, where either sewing ring, stent posts, or characteristic parts of stent posts can be clearly visible [25]. In some stented valves (Dokimos, Laborc, Aspire, and Intact) and all stentless valves/homografts, there are no radiopaque elements and, in this case, multi-detector CT (as with native TAVI) should be used to get more specific evaluation.

After having identified the type of SAV, in the next step one should determine the size of the annulus of SAV (surgical neo-annulus). It is usually possible to assess it starting from the nominal/label diameter (usually basal ring outer diameter) and corresponding stent internal diameter (ID) of the prosthesis provided by the manufacturer [26]. This is, however, not the size of the neo-annulus according to which the desired TAV size should be selected because it does not take into consideration leaflets that are most often sutured inside the stent thus reducing the final diameter that is referred to as true ID. In general, the exact true ID is calculated by deducting 1.5-4 mm with porcine leaflet (e.g. for 21 mm Hancock stent ID 18.5 mm and true ID 17 mm) and 1 mm with pericardial bovine (e.g. for 21 mm CE Peri-mount stent ID 20 mm and true ID 19 mm). When stented SAV leaflets are mounted outside the stent (e.g. Mitroflow, Trifecta), the stent ID is equal to the true ID. Similarly, for most stentless SAVs (bar Freedom Solo and Pericarbon Freedom), true ID is smaller than stent ID (up to 3 mm). Thus, for most identified SAVs, adequate TAV size can be selected based on true ID and available sizing charts with similar oversizing rules as with native TAVI [27]. However, CT is also important in the neo-annulus sizing for ViV-TAVI, especially when the initial SAV label size is not available in patients’ medical records or double-checking is needed (in case there may be a mistake). Moreover, most of the sizing charts are based on true IDs of unused SAVs (bench testing) and, therefore, do not take into account possible severe calcifications or even pannus formation of failed SAVs, which may lead to further decrease in the true ID and may be important for choosing proper TAV size, especially in borderline measurements.

**Predicting hemodynamic performance after ViV-TAVI**

ViV-TAVI, in general, is associated with elevated post-procedural gradients and suboptimal hemodynamics as compared to the native TAVI (odds ratio [OR], 2.8), and this is perceived as a limitation of this procedure [24]. In the VIVID registry, gradients >20 mm Hg were found in 28.4% of patients, with similar frequency reported in the Polish population (21%) [10, 24]. Three major baseline features of future poor hemodynamics were identified.

First, the mechanism of SAV failure is important. Data from the Polish Transcatheter Aortic Valve-in-Valve Implantation (ViV-TAVI) Registry show that patients presenting with stenosis as compared to mixed or regurgitation cohorts had higher mean post-procedural gradients (16 mm Hg vs. 14.5 mm Hg; \( P = 0.004 \)) and smaller mean indexed EOA (0.8 cm²/m² vs. 0.84 cm²/m²; \( P = 0.049 \)) [10]. This was also shown earlier in larger registries (STS ACC/TVT and VIVID), and importantly it translated into higher 1-year mortality [24, 28].

Second is the small label size of SAV, usually stented (<21 mm) with small true ID (<20 mm). Of 130 patients in the Polish registry, 45% had small SAVs, and those resulted in a lower mean EOA (1.4 cm²) in comparison with the remaining cohort with bigger SAV prostheses (EOA of 1.58 cm²; \( P = 0.005 \)) [10]. Similarly, in one larger registry, failed SAV aortic valve area was the only independent baseline predictor of post-procedural gradients (OR, 0.87 per 0.1 cm² increment), and a small SAV size was associated with 2-fold (hazard ratio [HR], 2.04) increase in long-term mortality [24].

Last but not least, the baseline presence of PPM immediately after SAVR is already defined as non-structural valve deterioration with severe PPM defined as iEOA <0.65 cm²/m² or <0.55 cm²/m² with obese patients (body
Identifying coronary artery occlusion risk

It has been shown in the VIVID registry that the overall risk of coronary artery occlusion (CAO) with ViV-TAVI (across all SAV types in general) is still relatively low but nevertheless more frequent as compared with native TAVI (2.3% vs. 0.66%). As with native TAVI, when it occurs is deleterious with fast hemodynamic compromise and ca. 50% mortality despite attempts to perform emergent percutaneous coronary intervention (PCI) that is often technically challenging or impossible [30,31]. CAO of only the left main artery is most frequent (72%), followed by both left and right arteries (20%), and rarely only the right artery is obstructed (8%) — most probably due to usual higher take-off. The risk is not uniform and highly dependent on the specific SAV type: (1) as high as almost 7% for stented valves with externally mounted leaflets in relation to the surgical ring (Trifecta, Mitroflow, Dokimos); (2) intermediate but still high for stentless prostheses (3.7%); and (3) only 0.7% for stented with internally attached leaflets (comparable with the native TAVI rate) [31]. The supra-annular surgical implantation technique, design, and morphology of SAV leaflets — bulkiness, severe calcification, and high opening profile may further increase the risk. Also, it has been observed that in rare instances (less than 1% but more often as compared to native TAVI), CAO may be delayed (even beyond 60 days from index ViV-TAVI) and occur probably as a result of nitinol frame expansion with self-expanding (SE) TAVs and/or thrombus formation and embolization [32].

