Temporal trends of transcatheter aortic valve implantation in a high-volume academic center over 10 years

Zenon Huczek[1]*, Bartosz Rymuza[1]*, Maciej Mazurek[1], Radosław Wilimski[2], Piotr Scisło[1], Karol Zbroński[1], Kajetan Grodecki[1], Szymon Jędrzejczyk[1], Ewa Pędzich-Placha[1], Piotr Hendzel[2], Krzysztof J Filipiak[1], Grzegorz Opolski[1], Janusz Kochman[1]

[1]1st Department of Cardiology, Medical University of Warsaw, Warszawa, Poland
[2]Department of Cardiosurgery, Medical University of Warsaw, Warszawa, Poland
*Both authors equally contributed to the study.

ABSTRACT

Background: Indications for transcatheter aortic valve implantation (TAVI) have gradually expanded since its introduction.

Aims: The aim was to analyze temporal trends in TAVI characteristics based on the experience of a high-volume academic center over the period of 10 years.

Methods: Five hundred and six consecutive (n = 506) patients with 1-year follow-up were divided into early (G1, years 2010–2013, n = 130), intermediate (G2, 2014–2016, n = 164) and recent (G3, 2017–2019, n = 212) experience groups.

Results: Patient's age remained constant over time (mean [SD]; G1 = 79.1 [7.1] years vs G2 = 79.1 [7.1] years vs G3 = 79.7 [6.6] years, $P = 0.73$) but surgical risk in G3 was lower (log Euroscore, median [IQR]: G1 = 14.0 [8.4–20.2] vs G2 = 12.0 [7.0–22.2] vs G3 = 5.1 [3.5–8.5]; $P < 0.001$). Major/life-threatening bleeding (G1 = 26.9% vs G2 = 12.8% vs G3 = 9.4%; $P < 0.001$), major vascular complications (G1 = 15.4% vs G2 = 8.5% vs G3 = 5.7%; $P = 0.02$) and moderate/severe paravalvular leak (G1 = 16.2% vs G2 = 11% vs G3 = 7.5%; $P = 0.046$) were decreasing with time. There was a significant drop in all-cause 1-year mortality in G3 (G1 = 20% vs G2 = 17.7% vs G3 = 9.1%; log rank = 0.01).

Conclusions: The age of TAVI recipients remained unchanged over the last decade. Decreasing surgical risk coupled with improvements in procedural technique and care resulted in fewer periprocedural complications and better 1-year survival.

Key words: TAVI, low-risk population, 1-year mortality, stroke, bleeding complications

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INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is currently the least invasive procedure available for the definitive treatment of severe symptomatic aortic stenosis (AS). Initially, it has been a highly specialized procedure, carried out only in a few selected academic centers in Poland, and only on inoperable, highest risk patients [1–3]. As time went by, due to positive results from large randomized trials, TAVI was recognized for a broader population of AS patients in European guidelines on the management of valvular heart disease and subsequently became more routine [4–8].

While the standards of care were changing, the number of TAVI procedures in Poland grew slowly but steadily from its introduction in 2008. Parallel to guidelines modifica-tions, improvements in bioprosthesis design and function, and changes in procedural technique and periprocedural management of patients were observed. Therefore, the aim of the study was to analyze temporal trends in baseline characteristics, procedural as well as clinical outcomes of patients treated with TAVI based on the experience of a high-volume polish academic center over the period of 10 years.

METHODS

Study population

For the purpose of the study we included 506 consecutive patients who received TAVI from March 2010 to July

W H A T ' S   N E W ?

Transcatheter aortic valve implantation (TAVI) has grown from an innovative intervention reserved only for highest-risk or inoperable patients with severe aortic stenosis AS into an almost default procedure in elderly patients irrespective of baseline risk. However, the age of TAVI patients remained unchanged over the last decade and did not add to the overall risk reduction. Decreasing surgical risk coupled with improvements in delivery systems, bioprosthesis design, implantation technique, and periprocedural care resulted in fewer complications and better 1-year survival in the 2017–2019 group.

