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

Authors: Zenon Huczek, Marcin Protasiewicz, Maciej Dąbrowski, Radosław Parma, Damian Hudziak, Piotr Olszówka, Radosław Targoński, Kajetan Grodecki, Marek Frank, Piotr Scisło, Paweł Kralisz, Jarosław Trębacz, Jerzy Sacha, Krzysztof Wilczek, Andrzej Walczak, Grzegorz Smolka, Paweł Kleczyński, Krzysztof Milewski, Michał Hawranek, Janusz Kochman, Maciej Lesiak, Dariusz Dudek, Adam Witkowski, Jacek Legutko, Stanisław Bartuś, Radosław Wilimski, Wojciech Wojakowski, Marek Grygier

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Expert Opinion of the Association of Percutaneous Cardiovascular Interventions of the Polish Cardiac Society

Zenon Huczek1, Marcin Protasiewicz2, Maciej Dąbrowski3, Radosław Parma4, Damian Hudziak5, Piotr Olszówka6, Radosław Targoński7, Kajetan Grodecki1, Marek Frank8, Piotr Scisło1, Paweł Kralisz9, Jarosław Trębacz10, Jerzy Sacha11, Krzysztof Wilczek12, 13, Andrzej Walczak14, Grzegorz Smolka4, Paweł Kleczyński10, 15, Krzysztof Milewski16, Michał Hawranek12, 13, Janusz Kochman1, Maciej Lesiak17, Dariusz Dudek18, 19, Adam Witkowski3, Jacek Legutko10, 15, Stanisław Bartus20, 21, Radosław Wilimski22, Wojciech Wojakowski4, Marek Grygier17

Reviewers: Krzysztof Reczuch23, Dariusz Jagielak24

11st Department of Cardiology, Medical University of Warsaw, Warszawa, Poland
2Department and Clinic of Cardiology, Wrocław Medical University, Wrocław, Poland
3Department of Interventional Cardiology and Angiology, National Institute of Cardiology, Warszawa, Poland
4Department of Cardiology and Structural Heart Diseases, Medical University of Silesia, Katowice, Poland
5Department of Cardiac Surgery, Medical University of Silesia, Katowice, Poland
6Department of Cardiac Surgery, District Hospital No. 2, Rzeszów, Poland
71st Department of Cardiology, Medical University of Gdańsk, Gdańsk, Poland
8Department of Cardiac Surgery, Medical University of Białystok, Białystok, Poland
9Department of Invasive Cardiology, Medical University of Białystok, Białystok, Poland
10Clinical Department of Interventional Cardiology, John Paul II Hospital, Kraków, Poland
11Department of Cardiology, University Hospital, Institute of Medical Sciences, University of Opole, Opole, Poland
INTRODUCTION AND VIV-TAVI EXPERIENCE IN POLAND

Transcatheter aortic valve implantation (TAVI) in native severe aortic stenosis 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 accounting for as many as >20% of all heart surgery in Poland [3]. Interestingly with SAVR, diseased valves are more often replaced by bioprostheses at the expense of mechanical prostheses. To that end, considering the young age at the index procedure coupled with increasing lifespan one can predict the growing need for re-intervention in the future due to expected bioprosthetic failure (mainly structural valve
deterioration). Parallel to TAVI in native aortic stenosis, first transcatheter valve-in-valve TAVI (ViV-TAVI) procedures were introduced and showed to be feasible alternative to re-do surgery in symptomatic patients [4]. Most of the available data concerning ViV-TAVI safety, efficacy and specific underlying issues comes 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 less bleeding and stroke complications and 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 valve (SAV), both in recent 2021 European Society of Cardiology/European Society of Cardio-Thoracic Surgery and 2020 American College of Cardiology/American Heart Association valvular guidelines [1, 2, 6, 7]. Moreover, data from large TVT registry (Transcatheter Valve Therapy) show that ViV-TAVI accounts nowadays for as much as 5% of all TAVI procedures in North America [8].

At the beginning of TAVI programme in Poland the experience with ViV-TAVI was sparse and only small, single-center reports were available in literature [9]. Recently to change that, Polish Transcatheter Aortic Valve-in-Valve Implantation (ViV-TAVI) Registry (ClinicalTrials.gov identifier, NCT03361046) was established and both clinical and procedural data was obtained from each TAVI center in Poland that performed at least 1 ViV-TAVI procedure. This effort led to the first comprehensive summary of the frequency, characteristics and outcomes of ViV-TAVI [10]. From 2008 until database lock (mid 2020) there were 130 ViV-TAVI procedures performed, that constituted almost 2% of all TAVI procedures in that time span. 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 SAV’s treated — failed Hancock II, Freestyle and homografts were most often referred to ViV-TAVI, interestingly with 45% of all SAV’s design being stentless or homografts. On the other end, most frequently used (3/4 of all) transcatheter aortic valve (TAV) were self-expanding, supraannular 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 1/5 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 TAV’s were used as compared with 2nd generation (17.2% v s. 5%) [10].

