ORIGINAL ARTICLE

Transcatheter aortic valve-in-valve implantation for failed surgical bioprostheses: results from the Polish Transcatheter Aortic Valve-in-Valve Implantation (ViV-TAVI) Registry

Zenon Huczek[1*], Szymon Jędrzejczyk[1*], Dariusz Jagielak[2], Maciej Dąbrowski[3], Marek Grygier[4], Monika Gruz-Kwapisz[5], Wojciech Fil[6], Piotr Olszówka[7], Marek Frank[8], Krzysztof Wilczek[9], Andrzej Walczak[10], Jarosław Trębacz[11], Artur Telichowski[12], Marcin Protasiewicz[13], Jerzy Sacha[14], Bartosz Rymuza[1], Kajetan Grodecki[1], Piotr Scisło[1], Damian Hudziak[5], Radosław Gocoł[5], Michał Zembala[15], Radosław Wilimski[16], Janusz Kochman[1], Adam Witkowski[3], Wojciech Wojakowski[5]

1 1st Department of Cardiology, Medical University of Warsaw, Warsaw, Poland
2 Department of Cardiac and Vascular Surgery, Medical University of Gdansk, Gdańsk, Poland
3 Department of Interventional Cardiology and Angiology, National Institute of Cardiology, Warsaw, Poland
4 Department of Cardiology, Poznan University of Medical Sciences, Poznań, Poland
5 3rd Department of Cardiology, Medical University of Silesia, Katowice, Poland
6 Polish-American Heart Clinic, Bielsko-Biała, Poland
7 Department of Cardiac Surgery, District Hospital No. 2, Rzeszów, Poland
8 Department of Cardiac Surgery, Medical University of Bialystok, Białystok, Poland
9 Department of Cardiology, Congenital Heart Diseases and Electrotherapy, Silesian Center for Heart Diseases, Zabrze, Poland
10 Department of Cardiac Surgery, Medical University of Lodz, Łódź, Poland
11 Department of Interventional Cardiology, Institute of Cardiology, Jagiellonian University Medical College, John Paul II Hospital, Kraków, Poland
12 Department of Anesthesiology and Intensive Therapy, 4th Military Hospital, Wrocław, Poland
13 Department of Cardiology, Wroclaw Medical University, Wroclaw, Poland
14 Department of Cardiology, University Hospital in Opole, Opole, Poland
15 Department of Cardiac Surgery, Heart and Lung Transplantation and Mechanical Circulatory Support, Silesian Center for Heart Diseases, Zabrze, Poland
16 Department of Cardiac Surgery, Medical University of Warsaw, Warsaw, Poland

KEY WORDS

aortic stenosis, transcatheter aortic valve implantation, valve-in-valve

Correspondence to:
Szymon Jędrzejczyk, MD, 1st Department of Cardiology, Medical University of Warsaw, ul. Banacha 1a, 02-097 Warszawa, Poland, phone: +48 22 599 19 58, email: szymon.jedrzejczyk@wum.edu.pl
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* ZH and SJ contributed equally to this work.

ABSTRACT

INTRODUCTION Transcatheter aortic valve-in-valve implantation (ViV-TAVI) has emerged as an alternative to redo surgery in patients with failed surgical aortic bioprosthesis.

OBJECTIVES We evaluated the safety and efficacy of ViV-TAVI in Polish patients after surgical aortic valve replacement.

PATIENTS AND METHODS This was a nationwide multicenter registry of ViV-TAVI procedures. Data were collected using an online form, and the clinical follow-up lasted 1 year.

RESULTS From 2008 to 2020, 130 ViV-TAVI procedures were performed (1.9% of all transcatheter aortic valve implantation [TAVI] cases). A considerable increase in ViV-TAVI procedures since 2018 has been observed (n = 59, 45% of ViV-TAVI cases). Hancock II, Freestyle, and homograft were the most frequently treated bioprostheses. The self-expanding supra-annular Corevalve / Evolut valve was used in 76% of cases. In 21% of cases, the mean postprocedural pressure gradient (PG) exceeded 20 mm Hg. All-cause mortality at 1 year was 10.8%. Aortic valve stenosis was associated with a higher mean PG than aortic valve regurgitation or mixed disease ($P = 0.004$). Supra-annular transcatheter aortic valves were associated with lower mean PGs than intra-annular valves ($P = 0.004$). Second-generation devices were associated with shorter procedure time (120 min vs 135 min, $P = 0.04$), less frequent need for additional TAVI (2% vs 10%, $P = 0.04$), and lower 1-year cardiovascular mortality (95% vs 82.8%, $P = 0.03$) than first-generation valves.

CONCLUSIONS Transcatheter treatment of failed bioprostheses is increasingly common, with the best hemodynamic effect shown for supra-annular valves. The introduction of second-generation valves has improved procedural and clinical outcomes.

WHAT'S NEW?

Patients with failed surgical aortic bioprostheses requiring transcatheter valve-in-valve procedures constitute a very specific population of patients undergoing transcatheter aortic valve implantation (TAVI) that is expected to grow in the future. The present study reports the results from the Polish Transcatheter Aortic Valve-in-Valve Implantation (ViV-TAVI) Registry with the aim to better understand the frequency, characteristics, safety, and efficacy of this novel procedure in Poland.

