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Valve-in-valve transcatheter transfemoral mitral valve implantation (ViV-TMVI): Characteristics and early results from nationwide registry

Short title: Polish transcatheter mitral valve-in-valve implantation registry

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WHAT'S NEW?

This is the first study describing characteristics and short-term results of valve-in-valve transcatheter transfemoral mitral valve implantation (ViV-TMVI) in Poland. The paper demonstrates safety and short-term efficacy of ViV-TMVI when performed in a selected group of patients with failed mitral bioprostheses, who are not considered as candidates for surgery redo.

ABSTRACT

Background: Valve-in-valve transcatheter transfemoral mitral valve implantation (ViV-TMVI) is an emerging treatment alternative to reoperation in high surgical risk patients with a failed mitral bioprostheses.

Aim: To describe characteristics and evaluate 30-day outcomes of ViV-TMVI in the Polish population.

Methods: Nationwide registry was initiated to collect data of all patients with failed mitral bioprosthesis undergoing ViV-TMVI in Poland. This study presents 30-days clinical and echocardiographic follow-up.

Results: Overall, 27 ViV-TMVI were performed in 8 centers until May 2022 (85% since 2020). Mean (standard deviation [SD]) age was 73 (11.6) years with the median (interquartile range [IQR]) STS score of 5.3% (4.3%–14.3%). Mean (SD) time between surgical implantation and ViV-TMVI was 8.2 (3.2) years. Failed Hancock II (29%) and Perimount Magna (22%) were most frequently treated. Mechanisms of failure were equally often pure mitral regurgitation or stenosis (both 37%) with mixed etiology in 26%. Balloon-expandable Sapien 3/Ultra were used in all but 1 patient. Technical success was 96.3% (1 patient required additional prosthesis). Mean (SD) transvalvular mitral gradient reached 6.7 (2.2) mm Hg and mitral valve area was 1.8 (0.4) cm^2. None of the patients had moderate or severe mitral regurgitation with only 14.8% graded as mild. In 92.6% device success (2 patients had mean gradient ≥10 mm Hg) and in 85.6% procedural success was present. There were no deaths, cerebrovascular events or need for mitral valve surgery during 30-day follow-up.

Conclusions: In short-term observation ViV-TMVI is safe and effective alternative for patients with failed mitral bioprosthesis at high surgical risk of re-operation. Longer observations on larger sample are warranted.
Key words: bioprosthesis failure, left ventricle outflow tract obstruction, mitral valve, mitral valve-in-valve, transcatheter mitral valve implantation

INTRODUCTIONSignificant mitral valve dysfunction, including both regurgitation (MR) and stenosis (MS), is associated with poor quality of life and prognosis. Surgical intervention is currently the gold standard for the treatment of significant degenerative MR and selected patients with secondary MR and MS with acceptable operative risk [1]. Mitral valve repair is the preferred method over a valve replacement whenever it is doable and when a durable result is expected. However, numerous patients require surgical prosthetic valve implantation. In recent years an increasing number of mitral bioprosthetic valve implantations is observed. Such tendency is especially visible in the elderly and patients with significant comorbidities. The use of bioprosthetic versus mechanical mitral valves is associated with a lower rate of thrombotic and bleeding adverse events, but their clinical effectiveness may be limited by limited durability. After years, some patients develop bioprosthetic valve deterioration that may lead in consequence to bioprosthesis valve failure (BVF). These individuals oftentimes require redo surgery, but high surgical risk patients, are disqualified or not referred to the procedure. It is estimated that over a period of 10 years since surgical valve replacement approximately 35% of individuals require reoperation [2]. Redo surgery is associated with an unfavorable prognosis with 30-days mortality reaching from 5% to 15% [3, 4]. An emerging treatment alternative is valve-in-vale transcatheter mitral valve implantation (ViV-TMVI). Based on the evidence of safety and efficacy of transcatheter aortic valve-in-valve implantation (ViV-TAVI), it is possible to perform this procedure with the use of devices dedicated to TAVI [5]. However, due to difference of anatomical conditions, transcatheter valve placement in mitral position is usually more complex and challenging. Since the first ViV-TMVI in 2009, this method has been performed initially only through transapical approach [6]. But later, in order to further decrease the invasiveness and avoid complications inherent to transapical access, transfemoral route with transseptal puncture gained more attention with promising results coming from international registries [7]. Yet, there is a lack of available data regarding the Polish population other than case reports [8]. Therefore, the aim of this pilot study was to evaluate early (30-day) safety and efficacy of transfemoral ViV-TMVI in Poland on the basis of nationwide registry.