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

**DESIGN, CHARACTERISTICS AND SURGICAL IMPLANTATION TECHNIQUES OF SAV’S**

According to the current ACC/AHA and ESC/EACTS 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 high risk of bleeding or life expectancy shorter than the expected durability of the bioprosthesis [2]. 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 porcine valve or bovine pericardial tissue. 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, Vascutech 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 are devoid of the stent frame and the ring at its 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, it 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 technically 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 SAV’s [17, 18]. However, it is still difficult to draw meaningful conclusions on the durability of SAV’s 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 recent large systematic review, mostly based only on the rates of reoperation) [19]. In one representative study with 10-years follow-up, 7.3% 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 a 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 SAVR arm population [21].

Recently a novel classification of bioprosthetic valve dysfunction (BVD) was proposed and defined in several position papers [22, 23]. Differently to artificial mechanical prostheses, bioprosthetic SAV’s are uniquely mostly 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, tear, leaflet disruption or flail leaflet, fibrosis and/or calcification and suture line disruption. Furthermore, different mechanism of BVD consist of: non-structural valve dysfunction (e.g. para- and periprosthetic regurgitation, prosthesis-patient mismatch (PPM), dilatation of 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 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 by means of 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 simply defined as only morphological valve deterioration. Usually however at some point, hemodynamics is impacted 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 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 out of 3 should be present for the individual patient to qualify for respective stages. For regurgitation, the respective staging is simply 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 anticipating patient’s prognosis before ViV-TAVI. It has been demonstrated in one of VIVID analysis on the group of 459 patients that in terms of 1-year mortality, population of patients presenting with predominant stenosis has the worst outcome after ViV-TAVI (23.4%) when compared
with cohorts with mixed (stenosis and regurgitation, 16.1%) presentation 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 redo 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 differs somewhat from routine work-up before the native TAVI procedure. For ViV-TAVI the process should start with identifying of the type and size of failed SAV. Patient discharge records are usually valuable sources of information for that. If unavailable or the information is sometimes not definite, type of the majority of the stented SAV’s can quite easily be 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, Labcor, 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 implemented to get more specific evaluation.

Knowing 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 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 be 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 1mm with pericardial bovine (e.g. for 21 mm CE Perimount stent ID 20 mm and true ID 19 mm). When stented SAV’s leaflets are mounted outside the stent (e.g. Mitroflow, Trifecta) the stent ID is equal to the true ID. Similarly for majority of stentless SAV’s (bar Freedom Solo
and Pericarbon Freedom) true ID is smaller than stent ID (up to 3 mm). Thus, for most identified SAV’s, 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 initial SAV label size is not available in the patient medical records or double-checking is needed (in case there may be a mistake). Moreover, most of the sizing charts are based on the true ID’s of unused SAV’s (bench testing) and therefore do not take into account possible severe calcifications or even pannus formation of failed SAV’s which may lead to further decrease of the true ID and may be of importance for proper TAV size choice 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 limitation of this procedure [24]. In VIVID registry gradients >20 mm Hg were found in 28.4% with similar frequency reported in the Polish population (21%) [10, 24]. Three major baseline features of future poor hemodynamics were identified.

First, a mechanism of SAV failure is of importance. Data from Polish Transcatheter Aortic Valve-in-Valve Implantation (ViV-TAVI) Registry show that patients presenting with stenosis as compared to mixed or regurgitation cohort 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). Out of 130 patients in the Polish registry 45% had small SAV and those resulted in a lower mean EOA (1.4 cm²) in comparison with 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 small SAV size was associated with 2-fold (hazard ratio [HR], 2.04) increase in long-term mortality [24].