INTRODUCTION Since the first procedure in 2002, transcatheter aortic valve implantation (TAVI) has established its place as an effective treatment for symptomatic severe stenosis of the native aortic valve in inoperable patients or those at high-to-intermediate risk.[1,2] Moreover, recent randomized clinical trials have shown that TAVI with both self-expandable and balloon-expandable devices is noninferior to surgical aortic valve replacement (SAVR) in low-risk patients.[3,4] Nevertheless, aortic valve stenosis is the most common type of acquired structural heart disease in developed countries, and SAVR remains the gold standard treatment, especially in younger lower-risk patients. Currently, SAVR constitutes more than 20% of all cardiac surgery procedures in Poland[5] Importantly, irrespective of patient age, a considerable shift towards the use of biological (as opposed to mechanical) bioprostheses can be observed, driven primarily by a desire to avoid lifelong antithrombotic treatment.[5] Due to natural degeneration processes, the expected durability of bovine or porcine valves is still considerably shorter compared with that of mechanical ones, especially when implanted in younger populations.[6] Therefore, with the growing life expectancy of patients currently undergoing SAVR, a considerable rise in the number of patients requiring valve-in-valve TAVI (ViV-TAVI) is expected. Currently, a ViV-TAVI procedure is recognized as a viable therapeutic option for symptomatic patients with aortic bioprosthesis dysfunction. Its use was comprehensively evaluated in a large international registry, showing promising results and underlining important issues.[7] However, little is known about the Polish population of patients undergoing ViV-TAVI procedures. Available data are limited to several small, single-center studies or case reports, which limits the generalizability of the results.[8,9] Therefore, to assess the safety and efficacy of ViV-TAVI in Poland, we designed a nationwide registry of all cases undergoing this novel procedure.

PATIENTS AND METHODS The Polish Transcatheter Aortic Valve-in-Valve Implantation (ViV-TAVI) Registry (ClinicalTrials.gov identifier, NCT03361046) was initiated on January 1, 2018. It was designed to collect data of all patients who underwent ViV-TAVI (including any type of a surgical aortic prosthesis or homograft) in all 14 centers performing ViV-TAVI in Poland. Procedures performed in a position other than the aortic valve were excluded. A decision to refer a patient for ViV-TAVI was made by a Heart Team at each individual center. Anonymized data were collected retrospectively since 2010 and then prospectively after the start of the registry. Data collection was completed in May 2020. Investigators at contributing centers reported the data using a dedicated online case report form. The reported data were continuously monitored for inconsistencies.

The following data were reported: baseline demographic and clinical characteristics of patients, the type of the aortic valve used for SAVR, procedural data including the type of the transcatheter aortic valve, echocardiographic parameters before and after the procedure, and clinical outcomes at 1-year follow-up. Cases were also divided into subgroups according to the mechanism of failure (stenosis vs aortic valve regurgitation or mixed aortic valve disease), design type of a degenerated aortic valve (stented vs stentless or homograft), size of the aortic valve (small [≤21 mm] vs large [>21 mm]), type of transcatheter bioprosthetic valve (supra-annular [Corevalve, Evolut R, Evolut Pro, Symetis] vs intra-annular [Sapien XT, Sapien 3, Lotus, Portico] leaflet attachment), and generation of the implanted transcatheter aortic valve (first-generation [CoreValve, Sapien XT] vs second-generation [Evolut R, Evolut Pro, Sapien 3, Lotus, Portico, Symetis]). The body surface area was calculated using the Mosteller formula. Before the procedure, surgical risk was evaluated using the online calculators: logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) and STS (Society of Thoracic Surgeons) score. Major clinical end points were assessed according to Valve Academic Research Consortium-2 (VARC-2) criteria.[10] Patients with at least a moderate degree of stenosis (mean pressure gradient [PG] >20 mm Hg) and concomitant regurgitation (at least grade 3 or 4) at baseline were classified as having a mixed mechanism of bioprosthetic valve failure.

Statistical analysis The distribution of continuous variables was assessed using the Shapiro–Wilk test. Continuous variables with normal distribution were presented as mean (SD), and those without normal distribution, as median (interquartile range [IQR]). Categorical variables were presented as number (percentage). The 2-sample *t* test was used for quantitative variables with normal distribution, while the Mann–Whitney test was applied for variables without normal distribution. The χ^2 test was used to compare nominal variables. The Kaplan–Meier curves were generated to compare the rates of all-cause and cardiovascular mortality in different study subgroups (first-generation vs second-generation devices; failed small (≤21 mm) vs large [>21 mm] aortic valves; the use of supra-annular vs intra-annular transcatheter aortic valves; surgical aortic valve stenosis vs regurgitation or mixed aortic valve disease at baseline). The Cox proportional hazard