METHODS

In order to collect reliable data from all Polish centers performing the procedure, the nationwide ViV-TMVI registry was initiated in 2021 *(Polish Transcatheter Transfemoral Mitral Valve-in-Valve Implantation, ClinicalTrials.gov identifier NCT05625607)*. Inclusion criteria were mitral BVF demonstrating ≥moderate stenosis and/or ≥moderate regurgitation, referral for ViV-TMVI by decision of the local Heart Team and patient-provided written informed consent. All patients undergoing transfemoral ViV-TMVI were eligible for the study.

Reported data consisted of patients' baseline characteristics (sex, age, weight, height, New York Heart Association [NYHA] symptoms class, mechanism of BVF, time between surgical replacement and transcatheter reintervention, characteristics of failed surgical bioprosthetic valve, patient's comorbidities, surgical risk presented in Society of Thoracic Surgeons (STS) replacement score and baseline echocardiographic characteristic), procedural characteristics (type of anesthesia, type and size of the implanted transcatheter prosthesis, the necessity of performing pre- and postdilatation) and 30-day follow-up (cerebrovascular events, major bleeding, major vascular complications, acute kidney injury stage 2 or 3, need for mitral surgery, echocardiographic characteristics and all-cause follow-up death).

The primary endpoint was all-cause mortality at 30 days. Secondary outcomes were technical, device and procedural success according to Mitral Valve Academic Research Consortium (MVARC) document with device success modified according to the American Society of Echocardiography guidelines [9, 10]. Clinical endpoints were assessed based on the presence or absence of events defined in MVARC consensus document criteria. The safety and performance of the device included in the MVARC device success endpoint were assessed in echocardiography. Modified device success definition involved the acceptance of mean postprocedural transmitral pressure gradient <10 mm Hg, as a value reported in properly functioning bioprostheses. Technical success was assessed at the exit from the catheterization laboratory. Other endpoints were recorded at 30-day follow-up.

ViV-TMVI work-up and procedure overview

Multi-slice computed tomography (CT) is an important imaging modality to plan the procedure in the respect of assessing aorto-mitral angulation (preferably >120 degrees) and predicting post-procedural LVOT area with superimposing the transcatheter valve that is intended to be placed (so called neo-LVOT, minimum area of at least 200 mm^2) in order to avoid LVOT obstruction. (Figure 1) The correct valve size is usually based on CT and available sizing chart in respect to true internal diameters of surgical mitral devices — viv-mitral app (developed by

Vinnie Bapat). Differently to TAVI, mitral valve is characterized by high closing pressures, thus the transcatheter device should be more oversized and ideally conical shape after deployment is desired in order to prevent immediate and late transcatheter prosthesis migration or embolization. In borderline measurements type of BVF may influence the correct size choice — larger in regurgitation, smaller in severe stenosis. Oversizing can be achieved by adding more balloon volume during valve inflation.

Procedure is performed under general anesthesia or conscious sedation depending on the standard protocol of the valve centers and starts with right femoral venous puncture that can be secured with 2 Proglides. Then, in order to reach the left atrium under the guidance of transesophageal echo (TEE), septal puncture is performed typically in the low and inferior position in fossa ovalis. Subsequently, using a steerable catheter (Agilis, Abbott Vascular, Chicago, IL, US) surgical prosthesis is crossed with the pigtail catheter and stiff wire (e.g. Lunderquist or two Safari wires) is positioned with the pre-shaped tip facing downwards. Afterwards, balloon septostomy (usually 10–14 mm non-compliant balloon with prolonged low-pressure inflation) is performed to facilitate the crossing of delivery system with the balloon-expandable valve. Predilatation of failed surgical valve is rarely needed as it also carries risk of embolism or acute regurgitation but can be performed in selected borderline sizing situations. After achieving optimal position of transcatheter prosthesis (importantly, it is mounted in the opposite direction in comparison when used for TAVI), which is a 10–20% located in the left atrium and 80%–90% in the left ventricle, the valve is expanded during rapid ventricular pacing. In case of suboptimal expansion or paravalvular leak, postdilatation may be performed by adding more volume to the balloon catheter to fully expand the valve. Respective angiographic steps and echocardiographic images of exemplary ViV-TMVI procedure are presented in Figures 2 and 3, respectively. Fluoroscopic appearances of different surgical mitral valves are presented in Figure 4.

Statistical analysis

Continuous variables are presented as mean values with standard deviation (SD) or as medians with interquartile range (IQR). Qualitative variables are presented as numbers and percentages. Statistical analysis was performed in IBM SPSS Statistics 29.