Last, but not least is the baseline presence of PPM immediately after SAVR — that by itself 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 mass index [BMI] >30 kg/m²) [22]. For example, PPM may be observed very often in 19 mm label size SAV’s that are up-front characterized by manufacturers mean gradients as high as 25 mm Hg (e.g Carpentier Edwards Pericardial). This may sometimes lead to BVF occurrence immediately after SAVR or will accelerate SVD and BVF as compared to non-PPM patients [24]. If either is present, this subpopulation constitutes one of the most difficult cohorts for decision-making before ViV-TAVI and should always be considered first for re-SAVR when clinical risk is acceptable and allowing for surgical re-do and technical possibility of root enlargement/replacement and implantation of another bigger SAV prosthesis exist. Obviously, as with the latter 2 mechanisms of poor post ViV-TAVI hemodynamic performance, baseline PPM (especially severe) in SAV increases the risk for high post-ViV-TAVI gradients and impacts negatively its clinical prognosis [29].

**Identifying coronary artery occlusion risk**

It has been shown in VIVID registry that overall risk of coronary artery occlusion (CAO) with ViV-TAVI (across all SAV types in general) is still relatively rare 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 of emergent PCI that is often technically challenging or impossible [30,31]. CAO of only left main artery is most frequent (72%), followed by both left and right (20%) and rarely only right 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) being 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 rate with native TAVI) [31]. The supra-annular surgical implantation technique, design and morphology of SAV leaflets — bulkiness, severe calcification and high opening profile may further increase 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) TAV’s 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 SAV’s small aortic root dimension often coupled with non-coaxial or tilted/canted position od 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 work-up, does not adequately describe the risk and additional estimations are needed [33]. Obviously, if the coronaries originate above the tips of SAV posts/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 leaflet, when expanded TAV frame pushes the leaflets of 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 shallow sinus the tip of failed SAV leaflet reaches to or above the narrow sino-tubular junction (STJ) thus leading to a 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 the caliper measurement from the ring to the coronary ostium (separately, both for left and right coronary artery) [33]. This is called valve-to-coronary (VTC) distance and the established value of less than 4 mm is believed to serve as cut-off for high risk of CAO (OR, 0.22 for each millimeter increase of VTC) [31, 35]. In order to predict possible sinus sequestration in short SOV with leaflets extending high to or above STJ, the same virtual ring has to be applied at this level and the measured distance between expanded TAV and aortic wall is called VTSTJ (valve-to-STJ) distance. However, in the instance of VTSTJ the threshold for high risk is less known and considered as less than 2–2.5 mm [34] (Figure 2).

In the past, due to believed non-obstructive properties of surgical stentless prostheses design, the anticipated reduction in transvalvular gradients and improved flow characteristics, these 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 interpreted similar to native aortic stenosis cases regarding risk of CAO, with the sinus dimensions and coronary heights measurements in work-up CT [33] (Figure 2).

PROCEDURAL TECHNIQUE

In terms of vascular access and anesthesia in analogy to native TAVI there is an increasing rate of purely percutaneous transfemoral approach with only cautious sedation or local anesthesia instead of general [10]. Most of the available TAVs can be used for ViV-TAVI, however only 2 of them 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 standard straight wire, especially with a tilted SAV position and/or horizontal root. In such cases, using a hydrophilic wire or even crossing the SAV with pigtail or wire-supported pigtail especially in regurgitant SAVs can be successful. For highly stenotic SAVs stiffer preshaped wires (e.g. Lunderquist) may be needed to cross the valve with delivery system and position TAV. Most of the stented SAVs have clear radiopaque parts with sewing ring, stent posts or both, thus being clearly visible on fluoroscopy. This usually allows for better orientation than with native TAVI and saving contrast injections. The sewing ring serves as neo-annulus according to which frame of TAV should be oriented. Careful aligning of fluoroscopic markers allows for setting the implantation plane and the deployment views. The basic projection where the posts are aligned in 1–1–1 fashion corresponds with 3-cusp co-planar view used in native TAVI (used especially with balloon-expandable (BE) prostheses) [36] (Figure 3). 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 left cusp with left main take-off and thus facilitating assessment if coronary obstruction is at risk, while showing SAV in a perpendicular fashion [37] (Figure 3). Finally, if SE Evolut R prosthesis is used for ViV-TAVI a RAO cusp overlap view substitute (usually combination of RAO and caudal view) may facilitate alignment of SE
TAV commissures with SAV commissures and therefore increase the ease of future coronary access if PCI is needed (Figure 4).

**Predilatation of SAV**

Routine SAV predilatation is in most ViV-TAVI cases not necessary and even should be avoided as failed SAV leaflets are more prone to tearing and inducing acute aortic regurgitation than native ones [36]. But it may be useful in selected cases allowing for TAV passage in very small stenosed and canted SAVs or the presence of horizontal aorta — when needed, small size balloon not exceeding the true ID is recommended. Another possible indication for SAV pre-dilatation can be the assessment of coronary occlusion risk — as mentioned above this nowadays is usually best defined by careful CT analysis as part of decision making — but in borderline cases adequately sized (1:1 balloon size to true ID size) compliant balloon inflated low (not to occlude contrast flow at the level of STJ) can help evaluate the geometric relationship between open SAV leaflets and 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 non-compliant balloon in an attempt to fracture of modify small SAV’s rings (*see below*).