Hence, the role of cardiac CT is pivotal and unique to ViV-TAVI when it comes to pre-procedural assessment of CAO. In stented SAVs, small aortic root dimension often coupled with a non-coaxial or tilted/canted position of the SAV in relation to the aortic root long axis and, subsequently, coronary take-offs are well-known factors responsible for this increased risk. Thus, following routine measurements of sinus of Valsalva (SOV) width and the height of coronary take-offs in relation to the annulus characteristic for native TAVI workup does not adequately describe the risk, and additional estimations are needed [33]. Obviously, if the coronary arteries originate above the tips of SAV leaflets, there is no risk of CAO. If located below, coronary flow may be blocked or impaired basically in 2 mechanisms during ViV-TAVI (1) most often directly by blocking the coronary ostium by a leaflet, when an expanded TAV frame pushes the leaflets of the failed SAV outwards into an open position in front of coronary take-off (sometimes called deficient sinus); or/and (2) less frequently, not directly affecting coronary artery, but blocking the flow when, in a shallow sinus, the tip of the failed SAV leaflet reaches to or above the narrow sinotubular junction (STJ) thus leading to so-called sinus sequestration [34]. Therefore, pre-ViV-TAVI cardiac CT has to estimate the most lateral and upper location of the deflected leaflet. To do that, a virtual ring simulating the size of the desired fully expanded TAV is superimposed along the geometric center of the SAV and followed by caliper measurement from the ring to the coronary ostium (separately, both for the left and right coronary arteries) [33]. This is called valve-to-coronary (VTC) distance, and the established value of less than 4 mm is believed to serve as the cut-off for high risk of CAO (OR, 0.22 for each millimeter increase in VTC distance) [31, 35]. In order to predict possible sinus sequestration in short SOV with leaflets extending high to or above the STJ, the same virtual ring has to be applied at this level and the measured distance between the expanded TAV and the aortic wall is called VTSTJ (valve-to-STJ) distance. However, in the case of VTSTJ, the threshold for high risk is less certain and considered as less than 2–2.5 mm [34] (Figure 2).

In the past, due to belief in non-obstructive properties of surgical stentless prostheses design, anticipated reduction in transvalvular gradients, and improved flow characteristics, these prostheses were frequently chosen in younger patients and specifically in those with small root and annulus anatomies [11–13]. Combined with anatomical distortion after surgery (e.g. effaced sinuses, shallow SoV), this also may increase the risk of CAO during failed stentless SAV treatment. With stentless valves, there is no rigid scaffold for TAV anchorage, and therefore ViV-TAVI procedure is mechanically more similar to native TAVI. Thus, stentless surgical valve cases should be dealt with as native aortic stenosis cases as far as CAO risk is concerned, with sinus dimensions and coronary height measurements obtained on workup CT [33] (Figure 2).

PROCEDURAL TECHNIQUE

In terms of vascular access and anesthesia by analogy with native TAVI, there is an increasing rate of purely percutaneous transfemoral approaches with only cautious sedation or local anesthesia instead of general [10]. Most of the available TAVs can be used for ViV-TAVI; however, only two were approved by FDA (Corevalve/Evolut R/Pro in 2015 and Edwards Sapien XT/S3 in 2017) and in everyday practice, these 2 systems constitute the majority of procedures worldwide and also in Poland [10]. Additionally, there...
are different technical caveats of ViV-TAVI associated with 2 main SAV designs (stented vs. stentless).

**STENTED SAV**

**Wire crossing and implantation views**

It may be more difficult to cross the valve with the standard straight wire, especially in a tilted SAV position and/or with horizontal root. In such cases, using a hydrophilic wire or even crossing the SAV with a pigtail or wire-supported pigtail, especially in regurgitant SAVs, can be successful. For highly stenotic SAVs, stiffer pre-shaped wires (e.g. Lunderquist) may be needed to cross the valve with a delivery system and position a TAV. Most of the stented SAVs have clear radiopaque parts with sewing rings, stent posts, or both, which makes them clearly visible on fluoroscopy. This usually allows for better orientation than with native TAVI and saves contrast injections. The sewing ring serves as a neo-annulus according to which the TAV frame should be oriented. Careful aligning of fluoroscopic markers allows for setting the implantation plane and deployment views. The basic projection where the posts are aligned in 1–1–1 fashion corresponds with the 3-cusp co-planar view used in native TAVI (used especially with balloon-expandable [BE] prostheses) [36] (Figure 3). A different view, with posts aligned as 1–2 (usually LAO with some cranial positioning of the X-ray enhancer, with right and non-coronary cusp overlap) may be useful in isolating the left cusp with left main take-off and thus facilitating assessment of the potential risk of coronary obstruction while showing SAV in a perpendicular fashion [37] (Figure 3). Finally, if SE Evolut R prosthesis is used for ViV-TAVI, an RAO cusp overlap view substitute (usually a combination of RAO and a caudal view) may facilitate alignment of SE TAV commissures with SAV commissures and, therefore, increase future coronary access if PCI is needed (Figure 4).

**Predilatation of SAV**

In most ViV-TAVI cases, routine SAV pre-dilatation is not necessary and even should be avoided as failed SAV leaflets are more prone to tearing than native ones, which can induce acute aortic regurgitation [36]. But it may be useful in selected cases to allow for TAV passage in very small stenosed and canted SAVs or in the presence of horizontal aorta — a small size balloon not exceeding the true ID is recommended when needed. Another possible indication for SAV pre-dilatation can be coronary occlusion risk assessment. As mentioned earlier, nowadays this is usually best defined by careful CT analysis as part of decision-making — but in borderline cases, an adequately sized (1:1 balloon size to true ID size) compliant balloon at low pressure (not to occlude contrast flow at the level of the STJ) can help evaluate the geometric relationship between the open SAV leaflets and the coronary ostia. The contrast injection and coronary flow check should be performed after full inflation of the balloon (usually in 1–2 cusp projection) [37]. Finally, pre-dilatation can be performed with a non-compliant balloon to fracture or modify small SAV rings (see below).

