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Femoral transcatheter valve-in-valve implantation as alternative strategy for failed aortic bioprostheses: A single-centre experience with long-term follow-up

Tomasz Stankowski [a,*], Sleiman Sebastian Aboul-Hassan [b], Farzaneh Seifi Zinab [a], Volker Herwig [a], Piotr Stępiński [c], Oliver Grimmig [a], Soeren Just [a], Axel Harnath [a], Anja Muehle [a], Dirk Fritzsche [a], Bartłomiej Perek [d]

[a] Sana Heart Center Cottbus, Department of Cardiac Surgery, Cottbus, Germany
[b] Department of Cardiac Surgery, Heart Diseases Center MEDINET, Nowa Sol, Poland
[c] Department of Cardiac Surgery, Lodz Medical University, Lodz, Poland
[d] Department of Cardiac Surgery and Transplantology, Poznan University of Medical Sciences, Poznan, Poland

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ABSTRACT

Background: Surgical reoperation is still a standard procedure performed for degenerated aortic bioprostheses. On the other hand femoral minimally invasive valve-in-valve implantation (femTAVI-VIV) is an intriguing alternative. This clinical study was design to compare the early and late outcomes of redo-surgery (Redo-AVR) and femTAVI-VIV procedures for failed aortic bioprostheses.

Methods: We retrospectively reviewed 108 patients with degenerated aortic bioprostheses qualified for isolated Redo-AVR (n = 40) or femTAVI-VIV (n = 68) between 2003 and 2018. Both cohorts were divided into intermediate and high-risk groups according to the EuroSCORE II (4–9% and >9%). Propensity score matching selected 20 pairs in Intermediate-risk group and 10 pairs in High-risk group for the final comparison.

Results: Patients qualified for femTAVI-VIV were older (79.2 vs 72.9 years, $p < 0.001$) and at higher risk (EuroSCORE II 10.9 vs 7.8%, $p = 0.005$) than Redo-AVR subjects. Overall survival in femTAVI-VIV and Redo-AVR was comparable at 30-days, 1- and 5-years, respectively (92.6% vs 92.5%, 85.2% vs 85.0% and 62.9% vs 72.5%, $p = 0.287$). After PSM no differences in mortality, myocardial infarction, pacemaker implantation, stroke or acute renal insufficiency were found. Transcatheter procedure was associated with shorter hospital stay, lower rate of blood products transfusions and higher incidence of mild paravalvular leaks.

Conclusion: Our study supports the opinion that transcatheter approach for treatment of patients with degenerated aortic bioprostheses is a safe alternative to Redo-AVR procedures particularly for those at high-risk.

1. Introduction

The first transcatheter aortic valve implantation was performed in Rouen on April 16th, 2002 by Alan Cribier [1]. Seventeen years later TAVI seems to be a routine procedure for inoperable, high-risk or even intermediate-risk patients in most symptomatic aortic valve diseases [2,3]. Greater experience with TAVI has resulted in an extension of its indications. Also, the use of biological valves in aortic position in younger patients has led to a growing number of degenerated prostheses, requiring aortic valve re-interventions [4]. Surgical open-heart redo aortic valve replacement (Redo-AVR) has been the standard procedure for many years, although transfemoral transcatheter valve-in-valve (femTAVI-VIV) implantation as a less invasive alternative seems to be a new method of choice for at least high risk patients [5,6]. Up to now many reports comparing Redo-AVR to TAVI-VIV have been published but all of them analyzed only early outcomes (usually one year) [5–7]. Unfortunately, there is a shortage of studies dealing with long-term outcomes.

The aim of this retrospective study was not only to compare early mortality and morbidity of patients undergoing Redo-AVR and femTAVI-VIV for failed aortic bioprostheses but also to estimate late probability of late survival following these interventions.

2. Methods

2.1. Patients

Between March 2003 and April 2018, a total of 108 consecutive patients with failed aortic bioprostheses were qualified for the femTAVI-

* Corresponding author at: SANA Heart Center Cottbus, Department of Cardiac Surgery, Leipziger Str. 50, 03048 Cottbus, Germany.
E-mail address: tomekstankowski89@gmail.com (T. Stankowski).

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VIV implantation (n = 68;63%) or surgical isolated Redo-AVR (n = 40;37%) in the Department of Cardiac Surgery, Sana Heart-Center Cottbus, Germany. Individuals with acute endocarditis, requiring concomitant cardiac procedures, having an approach other than femoral for TAVI-VIV, with previously implanted mechanical or transcatheter valves were excluded (Fig. 1). Institutional review board waived an individual patient's consent due to the retrospective nature of the study. The Heart Team, consisting of a cardiac surgeon, a cardiologist, and an anesthesiologist, always carefully discussed the treatment strategy. Complete follow-up was performed mainly by family physicians with a few interviews conducted by phone, with a mean period of 5.6 years (12 months–16 years). Clinical study end-points were defined using The Valve Academic Research Consortium-2 (VARC-2) [8].

2.2. Re-intervention

After careful qualification by "Heart Team" standard preoperative preparation, surgical reoperation was performed under general anesthesia through median re-sternotomy using an oscillating saw. Standard intrathoracic or femoral cannulation was used as an approach for cardio-pulmonary bypass (CPB) employment. The myocardium was protected by antegrade warm blood-cardioplegia or cold crystalloid-cardioplegia, injected into the aortic root or directly into the native coronary and graft ostia. The new valve size was chosen by the surgeon on the base of intraoperative inspection and measurements as well as diameter of the previously implanted bioprosthesis (Appendix Table 1).

As for transfemoral approach for TAVI-VIV, the most common access was through the right femoral artery (n = 66;97.1%). Conscious sedation with local anesthesia was possible in 60 patients (88.2%). In all cases, the balloon-expandable Medtronic (Medtronic, Minneapolis, MN) valves were used. The size of the valves was chosen after an analysis of the multi-slice computed tomography with dedicated OsiriX imaging software (Pixmeo, Geneva, Switzerland). Pre-balloon dilation was routinely performed in all patients and three patients required post-dilatation due to the high residual gradient. Thirty four initial procedures were performed with the Medtronic CoreValve, then with the CoreValve Evolut R valves. Fourteen out of thirty-four patients with CoreValve Evolut-R underwent repositioning of the prosthesis to optimize the position and in 4 patients, the repositioning was performed ≥2 times.