**TAV selection and implantation**

As mentioned above sizing of TAV is based on the valve type properties (true ID) supported by CT assessment. Implantation of too oversized TAV (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 rigid scaffold of stented SAV will most likely not reduce post-procedural gradients and in longer term due to under expansion of SE TAV may lead to accelerated BVD [38, 39]. It has been however proved that placement of correctly sized and positioned SE TAV with 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 SAV’s 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 SAV’s (<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
lower rate of severe PPM (44% vs. 64%, P=0.07), the difference however not impacting short-term clinical outcome [41]. Similarly, in Polish registry SE supra-annular TAV’s were associated with lower mean PGs than BE intra-annular (P = 0.004) and there was a trend towards larger indexed EOA in supra-annular vs intra-annular (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 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 echo) [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 greater extent compared with native AS). This simplification basically ignores other factors (other than transaortic gradients) that may contribute to increased transaortic velocity like: 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]. 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 TAVI. However, when echocardiographic measurement was applied (with abovementioned limitations) small BE TAV (20- or 23-mm size) display higher gradients than the remaining large BE TAV and all SE TAV. Another important observation from this study was that irrespective of type and size of TAV echocardiographic gradients are 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 measurements modalities (invasive vs. echo) suggest that they cannot be used interchangeably in order to avoid a clinical scenario where good hemodynamics achieved immediately after TAVI (also ViV-TAVI, especially with small BE TAV) with low invasive gradient measurement is questioned at discharge when echocardiography is applied.

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

Another recently brought up aspect of optimizing flow through TAV, also particularly important in ViV-TAVI setting, is the aligning of TAV commissures with SAV commissures, so called commisural 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 SE supra-annular TAV, lower gradients are recorded even with deeper TAV position [49]. Conversely, commissural misalignment may also contribute to 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 lack of radiopaque markers and rigid anchoring elements, respectively present in most stented prostheses. We have shown previously in the first, at that time largest report comparing stented and stentless ViV-TAVI in polish population, that the latter cohort is younger with 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 is most frequently the mechanism leading to BVF. This resulted in lower rate of technical success mostly due to incorrect positioning, displacement or embolization of the first TAV, the need for second prosthesis and higher rates of moderate or severe paraavalvular leak [51]. On the good side, stentless valves post TAV implantation were characterized by smaller mean transvalvular gradients, larger effective orifice areas and less PPM. These features were largely confirmed a year later in VIVID registry subanalysis on bigger cohort adding also substantially overall higher CAO risk in stentless cohort vs. stented, but mainly due to non-homograft stentless prostheses [52]. They also noted that new generations of both SE and BE TAV reduced the rates of paraavalvular 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 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 neo-annulus so pre-dilatation with 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 safer and efficient procedure with no need for second prosthesis. To address CAO risk especially in non-homograft stentless prostheses pre-emptive strategies to prevent occlusion like 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]. Therefore, 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 sized preferably at least 3 mm larger than the true internal diameter of the SAV [57]. It requires a combination of hand inflation with a syringe connected by the stopcock to 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 VIV TAVI to 6.7 ± 3.7 mm Hg after fracturing (P <0.001) [58].

Although the annular rupture might be feared of — 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, atroventricular 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 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 — showing lower final gradients and possibly avoiding stroke risk compared to preprocedural fracturing [57].

As long-term outcomes are yet to be determined our recommendation is to perform fracturing at the 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, applying 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 intubation 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 coronary ostium with its length ideally allowing it to reach to sinotubular junction. During TAV implantation guiding catheter is withdrawn to ascending aorta. After TAV is implanted, the stent should be retracted into coronary ostium so that its proximal end would reach above the displaced SAV leaflets/STJ and distal end cover the ostium and proximal part of the coronary and then deployed — parallel to implanted TAV to create a channel between SAV and aorta. If postdilatation of TAV is required (especially if non-compliant balloon fracturing/modification of the ring is planned), simultaneous kissing balloon inflation can be performed between TAV and chimney stent to prevent deformation of the latter (Figure 8). Final angiographic assessment with contrast is needed to confirm adequate filling of 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 protecting of the coronaries is beneficial. Absence of up-front coronary protection, in other words, attempting 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% 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% (n = 3) and reengagement was possible in 3 out of 4 patients [65].