RESULTS

Baseline clinical characteristics

Overall, until May 2022, 27 procedures were performed in 8 Polish centers (26 valve-in-valve and 1 valve-in-ring). An increasing number of procedures was observed since 2020, comprising 85% of reported cases (n = 23). Women constituted 59.3% (n = 16) of the cohort. The mean (SD) age of the study population reached 73 (11.6) years. The mean (SD) time between surgical valve replacement and BVF requiring transcatheter treatment was 8.2 (3.2) years. At baseline 70.4% (n = 19) of patients were in NYHA III or IV symptoms class. The median (IQR) STS replacement score reached 5.3% (4.3%–14.3%). (Table 1).

Surgical prostheses characteristics

Hancock II and Perimount Magna composed the majority of dysfunctional bioprostheses. Other were Epic, Mosaic, Labcor, CE Standard and Physio1 annuloplasty ring. The percentage of particular devices is demonstrated in Figure 5. In more than half of the population the label size of failed prosthesis was 29 mm (55.5%), followed by 27 mm (25.9%). 3 patients had 31 mm valve and one 33 mm. The only failed ring was 34 mm.

Baseline echocardiographic assessment

The mechanisms of BVF were equally pure mitral regurgitation (37%, n = 10) and stenosis (37%, n = 10). In 7 (26%) patients mixed dysfunction was diagnosed. The mean (SD) left ventricle ejection fraction before the transcatheter procedure was 48.8 (16%). Mean (SD) mitral transvalvular pressure gradient was 10.2 (4) mm Hg and mitral valve area 1.1 (0.6) cm^2. More than 80% (n = 22) of patients demonstrated mean transvalvular pressure gradient ≥5 mmHg and more than one-third (n = 9) ≥10 mm Hg. Moderate or severe regurgitation was present in 17 patients (63%).

Transcatheter prostheses characteristics

All procedures were performed with transesophageal guidance. In 96.3% of patients balloon-expandable Sapien 3/Ultra bioprosthesis was used (Edwards Lifesciences, Irvine, CA, US) except 1 Myval valve implantation (Meril Lifesciences, Gujarat, India). The majority of patients received 29 mm size valve (59.2%), followed by 26 mm (37%) and 1 patient was implanted with 23 mm prosthesis. In 4 (14.8%) cases predilatation was done. Only 1 patient required postdilatation in order to fully expand the transcatheter prosthesis.

Outcomes

In all patients transcatheter prosthesis was successfully delivered into mitral position. There were no periprocedural deaths, no cases of LVOT obstruction or need for conversion to surgery. The frequency of major vascular complications, major bleeding, and acute kidney injury was 3.7% (n = 1), each. Technical success was achieved in 26 out of 27 patients, which constituted 96.3% of all procedures. In this case, due to partial transcatheter prosthesis displacement towards the left ventricle, there was a need for second valve for stabilizing and anchoring of the first valve. After that, proper prosthesis function was achieved with the mean transvalvular gradient of 5 mm Hg, no evidence of LVOT obstruction and the patient was discharged in a good condition (Table 2).

Device success using strict MVARC criteria of mean transvalvular gradient less than 5 mmHg were fullfilled only in 29.6% (n = 8), but modified device success according to The American Society of Echocardiography with cut-off at less than 10 mmHg that is more suitable for valve-in-valve procedures and previously adopted by others [11] was present in 92.6% (n = 25). Overall, mean (SD) transvalvular pressure gradient decreased to 6.7 (2.2) mmHg and mean (SD) effective orifice area (EOA) increased to 1.8 (0.4) cm^2. Survival, freedom from stroke/TIA or need for surgery at 30 days was 100% (Table 3).

Most of the patients were discharged on oral anticoagulation alone (n = 20, 74%) in 6 (22%) patients double therapy combining oral anticoagulation with single antiplatelet was used and in 1 case double antiplatelet therapy was prescribed.

DISCUSSION

The abovementioned results suggest that in short-term observation transfemoral ViV-TMVI is safe and effective treatment for failed surgical mitral bioprosthesis. In recent time an increasing number of ViV-TMVI procedures is observed, which might be correlated with longer patients' survival after cardiac surgery and general patients' preference for biological prosthesis. In the evaluated present study of polish population 30-day survival rate was 100% and there were no or minimal major adverse clinical events, e.g. cerebrovascular or bleeding/vascular, repeat surgery. Other larger cohort international papers report 30-day mortality reaching up to 8% with other adverse events also more frequently occurring when describing outcomes of early experiences [12]. These promising clinical results coming from this first experience in Poland are probably attributable to the later adoption of this technique in Poland and thereby avoidance of most of the issues characteristic for early stages of ViV-TMVI (e.g. LVOT obstruction prevention by CT imaging simulation, proper transseptal puncture position, greater oversizing of transcatheter prosthesis to avoid displacement or embolization, positioning of stiff wire to

avoid apical perforation, etc). This also highlights the importance of precise preprocedural assessment by both CT and echocardiography to properly refer and plan safe procedure.