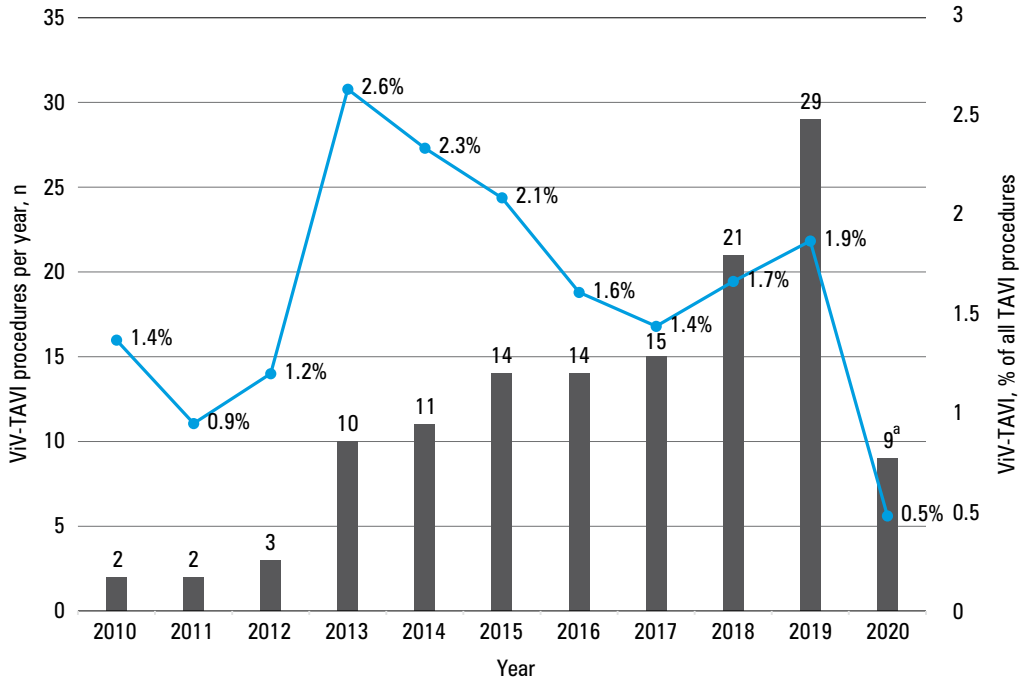

FIGURE 1 Temporal trends in the number of transcatheter aortic valve-in-valve implantation (ViV-TAVI) procedures and the percentage of ViV-TAVI procedures of all transcatheter aortic valve implantation (TAVI) procedures performed in Poland from 2008 to 2020
a Until the first quarter of 2020

regression model was used to identify predictors of all-cause and cardiovascular death. Variables with a *P* value of less than 0.1 were included in the multivariable analysis. The following clinical predictors for all-cause mortality were entered into the backward stepwise multivariable regression model: second-generation transcatheter bioprostethetic valves, small bioprostethic valves, and balloon-expandable bioprostethic valves. The following clinical predictors of cardiovascular mortality were entered into the backward stepwise multivariable regression model: male sex, intra-annular surgical bioprostethic valves, and second-generation transcatheter aortic valves. The results were presented as hazard ratio (HR) with 95% CIs. A 2-sided *P* value of less than 0.05 was considered significant. The analysis was processed using the SPSS software, version 26 (IBM Statistics, New York, United States).

Ethics Owing to the retrospective and noninterventional design of the study, the approval of the ethics committee and written consent from patients were not required.

RESULTS

Characteristics of transcatheter aortic valve-in-valve procedures and study population

Since the introduction of TAVI in Poland in 2008 until the end of this registry (March 2020), a total of 130 ViV-TAVI procedures were performed and reported from the 14 centers. The numerical increase in ViV-TAVI procedures reflected an increase in the total annual number of TAVI, with the largest gain observed since 2018 (n = 59; 45% of all ViV-TAVI procedures) (FIGURE 1). During the study period, ViV-TAVI procedures constituted 1.9% of all TAVI cases in Poland.[11] The mean number of ViV-TAVI procedures per center was 9.3, with only 3 centers having performed more than 10 procedures.

The median age of the study population was 76 years (IQR, 68–80), the median STS score was 4 (IQR, 2.9–7.0), and the median time from the last aortic valve surgery was 8 years (IQR, 5.0–11.0). More than one-third of patients (n = 51; 39%) had atrial fibrillation and a history of coronary artery bypass grafting (n = 48; 37%) (TABLE 1).

Characteristics of failed surgical bioprosthetic valves

Isolated stenosis was the underlying cause of bioprosthetic failure in nearly half of the population (n = 64; 49%), and the median left ventricular ejection fraction was 50% (TABLE 1). Hancock II (21% of procedures), Freestyle (13%), and homograft (11.5%) were identified as the most frequently treated failed bioprosthetic valves (Supplementary material, *Figure S1*).

Stented bioprostheses constituted the majority of failed bioprosthetic valves (n = 73; 56%). Patients with stentless valves or homografts were younger at the time of ViV-TAVI than those with stented valves (median, 74 years [IQR, 63–78] vs 77 years [IQR, 70–81]; *P* = 0.04) and had a longer time since the last SAVR (median, 10.5 years [IQR, 6–15] vs 7 years [IQR, 4.5–10]; *P* = 0.001). The size of failed bioprostheses was 21 mm or smaller in almost half of the population (45%). The remaining characteristics are presented in TABLE 2.