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**Figure 2.** CT-based risk estimation of CAO during ViV-TAVI. Modified, based on [34, 35]

Abbreviations: CT, computed tomography; CAO, coronary artery occlusion; STJ, sinotubular junction; TAVI, transcatheter aortic valve implantation; ViV, valve-in-valve; VTC, called valve-to-coronary.
TAV selection and implantation

As mentioned above, sizing of TAVs is based on the valve type properties (true ID) supported by CT assessment. Implantation of too oversized TAVs (e.g. choosing 26 mm SE supra-annular TAV over 23 mm SE TAV in 23 mm Mitroflow SAV with true ID of 19 mm) due to the rigid scaffold of the stented SAV most likely will not reduce post-procedural gradients, and in the longer term, due to under expansion of the SE TAV may lead to accelerated BVD [38, 39]. It has been, however, shown that placement of a correctly sized and positioned SE TAV with a supra-annular attachment of the leaflets (CoreValve/Evolut family) is beneficial in terms of achieving lower post-VIV-TAVI gradients and larger EOA, especially in small stented SAVs as leaflets in the supra-annular position are better suited to expand and coapt without the constraint of the rigid surgical valve ring [24, ].

In a recent randomized comparison of BE intra-annular TAV and SE supra-annular TAV in small SAVs (<23 mm), the latter were characterized by lower mean transvalvular gradients (15 ± 8 mm Hg vs 23 ± 8 mm Hg; \( P < 0.001 \)) and a tendency towards a lower rate of severe PPM (44% vs. 64%, \( P = 0.07 \)), the difference, however, did not impact short-term clinical outcomes [41]. Similarly, in the Polish registry, SE supra-annular TAVs were associated with lower mean pressure

Figure 3. Typical angiographic views for ViV-TAVI in failed stented SAV (CE Magna). A, B, 1–1–1 and C, D, 1–2 (left main take-off isolation, white arrow). SAV in the mitral position

Abbreviations: see Figures 1, 2

Figure 4. Commissural alignment of Evolut R inside CE Magna. A. 2–1 view, hat marker (white arrow) on outer aortic curvature. B. RAO CAUD (cusp overlap) view with hat marker (white arrow) at center front. C. Commissural alignment in fluoroscopy — TAV commissural tab (white arrow) aligned with Magna commissure between the left and right cusp (black arrow). D. Confirmation on post-operative CT

Abbreviations: see Figures 1, 2
gradients than BE intra-annular \((P = 0.004)\) ones, and there was a trend towards larger indexed EOA in supra-annular vs. intra-annular TAVs \((0.9\ vs.\ 0.74; P = 0.08)\) [10].

It is worth noting that those differences favoring SE supra-annular TAVs, especially in small anatomies, are based on reported Doppler echocardiographic evaluations. However, recently it has been shown that despite a good correlation of transvalvular gradients in native stenosis, there is a significant discordance between direct invasive measurements and echocardiography-derived measurements post-TAVI (poor correlation and, above all, overestimation of gradients by echocardiography) [41, 42]. This overestimation is attributable to the fact that echocardiographic gradients derived from transaortic velocity are based on the simplified Bernoulli equation which has important limitations when it is applied to prosthetic valves (to a greater extent compared with native AS). This simplification basically ignores other factors (other than transaortic gradients) that may contribute to increased transaortic velocity, e.g. proximal left ventricular outflow tract (LVOT) pressure, flow acceleration, viscous forces, pressure recovery, flow amount and type characteristics between short and long-frame prostheses [43, 44]. A recent study in native TAVI comparing BE and SE TAV has shown that irrespective of type and size all of them exhibit similar low transvalvular gradients when measured invasively immediately after

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**Figure 5.** Different stented SAVs with balloon- and self-expandable TAVs. 

Abbreviations: see Figures 1, 2
TAVI. However, when the echocardiographic measurement was applied (with the abovementioned limitations), small BE TAVs (20- or 23-mm size) displayed higher gradients than the remaining large BE TAVs and all SE TAVs. Another important observation from this study was that regardless of type and size of TAVs, echocardiographic gradients were higher at discharge in comparison with immediate post-TAVI, and again the increase was most pronounced for small BE TAVs [42]. These specifics of different measurement modalities (invasive vs. echocardiographic) suggest that they cannot be used interchangeably to avoid a clinical scenario where good hemodynamics achieved immediately after TAVI (also ViV-TAVI, especially with small BE TAVs) with low invasive gradient measurement is questioned on discharge when echocardiography is applied.

Regardless of the TAV design (SE vs. BE; supra vs. intra-annular), it was shown that implantation height within the stent of the SAV prosthesis is important to facilitate full expansion and thus avoid constriction at the level of functioning TAV leaflets [45]. So, also when supra-annular TAV is implanted too low, its leaflets become constrained within the rigid scaffold of SAV, and thereby its potential superiority over intra-annular TAV is lost. Analogically, a higher position of intra-annular TAV is desired for it to function as “supra-annularly” as possible. The high positioning obviously has to be reasonable and balanced against the risk of paravalvular leak or aortic pop-up and embolization. Based on both bench testing and clinical experience, the recommended cut-offs for depth below the surgical neo-annulus are currently 0–5 mm for SE CoreValve/Evolut R and 80%–90% of aortic/10%–20% ventricular position for BE Sapien 3/Ultra [45–47].