A life-threatening complication, requiring special consideration during ViV-TMVI is LVOT obstruction created by displacement of surgical prosthesis leaflet into open position and thus limiting blood flow through aortic valve. A small area of neo-LVOT (estimated on the basis of computed tomography simulation), acute mitral aorta-outflow-angle (aortomitral angulation), high ejection fraction and small cavity size are proven predictors of LVOT obstruction [13, 14]. Again, in our population none of the patients experienced this event due to routine pre-procedural CT planning and the use of established cut-offs, however other papers reporting from earlier experiences show its incidence ranging from 0.7 to 5% [7, 15, 16].

Postprocedural gradients/area in our cohort (mean [SD] transvalvular mitral gradient of 6.7 [2.2] mm Hg, 70.3% ≥5 mm Hg, 7.4% ≥10 mm Hg and mitral valve are of 1.8 [0.4] cm^2) are in line with other previously reported data. Largest VIVID registry data showed a mean (SD) transmitral gradient 5.6 (2.7) mm Hg with 60% of the population presenting values ≥5 mm Hg and 8.2% ≥10 mm Hg and mitral valve area of 2 (0.7 cm^2) [7]. The mean (IQR) transvalvular gradient and mitral valve area presented in TVT registry reached respectively 6 (4–8) mm Hg with area of 1.9 (1.4–2.5) cm^2 [15]. Smaller observation from Eleid et al. [16] on 60 patients demonstrated mean (SD) gradient of 6.9 (1.8) mm Hg and area of 1.9 (0.7) cm^2.

The presence of a radiologically translucent dysfunctional valve makes a TMVR more challenging procedure and increases the risk of suboptimal valve position or displacement. However, under precise 3D transesophageal echocardiographic guidance, it is feasible to successfully implant new bioprosthesis into failed valve even in the absence of radiopaque markers [17].

It is worth noting that it is feasible to perform ViV-TMVI implantation also via surgical access [18, 19]. The field started with transapical route, later also open transatrial deployment was rarely implemented, both allowing for more direct transcatheter valve delivery and immediate intervention in case of major complications requiring surgical management. However, these surgical access sites by nature are more invasive in high-risk populations compared with transfemoral venous access with transseptal puncture leading to the increasing adoption of the latter.

Limitations

This study presents several limitations, which must be taken into consideration when interpreting the results. Firstly, our registry includes also retrospective data with all its inherent

limitations. Secondly, due to still early experiences in ViV-TMVI procedures in Poland, the study cohort was limited and that precluded any meaningful subanalysis or comparisons. Finally, the study includes echocardiographic data provided by respective reporting centers, which are physicians-depended and were not validated by core laboratory.

CONCLUSIONS

Promising results of this pilot study suggest, that transfemoral ViV-TMVI is a safe and efficient method for failed mitral bioprostheses treatment when performed in a selected group of high-risk patients. This intervention has emerged as an alternative to surgery redo in significantly burdened populations. However, meticulous preprocedural assessment and proper patient referral are crucial to avoid major complications. Further studies on larger cohorts and longer follow-up are required for more definite evaluation.

Article informations

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Table 1. Baseline characteristics

	All (n = 27)
Demographics and presentation	
Female sex, n (%)	16 (59.3)
Age, years, mean (SD)	73.0 (11.6)
Time since surgery, years, mean (SD)	8.2 (3.2)
STS, %, median (IQR)	5.3 (4.3–14.3)
NYHA II, n (%)	8 (29.6)
NYHA III, n (%)	17 (63.0)
NYHA IV, n (%)	2 (7.4)
Comorbidities	
Diabetes mellitus, n (%)	8 (29.6)
Peripheral vascular disease, n (%)	8 (29.6)
Chronic kidney disease, n (%)	9 (33.3)
Atrial fibrillation, n (%)	21 (77.8)
Cerebrovascular disease, n (%)	6 (22.2)

Chronic lung disease, n (%)	2 (7.4)
Permanent pacemaker, n (%)	7 (25.9)

Abbreviations: NYHA, New York Heart Association; STS, Society of Thoracic Surgeons