Procedural characteristics of transcatheter aortic valve-in-valve implantation

Most ViV-TAVI procedures were performed using general anesthesia (n = 92; 71%) and a femoral delivery route (n = 117; 90%). Self-expanding supra-annular valves (Corevalve, Evolut R, or Pro) were most commonly used in the study population (n = 99; 76%) (FIGURE 2). The median diameter of all types of transcatheter aortic valves was 23 mm (IQR, 21–26). Balloon postdilation was performed in 20 cases (15%). Recently, there has

TABLE 1 Baseline characteristics of patients referred for transcatheter aortic valve-in-valve implantation

Parameter	Total (n = 130)
Demographic and clinical characteristics	
Age, y	76 (68–80)
Female sex, n (%)	56 (43)
Body mass index, kg/m^2	27.3 (24.2–29.0)
Body surface area, m^2	1.83 (1.72–1.98)
Time since last SAVR, y	8 (5–11)
Hypertension, n (%)	102 (78)
Atrial fibrillation, n (%)	51 (39)
Permanent pacemaker, n (%)	21 (16)
Stroke or TIA n (%)	16 (12)
Myocardial infarction, n (%)	12 (9)
CABG, n (%)	48 (37)
PCI, n (%)	21 (16)
NYHA functional class III or IV, n (%)	83 (64)
Oral anticoagulant therapy, n (%)	43 (33)
Diabetes mellitus, n (%)	41 (32)
COPD, n (%)	9 (7)
GFR, ml/min/1.73 m^2	56.3 (20.3)
STS score	4 (2.9–7.0)
Echocardiographic parameters	
LVEF, %	50 (4–60)
EOA, cm^2	0.81 (0.51–1.1)
EOAi, cm^2/m^2	0.45 (0.31–0.60)
Mean pressure gradient, mm Hg	38 (26–50)
Maximum pressure gradient, mm Hg	64.5 (46–83)
Stenosis, n (%)	64 (49)
Regurgitation, n (%)	23 (18)
Mixed aortic valve disease, n (%)	43 (33)

Data are presented as median (IQR) or mean (SD) unless otherwise indicated.

Abbreviations: CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; EOA, effective orifice area; EOAi, indexed effective orifice area; GFR, glomerular filtration rate; IQR, interquartile range; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; TIA, transient ischemic attack

been an increase in the use of postdilation. In the period from 2010 to 2017, it was required in only 11.3% of cases, while from 2018 to 2020, it was used in 20.3% of cases (P = 0.22). Bioprosthetic aortic scallop intentional laceration to prevent iatrogenic coronary artery obstruction (BASILICA) was not performed during ViV-TAVI in any of the cases, while a single case of chimney stenting was reported (TABLE 2). The most common combination reported in the registry was the implantation of Evolut R into Hancock II (n = 20; 15%) (Supplementary material, *Figure S4*).

There were no differences in the STS score between first-generation and second-generation groups (median, 4.4 [IQR, 3.1–8.8] vs 3.9 [IQR, 2.8–8.5]; P = 0.86). The most important procedural differences between the first-generation and second-generation transcatheter aortic valves are presented in TABLE 3. In patients implanted with the second-generation valves, general anesthesia was used less frequently than in those receiving the first-generation valves (TABLE 3). The use of the second-generation valves was also associated with a shorter procedure time and a lower need for the implantation of an additional valve, as compared with the first-generation valves.

Echocardiographic parameters Echocardiographic outcomes of ViV-TAVI are presented in TABLE 4. Stenosis of failed surgical bioprostheses at baseline was associated with a higher mean PG than regurgitation or mixed disease (median, 16 mm Hg [IQR, 13.5–22.5] vs 14.5 mm Hg [IQR, 10–19]; P = 0.004). The ViV-TAVI procedures performed in small surgical bioprostehses (≤21 mm) were associated with a smaller effective orifice area after the procedure, as compared with larger bioprostheses (median, 1.4 cm^2 [IQR, 1.2–1.6] vs 1.58 cm^2 [IQR, 1.45–1.7]; P = 0.005) (Supplementary material, *Figure S2*). There were no differences in preprocedural mean PG between supra-annular and intra-annular valves (median, 37 mm Hg [IQR, 25–50] vs 39 mm Hg [IQR,