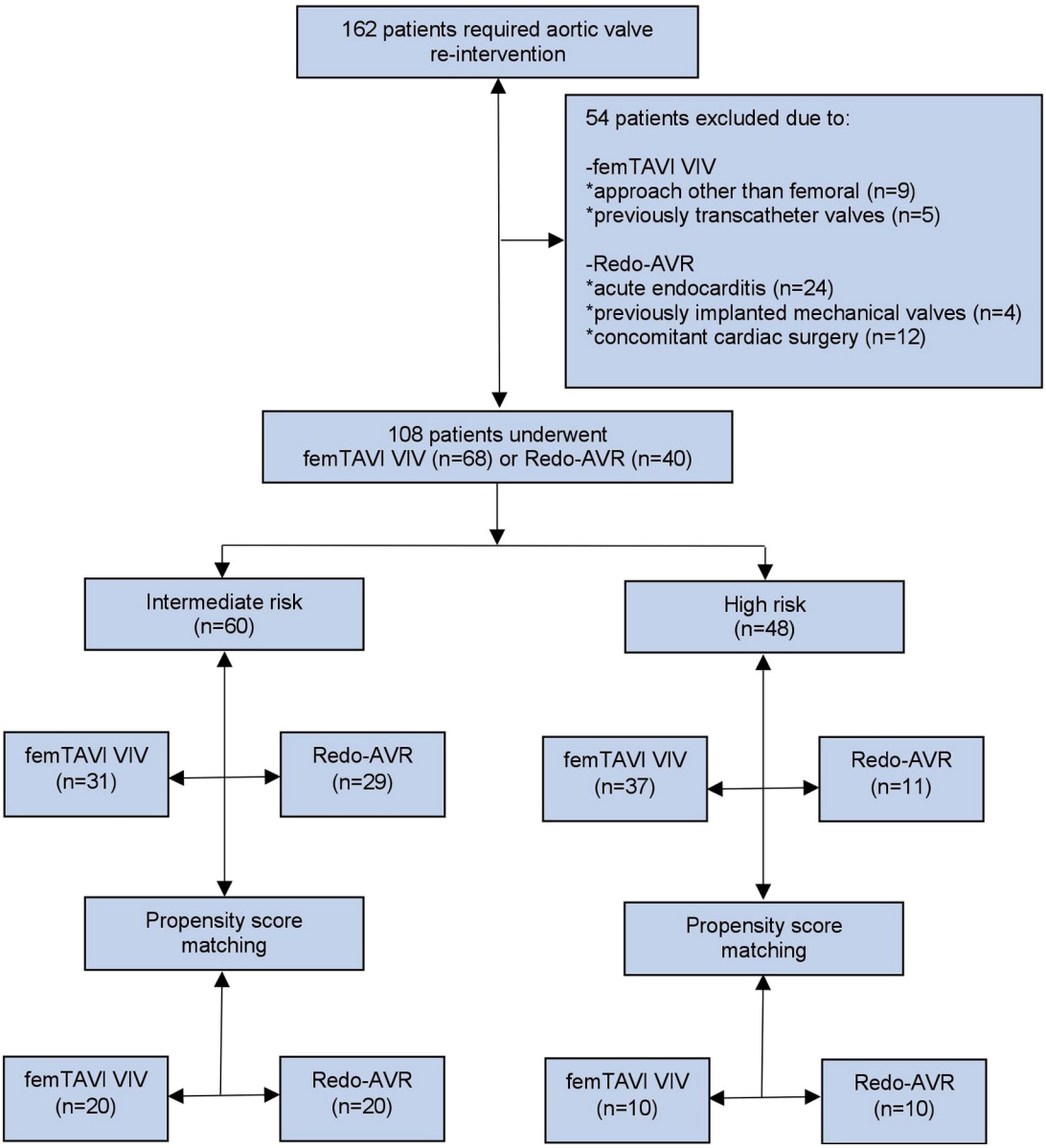

Fig. 1. Defining the study population.

2.3. Statistical analysis

Continuous variables were expressed as means ± SD, while categorical variables as number and percentages. For continuous data Student's *t*-test or Mann–Whitney's *U* test were used for between groups comparisons, while categorical variables were compared with Pearson-χ2 test. To reduce the risk of selection due to the observational character of the study, a propensity score (PS) matching was used between the groups of patients with intermediate-risk and high-risk based on EuroSCORE II(ESII), separately. In the intermediate risk patients, propensity scores were generated from a logistic regression model based on age and ESII, whereas in the high risk group, PS were generated from a logistic regression model based on age. Patients were then matched in 1:1 fashion using caliper matching method without replacement with a caliper width of 0.2 standard deviation of the logit of the PS (Fig. 1) [9,10]. The balance of the covariates was tested using standardized mean difference (SMD). Statistical guidelines suggest a meaningful covariate balance of the variables used to generate the PS between the two groups to be between $-0.1 < SMD < 0.1$ [9]. Unadjusted and PS adjusted populations were estimated using the Kaplan-Meier method and were expressed as percentage. Log-rank test was used to compare the data. Statistical significance was defined as *p*-value of<0.05.Statistical analysis was computed with STATISTICA ver.13 for Windows software (TIBCO StatSoft, Inc., Tulsa, OK, USA).

3. Results

3.1. Baseline characteristics

All demographics and preoperative clinical data are presented in Table 1. Overall, patients qualified for femTAVI-VIV were significantly older and presented a higher operative risk. They were also burdened with more comorbidities such as coronary artery disease and presented worse kidney function, left ventricular ejection fraction and more often mitral or tricuspid valve regurgitation. Patients referred for femTAVI-VIV presented more often leading stenosis as the mean cause of re-intervention. Severe prosthesis-patient mismatch(PPM) (ie., iEOA ≤0.65cm^2/m^2) after primary surgical aortic valve interventions was observed in seven patients in the femTAVI-VIV group and in three patients qualified for Redo-AVR. All patients with severe PPM had a valve with a diameter ≤ 21mm.

Patients were subsequently divided according to their ESII (Intermediate-risk 4–9% and High-risk >9%) and type of surgery. PS matching selected 20 matched pairs in intermediate-risk-group and 10 pairs in high-risk group for final comparison. All demographics and preoperative clinical data of the matched subgroups are similar except the mean and peak transaortic gradients in intermediate-risk group.

3.2. Intraoperative data

One patient died during the femTAVI-VIV procedure due to acute tamponade caused by the perforation of the left ventricle by the guidewire and despite of the emergency conversion to full median re-sternotomy. Mean skin-to-skin time was significantly shorter (>3-fold) in the femTAVI-VIV group before and after matching. Transcatheter interventions required a mean fluoroscopy time of 13.8 ± 7.5 min and an average contrast load of 213.1 ± 83.8 mL. Over three quarters of TAVIs were performed with an implantation level below 4 mm below the neoannulus.

All patients survived the Redo-AVR. The mean CPB-time during Redo-AVR was 114.1 ± 47.9 min and aortic cross-clamping time 76.1 ± 27.9 min. The types and sizes of the new valves are listed in Appendix Table 1. Surgical re-exploration due to excessive postoperative bleeding was necessary in three patients (7.5%). One patient needed vacuum-assisted closure (VAC) therapy to treat the deep sternal wound infection.

3.3. Overall femTAVI-VIV vs Redo-AVR

Five patients in transcatheter group and three patients in reoperation group died during the first 30- days after the procedure (Appendix Table 2). Mean length of intensive care unit (ICU) stay and in-hospital stay were significantly longer after the Redo-AVR, respectively. No significant differences were found between femTAVI-VIV and Redo-AVR in post-procedural new dialysis rate, incidence of multiple organ dysfunction syndrome (MODS), myocardial infarction, stroke or pacemaker implantation (Table 2). Patients treated with transcatheter method compared with Redo-AVR, showed a lower rate of new onset post procedural atrial fibrillation (5.7% vs 29.2%, p = 0.014). Femoral artery stent-graft implantation was required in four patients due to access-related vascular injury and was the complications associated only with femoral transcatheter approach. Moreover, the average amount of red blood cells (RBCs), fresh frozen plasma(FFPs) and platelets(PLTs) were greater in the redo-AVR group.

3.4. Intermediate risk group

No significant differences were found between groups before and after matching in: 30-day mortality, ICU-stay, stroke, post-procedural new dialysis rate, MODS, myocardial infarction and pacemaker implantation. Hospital-stay was significant shorter in transcatheter groups. Patients after Redo-AVR presented greater rate of new onset post procedural atrial fibrillation in the both unmatched and matched cohorts. Before matching the average amount of RBCs, FFPs and PLTs were greater after Redo-AVR, however after PSM only the overall transfusion rate was significant different (Table 2).

3.5. High risk group

High-risk patients who underwent femTAVI-VIV versus Redo-AVR did not show significant differences in 30-day mortality, stroke, post-procedural new dialysis rate, MODS, myocardial infarction, rate of new onset post procedural atrial fibrillation and pacemaker implantation, in both the unmatched and matched cohorts. Shorter ICU and hospital-stay were observed in unmatched patients after femTAVI-VIV. After matching, patients who underwent femTAVI-VIV versus redo-AVR did not show significant differences in mean length of intensive care unit, however in the Redo-AVR cohort patients required longer hospital stay. Furthermore, in the transcatheter group, we detected a decreased need of transfusion rate in transcatheter patients.

3.6. Post-procedural hemodynamic results

We observed a significant reduction of transvalvular mean and peak gradients following both procedures and gradients were also comparable postoperatively after femTAVI-VIV and Redo-AVR in unmatched und matched patients. Regardless of the procedure type, around 30% of patients had a postoperative transvalvular mean gradient over 20 mmHg. Four out of ten patients with severe PPM after the primary surgery presented a high postoperative transvalvular gradient >20 mmHg, three of them underwent femTAVI-VIV and one patient got a new valve through re-sternotomy. All these patients survived the follow-up period.