Table 2. Procedural outcomes

	All (n = 27)
Procedure-related death	0 (0)
Conversion to surgery	0 (0)
LVOT obstruction	0 (0)
Valve displacement	1 (3.7)
Need for second valve	1 (3.7)
Technical success[a]	26 (96.3)

Values are n (%)

Abbreviation: LVOT, left ventricular outflow tract

[a]Defined as a procedure meeting all of the following: absence of procedural mortality; successful access, delivery, and retrieval of the device delivery system; successful deployment and correct positioning of the first intended device; and freedom from emergency surgery or reintervention related to the device or access procedure

Table 3. Clinical and echocardiographic outcomes at 30 days

	All (n = 27)
Clinical	
All-cause mortality, n (%)	0 (0)
Stroke/transient ischemic attack, n (%)	0 (0)
Major bleeding, n (%)	1 (3.7)
Major vascular complication, n (%)	1 (3.7)
Acute kidney injury (stage 2 or 3), n (%)	1 (3.7)
Echocardiography	
Left ventricular ejection fraction, %, mean (SD)	47.9 (13.6)
Mean transmitral gradient, mm Hg, mean (SD)	6.7 (2.2)
Mean transmitral gradient ≥10 mm Hg, n (%)	2 (7.4)
Mitral valve area, cm^2, mean (SD)	1.8 (0.4)
Regurgitation none/trace, n (%)	21 (77.8)
Regurgitation mild, n (%)	6 (22.2)
Regurgitation moderate/severe, n (%)	0 (0)

Device success[a], n (%)	25 (92.6)
Procedural success[b], n (%)	23 (85.1)

[a]Defined as follows: absence of procedural mortality or stroke; proper placement and positioning of the device; freedom from unplanned surgical or interventional procedures related to the device or access procedure continued intended safety and performance of the device, including: (1) no evidence of structural or functional failure; (2) no specific device-related technical failure issues and complications; and (3) reduction of mitral regurgitation to acceptable levels without significant mitral stenosis (defined as a transmitral gradient ≥10 mm Hg and/or an effective orifice area ≤1.0 cm^2 following American Society of Echocardiography guidelines) and with no greater than moderate (2+) paravalvular mitral regurgitation (and without associated hemolysis). [b]Defined as a procedure that has achieved device success without major clinical complications, including death, stroke, life-threatening/fatal bleeding, major vascular complications, stage 2 or 3 acute kidney injury, severe congestive heart failure, valve-related dysfunction, or other complications requiring surgery or repeat intervention

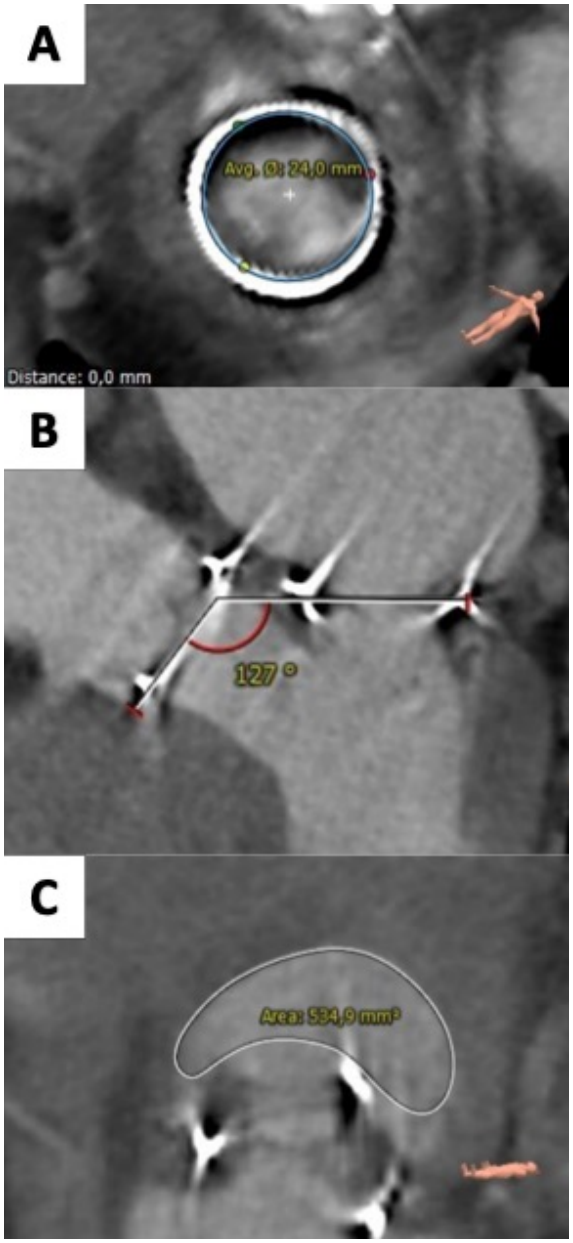

Figure 1. Basic pre-procedural computed tomography parameters (Hancock II 29 mm). **A.** Annulus size (24 mm) equal to true internal diameter of 29 mm Hancock II. **B.** Aorto-mitral angle >120 degrees. **C.** Large predicted neo-LVOT area suggesting low risk of LVOT obstruction