Given the relative simplicity of the procedure, especially for interventional cardiologists skilled in coronary interventions, and the relative complexity of 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 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 to perform chimney stenting in CT-identified high-risk CAO regardless of normal flow to 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 TAV are used that may still expand over time. Preliminary single-center experiences show some potential added value of intravascular ultrasound to predict CAO after
TAV implantation by visualizing the SAV leaflet in relation to coronary ostia, but remain to be proven in larger observations in order to impact decision-making [66].

Leaflet splitting (BASILICA)

This is a different method of protecting coronary flow - aiming at the underlying cause of CAO — the leaflet of SAV itself, without manipulating and leaving material (stents) in coronary arteries at risk. In 2018 a concept, animal testing and first human application results of Bioprosthetic or native Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstruction (BASILICA) were published and later the technique was described in detail [67, 68].

Briefly, it starts with securing bifemoral arterial access and placing through the right groin a “traversal system” (telescope system consisting of: 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 shaved distal end). It is usually placed through 14 Fr sheath allowing for multiple catheters manipulation without blood loss. On the left side “snare system” is introduced into LVOT (consisting of 6 Fr MP guide, gooseneck snare and 0.018 wire for support). In case of double BASILICA of both left and right leaflet usually 2 large sheaths are needed. After placing the snare in LVOT parallel to aortic annulus plane, 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 Astato wire, using a very short energy burst (30 to 70 W depending on the leaflet type and amount of calcifications) from electrosurgical generator set in cut mode and applied to the shaved end of the wire. After snaring (with the wire still inside the body) IM catheter is removed and piggyback microcatheter is backed-up in order to form a V-shaped shaved part of the Astato. 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 anticipating possible acute aortic regurgitation a pigtail catheter (inserted parallel to traversal system via 14 Fr sheath) should be introduced to LV to secure quick TAV delivery if needed. With 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 V-shaped Astato wire is pulled up gently and the leaflet splits creating a triangle of flow to the coronary artery at risk [68] (Figure 9).

Then 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 coronary ostium and very short VTC distance) coronary protection with undeployed stent ready for chimney stenting can also be applied during ViV-TAVI, even after BASILICA. Also, it is of importance to correctly position TAV after BASILICA in terms of implantation height (usually aiming for slightly lower implant, however balanced with expected hemodynamic result) and most importantly attempt to align commisures 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 with the price of 3 stroke events (10%) [69]. In the large international registry BASILICA was associated with similar technical success and the stroke rate was reduced to 2.8%, however in almost 5% this technique alone did not prevent coronary occlusion [70].

Given the added complexity of current leaflet splitting technique and a specific toolbox needed, we would recommend performing BASILICA in experienced high-volume centers targeting selected younger patients, with longer life expectancy and likely need for future coronary re-access or requiring oral anticoagulant therapy (Figure 2). Considering signaled elevated stroke risk — brain protection would be 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 aortic stenosis, currently aimed at both high and intermediate risk patients, are expanding. Current guidelines supported strategy, coupled with positive results from TAVI trials showing non-inferiority to SAVR in low-risk younger populations (at least in short-term follow-up), will eventually result in growing population of patients outliving their TAV prostheses and requiring re-intervention (most probably re-do TAVI) [71, 72]. However, currently available registries, analyzing procedures since as early as 2012, report low incidence of re-do TAVI of 0.29 to 0.33% [73, 74]. 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 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 TAV; and (2) late, accounting for two-thirds — 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 existing registries are rather promising, showing 85% device success limited mainly by high residual gradients and in lesser extent by residual regurgitation and low rates of periprocedural stroke or coronary obstruction. Early (30 days) and 1-year mortality are estimated at 5% and 15%, respectively, with 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 failed TAV, position of its leaflets relative to coronary ostia and surrounding aortic root. For patients with early BVF resulting from PVL due to undersizing or underexpansion of TAV, re-do TAVI is suboptimal as the PVL would likely not improve e.g. due to presence of calcium surrounding TAV frame. Probably best result is expected with the use of BE TAV with higher radial force, especially positioned in leaking SE TAV. PVL closure often successfully performed for leaking SAV is much more technically challenging, especially in high frame SE TAV’s implanted in narrow aortic roots [76, 77]. Differently, re-do TAVI seems better suited for those early BVF cases resulting 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 concentrate 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 most recent subanalysis from FRANCE-TAVI registry, we now have observational data suggesting that in small native aortic annuli (<23 mm) SE supraannular TAV provides lower gradients and reduces severe PPM by almost 3-fold in comparison to BE TAV. Notably, the PPM observed at 1-year is a predictor of 3-year mortality (HR, 2.01) [78]. 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 type choice of the second TAV is not well defined. CT-derived diameter at the level of first TAV leaflet attachment can be useful in 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 as the first one (60%), followed by undersizing (25%) and least frequently oversizing (15%) [73]. Sizing should probably be guided also by the underlying BVF mechanism with oversizing more suitable in PVL and undersizing in highly stenotic calcified first TAV, 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 largest multi-center registry show that in 59% same type of prosthesis was used during re-do TAVI (SE in SE or BE in BE) and in the remaining minority different type (SE in BE and BE in SE) [73]. It can be suspected that the higher percentage of choice of the same type of TAV was impacted by the preference and experience of participating centers for specific TAV types. However, we would recommend in the majority of cases the second TAV to be different to 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 TAV) 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 TAV (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 second supraannular SE in failed SE seems to be least favorite scenario, again due to potential CAO and re-engagement difficulties. In patients with severe PPM and failed BE TAV, transcatheter re-do with SE supraannular may provide the best effect (however without the possibility of fracturing as in most ViV-TAVI cases) and if PPM is present in SE, whenever clinically possible, only SAVR with root enlargement may be considered. Sizing and positioning of 2nd TAV cannot be generalized and is determined by the 1st TAV type, position and size combined with native sinus/coronary anatomy. First algorithms of 2nd TAV positioning in 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 wider range of most prevalent failed TAV’s [82].