The implantation level proved to have no effect on the transvalvular gradient (<4 mm vs 4–8 mm: 16.3 ± 8.4 vs 18.9 ± 9.3 mmHg, p = 0.560). Patients after femTAVI-VIV experienced paravalvular leakage (PVL) more commonly than patients after Redo-AVR in intermediate- to high-risk profile groups. Higher incidence of PVL after TAVI-VIV was also observed in both matched groups (Table 2). However, almost all these patients showed mild regurgitation, without clinical relevance

Table 1
Patient demographic characteristics and preoperative echocardiographic findings.

Clinical characteristics[a]	Overall			Intermediate risk							High risk						
	TAVI-VIV (n = 68)	Redo-AVR (n = 40)	p-value[*]	Before PSM			After PSM				Before PSM			After PSM			
				TAVI-VIV (n = 31)	Redo-AVR (n = 29)	p-value	TAVI-VIV (n = 20)	Redo-AVR (n = 20)	p-value	SMD	TAVI-VIV (n = 37)	redo-AVR (n = 11)	p-value	TAVI-VIV (n = 10)	redo-AVR (n = 10)	p-value	SMD
Age, years	79.2 ± 5.7	72.9 ± 7.2	<0.001	77.0 ± 4.7	71.9 ± 8.1	0.004	75.7 ± 4.4	75.8 ± 4.3	0.971	0.010	81.0 ± 5.9	75.6 ± 3.5	<0.001	75.8 ± 3.6	75.8 ± 3.6	1.000	0.000
Male	28 (41.2%)	25 (62.5%)	0.032	14 (45.2%)	20 (69.0%)	0.063	8 (40%)	14 (70%)	0.057		14 (37.8%)	5 (45.5%)	0.650	3 (30%)	5 (50%)	0.361	
BMI, kg/m^2	27.2 ± 4.2	28.6 ± 4.0	0.095	27.2 ± 4.1	28.5 ± 4.2	0.255	27.3 ± 4.6	28.5 ± 4.5	0.855		27.2 ± 4.3	29.0 ± 3.6	0.226	29.8 ± 3.9	28.9 ± 3.8	0.603	
EuroSCORE II, %	10.9 ± 6.2	7.8 ± 4.3	0.005	5.9 ± 1.3	5.5 ± 1.6	0.315	5.8 ± 1.5	5.8 ± 1.4	0.934	−0.03	15.2 ± 5.4	13.7 ± 3.4	0.387	15.8 ± 5.3	13.6 ± 3.6	0.299	
Preoperative NYHA Class III/IV	63 (92.6%)	34 (85%)	0.376	26 (83.9%)	24 (82.8%)	0.908	16 (80%)	17 (75%)	0.677		27 (73.0%)	10 (90.9%)	0.064	10 (100%)	9 (90%)	0.305	
Preoperative clinical data																	
CAD	41 (60.3%)	14 (35.0%)	0.011	16 (51.6%)	9 (31.0%)	0.106	10 (50%)	8 (40%)	0.525		25 (67.6%)	5 (45.5%)	0.184	8 (80%)	5 (50%)	0.160	
Previous CABG	26 (38.2%)	8 (20.0%)	0.049	12 (38.7%)	5 (17.2%)	0.065	8 (40%)	4 (20%)	0.168		14 (37.8%)	3 (27.3%)	0.483	7 (70%)	3 (30%)	0.074	
Previous cardiac surgery > 1	5 (7.4%)	0 (0%)	0.079	2 (6.5%)	0 (0%)	0.164	2 (10%)	0 (0%)	0.147		3 (8.1%)	0 (0%)	0.330	1 (10%)	0 (0%)	0.305	
Previous pacemaker	16 (23.5%)	5 (12.5%)	0.161	4 (12.9%)	3 (10.3%)	0.758	4 (20%)	2 (10%)	0.376		12 (32.4%)	2 (18.2%)	0.361	2 (20%)	2 (20%)	1.000	
Atrial fibrillation	33 (48.5%)	16 (40.0%)	0.390	13 (41.9)	10 (34.5%)	0.553	7 (35%)	9 (45%)	0.519		20 (54.1%)	6 (54.5%)	0.977	3 (30%)	6 (60%)	0.178	
TIA	2 (2.9%)	1 (2.5%)	0.892	2 (6.5%)	1 (3.4%)	0.594	1 (5%)	1 (5%)	1.000		0 (0%)	0 (0%)	1.000	0 (0%)	0 (0%)	1.000	
Stroke	7 (10.3%)	2 (5.0%)	0.336	3 (9.7%)	1 (3.4%)	0.334	2 (10%)	1 (5%)	0.548		4 (10.8%)	1 (9.1%)	0.870	3 (30%)	1 (10%)	0.264	
PAD	11 (16.1%)	2 (5.0%)	0.085	1 (3.2%)	1 (3.4%)	0.962	1 (5%)	1 (5%)	1.000		10 (27.0%)	1 (9.1%)	0.214	3 (30%)	1 (10%)	0.264	
Carotis stenosis > 50%	5 (7.4%)	5 (12.5%)	0.373	1 (3.2%)	1 (3.4%)	0.962	0 (0%)	1 (5%)	0.311		4 (10.8%)	4 (36.4%)	0.046	2 (20%)	3 (30%)	0.606	
Severe pulmonary hypertension	3 (4.4%)	3 (7.5%)	0.499	0 (0%)	1 (3.4%)	0.329	0 (0%)	1 (5%)	0.311		3 (8.1%)	2 (18.2%)	0.337	0 (0%)	2 (20%)	0.136	
Renal impairment	64 (94.1%)	28 (70.0%)	<0.001	27 (87.1%)	17 (58.6%)	0.013	17 (85%)	13 (65%)	0.144		37 (100%)	11 (100%)	1.000	10 (100%)	10 (100%)	1.000	
Moderate	30 (44.1%)	16 (40.0%)		23 (74.2%)	11 (37.9%)		13 (65%)	8 (40%)			7 (18.9%)	5 (45.4%)		1 (10%)	4 (40%)		
Severe	32 (47.1%)	12 (30%)		4 (12.9%)	6 (20.7%)		4 (20%)	5 (25%)			28 (75.7%)	6 (54.4%)		8 (80%)	6 (60%)		
Dialysis	2 (2.9%)	0 (0%)		0 (0%)	0 (0%)		0 (0%)	0 (0%)			2 (5.4%)	0 (0%)		1 (10%)	0 (0%)		
COPD	11 (16.2%)	8 (20.0%)	0.614	4 (12.9%)	6 (20.7%)	0.419	3 (15%)	5 (25%)	0.429		4 (12.9%)	2 (20.7%)	0.956	4 (40%)	2 (20%)	0.329	
Active smoker	6 (8.8%)	2 (5.0%)	0.464	3 (9.7%)	1 (3.4%)	0.334	2 (10%)	1 (5%)	0.548		3 (8.1%)	1 (9.1%)	0.918	1 (10%)	1 (10%)	1.000	
Arterial hypertension	63 (92.6%)	36 (90.0%)	0.631	29 (93.5%)	26 (89.7%)	0.586	18 (90%)	19 (95%)	0.548		34 (91.9%)	10 (90.9%)	0.918	9 (90%)	9 (90%)	1.000	
Diabetes mellitus	23 (33.8%)	18 (45.0%)	0.248	6 (19.4%)	10 (34.5%)	0.185	4 (20%)	7 (35%)	0.289		17 (45.9%)	8 (72.7%)	0.119	7 (70%)	7 (70%)	1.000	
Insulin dependent diabetes mellitus	10 (14.7%)	3 (7.3%)	0.266	1 (3.2%)	1 (3.4%)	0.962	0 (0%)	0 (0%)	1.000		9 (24.3%)	2 (18.2%)	0.670	4 (40%)	1 (10%)	0.121	
Hyperlipoproteinemia	51 (75.0%)	26 (65.0%)	0.267	23 (74.2%)	19 (65.5%)	0.464	16 (80%)	15 (75%)	0.705		28 (75.7%)	7 (63.6%)	0.430	9 (90%)	6 (60%)	0.121	
Elective procedure[b]	57 (83.8%)	31 (77.5%)	0.414	29 (93.5%)	26 (89.7%)	0.586	19 (95%)	19 (95%)	1.000		28 (75.7%)	5 (45.4%)	0.576	8 (80%)	5 (50%)	0.160	
Urgent procedure[c]	6 (8.8%)	7 (17.5%)	0.180	1 (3.2%)	2 (6.9%)	0.514	0 (0%)	0 (0%)	1.000		5 (13.5%)	5 (45.4%)	0.022	1 (10%)	4 (40%)	0.121	
Emergency procedure[d]	5 (7.4%)	2 (5.0%)	0.631	1 (3.2%)	1 (3.4%)	0.962	1 (5%)	1 (5%)	1.000		4 (10.8%)	1 (9.1%)	0.870	1 (10%)	1 (10%)	1.000	
Preoperative intubation	2 (2.9%)	0 (0.0%)	0.274	0 (0%)	0 (0%)	1.000	0 (0%)	0 (0%)	1.000		2 (5.4%)	0 (0%)	0.341	0 (0%)	0 (0%)	1.000	
Time after previous AVR, years	9.5 ± 4.2	8.0 ± 4.2	0.068	9.5 ± 4.3	8.6 ± 4.6	0.423	8.5 ± 4.5	8.2 ± 5.1	0.807		9.6 ± 4.2	6.4 ± 2.8	0.023	7.5 ± 1.6	6.5 ± 2.9	0.361	
Degenerated valve ≤ 21 mm	28 (41.2%)	10 (25.0%)	0.089	12 (38.7%)	7 (24.1%)	0.225	10 (50%)	6 (30%)	0.197		16 (43.2%)	3 (27.3%)	0.342	6 (60%)	2 (20%)	0.068	
Severe PPM after previous surgery	7 (10.3%)	3 (7.5%)	0.629	2 (6.5%)	1 (3.4%)	0.594	2 (10%)	1 (5%)	0.548		5 (13.5%)	2 (18.2%)	0.700	3 (30%)	1 (10%)	0.264	
True ID of failed bioprosthesis, mm	19.8 ± 2.7	20.8 ± 3.3	0.077	19.8 ± 2.7	20.7 ± 3.2	0.221	19.6 ± 3.1	20.3 ± 2.8	0.503		19.7 ± 2.7	20.8 ± 3.5	0.263	18.5 ± 2.3	21.1 ± 3.6	0.073	
Preoperative echocardiographic parameters																	
Aortic prosthesis patology																	
Leading stenosis	52 (76.5%)	23 (57.5%)	0.039	25 (80.6%)	16 (55.2%)	0.034	18 (90%)	13 (65%)	0.058		27 (73.0%)	7 (63.6%)	0.550	8 (80%)	6 (60%)	0.329	
Leading regurgitation	16 (23.5%)	17 (42.5%)	0.039	6 (19.4%)	13 (44.8%)	0.034	2 (10%)	7 (35%)	0.058		10 (27.0%)	4 (36.4%)	0.550	2 (20%)	4 (40%)	0.329	
AV meanPG, mmHg	41.9 ± 19.3	40.1 ± 20.9	0.646	47.1 ± 19.7	37.8 ± 16.6	0.053	48.9 ± 21.4	33.4 ± 11.7	0.007		37.6 ± 18.2	46.2 ± 29.7	0.243	46.8 ± 16.2	42.3 ± 28.2	0.667	
AV peakPG, mmHg	71.7 ± 29.3	66.2 ± 29.5	0.354	79.2 ± 30.2	65.6 ± 26.9	0.071	80.9 ± 31.2	59.4 ± 19.1	0.012		65.4 ± 27.3	67.2 ± 37.0	0.810	77.6 ± 22.2	60.6 ± 29.7	0.165	
EOA, cm2	0.74 ± 0.32	0.75 ± 0.33	0.901	0.76 ± 0.36	0.82 ± 0.36	0.548	0.74 ± 0.36	0.78 ± 0.21	0.676		0.72 ± 0.29	0.56 ± 0.12	0.146	0.59 ± 0.2	0.58 ± 0.12	0.946	
MV stenosis ≥ 2°	1 (1.5%)	0 (0%)	0.441	0 (0%)	0 (0%)	1.000	0 (0%)	0 (0%)	1.000		1 (2.7%)	0 (0%)	0.582	0 (0%)	0 (0%)	1.000	
MV regurgitation ≥ 2°	32 (47.1%)	10 (25%)	0.023	9 (29.0%)	8 (27.6%)	0.901	4 (20%)	7 (35%)	0.289		23 (62.2%)	2 (18.2%)	0.010	4 (40%)	2 (20%)	0.329	
TV regurgitation ≥ 2°	15 (22.1%)	3 (7.3%)	0.049	2 (6.5%)	1 (3.4%)	0.594	1 (5%)	1 (5%)	1.000		13 (35.1%)	2 (18.2%)	0.287	1 (10%)	2 (20%)	0.531	