Another recently explored aspect of optimizing flow through TAV, also particularly important in the ViV-TAVI setting, is the aligning of TAV commissures with SAV commissures, the so-called commissural alignment. It is currently not fully controllable with available devices but best achievable with supra-annular SE prostheses (Evolut R and Accurate Neo) [48]. It has been shown that if commissural alignment is present after ViV-TAVI with a SE supra-annular TAV, lower gradients are recorded even with a deeper TAV position [49]. Conversely, commissural misalignment may also contribute to a significant peak stress increase on the TAV leaflets thus possibly predisposing to future accelerated BVD [50].

**STENTLESS SAV**

Failed stentless SAVs are less prevalent during ViV-TAVI but pose greater challenges in terms of accurate positioning and stability of TAV due to the lack of radiopaque markers and rigid anchoring elements, present in most stented prostheses. We have shown previously in the first and, at that time, largest report comparing stented and stentless ViV-TAVI in the Polish population that the latter cohort was younger with a longer time from index surgery [51]. Furthermore, it was observed that in failed stentless prostheses, pure regurgitation (often presenting with complete lack of calcifications), rather than stenosis, was most frequently the mechanism leading to BVF. This resulted in a lower rate of technical success (mostly due to incorrect positioning, displacement, or embolization of the first TAV), need for a second prosthesis, and higher rates of moderate or severe paravalvular leak [51]. On the good side, stentless valve post-TAV implantation was characterized by smaller mean transvalvular gradients, larger effective orifice areas, and less PPM. These features were largely confirmed a year later in a VIVID registry subanalysis on a larger cohort, which also reported a substantially higher overall CAO risk in the stentless cohort vs. stented but mainly due to non-homograft stentless prostheses [52]. The authors also noted that new generations of both SE and BE TAVs reduced the rates of paravalvular leak when compared with 1st generation devices lacking repositionability features and/or sealing cuffs (Figure 6).

So having all this in mind, it is recommended to precisely plan ViV-TAVI procedures in failed stentless prostheses based on the pre-procedural CT analysis in order to (1) appropriately size the TAV prosthesis especially due to the absence of available sizing charts for homografts; (2) assess aortic root dimensions and coronary occlusion risk (as described above). The procedure itself may more often require general anesthesia as TEE may be useful in TAV placement. Initial angiographic appearance can sometimes be deceptive as to the location of the neo-annulus so pre-dilatation with a semi-compliant balloon showing the typical waist may help to get better orientation and also may be useful in borderline coronary occlusion risk estimation (as with stented valves). Standard SE and BE prostheses are not designed for treatment of pure regurgitation, and devices specifically designed for that are still not widely available and under investigation in native TAVI (e.g. Jena Valve) [53]. Therefore, as of now, when using standard TAVs, greater oversize is usually needed, and implantation of SE valves using a stiffer pre-shaped wire with fast pacing may help to perform a safer and more efficient procedure with no need for a second prosthesis. To address the CAO risk, especially in non-homograft stentless prostheses, pre-emptive strategies to prevent occlusion such as chimney stenting or BASILICA are needed more frequently (see below).

**ADDITIONAL SOLUTIONS TO IMPROVE HEMODYNAMICS**

**Bioprosthetic valve fracture or remodeling**

Bioprosthetic valve fracture or remodeling is a modification of the surgical valve ring for more optimal expansion of the TAV to facilitate ViV-TAVI and has been introduced in 2015 as one of the strategies to avoid PPM [54]. Utilization of a supra-annular TAV along with high implantation minimizes the risk of PPM, however, this might not be enough in the setting of small stented surgical valves [55]. There-
fore, the SAV ring could be either fractured or stretched with high-pressure balloon inflation (e.g. Atlas Gold, Bard Medical, US) to provide more space for TAV expansion or to better expand the TAV itself. Only 2 types of stented prostheses are not fracturable or modifiable — Hancock II and Trifecta, but these types are prevalent in Poland [10, 56]. Fracturing could be achieved with a balloon preferably at least 3 mm larger than the true SAV ID [57]. It requires a combination of manual inflation with a syringe connected by the stopcock to an indeflator to complete the high-pressure inflation. The results can be observed on fluoroscopy usually as the release of balloon waist or sudden drop of pressure on the indeflator, rarely also accompanied by audible click (Figure 7). It was proved to be effective in reducing post-procedural gradients in small SAVs (20.5 ± 7.4 mm Hg after initial ViViTAVI to 6.7 ± 3.7 mm Hg after fracturing [P <0.001]) [58].

Although the annular rupture might be feared, it is very rarely observed due to the excision of calcium deposits from the aortic apparatus at the time of SAVR, but the procedure is not recommended in patients with aortic root enlargement or replacement [57, 59]. The remaining rare potential complications include iatrogenic ventricular septal defect, atrioventricular block requiring a permanent pacemaker, coronary artery obstruction, or stroke [59].

It is still unclear if fracturing should be performed before or after TAV implantation. Pre-implantation fracturing may allow for use of a larger-size TAV but at an increased risk of debris embolization (stroke risk) or acute aortic regurgitation. On the other hand, post-implantation fracturing...
may carry the risk of structural damage to the leaflets that can accelerate future BVF [60, 61]. A recent multicenter study in short-term follow-up seems to favor post-VIV-TAVI fracturing that shows lower final gradients and mitigates stroke risk compared to preprocedural fracturing [57].