Abbreviations: LVOT, left ventricular outflow tract

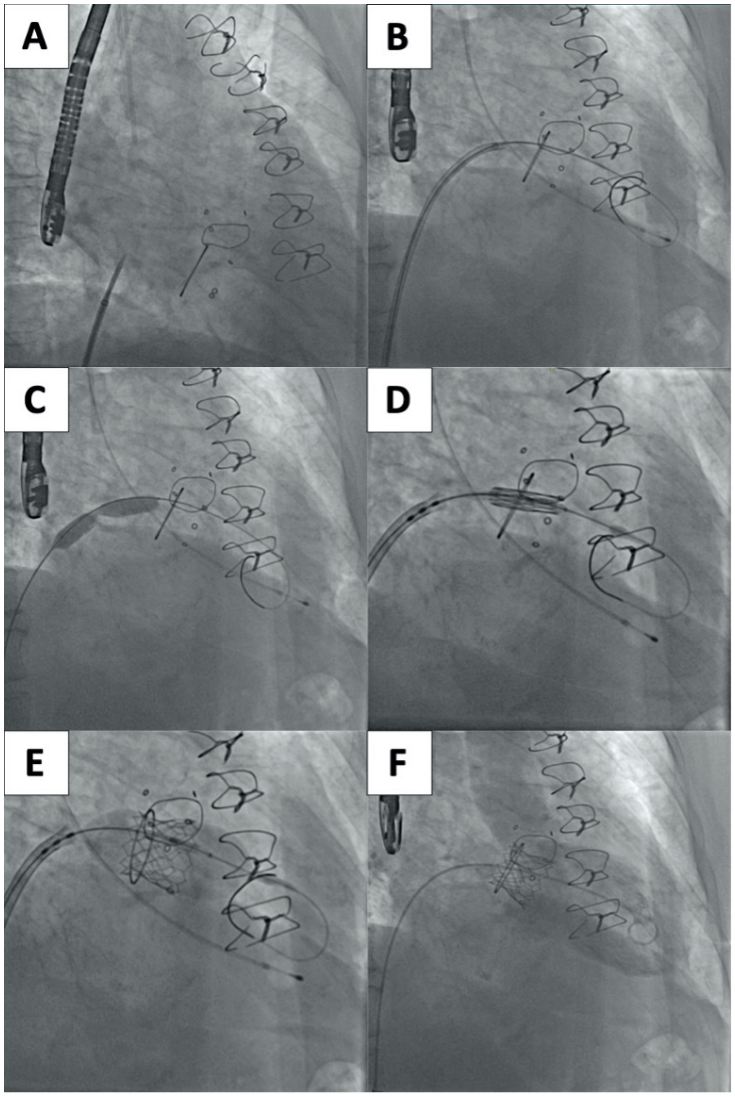

Figure 2. Step-by-step angiographic recordings of transfemoral ViV-TMVI in failed Hancock II 29 mm prosthesis. All examples in deep RAO projection to align the mitral prosthesis. **A.** After securing right femoral venous access TEE guided transseptal puncture. **B.** Placement of stiff pre-shaped wire in the left ventricle (facing downwards) with the use of deflectable Agilis catheter. **C.** Septostomy with non-compliant 10–14 mm balloon (prolonged, low-pressure inflation). **D.** Exchanging for S3 delivery system (with prosthesis mounted opposite to TAVI) and crossing the mitral prosthesis. **E.** Deployment of 26 mm S3 valve during rapid pacing with intended positioning of 10–20% atrial and 80%–90% ventricular. **F.** Final result showing good position with desired oversize and conical shape of S3 and no regurgitation

Abbreviations: RAO, right anterior oblique; TAVI, transcatheter aortic valve implantation; TEE, transesophageal echocardiography; ViV-TMVI, valve-in-valve transcatheter transfemoral mitral valve implantation