LA diameter, cm	4.6 ± 0.8	4.9 ± 0.8	0.157	4.3 ± 0.8	4.8 ± 0.6	0.060	4.3 ± 1.0	4.7 ± 0.7	0.145	4.9 ± 0.8	5.1 ± 1.2	0.448	4.8 ± 0.9	5.1 ± 1.2	0.675
LV EF, %	52.1 ± 10.7	56.3 ± 8.7	0.035	55.6 ± 7.6	57.6 ± 7.2	0.289	56.2 ± 8.7	58.0 ± 7.1	0.475	49.2 ± 12.0	52.9 ± 11.4	0.364	45.3 ± 14.7	52.7 ± 12.0	0.233
PASP, mmHg	44.8 ± 12.5	48.2 ± 12.7	0.292	42.4 ± 12.5	48.1 ± 12.4	0.153	43.0 ± 13.8	47.1 ± 13.1	0.423	46.9 ± 12.2	48.4 ± 15.1	0.802	46.2 ± 13.2	51.3 ± 15.8	0.550

Abbreviations: AV = aortic valve; AVR = aortic valve replacement; BMI = body mass index; BSA = body surface area; CABG = coronary artery bypass grafting; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; EOA = effective orifice area; LV EF = left ventricular ejection fraction; MV = mitral valve; NYHA = New York Heart Association functional classification; PAD = peripheral artery/arterial disease; PASP = pulmonary artery systolic pressure; PG = pressure gradient; PPM = prosthesis-patient mismatch; PSM = propensity score matching; SD = standard deviation; SMD = standardized mean difference; TAVI-VIV = transcatheter aortic valve implantation - valve-in-valve; TIA = transient ischemic attack; TV = tricuspid valve.

[a] Continuous variables are presented as the means ± SD whereas categorical data as the numbers (n) with percentages (%).

[b] Routine admission for operation.

[c] Intervention or surgery is performed on the current admission for medical reasons and these patients cannot be sent home without a definitive procedure.

[d] operation before the beginning of the next working day after decision to operate.

[*] *p* value <0.05 considered as of statistical significance.

(survival at 5 years- 69.9%, all survivors were in NYHA class I or II). Moderate regurgitation occurred only in one patient following femTAVI-VIV procedure and he survived the follow-up period, but with NYHA III class.

Twenty-eight patients in femTAVI-VIV group and ten patients in the Redo-AVR group with small degenerated bioprostheses (diameter ≤ 21 mm) were analyzed in this study. We did not observe any differences between mean postoperative gradients after both procedures (femTAVI-VIV:20.3 ± 10.7 vs Redo-AVR:22.2 ± 9.6 mmHg, p = 0.631).

3.7. Follow-up period

During the follow-up period died 35 patients. Fourteen of them died after Redo-AVR and twenty-one following femTAVI-VIV procedures. We did not find any significant differences in one-, and five- year cumulative survival rates between the groups (femTAVI-VIV vs Redo-AVR: 1-year:85.2% vs 85.0%, 5-year:62.9% vs 72.5%) (Fig. 2A). Similar results were observed in intermediate and high-risk profile: femTAVI-VIV vs Redo-AVR 1-year: 83.9% vs 89.7%, 5-year: 61.7% vs 80.4% and 1-year: 86.5% vs 72.7%, 5-year: 64.4% vs 51.9% (Fig. 2C,E). Propensity score matching did not significant change the survival curves: 1-year: 90.0% vs 85.0%, 5-year: 55.5% vs 71.9% and 1-year: 80.0% vs 70.0%, 5-year: 70.0% vs 46.7% (Fig. 2D,F).