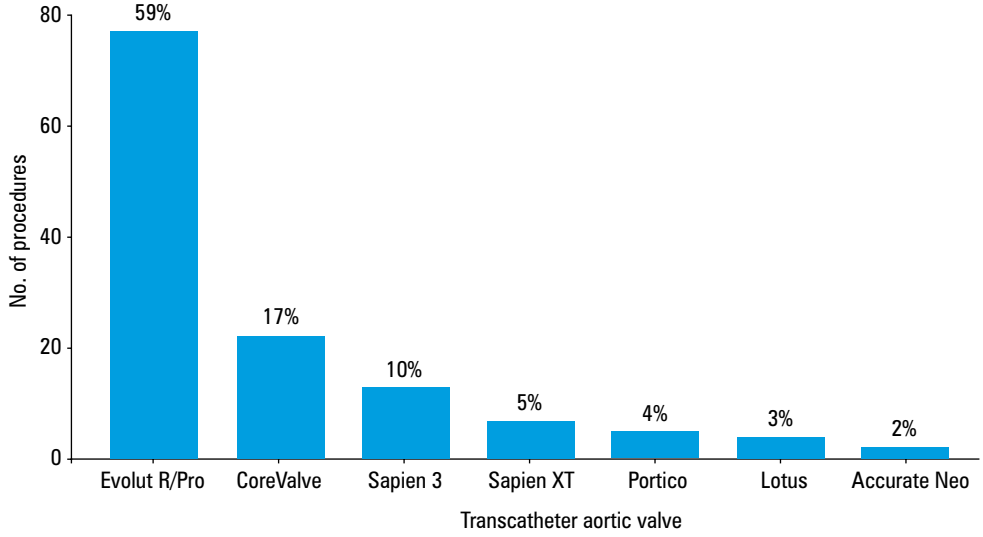

FIGURE 2 Types of implanted transcatheter aortic valves

TABLE 2 Baseline procedural characteristics of transcatheter aortic valve-in-valve implantation

Parameter	Total (n = 130)
General anesthesia, n (%)	92 (71)
Nontransfemoral access, n (%)	13 (10)
Size of surgical bioprosthetic valve, mm	21 (19–23)
Small bioprosthetic valve (≤21 mm), n (%)	58 (45)
Stented valve, n (%)	73 (56)
Stentless valve or homograft, n (%)	57 (44)
Predilatation, n (%)	23 (18)
Size of transcatheter aortic valve, mm	23 (21–26)
Self-expandable valve, n (%)	106 (82)
Balloon-expandable valve, n (%)	20 (15)
Mechanically expandable valve, n (%)	4 (3)
Supra-annular leaflet function, n (%)	100 (77)
Intra-annular leaflet function, n (%)	30 (23)
First-generation valve, n (%)	29 (22)
Second-generation valve, n (%)	101 (78)
Implantation depth, mm	4 (3–6)
Postdilatation, n (%)	14 (11)
Postdilatation – noncompliant balloon "cracking", n (%)	6 (5)
Chimney stenting, n (%)	1 (0.8)
≥1 transcatheter valve used, n (%)	5 (3.8)
Procedure time, min	120 (90–200)
Radiation dose, mGy	690 (426–1054)
Fluoroscopy time, min	24 (16–31)
Contrast volume, ml	130 (90–200)

Data are presented as median (IQR) unless otherwise indicated.

Abbreviations: see TABLE 1

TABLE 3 Procedural differences between the first-generation and second-generation transcatheter aortic valves in transcatheter aortic valve-in-valve implantation

Parameter	First-generation valves (n = 29)	Second-generation valves (n = 101)	*P* value
General anesthesia, n (%)	27 (93)	65 (64)	0.003
Nontransfemoral access, n (%)	5 (17)	8 (8)	0.14
>1 valve implanted, n (%)	3 (10)	2 (2)	0.04
Procedure time, min, median (IQR)	135 (108–200)	120 (80–165)	0.04
Radiation, mGy, median (IQR)	890 (528–2245)	620 (351–956)	0.02
Fluoroscopy time, minutes, median (IQR)	20 (18–43)	22 (15.5–29)	0.06
Contrast volume, ml, median (IQR)	140 (100–250)	125 (80–180)	0.08

Abbreviations: see TABLE 1

28.5–50]; $P = 0.65$). However, the implantation of supra-annular transcatheter valve resulted in a lower mean PG than the implantation of intra-annular bioprostheses (median, 14 mm Hg [IQR, 10.5–20] vs 19 mm Hg [IQR, 16–26]; $P = 0.004$) (FIGURE 3A–3D).

Clinical outcomes at 1 year During the 1-year follow-up, 14 patients died (10.8%), of whom 10 patients (7.7%) died due to cardiovascular causes. Typical complications associated with TAVI were rare and included stroke in 2 patients (1.5%), life-threatening bleeding in 5 patients (3.8%), and the need for a permanent pacemaker in 7 patients (5.3%). All survivors at 1 year were in New York Heart Association functional class I or II (TABLE 4).

There were no differences in all-cause survival between the second-generation and first-generation transcatheter valves (FIGURE 4A), but the use of the second-generation devices was associated with improved cardiovascular survival at 1 year (FIGURE 4B). Additional data, including the Kaplan–Meier curves for failed small (≤21 mm) vs large (>21 mm) surgical bioprostheses, the use of supra-annular vs intra-annular transcatheter aortic valves, and surgical aortic valve stenosis at baseline vs regurgitation or mixed disease, are shown in Supplementary material, *Figure S3*.