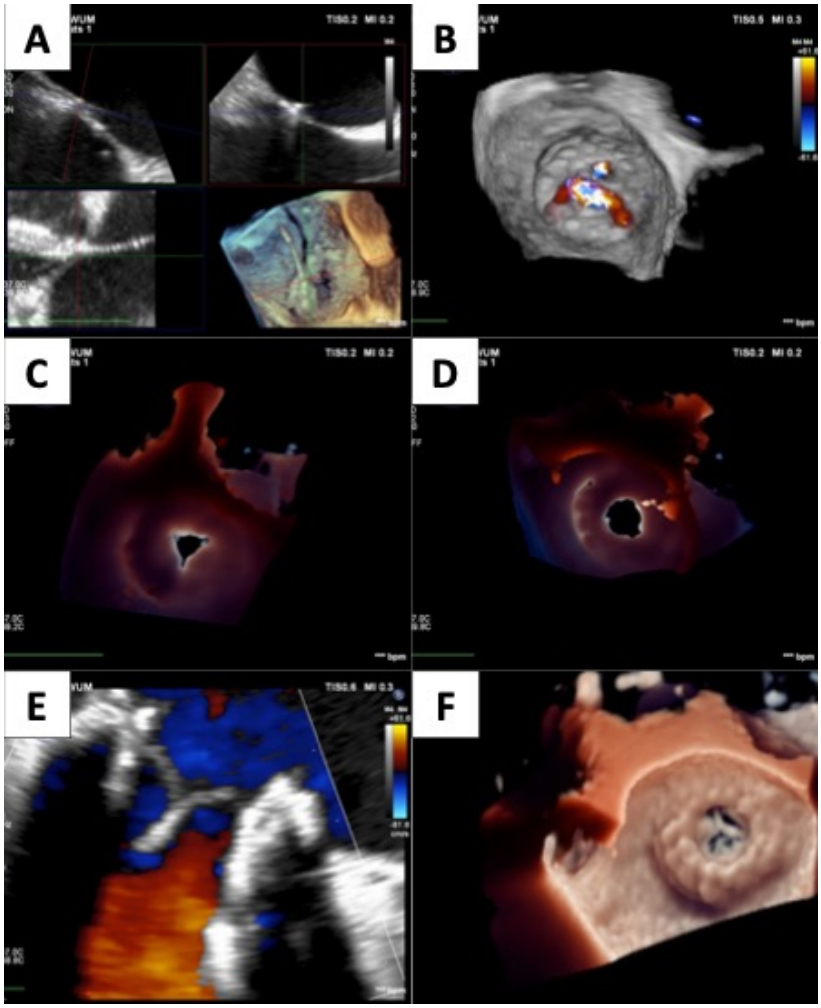

Figure 3. Transesophageal echocardiography during ViV-TMVI (26 mm S3 in 29 mm Hancock II with predominant stenosis). **A.** Inferior and posterior transseptal puncture. **B.** Baseline regurgitation. **C.** Pre-procedural mitral valve area. **D.** Post-procedural mitral valve area. **E.** Absence of regurgitation post implantation. **F.** S3 3D appearance inside Hancock II