As long-term outcomes are yet to be determined, our recommendation is to perform fracturing at experienced high-volume TAVI centers with backup cardiopulmonary support after careful imaging workup. In most cases, post-VIV-TAVI fracturing should be preferred with pre-TAV implantation fracturing reserved for smallest true IDs below 17 mm (e.g. 19 mm Mitroflow, Mosaic, or Dokimos) to better facilitate expansion and stability of the smallest TAVs. Additionally, using cerebral embolic protection in both strategies – particularly for pre-implantation fracturing – may be beneficial to minimize the risk of periprocedural stroke related to more extensive manipulations within the aortic anatomy [62].

ADDITIONAL TECHNIQUES TO MITIGATE CORONARY ARTERY OCCLUSION RISK

Chimney stenting
This method was originally developed for patients with abdominal aorta aneurysms, treated with endovascular aortic repair, in whom chimney stenting was performed to provide blood flow to renal or mesenteric arteries [63]. It was first described in the native TAVI setting in 2013 as a bailout for acute CAO [64]. There are several steps to perform chimney stenting in VIV-TAVI. First, after intuba-
tion of the coronary ostium with a guiding catheter, the coronary artery at risk should be wired and a drug-eluting stent parked in the middle part of the artery. The stent diameter should be suitable for the coronary ostium with its length ideally allowing it to reach to the STJ. During TAV implantation, the guiding catheter is withdrawn to the ascending aorta. After TAV is implanted, the stent should be retracted into the coronary ostium so that its proximal end reaches above the displaced SAV leaflets/STJ and the distal end covers the ostium and the proximal part of the coronary; then it should be deployed parallel to the implanted TAV to create a channel between the SAV and the aorta. If TAV postdilatation is required (especially if non-compliant balloon fracturing/modification of the ring is planned), simultaneous kissing balloon inflation can be performed between the TAV and the chimney stent to prevent deformation of the latter (Figure 8). Final angiographic assessment with contrast is needed to confirm adequate filling of the coronary artery [65].

It was shown in the multicenter Chimney Registry (70% ViV-TAVI) that CT-based planning and identifying patients with high CAO risk features followed by preemptive protection of the coronary arteries is beneficial. The absence of up-front coronary protection, in other words, and attempt at stenting when CAO was already present (through the metal frame of the valve) was difficult and associated with 7-fold higher risk of 30-day mortality, myocardial infarction, and cardiogenic shock. On the downside, it was also observed that in half of the patients after initial implantation due to coronary stent under expansion, postdilatation was needed, and more importantly in 18%, a second stent was implanted to increase radial force and ensure coronary flow. In a medium-term follow-up of almost 2 years, stent failure due to either restenosis or thrombosis was noted in 5.3%
Given the relative simplicity of the procedure, especially for interventional cardiologists skilled in coronary interventions and the relative complexity of the currently available leaflet splitting method, we can recommend preemptive chimney stenting in high-risk CAO cases based on CT (Figure 2), especially for older patients with a low anticipated probability of future coronary re-engagement. Also, prolonged dual antiplatelet therapy should be considered and managed case-by-case as this population is usually at higher bleeding risk. We would also advise performing chimney stenting in CT-identified high-risk CAO regardless of normal flow to the artery at risk after TAV implantation, as it (1) may be a result of coronary wire displacing the SAV leaflet from its final open position; and (2) will most probably prevent delayed CAO, especially when nitinol-based SE TAVs are used that may still expand over time. Preliminary single-center experience shows some potential added value of intravascular ultrasound to predict CAO after TAV implantation by visualizing the SAV leaflet in relation to the coronary ostia but this observations remains to be validated in larger cohorts to impact decision-making.

Leaflet splitting (BASILICA)

This is a different method of protecting coronary flow that aims at the underlying cause of CAO — the SAV leaflet itself, without manipulating or leaving material (stents) in coronary arteries at risk. In 2018 the concept of BASILICA (Bioprosthetic or native Aortic Scallop Intentional Lacera- tion) was introduced with a case report of one patient [65].

Briefly, it starts with securing bifemoral arterial access and placing, through the right groin, a “traversal system” (telescope system consisting of an 8 Fr AL 2/3 guiding catheter, diagnostic long 5 Fr IM catheter, piggyback microcatheter, and stiff peripheral 0.014 wire [e.g. Astato XS 20, Asahi Intecc, US] with a shaved distal end). It is usually placed through a 14 Fr sheath allowing for repeated catheter manipulation without blood loss. On the left side, a “snare system” is introduced into the LVOT (consisting of a 6 Fr MP guide, gooseneck snare, and 0.018 wire [e.g. support]). In the case of double BASILICA of both left and right leaflets, usually 2 large sheaths are needed. After placing the snare in the LVOT, parallel to the aortic annulus plane, a traversal system is introduced and correctly positioned under fluoroscopic guidance in side and front views (determined by pre-procedural CT) allowing for puncturing the leaflet at the base and in the middle of the leaflet with the Astato wire, using a very short energy burst (30 to 70W depending on the leaflet type and amount of calcifications) from an electrosurgical generator (set in cut mode) and applied to the shaved end of the wire. After snaring (with the wire still inside the body), an IM catheter is removed and the piggyback microcatheter is backed up to form a V-shaped shaved part of the Astato wire. After that, the piggyback microcatheter is locked (maintaining the same distance from the V), and then by externalizing the Astato — the V-shaped part is delivered exactly at the puncture site. When this is done, in anticipation of possible acute aortic regurgitation, a pigtail catheter (inserted parallel to the traversal system via a 14 Fr sheath) should be introduced to the LV to secure quick TAV delivery if needed. With the pigtail in place, after flushing the traverse and snare catheters (preferably with dextrose), again a short burst of energy (50–100 W) is applied, and at the same time the V-shaped Astato wire is pulled up gently whereby the leaflet splits creating a triangle of flow to the coronary artery at risk (Figure 9).