At the end of the follow-up period 41 out of 47 survivors(87.2%) after femTAVI-VIV and 22 out of 26 survivors(84.6%) after Redo-AVR were found in NYHA I or II classes(p = 0.755). Four patients after femTAVI-VIV and three patients after Redo-AVR remaining in the NYHA III had mean transvalvular gradient at discharged over 20 mmHg. Neither one of survivors was found in NYHA class IV at the end of the follow-up.

Additionally, in a special subgroup of patients with small degenerated bioprostheses, one-, and five- year survival rates after both therapeutic methods were similar (femTAVI-VIV vs Redo-AVR: 1-year survival rate: 89.3% vs 80.0%, 5-year survival rate: 63.4% vs 70.0%, p = 0.793)(Fig. 2B). Four out of twenty one survivors with small failed bioprosthesis in transcatheter group remained in NYHA III class and all survivors after surgical redo were found in NYHA II class.

One patient required TAVI-Valve-in-Valve-in-Valve (1.47%) for aortic valve dysfunction after 7 years post femTAVI-VIV and survived the further follow-up period uneventful. No patients after Redo-AVR needed re-intervention.

4. Discussion

The potential benefits of the transcatheter valve re-intervention are less surgical trauma, local anesthesia, lower risk of wound infection, and absence of extracorporeal circulation; however, the conventional surgical solution allows performing concomitant procedures, avoiding the fluoroscopy, radiation or contrast load, and more cost-effective [11]. Cardiac surgeons and cardiologists are still debating which treatment ensures the most favorable hemodynamic outcomes with simultaneously reduced mortality. Data are limited to several studies with small groups of patients and the optimal strategy for patients with degenerated xenograft bioprostheses is still controversial. In our paper, we focused on the less invasive approach of transcatheter methods, that is the femoral TAVI and then compared the results with a conventional open chest reintervention [12–14].

We can currently observe a higher risk profile of patients qualified for TAVI-VIV; however, the mortality rate appears comparable to that in the conventional reoperation [15,16]. In our paper, one patient died intraprocedural during femTAVI-VIV and all patients survived the conventional Redo-AVR. Mortality rates of our subjects at 30- days after the procedures were comparable to those presented in the literature (TAVI-VIV:3.9–8.4% vs Redo-AVR:0.0–16.4%) [5,15,17–20].

Three meta-analyses performed by Tam et al. [14], Nalluri et al. [15], and Takagi et al. [21] that compared Redo-AVR with TAVI-VIV revealed

Table 2
Procedure-related variables.

Clinical characteristics[a]	Overall			Intermediate risk						High risk					
				Before PSM			After PSM			Before PSM			After PSM		
	TAVI-VIV (n = 68)	Redo-AVR (n = 40)	p-value*	TAVI-VIV (n = 31)	Redo-AVR (n = 29)	p-value	TAVI-VIV (n = 20)	Redo-AVR (n = 20)	p-value	TAVI-VIV (n = 37)	Redo-AVR (n = 11)	p-value	TAVI-VIV (n = 10)	Redo-AVR (n = 10)	p-value
Technical indices															
Anesthetic management															
General anesthesia	8 (11.8%)	40 (100%)	<0.001	3 (9.7%)	40 (100%)	<0.001	3 (15%)	40 (100%)	<0.001	5 (13.5%)	40 (100%)	<0.001	1 (10%)	40 (100%)	<0.001
Local anesthesia	60 (88.2%)	0 (0%)	<0.001	28 (90.3%)	0 (0%)	<0.001	17 (85%)	0 (0%)	<0.001	32 (86.5%)	0 (0%)	<0.001	9 (90%)	0 (0%)	<0.001
Operative time, min	58.7 ± 34.9	194.8 ± 62.8	<0.001	60.8 ± 45.3	195.1 ± 67.6	<0.001	63.8 ± 53.7	210.1 ± 73.7	<0.001	56.9 ± 23.4	194.1 ± 50.6	<0.001	63.0 ± 33.6	194.0 ± 53.3	<0.001
CPB time, min	–	90.0 ± 37.6		–	93.8 ± 40.9		–	98.6 ± 45.0		–	80.1 ± 25.9		–	78.1 ± 26.4	
Cross clamp time, min	–	79.8 ± 30.8		–	85.4 ± 33.5		–	88.9 ± 34.6		–	64.7 ± 14.7		–	63.5 ± 14.9	
Contrast load, mL	213.1 ± 83.8	–		217.4 ± 94.7	–		221.0 ± 110.6	–		209.3 ± 74.1	–		222.5 ± 13.1	–	
Fluoroscopy time, min	13.8 ± 7.5	–		14.8 ± 8.1	–		15.5 ± 8.9	–		13.0 ± 7.0	–		81.0 ± 5.4	–	
Pre-dilatation	68 (100%)	–		31 (100%)	–		20 (100%)	–		37 (100%)	–		10 (100%)	–	
Post-dilatation	3 (4.4%)	–		1 (3.2%)	–		0 (0%)	–		2 (5.4%)	–		0 (0%)	–	
Evolut R Repositioning	14/34 (41.2%)	–		5/13 (38.5%)	–		2/7 (28.6%)	–		9/21 (42.9%)	–		0/1 (0%)	–	
Implantation level															
<4 mm	52 (76.5%)	–		25 (80.6%)	–		17 (85%)	–		27 (73.0%)	–		7 (70%)	–	
>4 < 8 mm	16 (23.5%)	–		6 (19.4%)	–		3 (15%)	–		10 (27.0%)	–		3 (30%)	–	
Postoperative echocardiography															
AV meanPG, mmHg	16.8 ± 8.6	19.0 ± 11.3	0.278	17.9 ± 8.7	19.9 ± 11.4	0.461	18.3 ± 9.3	17.1 ± 5.9	0.650	16.0 ± 8.5	17.0 ± 11.1	0.748	21.9 ± 12.0	17.1 ± 11.7	0.378
AV peakPG, mmHg	29.8 ± 15.0	35.3 ± 18.5	0.103	30.4 ± 15.2	36.7 ± 17.7	0.159	30.9 ± 17.2	32.4 ± 9.8	0.760	29.2 ± 14.9	32.0 ± 20.7	0.627	39.4 ± 21.0	32.0 ± 21.8	0.449
Paravalvular leaks	24 (35.3%)	1 (2.5%)	<0.001	8 (25.8%)	0 (0%)	0.003	6 (30%)	0 (0%)	0.008	16 (43.2%)	1 (9.1%)	0.038	5 (50%)	1 (10%)	0.050
Mild	23 (33.8%)	1 (2.5%)		7 (22.6%)	0 (0%)		5 (25%)	0 (0%)		16 (43.2%)	1 (9.1%)		5 (50%)	1 (10%)	
Moderate	1 (1.5%)	0 (0%)		1 (3.2%)	0 (0%)		1 (5%)	0 (0%)		0 (0%)	0 (0%)		0 (0%)	0 (0%)	
Severe	0 (0%)	0 (0%)		0 (0%)	0 (0%)		0 (0%)	0 (0%)		0 (0%)	0 (0%)		0 (0%)	0 (0%)	
MV stenosis ≥ 2°	1 (1.5%)	0 (0%)	0.441	0 (0%)	0 (0%)	1.000	0 (0%)	0 (0%)	1.000	1 (2.7%)	0 (0%)	0.582	0 (0%)	0 (0%)	1.000
MV regurgitation ≥ 2°	18 (26.5%)	5 (12.5%)	0.087	4 (12.9%)	3 (10.3%)	0.758	2 (10%)	3 (30%)	0.633	14 (37.8%)	2 (18.2%)	0.225	5 (50%)	2 (20%)	0.160
TV regurgitation ≥ 2°	9 (13.2%)	1 (2.5%)	0.063	2 (6.5%)	0 (0%)	0.164	2 (10%)	0 (0%)	0.147	7 (18.9%)	1 (9.1%)	0.443	1 (10%)	1 (10%)	1.000
LV EF, %	52.4 ± 9.4	53.1 ± 6.0	0.675	55.2 ± 6.5	52.8 ± 6.0	0.170	54.7 ± 7.2	53.4 ± 6.0	0.569	50.0 ± 10.8	53.8 ± 6.4	0.274	51.1 ± 11.4	52.5 ± 4.9	0.724
Postoperative complications															
Intraoperative mortality	1 (1.5%)	0 (0%)	0.441	1 (3.2%)	0 (0%)	0.297	1 (5%)	0 (0%)	0.311	0 (0%)	0 (0%)	1.000	0 (0%)	0 (0%)	1.000
30-days mortality	5 (7.4%)	3 (7.5%)	0.978	2 (6.5%)	3 (10.3%)	0.697	1 (5%)	3 (15%)	0.292	3 (8.1%)	0 (0%)	0.330	0 (0%)	0 (0%)	1.000
ICU stay, days	1.5 ± 1.1	3.5 ± 5.9	<0.001	1.3 ± 0.7	3.3 ± 6.6	0.084	1.2 ± 0.8	4.0 ± 7.8	0.096	1.7 ± 1.4	3.9 ± 4.2	0.008	1.7 ± 1.5	4.2 ± 4.3	0.097
Hospital stay, days	7.1 ± 2.2	11.4 ± 10.3	0.001	7.1 ± 2.4	10.0 ± 6.9	0.031	6.9 ± 2.3	10.6 ± 8.1	0.041	7.1 ± 2.1	15.3 ± 16.0	0.003	7.0 ± 1.1	16.1 ± 16.6	0.044
New dialysis	1 (1.5%)	3 (7.5%)	0.109	0 (0%)	1 (3.4%)	0.329	0 (0%)	2 (10%)	0.147	1 (2.7%)	1 (9.1%)	0.352	0 (0%)	1 (10%)	0.305
Post-procedural MODS	2 (2.9%)	2 (5%)	0.584	1 (3.2%)	1 (3.4%)	0.962	1 (5%)	1 (5%)	1.000	1 (2.7%)	1 (9.1%)	0.352	0 (0%)	1 (10%)	0.305
Myocardial infarction	1 (1.5%)	1 (2.5%)	0.701	1 (3.2%)	1 (3.4%)	0.962	1 (5%)	1 (5%)	1.000	0 (0%)	0 (0%)	1.000	0 (0%)	0 (0%)	1.000
Femoral artery stentgraft	4 (5.9%)	0 (0%)	0.118	3 (9.7%)	0 (0%)	0.086	2 (10%)	0 (0%)	0.147	1 (2.7%)	0 (0%)	0.582	0 (0%)	0 (0%)	1.000
First episode of AF	2/35 (5.7%)	7/24 (29.2%)	0.014	1/18 (5.6%)	6/19 (31.6%)	0.043	1/13 (7.7%)	5/11 (45.5%)	0.033	1/17 (5.9%)	1/5 (20%)	0.334	0/7 (0%)	1/4 (25%)	0.165
Need for PM	4 (5.9%)	2 (5%)	0.847	1 (3.2%)	1 (3.4%)	0.962	1 (5%)	0 (0%)	0.311	3 (8.1%)	1 (9.1%)	0.918	1 (10%)	1 (10%)	1.000
Stroke	3 (4.4%)	3 (7.5%)	0.499	2 (6.5%)	2 (6.9%)	0.945	2 (10%)	1 (5%)	0.548	1 (2.7%)	1 (9.1%)	0.352	0 (0%)	1 (10%)	0.305
Blood transfusion	7 (10.3%)	26 (65%)	<0.001	2 (6.5%)	17(58.6%)	<0.001	2 (10%)	12 (60%)	0.037	5 (13.5%)	9 (81.8%)	<0.001	2 (20%)	8 (80%)	0.007
RBC, U/patient	0.26 ± 0.94	1.95 ± 3.02	<0.001	0.23 ± 0.96	1.31 ± 2.05	0.010	0.35 ± 1.82	1.35 ± 2.03	0.065	0.30 ± 0.94	3.64 ± 4.41	<0.001	0.20 ± 0.42	3.90 ± 4.56	0.020
FFP, U/patient	0.12 ± 0.76	1.48 ± 2.91	<0.001	0.19 ± 1.08	1.07 ± 1.53	0.013	0.30 ± 1.34	1.25 ± 1.68	0.056	0.05 ± 0.33	2.55 ± 4.97	0.003	0.00 ± 0.00	2.80 ± 5.16	0.103
Platelets, U/patient	0.03 ± 0.24	0.53 ± 1.17	0.001	0.06 ± 0.36	0.45 ± 0.83	0.022	0.10 ± 1.45	0.35 ± 0.75	0.206	0.00 ± 0.00	0.73 ± 1.85	0.018	0.00 ± 0.00	0.80 ± 1.93	0.207