Abbreviation: see Figure 2

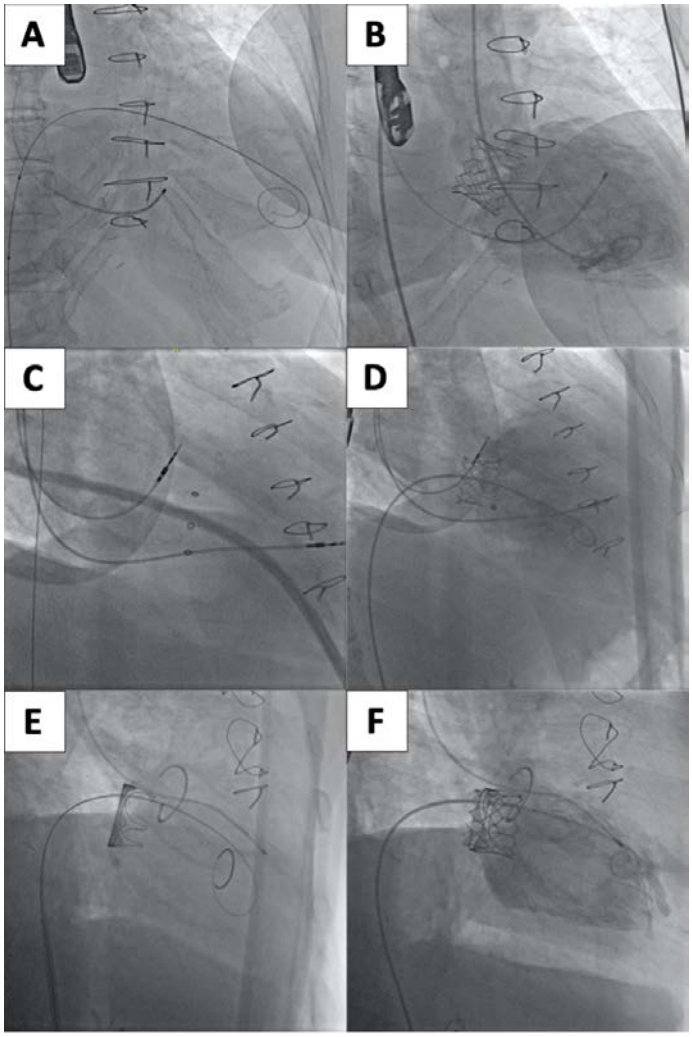

Figure 4. Fluoroscopic pre- and post-procedural (after S3 implantation) presentation of different surgical prostheses. **A, B.** Minimal visibility of Epic prosthesis ring. **C, D.** Radiopacity of prosthesis posts only in Mosaic valve. **E, F.** Good visibility of both annulus and posts in Perimount Magna

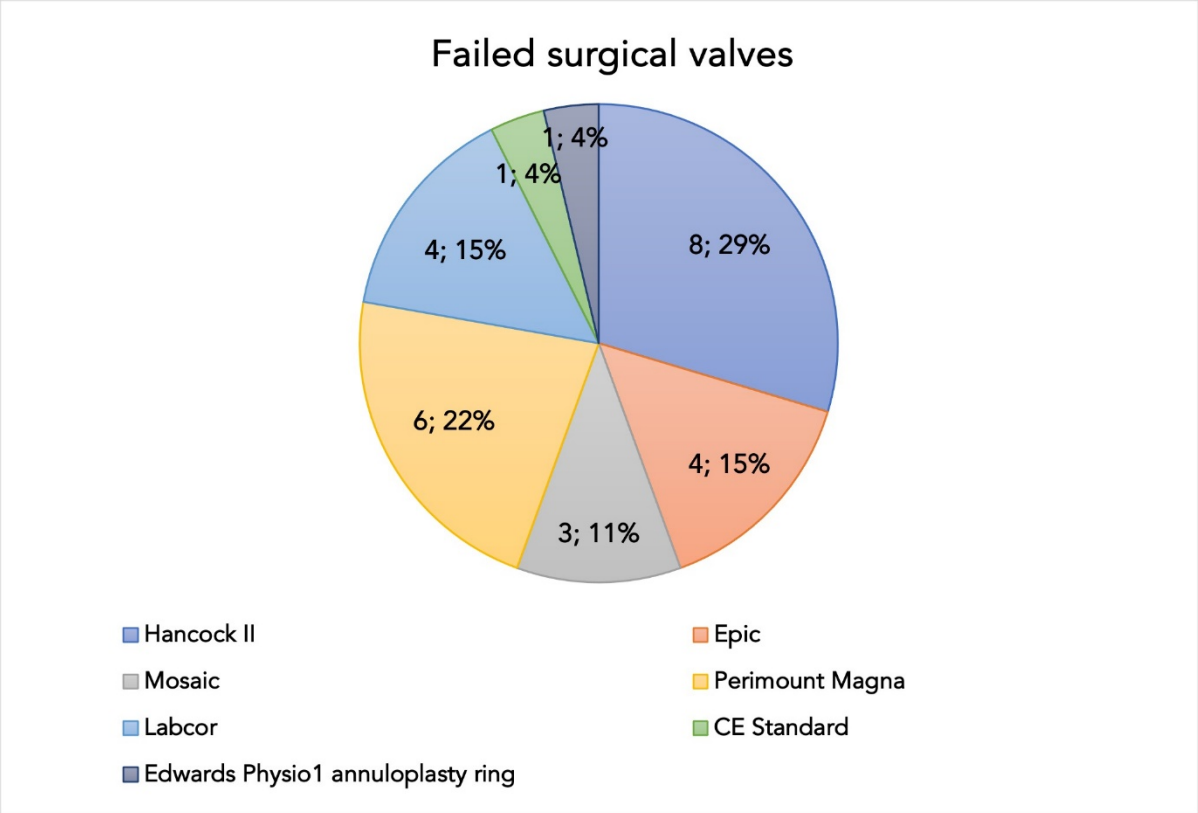

Figure 5. Types and percentages of failed mitral bioprostheses