2019 and who gave their informed consent to enter Transcatheter Valve Treatment Sentinel Registry (2010–2012), which later was continued by the national POL-TAVI registry database [9, 10]. Data concerning patients' characteristics and periprocedural outcomes were gathered prospectively. All patients completed a 12-month follow-up, as obligated by the registry protocol. The study was approved by the ethics committee of the Medical University of Warsaw and that patients provided written informed consent to participate in the study.

Given certain changes in clinical practice throughout the studied period, we decided to divide the study population into 3 groups. Group 1 (G1), early experience, procedures performed from March 2010 until the end of 2013. This period was characterised by no clinical practice guidelines or early introduction of the 2012 European Society of Cardiology (ESC) Valvular Heart Disease (VHD) guidelines. Also, first-generation bioprosthetic valves were used. Group 2 (G2), intermediate experience, from January 2014 until the end of 2016. Age of implementing 2012 ESC VHD guidelines with improved and new types of bioprosthesis being introduced. Group 3 (G3), recent experience, from January 2017 until July of 2019. Time of implementing the 2017 ESC VHD guidelines implementation and growing use of second-generation devices use.

Data collection and definitions
Data was acquired using the hospital electronic database and outpatient clinic charts. All patients with an unconfirmed status were followed up remotely by telephone visits. All definitions are in accordance with Valve Academic Research Consortium Criteria-2 [11].

Statistical analysis
The Shapiro-Wilk test was used to confirm or reject the normal distribution of each continuous variable. Continuous variables with normal distribution were presented as means (SD) and compared between three groups using ANOVA with Welch statistics. Tukey post-hoc analysis for ANOVA test was applied when appropriate. Continuous variables with non-normal distribution were presented as medians with interquartile range (IQR) and compared with the Kruskal-Wallis test. Categorical variables, expressed as counts and percentages, were compared using the Chi-square test or Fisher's exact test, as appropriate.

Kaplan-Meier curves and log-rank tests of the time-to-event data were used to assess the differences of 1-year all-cause mortality between the groups. Cox proportional hazard analysis was performed to find possible predictors of mortality in 1-year observation for all groups. All probability values reported are 2-sided and a value <0.05 was considered to be significant. Data were processed using the SPSS software, version 26 (IBM SPSS Statistics, NY, USA) and Medcalc, version 16 (MedCalc Software, Ostend, Belgium).

RESULTS

Baseline clinical and echocardiographic characteristics
After dividing into subgroups the population of G1 consisted of 130 patients, G2 and G3 of 164 and 212 patients, respectively. There were no significant between-group differences in terms of either mean age or percentage of the female sex (Table 1). There was however a clear decrease in logistic Euroscore values with G3 being of the lowest risk (G1 = 14.0 [8.4–20.2] vs G2 = 12.0 [7.0–22.2] vs G3 = 5.1 [3.5–8.5]; P <0.001). Patients in G3 also had higher rates of previous percutaneous interventions and the lowest frequency of previous coronary artery bypass grafting. The presence of peripheral artery disease changed with time. There were significant differences in baseline aortic valve area but not in terms of left ventricular ejection fraction (Table 1). Group 1 was characterized by the highest mean pressure gradient before TAVI (G1 = 47 [39–60] mm Hg vs G2 = 43 [34–51] mm Hg vs G3 = 43 [34–51] mm Hg; P <0.001) (Figure 1).

Procedural characteristics
Procedural management changed significantly during the analyzed time (Table 2). In G1 there were only 2 types of prostheses used (Corevalve 64.6% and Sapien/Sapien XT 34.6%) with the biggest diversification of the devices reached in G2. In G3 there was a visible reversion into utilizing 2 types of valves, both of them being self-expandable (Evolut R/PRO 47.6% and Portico 47.2%).