DISCUSSION Polish Transcatheter Aortic Valve-in-Valve Implantation (ViV-TAVI) Registry is the first multicenter comprehensive, specifically designed evaluation of TAVI procedures for failed surgical bioprostheses. To the best of our knowledge, it covers all of ViV-TAVI procedures performed in Poland until 2020. The registry revealed that the number of these procedures has been increasing. Moreover, they were shown to constitute about 2% of all TAVI cases, which is in line with a recent Swiss national registry reporting the proportion of slightly above 3%.[12] Considering the current preference for implanting biological prostheses in younger low-risk adults with severe aortic stentosis, who are more prone to subsequent valve degeneration, these numbers are expected to rise.[5]

The most important finding of the present registry is the safety of ViV-TAVI for failed surgical bioprostheses. The all-cause and cardiovascular mortality rates at 1 year were 10.8% and 7.7%, respectively. This is in agreement with the results of various international registry studies as well as national registries from other countries (1-year all-cause mortality of 12.4% in VIVID [Valve-in-Valve International Data], 16.8% in PARTNER 2 (Placement of Aortic Transcatheter Valves 2), and 6.8% in Swiss TAVI Registry).[12-14] Furthermore, the safety of ViV-TAVI was confirmed by a low rate of typical complications associated with native TAVI, including life-threatening bleeding, stroke, moderate or severe paravalvular leak, or the need for permanent pacemaker implantation. Interestingly, we found that 1-year cardiovascular mortality was significantly higher for the early period of ViV-TAVI experience when only the first-generation valves were available. Better cardiovascular survival with second-generation devices can be explained first of all by their improved deliverability and design, allowing for repositioning and better sealing. Another explanation, as supported by our findings, is the evolution of the implantation procedure itself with a lower requirement for general anesthesia, nontransfemoral access,

TABLE 4 Echocardiographic and clinical outcomes after transcatheter aortic valve-in--valve implantation

Parameter	Total (n = 130)
Echocardiography	
LVEF, %	50 (45–60)
EOA, cm^2	1.48 (1.3–1.6)
EOAi, cm^2/m^2	0.82 (0.7–0.96)
Mean pressure gradient, mm Hg	16 (11–20)
Maximum pressure gradient, mm Hg	28 (20–40)
Moderate or severe patient-prosthesis mismatch, n (%)	32 (25)
Mean pressure gradient >20 mm Hg, n (%)	27 (21)
Moderate or severe perivalvular regurgitation, n (%)	5 (3.8)
Clinical outcomes at 1 year, n (%)	
NYHA functional class III or IV	0
Cardiovascular death	10 (7.7)
All-cause death	14 (10.8)
Stroke	2 (1.5)
Life-threatening bleeding	5 (3.8)
Myocardial infarction	2 (1.5)
Coronary obstruction	2 (1.5)
Acute kidney injury	5 (3.8)
Permanent pacemaker	7 (5.3)

Data are presented as median (IQR) unless otherwise indicated.

Abbreviations: see TABLE 1

contrast medium, and the overall shortening of the procedure time.

Despite these positive results, ViV-TAVI is not without limitations. First, there are some safety concerns related to the baseline aortic root anatomy and the type of failed surgical bioprosthesis that may be associated with the risk of life-threatening coronary obstruction in some patients undergoing ViV-TAVI.[15] The underlying mechanism is usually immediate (or, rarely, delayed) coronary ostial occlusion by the displaced leaflet of the surgical bioprosthesis. The clinical presentation of coronary obstruction after native and valve-in-valve TAVI is similar and includes severe hypotension and abnormal electrocardiographic parameters, resulting in high mortality rates. However, this can be prevented by a thorough computed tomography examination before the procedure, and even if the risk of obstruction is high, preventive measures can be taken, such as simultaneous coronary stenting (chimney stenting) or laceration (BASILICA) of the bioprosthesis leaflet (or leaflets).[16,17] In the present registry, the rate of coronary obstruction was only 1.5% and was slightly lower compared with that reported in the VIVID registry. This is probably due the fact that our patients were less often implanted with stented bioprostheses with externally mounted leaflets, which are most likely to cause occlusion after TAVI.[15]

In terms of the efficacy, ViV-TAVI may not provide optimal hemodynamic results in patients after SAVR with stenosis of a small valve (≤21 mm, constituting 45% of the Polish population) or with preexisting patient--prosthesis mismatch.[17] In the present registry, unsatisfactory PGs after the procedure were present in 25% of patients, and indeed baseline stenosis and the small size of surgical bioprosthesis were associated with elevated PGs and a smaller effective orifice area after ViV--TAVI, respectively. However, this had no negative effect on 1-year survival rates, which is in line with findings from other registries.[12,18] Nevertheless, this seems to be an important issue, especially when younger patients with longer life expectancy are being considered for ViV-TAVI. To overcome the problem of elevated PGs after the procedure, several measures can be taken. First, noncompliant balloons can be used to fracture or crack the rings of stenosed valves either as predilation or postdilation with TAVI (also reported in our registry). This procedure is effective and safe but is not technically feasible in several popular types of bioprostheses, such as Hancock II.[19] Second, an appropriate transcatheter aortic valve can be seletect that may offer the best hemodynamic results for small aortic valve annuli. In our registry, we found that transcatheter valves with the supra-annular leaflet attachment (mostly Corevalve or Evolut R/Pro) seem to provide lower gradients as compared with the remaining valve types.[20]

Considering the above safety and efficacy concerns, the imaging protocol to determine eligibility for ViV-TAVI differs from that used in traditional TAVI and requires, for example, simulation and assessment of virtual valve-to-coronary distance (predictor of coronary obstruction), measurement of the sinus diameter, sinotubular junction height, and virtual valve-to-sinotubular junction distance. The identification of patients who would most likely benefit from surgical valve fracturing or cracking with a high-pressure balloon or who should be referred for a redo surgery (if eligible) is also necessary.