Abbreviations: AF = atrial fibrillation; AV = aortic valve; CBP = cardiopulmonary bypass; FFP = fresh frozen plasma; LV EF = left ventricular ejection fraction; ICU = intensive care unit; MODS = Multiple organ dysfunction syndrome; MV = mitral valve; PG = pressure gradient; PM = pacemaker; PSM = propensity score matching; SD = standard deviation; TAVI-VIV = transcatheter aortic valve implantation - valve-in-valve; RBC = red blood cell; TV = tricuspid valve.

* p value <0.05 considered as of statistical significance.

[a] Continuous variables are presented as the means ± SD whereas categorical data as the numbers (n) with percentages (%).

that both techniques were equal to one another in terms of their mid-term survival, however the long-term follow-up is still missing. The multicenter investigation performed by Guimarães et al. [22] determined the long-term clinical outcomes after TAVI-VIV in consecutive patients undergoing TAVI-VIV in nine heart centers between 2009 and 2015. Five-year survival rate was 67.9%, what is comparable to results in our study. The PARTNER 2-VIV registry provided most recent data on long-term outcomes after TAVI-VIV and suggest the favorable outcomes [23]. At 3-year follow-up, the all-cause mortality was 32.7%, which is similar to the results presented in our investigation and data delivered by Guimarães et al. [22,23].

It is worth noting that patients qualified for transcatheter treatment in our study population were significantly older with preoperative worse kidney function, which are widely known risk factors associated with increased mortality [22]. Nonetheless, we did not observe any significant differences in all-cause 1-, 3-, and 5-year mortality rates after both methods. Moreover, regardless of treatment strategy, around 90% of survivors experienced significant reduction in NYHA class, being in