Procedural anesthesia has also been significantly transformed — from 95.4% of cases done in general anesthesia in G1 to only 26.9% in G3 (replaced by conscious sedation). Time has brought a significant increase in applying trans-femoral access for TAVI with 91.5% of cases performed this way in G3. With the introduction of trans-carotid access

Table 1. Baseline characteristics

	All	Group 1 (2010–2013)	Group 2 (2014–2016)	Group 3 (2017–2019)	*P*-value
Baseline characteristics	n = 506	n = 130	n = 164	n = 212	
Age, years	79.4 (7)	79.1 (7.1)	79.1 (7.1)	79.7 (6.6)	0.73
Female sex, n (%)	259 (51.2)	64 (49.2)	85 (51.8)	110 (51.9)	0.88
BMI, kg/m², mean (SD)	27.1 (5)	27.4 (6)	27.4 (6)	27 (4.5)	0.72
Logistic Euroscore, median (IQR)	8.5 (4.8–17.4)	14.0 (8.4–20.2)	12.0 (7.0–22.2)	5.1 (3.5–8.5)	<0.001
Hypertension, n (%)	400 (79.1)	97 (74.6)	128 (78)	175 (82.5)	0.21
Diabetes, n (%)	187 (37)	49 (37.7)	64 (39)	74 (34.9)	0.70
CKD stage >3, n (%)	52 (10.3)	17 (13.1)	18 (11)	17 (8)	0.21
COPD, n (%)	86 (17)	28 (21.5)	23 (14)	35 (16.5)	0.25
Atrial fibrillation, n (%)	189 (37.4)	48 (36.9)	56 (34.1)	85 (40.1)	0.47
PCI, n (%)	148 (29.2)	35 (26.9)	37 (22.6)	76 (35.8)	0.01
CABG, n (%)	59 (11.7)	15 (11.5)	28 (17.1)	16 (7.5)	0.02
MI, n (%)	107 (21.1)	36 (27.7)	35 (21.3)	36 (17)	0.07
Stroke, n (%)	67 (13.2)	24 (18.5)	17 (10.4)	26 (12.3)	0.12
Pacemaker, n (%)	86 (17)	20 (15.4)	27 (16.5)	39 (18.4)	0.78
PAD, n (%)	107 (21.1)	22 (16.9)	55 (33.5)	30 (14.2)	<0.001
Baseline echocardiography					
AVA, cm², median (IQR)	0.7 (0.6–0.9)	0.7 (0.6–0.8)	0.8 (0.6–0.9)	0.7 (0.6–0.9)	0.02
EF, %, median (IQR)	55 (45–64)	52 (40–60)	55 (45–65)	58 (46–63)	0.08
Mean PG, mm Hg, median (IQR)	44 (34–53)	47 (39–60)	43 (34–51)	43 (34–51)	0.003

Abbreviations: AVA, aortic valve area; BMI, body mass index; CABG, coronary-artery bypass grafting; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; EF, ejection fraction; IQR, interquartile range; MI, myocardial infarction; PAD, peripheral artery disease; PCI, percutaneous intervention; PG, pressure gradient; SD, standard deviation
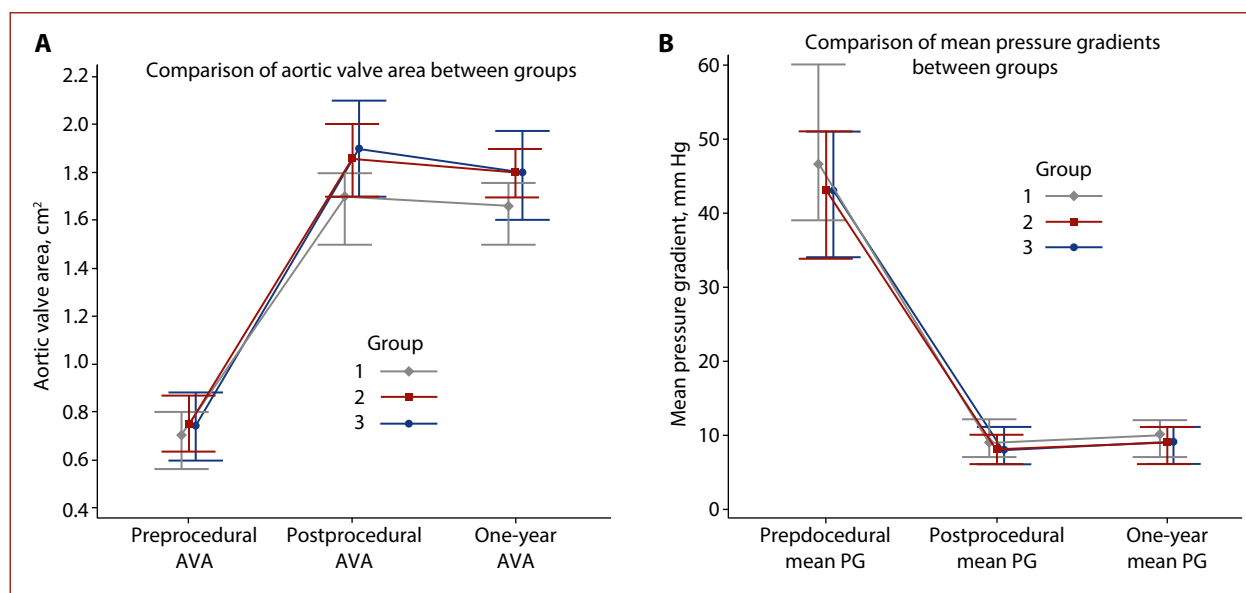
Figure 1. A. Comparison of aortic valve area (AVA); **B.** and mean pressure gradients.