**CAO risk and prevention**

We described above the recommended CT-based features and strategies for identifying risk and dealing with threatening CAO in ViV-TAVI, respectively. In the re-do TAVI, the potential mechanisms of CAO are somewhat different and may result from: (1) pushing native calcified leaflet (by TAV frame) towards 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 STJ is lower than the first TAV commissural level and the radial distance between commisural level/pinned leaflets (“neoskirt”) and aortic wall or sinus is short (VTA, valve-to-aorta) [80, 81]. The second scenario is much more prevalent for failed supra-annular SE implanted in shallow and narrow sinuses in comparison to lower frame intra-annular BE TAV [75, 80]. It may be avoided with lower BE in SE implantation sized to native annulus and allowing for SE leaflet overhang and resulting in shorter neo-skirt [81]. Moreover, the leaflet splitting method to mitigate risk of CAO in re-do TAVI is obviously futile if commissures of first failed TAV oppose coronary ostia (as the commissure will still stay in front of coronary ostium after BASILICA), thus underscoring 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 recannulation potentially even more cumbersome than after ViV-TAVI.

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

Thrombosis of SAV or TAV implanted in native AS is not uncommon and 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) in 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. Clinical significance of SLT is still not entirely clear. In the 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 for the development of SLT compared with use of supra-annular valves. In patients with diagnosed SLT at follow-up, the risk for 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 possibly may impact valve durability and promote SVD, especially if recurrent (8.5% patients had a history of thrombosis in the period between index and re-do TAVI) [73].

Transcatheter valve-in-valve procedures (both in failed SAV or TAV) are associated with an 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 implantations compared to native valve procedures (TAVI or SAVR) [87]. The precise mechanisms of such an increased risk for 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 the 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 internal diameter of the surgical valve could also potentially contribute to the risk of thrombosis [91]. Given the current knowledge on clinical impact of SLT, the 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 the progression to systemic embolism or the need for reintervention (in this cases 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 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 for 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).

Almost 15-year experience and multiple large-scale observational studies followed by guidelines, show good efficacy and safety of ViV-TAVI, thereby reducing 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 not only limited to patients taking OAC for different indications. When bioprosthetic SAV is chosen, future improvements should start with the index SAVR technique aiming at maximizing bioprosthetic SAV sizes through root enlargement techniques in small annuli or replacing stenosed native valve with specific expandable SAV [95]. From the transcatheter perspective, TAV allowing for easy, reproducible commissural alignment and treatment of pure regurgitation (stentless valves and homografts) are in demand [53]. Additionally, 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 [96, 97].

Differently, to SAV failure, re-do TAVI is to date much less prevalent and occurs in older population, already defined as intermediate or high risk at the time of index TAVI. Thus, wider experience and reliable data are still sparse and lacking. Despite, the age of current European real-life TAVI population remaining 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 current re-do TAVI landscape, less 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 has already largely solved this problem. In those patients receiving TAVI as first procedure for AS treatment and with longer life time expectancy, the choice of the first TAV prosthesis is crucial and should be tailored to native aortic root anatomy on the basis of CT. Such scrutiny will help delay BVF, preserve coronary access and facilitate safe and effective re-do TAVI in the future.