Afterward ViV-TAVI can be performed with non-selective angiography used for confirming coronary flow after TAV deployment. In some instances, in extreme risk cases (very low baseline height of the coronary ostium and very short VTC distance), coronary protection with an undeployed stent ready for chimney stenting can also be applied during ViV-TAVI, even after BASILICA. Also, it is important to correctly position the TAV after BASILICA in terms of implantation height (usually aiming for a slightly lower implant, however, balanced with the expected hemodynamic result) and, most importantly, attempt to align commissures for maintaining the immediate effect of BASILICA and facilitate future coronary access. Current experience with leaflet splitting provides rather encouraging data — in the first BASILICA IDE trial, technical success was achieved in 93% of patients, however, at the price of 3 stroke events (10%) [69]. In a large international registry, BASILICA was associated with similar technical success and the stroke rate was reduced to 2.8%, however, in almost 5% of cases this technique alone did not prevent coronary occlusion [70].

Given the added complexity of the current leaflet splitting technique and specific toolbox needed, we recommend performing BASILICA in experienced high-volume centers and targeting selected younger patients, with longer life expectancy and likely need for future coronary re-access or requiring oral anticoagulant therapy (Figure 2). Considering mentioned elevated stroke risk — brain protection is strongly advised with each procedure. Promising early experiences with dedicated leaflet splitting devices (e.g. ShortCut®), if confirmed in ongoing clinical trials and subsequently made available in clinical practice, should eventually widen indications for leaflet splitting and largely replace chimney stenting.

RE-DO TAVI

Frequency, BVF mechanisms, and early results

Indications for transcatheter treatment of A5, currently aimed at both high and intermediate-risk patients, are expanding. This strategy supported by current guidelines...
and positive results from TAVI trials showing its non-inferiority to SAVR in low-risk younger populations (at least in short-term follow-up) will eventually result in a growing population of patients outliving their TAV prostheses and requiring re-intervention (most probably re-do TAVI) [71, 72]. However, the currently available registries, analyzing procedures since as early as 2012, report a low incidence of re-do TAVI from 0.29 to 0.33% [73, 74]. The main TAV types are presented in Figure 10.

Although the literature data on the mechanisms of TAV failure are sparse, we can spot a difference in comparison with SAV failure. Generally, BVF after TAVI can be divided according to the time of occurrence after the index procedure, as (1) early, accounting for one-third of cases — usually up to 1 year, also called “procedural failure”, predominantly due to paravalvular leaks originating from undersizing, incomplete expansion, or malpositioning of the TAV; and (2) late, accounting for two-thirds of cases — occurring later mainly as a result of SVD and manifesting itself as stenosis or intravalvular regurgitation (similar to SAV) [73, 75]. Overall, preliminary results of the existing registries are rather promising, showing 85% device success limited mainly by high residual gradients and, to a lesser extent, by residual regurgitation and low rates of peri-procedural stroke or coronary obstruction. Early (30 days) and 1-year mortality rates are estimated at 5% and 15%, respectively, with a possible trend towards higher early mortality in cases of early procedural failure [73, 74].

**Sizing and second TAV choice**

Nevertheless, there are still many gaps in knowledge on how to optimally perform re-do TAVI. It seems highly dependable on the underlying mechanism of BVF, type of the failed TAV, and the position of its leaflets relative to the coronary ostia and surrounding aortic root. For patients with early BVF resulting from paravalvular leak (PVL) due to TAV undersizing or underexpansion, re-do TAVI is sub-optimal as the PVL would likely not improve e.g. due to the presence of calcium surrounding the TAV frame. Probably the best result is expected with BE TAVs with higher radial
force, especially positioned in leaking SE TAV. PVL closure often successfully performed for leaking SAVs is much more technically challenging, especially in high-frame SE TAVs implanted in narrow aortic roots [76, 77]. Conversely, re-do TAVI seems better suited for those early BVF cases that result from malpositioning of the first TAV as higher or lower implantation of the second prosthesis usually solves the problem.

Issues associated with late post-TAVI BVF seem to be similar to those after SAV failure and require concentration on avoiding high residual gradients and CAO. To tackle that, TAV choice at index TAVI becomes crucial in those with longer life expectancy. Based on the most recent subanalysis from the FRANCE-TAVI registry, we now have observational data suggesting that in small native aortic annuli (<23 mm) SE supra-annular TAV provides lower gradients and reduces severe PPM almost 3-fold in comparison to BE TAV. Notably, PPM observed at 1 year is a predictor of 3-year mortality (HR, 2.01) [78]. A randomized trial (SMART) has been initiated to confirm these findings [79]. On the other hand, when high gradients are not feared, lower frame BE prostheses at index TAV could provide easier coronary re-access and possibly lower CAO risk with re-do TAVI [80].