The present registry has several limitations. First, there are limitations inherent to the (partly) retrospective design. Second, the cohort of patients undergoing ViV-TAVI was not large enough to allow a more comprehensive analysis. However, this is the largest registry in Poland to date. Third, since the registry covers 10 years of ViV--TAVI use in Poland, some findings (eg, a comparison of first-generation vs second-generation devices) may be affected by the learning curve and operators' experience with this novel and constantly evolving procedure.

In conclusion, transcatheter treatment of failed surgical bioprostheses is becoming increasingly common in Poland, showing the best hemodynamic effect with the use of supra-annular transcatheter aortic valves as well as improved procedural and clinical outcomes following the introduction of second-generation devices.

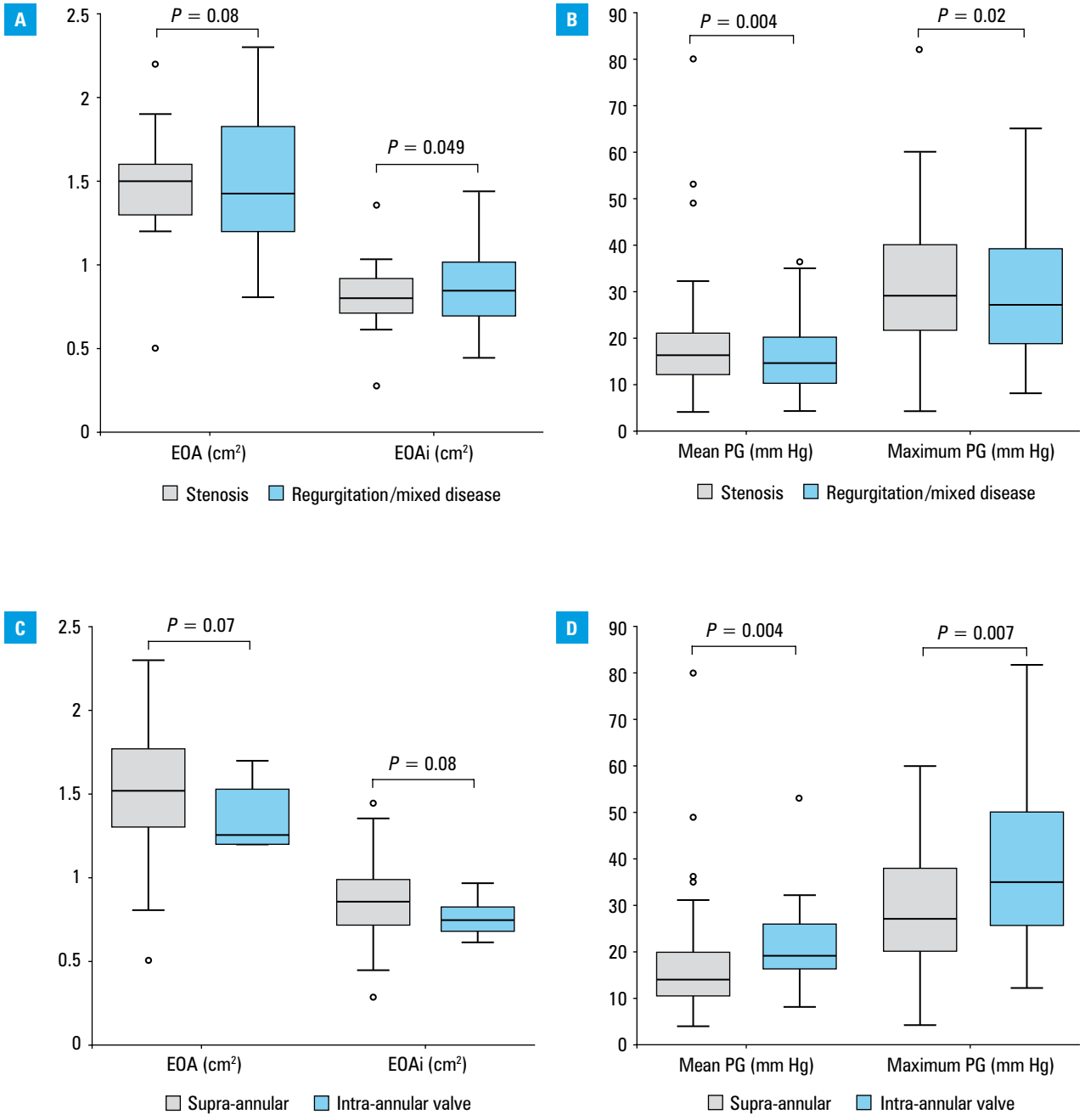

FIGURE 3 Comparison of effective orifice area (EOA) and indexed effective orifice area (EOAi) after transcatheter aortic valve-in-valve implantation (ViV-TAVI) in patients with surgical aortic valve stenosis at baseline and those with regurgitation or mixed aortic valve disease (**A**) and in those with the use of supra-annular vs intra-annular transcatheter aortic valve (**B**). Comparison of mean and maximum transvalvular pressure gradients (PGs) after ViV-TAVI in patients with surgical aortic valve stenosis at baseline and those with regurgitation or mixed disease (**C**) and in those with the use of supra-annular vs intra-annular transcatheter aortic valve (**D**). The black center line indicates the median value. The top and bottom of the boxes indicate the interquartile range.