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REFERENCES


54. Nielsen-Kudsk JE, Christiansen EH, Terkelsen CJ, et al. Fracturing the ring of small mitroflow bioprostheses by high-pressure balloon predilatation in transcatheter aortic


Table 1. Hemodynamic valve deterioration definitions. Based on [22, 23]

<table>
<thead>
<tr>
<th>Mean PG, mm Hg</th>
<th>EOA, cm²</th>
<th>DVI</th>
<th>Regurgitation</th>
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<tr>
<td>Moderate HVD</td>
<td>↑ ≥10 (to at least 20)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>↓ ≥0.3 or ≥25%</td>
<td>↓ ≥0.1 or ≥20%</td>
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<td>(stage 2)</td>
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<tr>
<td>Severe HVD</td>
<td>↑ ≥20 (to at least 30)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>↓ ≥0.6 or ≥50%</td>
<td>↓ ≥0.2 or ≥40%</td>
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<tr>
<td>(stage 3)</td>
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All changes compared to the baseline evaluation (1–3 months after index SAVR)

<sup>a</sup>Together with EOA and/or DVI (at least 2 parameters needed including PG).  
<sup>b</sup>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)
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<td>Non-small&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Coronary re-access</td>
<td>BE intraannular (short frame) SE suprannular (with attempting commisural alignment)</td>
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<td>Small&lt;sup&gt;a&lt;/sup&gt; stented</td>
<td>Residual gradients PPM</td>
<td>SE suprannular + fracturing</td>
<td>Maximizing index SAV size/fragmentable or expandable frame SAV&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Baseline PPM</td>
<td>Residual gradients worsening PPM</td>
<td>≫SE suprannular + fracturing re-do SAVR</td>
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<tr>
<td>Baseline PPM</td>
<td></td>
<td>Re-do SAVR SE suprannular</td>
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<td>Hancock II Trifecta</td>
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<td>Leaflet splitting chimney stenting</td>
<td>Dedicated leaflet splitting devices&lt;sup&gt;c&lt;/sup&gt;</td>
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<tr>
<td>Leaflets outside the stent, stentless, short VTC/VTSTJ</td>
<td>CAO risk</td>
<td>Leaflet splitting chimney stenting</td>
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<tr>
<td>Stentless (incl. homografts)</td>
<td>TAV positioning</td>
<td>Repositionable TAV</td>
<td>TAV dedicated for pure regurgitation&lt;sup&gt;d&lt;/sup&gt;</td>
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<td>PVL</td>
<td>Surgical technique endocarditis</td>
<td>Transcatheter PVL closure BE (high radial force)</td>
<td></td>
</tr>
</tbody>
</table>

TAV (re-do TAVI)
<table>
<thead>
<tr>
<th>Early (PVL) in BE</th>
<th>Severe calcium, bicuspid, 1st gen TAV, undersizing</th>
<th>Transcatheter PVL closure postdilatation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early (PVL) in SE</td>
<td>BE (high radial force)</td>
<td>TAV refinement, sealing cuffs, repositionability (currently available with 2nd gen. TAV)</td>
</tr>
<tr>
<td>Early (malpositioning)</td>
<td>BE in SE, SE supraannular in small BE, BE in non-small BE</td>
<td></td>
</tr>
<tr>
<td>Late (SVD)</td>
<td>Residual gradients PPM</td>
<td>SE supraannular preferred in small native annuli</td>
</tr>
<tr>
<td>Late (SVD)+ PPM</td>
<td>Residual gradients worsening PPM</td>
<td></td>
</tr>
<tr>
<td>BVF in SE supraannular (commissures higher than STJ)</td>
<td>CAO risk (sinus sequestration, by “neoskirt”)</td>
<td>BE positioned lower, sized to native annulus with SE leaflet overhang</td>
</tr>
<tr>
<td>›Short native leaflet to coronary distance</td>
<td>CAO risk (direct occlusion)</td>
<td>TAV with commissural alignment/shorter frame TAV</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dedicated leaflet splitting devices</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Choosing 1st TAV with CT-based simulation for safe 2nd TAV in longer life time expectancy</td>
</tr>
</tbody>
</table>

*True ID <20 mm. †Inspiris Resilia®, ‡ShortCut® (under investigation). ‡JenaValve (under investigation). †20 and 23 mm BE. ‡Mean native annulus diameter <23 mm