Unlike SAV failure, the sizing and choosing the type of the second TAV are not well defined. CT-derived diameter at the level of first TAV leaflet attachment can be useful in

Figure 10. Selected, most prevalent transcatheter aortic valve (TAV) types. Manufacturers details: Sapien XT, Sapien 3, Sapien Ultra (Edwards Lifesciences, US); CoreValve, Evolut R, Evolut Pro (Medtronic, US); Accurate Neo, Neo 2 (Boston Scientific, US); Portico, Navitor (Abbott, US). Modified, based on [101, 102]
Abbreviations: see Figures 1, 2
determining its label size when unknown [33]. As we do not have the exact true ID distances used routinely in ViV-TAVI due to different expansion scenarios of the first TAV, the role of pre-procedural CT is believed to be of paramount importance for re-do TAVI sizing. Current practices show that the second TAV in the majority of patients is similar in size to the first one (60%), followed by undersizing (25%) and least frequently oversizing (15%) [73]. Sizing should probably be guided also by the underlying BFV mechanism, with oversizing more suitable in PVL and undersizing in highly stenotic calcified first TAVs, also with regard to CAO risk and the type of second TAV (BE vs. SE). There is also no clear consensus on the type of second prosthesis. Data from the largest multi-center registry show that in 59% of cases, the same type of prosthesis was used during re-do TAVI (SE in SE or BE in BE), and in the remaining minority, different types (SE in BE and BE in SE) [73]. It can be suspected that the higher percentage of choices of the same TAV type was impacted by the preference and experience of participating centers for specific TAV types. However, we would recommend in most cases that the second TAV be different from the first (SE in BE and BE in SE) (Figure 11). Second supra-annular SE TAV in this scenario would provide lower residual gradients in failed BE (especially in smaller-sized BE TAVs), and lower-frame/higher radial force BE in SE could improve PVL, provide greater stability, and possibly facilitate easier coronary re-access in the future. For bigger-sized failed BE TAVs (size cut-off undetermined), especially regurgitant, when residual gradients are not expected to be high, BE in BE strategy could be the best option, especially with regard to future need for coronary engagement. Placement of a second supra-annular SE

Figure 11. Different re-do TAVI scenarios. A. Sapien 3 in Portico. B. Sapien 3 in Corevalve. C. Portico in Sapien XT. D. Evolut R in Sapien XT. E, F. Sapien 3 in Accurate Neo. All examples of late TAV BFV

Abbreviations: see Figures 1, 2
in failed SE seems to be the least favored scenario, again due to potential CAO and re-engagement difficulties. In patients with severe PPM and failed BE TAV, transcatheter re-do with SE supra-annular TAV may provide the best effect (however, without the possibility of fracturing as in most ViV-TAVI cases), and if PPM is present in SE TAV, whenever clinically possible, only SAVR with root enlargement may be considered. Sizing and positioning of the 2nd TAV cannot be generalized and are determined by the 1st TAV type, its position and size combined with native sinus/coronary anatomy. First algorithms for 2nd TAV positioning in the potentially most prevalent combination (BE S3 in failed Evolut R/Pro) are already available and useful [81]. A recent expert consensus on the use of BE in re-do TAVI provides further guidance on CT screening, valve sizing, and positioning in a wider range of most prevalent failed TAVs [82].

**CAO risk and prevention**

We have described so far the recommended CT-based features and strategies for identifying risk and dealing with threatening CAO in ViV-TAVI. In the re-do TAVI, the potential mechanisms of CAO are somewhat different and may result from (1) pushing the native calcified leaflet (by the TAV frame) towards the coronary ostia as the failed TAV leaflet is prevented from major movement by metal frame (so VTC, in this case, is also important but the high-risk cut-off is unknown); or, (2) sinus sequestration when the STJ is lower than the first TAV commissural level and the radial distance between the commissural level/pinned leaflets (*neoskirt*) and the aortic wall or sinus is short (VTA, valve-to-aorta) [80, 81]. The second scenario is much more prevalent for failed supra-annular SE TAVs implanted in shallow and narrow sinuses in comparison to lower frame intra-annular BE TAVs [75, 80]. It may be avoided with lower BE in SE implantation sized to the native annulus and allowing for SE leaflet overlap, which results in a shorter neoskirt [81]. Moreover, the leaflet splitting method to mitigate the risk of CAO in re-do TAVI is obviously futile if the commissures of the first failed TAV oppose the coronary ostia (as the commissure will still stay in front of the coronary ostium after BASILICA), which underscores the importance of aligning commissures with first TAV implantation. Additionally, even if alignment is present, classical BASILICA may be not sufficient for TAV leaflet splitting and balloon-assisted BASILICA has been proposed to create a wider opening in the leaflet, especially at its base [83]. Chimney stenting remains a possible option for preventing CAO but makes the need for future coronary cannulation potentially even more cumbersome than after ViV-TAVI.

**SAV/TAV THROMBOSIS AND ANTICOAGULATION STRATEGIES AFTER ViV-TAVI AND RE-DO TAVI**

Thrombosis of SAVs or TAVs implanted in native AS is not uncommon and is defined as reversible, non-structural valve deterioration [22, 23]. It is primarily subclinical leaflet thrombosis (SLT) and diagnosed as hypoattenuating lesions (HALT) with or without reduced leaflet motion (RLM) on 4-dimensional CT [84, 85]. In these cases, when increased echocardiographic transvalvular gradients are noted, switching patients to oral anticoagulant (OAC) or optimizing its efficacy usually reverses the imaging findings and decreases gradients. The clinical significance of SLT is still not entirely clear. In a recent meta-analysis of 25 studies including 11 098 patients after TAVI, the median incidence of SLT was 6% at a median follow-up of 30 days. Use of intra-annular valves was associated with 2-fold greater risk of the development of SLT compared with using supra-annular valves. In patients with SLT diagnosed at follow-up, the risk of stroke or transient ischemic attack was increased by 2.6-fold and the odds of SLT resolution increased by 99% after switching from antiplatelet agents to OAC (P <0.00001) [86]. Moreover, SLT may impact valve durability and promote SVD, especially if recurrent (8.5% of patients had a history of thrombosis in the period between index and re-do TAVI) [73].