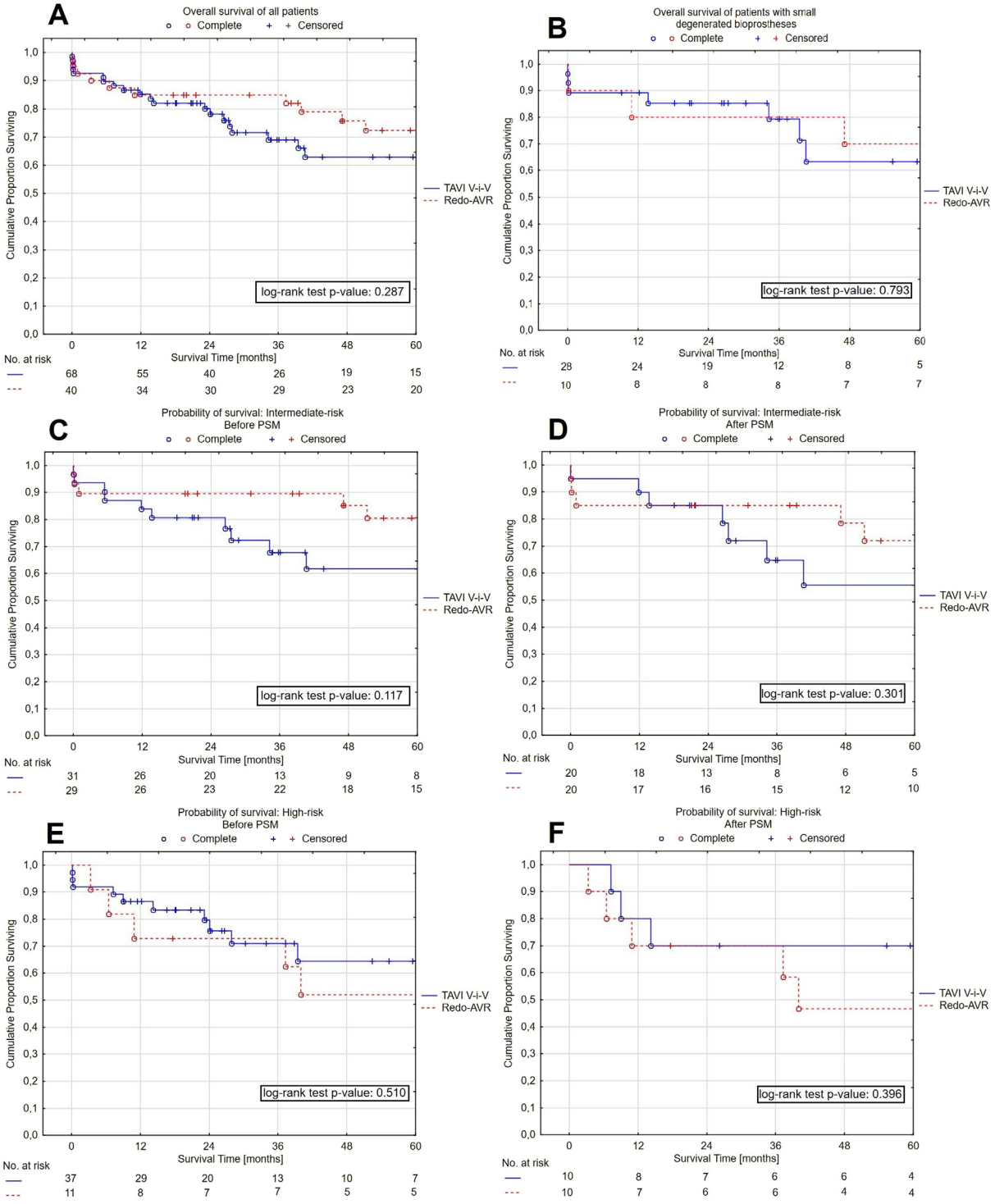

Fig. 2. A: Kaplan-Meier survival curve of all patients. B: Patients with small degenerated valves. C: Intermediate-risk before PSM. D: Intermediate-risk after PSM. E: High-risk before PSM. F: High-risk after PSM.

class I or II. The sustained improvement of functional status was similarly observed in PARTNER 2-VIV trial [23].

The old frame of the degenerated valve seems to have a protective function for the conduction system during the Valve-in-Valve procedure [24]. These findings were confirmed by meta-analyses performed by Nalluri et al. [15], Neupane et al. [25], Tam et al. [16], and Gozdek et al. [6]. Notwithstanding, our investigation recorded a similar need for a new heart rhythm device implantation after transcatheter- and redo procedure (5.9% vs 5.0%, p = 0.847).

The catheter procedure was less invasive, shorter, and required significantly shorter hospital stay, furthermore, 73% of surviving TAVI patients left the ICU within the first 24 h after the procedure and 62% of our TAVIs were discharged during the first postoperative week. The reduction of the invasiveness of the procedure and of the body trauma had observable consequences in the need for transfusions of all types of blood products [26].

The main challenge of reoperation is adhesions, aggressive preparations of which may result in catastrophic complications. Every chest reopening is associated with increased risk of life-threatening adverse events compared to the primary procedures [4]. On the other hand open chest surgery gives the opportunity to perform additional procedures. Furthermore, reoperation is a risk factor of reoperation for bleeding. Although particular attention was paid to this aspect of redo surgeries in about 7.5% of our patients rethoracotomy due to postoperative bleeding was not avoided. Although this rate seems to be relatively high it is less than that previously reported by Onorati et al. (15.3%) [27]. Additionally, redo operation is a well-known risk factor of deep sternal wound infection (DSWI). Luckily, only one patient in our group developed such complication and required vacuum-assisted closure that considered as effective therapeutic option in DSWI cases [28].

The most controversial issue in failed aortic valves are still the hemodynamical outcomes after re-interventions and available data are conflicting. Most studies suggest a favorable postoperative mean gradient after a conventional reoperation [5–7,29], whereas meta-analyses performed by Tam et al. [16] and Gozdek et al. [6] did not confirm previous findings. Our study is the first single-center analysis that also revealed comparable mean postoperative gradients and similar rate of such gradients over 20 mmHg after both procedures. During Redo-AVR the aortic root is usually stiffer and more calcified than a few years earlier which consequently leads to use a valve of the same or even smaller size [30]. This fact can explain comparable gradients after Redo-AVR and TAVI-VIV.

The paravalvular leak is the known “Achilles' heel” of the TAVI procedure and was widely described in the literature [5,31]. Our investigation confirms this finding. We observed significantly more PVL after TAVI-VIV, but only one out of twenty five PVL was moderate. The rate of PVL (35%) appears higher than what has previously been reported after TAVI-VIV procedures (Tam et al. 21.1% [16]), however 95% of PVL were mild without affecting mortality or NYHA class in survivors. The currently available evidence is not strong enough to suggest or claim an inferiority of hemodynamical results after transcatheter intervention compared to the surgical Redo-AVR.

Femoral TAVI-VIV has become a preferred treatment option for high-risk patients to avoid general anesthesia and any injuries during reopening of the chest. The new valve anchor within the frame of the old prosthesis means that the implantation is technically simple but carries the risk of coronary ostia obstruction and is limited by the valve size. Surgical Redo-AVR offers much many more options to treat a small root and has decreased its complication rate over the past decade. Some authors suggest considering the surgical solution as the first line treatment in patients with small-caliber degenerated biological aortic valves [18]. We compared the results of femTAVI-VIV and reoperation in these challenging patients with the valve diameter ≤ 21 mm. However, despite more mild PVL cases, no other hemodynamic consequences were noted. Moreover, this aforementioned fact did not impact negatively on survival probability. Most valves, except Medtronic Hancock and St. Jude Trifecta, could be fractured. However, the use of fracturing in the TAVI-VIV strategy has not been extensively investigated, the evidence is based on several small case-studies and with risks, including aortic root damage or coronary obstruction but may improve the hemodynamic results [32–36].

There are grave concerns about coronary obstruction, which occurs in 2.3% patients after TAVI-VIV procedure [37,38]. In our analysis, only one patient (1.5%) died suddenly three days after the percutaneous intervention probably because of coronary obstruction. However, the cause of death remained unknown as autopsy was not performed. This patient had a failed Sorin Mitroflow (21 mm diameter), which due to its long leaflets mounted externally over the stent, could stop the free-flow due to the coronary ostia. There are some technical tricks to protect from this severe adverse event such as the Chimney or Basilica technique; however, the evidence is very weak and the effectiveness of these techniques has not yet been confirmed [38]. We did not use any coronary obstruction protection techniques. All other four in-hospital deaths were caused by technical intraprocedural complications or poor preoperative condition.

5. Study limitations

It is a single center study with relatively small sample size. The main limitations of this study are the lack of randomization, retrospective nature of this investigation and the absence of echocardiographic results during follow-up period.

6. Conclusions

Our study supports the transcatheter approach for treatment of patients with degenerated aortic bioprostheses as a safe alternative to Redo-AVR, particularly for those at high-risk. Although TAVI-VIV procedures may result in paravalvular leaks, residual transvalvular gradients and the limited possibility of performing other cardiac interventions, long-term outcomes with respect to functional status and survival probability are comparable to surgical Redo-AVRs.

Appendix A

Appendix Table 1
Type of degenerated bioprosthesis and new implanted valves.