Abbreviations: BE, balloon-expandable; BVF, bioprosthetic valve failure; CAO, coronary artery occlusion; PPM, patient-prosthesis mismatch (severe); PVL, paravalvular 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
Figure 1. Selected, most prevalent types of surgical aortic valves (SAV). Manufacturers details: CE Perimount, CE Magna, Inspiris Resilia (Edwards Lifesciences, US); Mosaic,
Hancock II, Freestyle (Medtronic, US); Trifecta, Epic, Toronto SPV (Abbott, US); Mitroflow, Freedom (Sorin, Italy); Dokimos (Labcor, Brasil). Modified, based on [99, 100]

### CT-based risk estimation of coronary artery occlusion (CAO) during ViV-TAVI

<table>
<thead>
<tr>
<th>Decision Path</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stentless SAV</strong></td>
<td>narrow/short SoV and/or low coronary height</td>
</tr>
<tr>
<td>YES</td>
<td>VTC &gt;4 mm</td>
</tr>
<tr>
<td>NO</td>
<td>VTC &lt;4 mm</td>
</tr>
<tr>
<td><strong>Stented SAV</strong></td>
<td>coronary ostia above stent posts/top of leaflets*</td>
</tr>
<tr>
<td>VTC &gt;4 mm</td>
<td>Stent posts/top of leaflets* below STJ</td>
</tr>
<tr>
<td>VTC &lt;4 mm</td>
<td>Stent posts/top of leaflets* near or above STJ</td>
</tr>
<tr>
<td><strong>ViV-TAVI</strong></td>
<td></td>
</tr>
<tr>
<td><strong>ViV-TAVI + coronary protection (chimney stenting or BASILICA)</strong></td>
<td></td>
</tr>
</tbody>
</table>

*SAV Leaflets in simulated open position deflected by expanded TAV

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

Abbreviations: CT, computed therapy; CAO, coronary artery occlusion; STJ, sino-tubular junction; TAVI, transcatheter aortic valve implantation; ViV, valve-in-valve; VTC, called valve-to-coronary
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 also in mitral position.
**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 fluoro — TAV commissural tab (white arrow) aligned with Magna commissure between left and right cusp (black arrow). **D.** confirmation in post-op CT

Abbreviations: see Figures 1, 2
Figure 5. Different stented SAVs with balloon- and self-expandable TAVs. A, B. Sapien 3 in CE Perimount. C, D. Evolut R in Hancock II. E, F. Evolut R in Soprano. G, H. Sapien 3 in Mosaic

Abbreviations: see Figures 1, 2
Figure 6. ViV-TAVI in failed homograft and stentless prosthesis. A. Massive regurgitation in homograft, minimal calcifications. B, C. Evolut R 29 mm positioning, 2nd pigtail catheter; (white arrow). D. Good final effect after full deployment. E. Freedom Solo 25 mm stentless SAV with mildly calcified leaflets (black arrows). F. After Evolut R 29 mm implantation

Abbreviations: see Figures 1, 2
Figure 7. Bioprosthetic valve fracture of small 19 mm Mosaic SAV. A. 1–1–1 view. B. Semi-compliant balloon postdilatation after Evolut R 23 mm implant, visible waist. C. Short n-c 20
mm balloon, no waist (white arrow). D. Final effect. E, F. 2-step inflation: 1<sup>st</sup> — n-c balloon inflated with volume (syringe) and 2<sup>nd</sup> — exact pressure set with inflator (after switching the stopcock — black arrows)

Abbreviations: see Figures 1, 2
Figure 8. Left main chimney stenting with Evolut R 23 mm implantation and subsequent SAV (Mitroflow 19 mm) fracture. A, B. CT showing very small annulus perimeter and short VTC to left main distance. C. Angiographic appearance of SAV. D. Long DES chimney implantation after TAV deployment. E. Kissing balloon (DES balloon and 20 mm n-c aortic). F. Final result with fractured SAV

Abbreviations: DES, drug-eluting stent; other — see Figures 1, 2
Figure 9. Left leaflet splitting of 25 mm Trifecta (BASILICA). A. Loop snare positioned in left ventricular outflow tract and traversal system with Astato wire puncturing through the base of left leaflet (white arrow). B. Snaring Astato wire in LV after successful puncture (black arrow). C, D. V-shaped wire ready for leaflet splitting (white arrow — outside the patient and black arrow — delivered to leaflet puncture site). E, F. Successful splitting with energy burst.
Abbreviations: see Figures 1, 2

**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]
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 BVF

Abbreviations: see Figures 1, 2