Transcatheter valve-in-valve procedures (both in failed SAVs or TAVs) are associated with increased risk of thrombosis resulting from suboptimal hemodynamics of the second prosthesis within the artificial aortic valve apparatus. Recent multicenter observational studies showed that the incidence of both subclinical and clinical valve thrombosis is higher for ViV implantaions compared to native valve procedures (TAVI or SAVR) [87]. The precise mechanisms of such an increased risk of valve thrombosis are yet to be determined, but it seems that the local stasis may be promoted by the design differences in respective bioprostheses altering blood flow [88]. This was later confirmed in a computational study with flow fields, where areas of blood stagnation could be observed on TAV leaflets in the ViV intra-annular, but not the supra-annular, positioning of the leaflet roots [89, 90]. Additionally, smaller ratios of the implanted TAV to the true ID of the surgical valve could also potentially contribute to the risk of thrombosis [91].

Given the current knowledge of SLT clinical impact, routine prophylaxis with OAC seems not justified or may be even harmful [92]. Therefore, we suggest the application of antithrombotic management for ViV patients according to the effectual TAVI guidelines, but with regular follow-up of transvalvular pressure gradients to detect early signs of thrombosis [1, 87]. If this is the case, CT imaging should follow to detect possible SLT. Medical treatment of ViV thrombosis with OAC is an effective therapy preventing progression to systemic embolism or the need for reintervention (in this case, TAVI-in-TAVI-in-SAVR or TAVI-in-TAVI-in-TAVI) [91, 93]. If thrombosis recurs after OAC discontinuation, it would be advisable to hold OAC lifelong, according to the individual risk/benefit ratio.

**SUMMARY AND FUTURE PERSPECTIVES**

Different SAV and TAV BVF scenarios and recommendations were summarized in Table 2, with apparent limitations.
Table 2. Different BVF phenotypes and treatment recommendations

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1True ID <20 mm. 2Inspir Resilia. 3ShortCut (under investigation). 4JenaValve (under investigation). 5Bove-20 and 23 mm BE. 6Mean native annulus diameter <23 mm

Abbreviations: BE, balloon-expandable; BVF, bioprosthetic valve failure; CAO, coronary artery occlusion; PPM, patient-prosthesis mismatch (severe); PVL, paraavalvular leak; SAV, surgical aortic valve; SAVR, surgical aortic valve implantation; SE, self-expanding; STJ, sinotubular junction; SVD, structural valve deterioration; TAV, transcatheter aortic valve; VTC, valve-to-coronary distance; VTSTJ, valve-to-STJ distance

Concerning definite re-do TAVI strategies due to early experience and gaps in knowledge. It is important to stress that problematic issues can often occur concomitantly in a single patient (e.g., risk of elevated gradients, PPM can coincide with CAO risk). In these complex cases, preventive measures could be used in combination (e.g., chimney stenting/leaflet splitting with valve fracturing).

Over 15 years of clinical experience and multiple large-scale observational studies followed by guidelines, show good efficacy and safety of ViV-TAVI that reduce the need for re-do SAVR in high-risk patients. The number of procedures in Poland, estimated as ca. 2% of all TAVI in 2020, is expected to rise [10, 94]. However, ViV-TAVI is currently not recommended for interventional treatment of very young, low-risk patients with degenerated bioprostheses. This should be taken into consideration in regard to the increasing trend for implantation of bioprostheses in patients in whom life expectancy is much longer than expected valve degeneration time. To that end, also mechanical prostheses should not be avoided, and they should not be limited only to patients taking OAC for different indications. When a bioprosthetic SAV is chosen, future improvements should start with the index SAVR technique aiming to maximize bioprosthetic SAV sizes through root enlargement techniques in small annuli or replace stenosed native valves with specific expandable SAVs [95]. From the transcatheter perspective, TAVs allowing for easy, reproducible commissural alignment and treatment of pure regurgitation (stentless valves and homografts) are in demand [53]. Additionally, dedicated leaflet-splitting devices (e.g., ShortCut®) should eventually widen indications for leaflet splitting and largely replace chimney stenting if promising early experiences of using them are confirmed in ongoing clinical trials and if subsequently they are made available in clinical practice [96, 97].

Differently, to SAV failure, re-do TAVI is to date much less prevalent and occurs in older populations, already defined as intermediate or high risk at the time of index TAVI. Thus, wider experience and reliable data are still sparse and lacking. Although the age of the current European real-life TAVI population remains stable, their surgical risk is decreasing [98]. In this regard, also in combination with future inclusion of younger patients with longer life expectancy for index TAVI, re-do transcatheter procedure rather than SAVR, would be the default re-treatment option. On the other hand, unlike the current re-do TAVI landscape, fewer patients are likely to present with early TAV BVF due to PVL, malpositioning, and undersizing, as 2nd gen TAVI devices with sealing cuffs and better repositionability together with routine CT use for sizing have already largely solved
this problem. In those patients with longer life expectancy receiving TAVI as the first procedure for AS treatment, the choice of the first TAVI prosthesis is crucial and should be tailored to native aortic root anatomy based on CT. Such scrutiny will help delay BVF, preserve coronary access, and facilitate safe and effective TAVI re-do in the future.

**Article information**

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