Clinical characteristics*	Overall		Intermediate risk				High risk			
	TAVI-VIV (n = 68)	Redo-AVR (n = 40)	Before PSM		After PSM		Before PSM		After PSM	
			TAVI-VIV (n = 31)	Redo-AVR (n = 29)	TAVI-VIV (n = 20)	Redo-AVR (n = 20)	TAVI-VIV (n = 37)	redo-AVR (n = 11)	TAVI-VIV (n = 10)	Redo-AVR (n = 10)
Type of failing surgical bioprosthesis										
Sorin Mitroflow	19 (27.9%)	10 (25%)	8 (25.8%)	8 (27.6%)	7 (35%)	6 (30%)	11 (29.7%)	2 (18.2%)	5 (50%)	2 (20%)
Sorin Freedom SOLO	7 (10.3%)	7 (17.5%)	3 (9.7%)	5 (17.2%)	2 (10%)	3 (15%)	4 (10.8%)	2 (18.2%)	0 (0%)	2 (20%)

Appendix Table 1 (*continued*)

Clinical characteristics*	Overall		Intermediate risk				High risk			
	TAVI-VIV (n = 68)	Redo-AVR (n = 40)	Before PSM		After PSM		Before PSM		After PSM	
			TAVI-VIV (n = 31)	Redo-AVR (n = 29)	TAVI-VIV (n = 20)	Redo-AVR (n = 20)	TAVI-VIV (n = 37)	redo-AVR (n = 11)	TAVI-VIV (n = 10)	Redo-AVR (n = 10)
Sorin Soprano	7 (10.3%)	3 (7.5%)	2 (6.5%)	1 (3.4%)	1 (5%)	1 (5%)	5 (13.5%)	2 (18.2%)	3 (30%)	1 (10%)
Medtronic Hancock	18 (26.5%)	12 (30%)	8 (25.8%)	9 (31.0%)	7 (35%)	6 (30%)	10 (27.0%)	3 (27.3%)	2 (20%)	3 (30%)
Perimount	10 (14.7%)	1 (2.5%)	5 (16.1%)	1 (3.4%)	1 (5%)	1 (5%)	5 (13.5%)	0 (0%)	0 (0%)	0 (0%)
SJM Epic Supra	3 (4.4%)	1 (2.5%)	3 (9.7%)	1 (3.4%)	1 (5%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
SJM Toronto SPV	0 (0%)	2 (5%)	0 (0%)	2 (6.9%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Baxter	1 (1.5%)	2 (5%)	1 (3.2%)	1 (3.4%)	1 (5%)	0 (0%)	0 (0%)	1 (9.1%)	0 (0%)	1 (10%)
Medtronic Mosaic	1 (1.5%)	1 (2.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (2.7%)	1 (9.1%)	0 (0%)	1 (10%)
Shelhigh	1 (1.5%)	1 (2.5%)	0 (0%)	1 (3.4%)	0 (0%)	1 (5%)	1 (2.7%)	0 (0%)	0 (0%)	0 (0%)
SJM Biocor	1 (1.5%)	0 (0%)	1 (3.2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Size of failing surgical bioprosthesis										
18 mm	0 (0%)	1 (2.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (9.1%)	0 (0%)	0 (0%)
19 mm	3 (4.4%)	1 (2.5%)	0 (0%)	1 (3.4%)	0 (0%)	0 (0%)	3 (8.1%)	0 (0%)	1 (10%)	0 (0%)
20 mm	3 (4.4%)	2 (5%)	1 (3.2%)	1 (3.4%)	1 (5%)	1 (5%)	2 (5.4%)	1 (9.1%)	1 (10%)	1 (10%)
21 mm	22 (32.4%)	6 (15%)	11 (35.4%)	5 (17.2%)	9 (45%)	5 (25%)	11 (29.7%)	1 (9.1%)	4 (40%)	1 (10%)
22 mm	3 (4.4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (8.1%)	0 (0%)	2 (20%)	0 (0%)
23 mm	22 (32.4%)	17 (42.5%)	13 (41.9%)	12 (41.4%)	5 (25%)	9 (45%)	9 (24.3%)	5 (45.5%)	2 (20%)	5 (50%)
25 mm	10 (14.7%)	9 (22.5%)	3 (9.7%)	7 (24.1%)	2 (10%)	4 (20%)	7 (18.9%)	2 (18.2%)	0 (0%)	2 (20%)
27 mm	3 (4.4%)	2 (5%)	2 (6.5%)	2 (6.9%)	2 (10%)	0 (0%)	1 (2.7%)	0 (0%)	0 (0%)	0 (0%)
29 mm	2 (2.9%)	2 (5%)	1 (3.2%)	1 (3.4%)	1 (5%)	1 (5%)	1 (2.7%)	1 (9.1%)	0 (0%)	1 (10%)
New implanted valves type										
Medtronic Hancock	–	25 (62.5%)	–	17 (58.6%)	–	13 (65%)	–	8 (72.7%)	–	8 (80%)
SJM Epic Supra	–	10 (25%)	–	8 (27.6%)	–	4 (20%)	–	2 (18.2%)	–	2 (20%)
Sorin Mitroflow	–	2 (5%)	–	2 (6.9%(	–	2 (10%)	–	0 (0%)	–	0 (0%)
Medtronic Freestyle	–	1 (2.5%)	–	1 (3.4%)	–	0 (0%)	–	0 (0%)	–	0 (0%)
Sorin Freedom SOLO	–	1 (2.5%)	–	0 (0%)	–	0 (0%)	–	1 (9.1%)	–	0 (0%)
Perimount	–	1 (2.5%)	–	1 (3.4%)	–	1 (5%)	–	0 (0%)	–	0 (0%)
LivaNova Perceval	–	0 (0%)	–	0 (0%)	–	0 (0%)	–	0 (0%)	–	0 (0%)
LivaNova Crown PRT	–	0 (0%)	–	0 (0%)	–	0 (0%)	–	0 (0%)	–	0 (0%)
CoreValve	34 (50%)	–	18 (58.1%)	–	13 (65%)	–	16 (43.2%)	–	9 (90%)	–
CoreValve Evolut R	34 (50%)	–	13 (41.9%)	–	7 (35%)	–	21 (56.8%)	–	1 (10%)	–
New implanted valves size										
19 mm	0 (0%)	2 (5%)	0 (0%)	2 (6.9%)	0 (0%)	2 (10%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
21 mm	0 (0%)	14 (35%)	0 (0%)	9 (31.0%)	0 (0%)	5 (25%)	0 (0%)	5 (45.5%)	0 (0%)	4 (40%)
23 mm	35 (51.5%)	17 (42.5%)	16 (51.6%)	13 (44.8%)	12 (60%)	11 (55%)	19 (51.4%)	4 (36.4%)	7 (70%)	4 (40%)
25 mm	0 (0%)	2 (5%)	0 (0%)	1 (3.4%)	0 (0%)	1 (5%)	0 (0%)	1 (9.1%)	0 (0%)	1 (10%)
26 mm	27 (39.7%)	0 (0%)	12 (38.7%)	0 (0%)	6 (30%)	0 (0%)	15 (40.5%)	0 (0%)	3 (30%)	0 (0%)
27 mm	0 (0%)	3 (7.5%)	0 (0%)	2 (6.9%)	0 (0%)	0 (0%)	0 (0%)	1 (9.1%)	0 (0%)	1 (10%)
29 mm	3 (4.4%)	2 (5%)	2 (6.5%)	2 (6.9%)	1 (5%)	1 (5%)	1 (2.7%)	0 (0%)	0 (0%)	0 (0%)
31 mm	1 (1.5%)	0 (0%)	1 (3.2%)	0 (0%)	1 (5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
34 mm	2 (2.9%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (5.4%)	0 (0%)	0 (0%)	0 (0%)

Appendix Table 2
Causes of early death.

	Type of surgery	Urgency	Age [years]	EuroSCORE II	LV-EF	Failed bioprosthesis	New valve	Survival [days]	Cause of death
1	TAVI-VIV	Elective	78	4.11%	55%	Mitroflow [21 mm]	CoreValve [26 mm]	0	LV-Perforation
2	TAVI-VIV	Elective	84	6.27%	60%	Mitroflow [21 mm]	Evolut R [23 mm]	3	Sudden cardiac death
3	TAVI-VIV	Emergency	80	20.16%	45%	Freedom Solo [27 mm]	Evolut R [34 mm]	4	Sepsis, MODS
4	TAVI-VIV	Elective	83	10.46%	60%	Mitroflow [21 mm]	Evolut R [23 mm]	5	Pulmonary Embolism
5	TAVI-VIV	Elective	85	14.5%	50%	Hancock II [25 mm]	CoreValve [26 mm]	6	Intracranial hemorrhage
1	Redo-AVR	Elective	76	5.07%	60%	Freedom Solo [23 mm]	Hancock II [23 mm]	2	Sudden cardiac death
2	Redo-AVR	Elective	81	5.96%	69%	Hancock II [21 mm]	Hancock II [21 mm]	3	Heart failure
3	Redo-AVR	Elective	77	7.21%	70%	Mitroflow [21 mm]	SJM Epic [23 mm]	27	Sepsis, MODS

Abbreviations: LV EF = left ventricular ejection fraction; MODS = Multiple organ dysfunction syndrome.

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