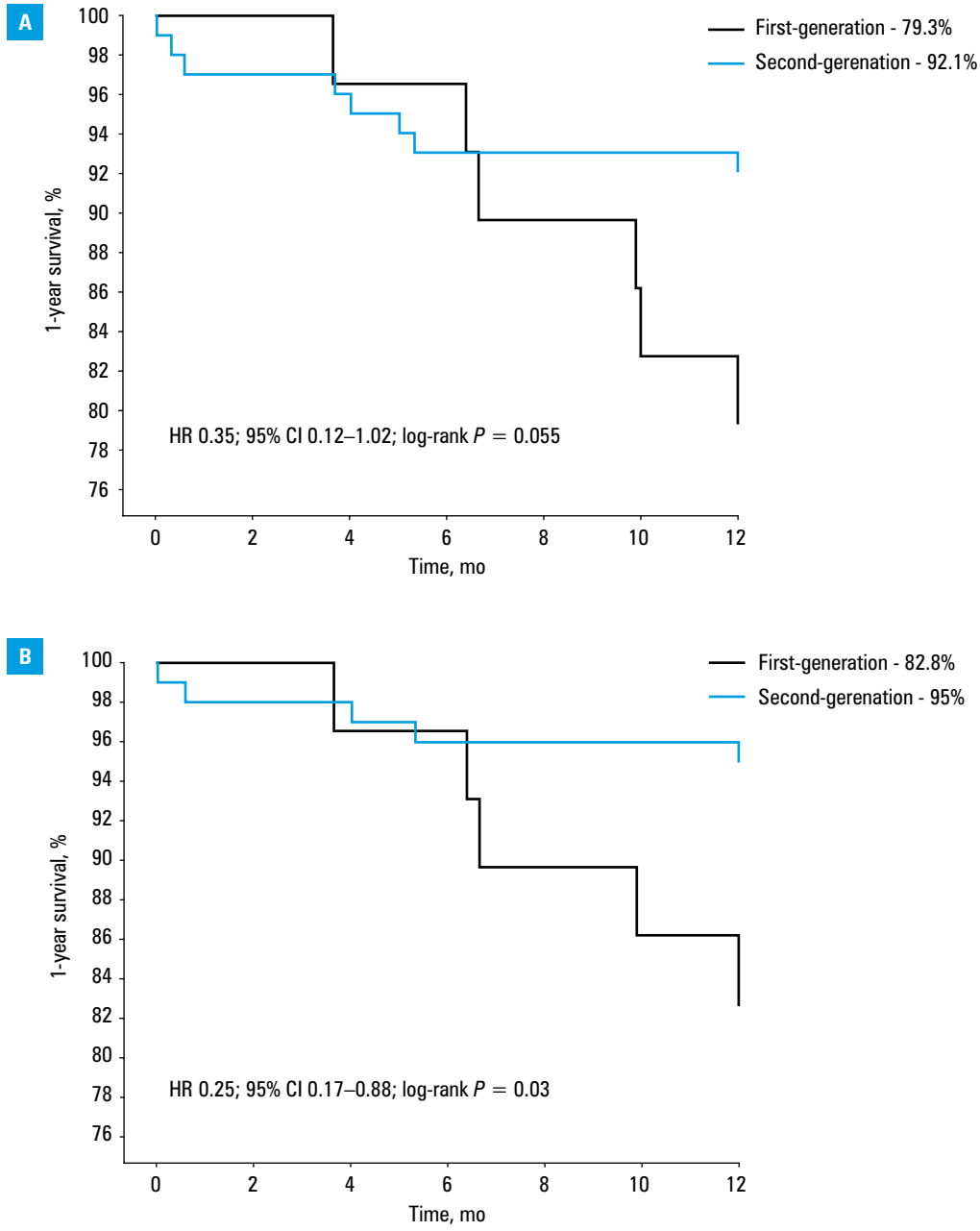

FIGURE 4 All-cause (**A**) and cardiovascular mortality (**B**) in patients implanted with first-generation vs second--generation transcatheter aortic valves

Abbreviations: TAV, transcatheter aortic valve; HR, hazard ratio for second-generation TAVI use in multivariable analysis

SUPPLEMENTARY MATERIAL

Supplementary material is available at www.mp.pl/paim.

ARTICLE INFORMATION

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CONTRIBUTION STATEMENT ZH, SJ, and WW contributed to the concept of the study. All authors were involved in data collection. ZH and SJ performed the statistical analysis and interpreted the results of the study. ZH and SJ prepared a draft version of the manuscript. All authors read, critically revised, and approved the manuscript and take responsibility for its final version.

CONFLICT OF INTEREST ZH served as proctor for Medtronic and Abbott, sat on an advisory board for Medtronic, and received lecture honoraria from Medtronic, Abbott, and Edwards Lifesciences. WW sat on an advisory board for Medtronic and received lecture honoraria from Edwards Lifesciences. KG is supported by the Foundation For Polish Science. Other authors declare no conflict of interest

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