Clustered multiple variables graphs of mean preassure gradients and aortic valve area presented as median with interquartile ranges. Pre-procedural AVA G1 0.7 (0.6–0.9) cm² vs G2 0.7 (0.6–0.8) cm² vs G3 0.7 (0.6–0.9) cm²; *P* = 0.02. Post-procedural AVA G1 1.70 (1.5–1.8) cm² vs G2 1.86 (1.7–2.0) cm² vs G3 1.90 (1.7–2.1) cm²; *P* <0.001. 1-year AVA: G1 1.66 (1.5–1.8) cm² vs G2 1.80 (1.7–1.9) cm² vs G3 1.80 (1.6–2.0) cm²; *P* = 0.002. Pre-procedural MeanPG G1 47 (39–60) cm² vs G2 43 (34–51) cm² vs G3 43 (34–51) cm²; *P* = 0.003. Post-procedural MeanPG G1 9 (7–12) cm² vs G2 8 (6–10) cm² vs G3 8 (6–11) cm²; *P* = 0.002. One-year MeanPG: G1 10 (7–12) cm² vs G2 9 (6–11) cm² vs G3 9 (6–11) cm², *P* = 0.19

in late 2014 [12], more invasive trans-apical and direct-aortic access were gradually withdrawn. With higher rates of application of trans-femoral access came wider use of percutaneous closing devices (Prostar XL in G1, Prostar XL and Proglide in G2 and Proglide in G3) reaching 84.9% in G3.

There has been a gradual decrease in using predilatation before valve implantation (93.8% in G1 to 59.9% in G3) with a parallel increase in postdilatation (20.8% in G1 to 35.8% in G3). The procedural time was shortened and contrast use decreased (Table 2).

Echocardiographic follow-up

All patients achieved significant improvement in the aortic valve area (AVA), which was sustained in 1-year observation

Table 2. Procedural characteristics

	All	Group 1 (2010–2013)	Group 2 (2014–2016)	Group 3 (2017–2019)	*P*-value
Prosthesis type	n = 506	n = 130	n = 164	n = 212	
Corevalve, n (%)	116 (22.9)	84 (64.6)	32 (19.5)	0 (0)	<0.001
Sapien/Sapien XT, n (%)	76 (15)	45 (34.6)	31 (18.9)	0 (0)	<0.001
Sapien 3, n (%)	2 (0.4)	0 (0)	0 (0)	2 (0.9)	0.25
Lotus, n (%)	34 (6.7)	0 (0)	27 (16.5)	7 (3.3)	<0.001
Evolut R/PRO, n (%)	167 (33)	0 (0)	66 (40.2)	101 (47.6)	<0.001
Portico, n (%)	104 (20.6)	0 (0)	4 (2.4)	100 (47.2)	<0.001
Other[a], n (%)	7 (1.4)	1 (0.8)	4 (2.4)	2 (0.9)	0.82
Access					
Femoral, n (%)	429 (84.8)	96 (73.8)	139 (84.8)	194 (91.5)	<0.001
Subclavian, n (%)	19 (3.8)	10 (7.7)	2 (1.2)	7 (3.3)	0.01
Carotid, n (%)	25 (4.9)	0 (0)	14 (8.5)	11 (5.2)	0.003
Transapical, n (%)	9 (1.8)	6 (4.6)	3 (1.8)	0 (0)	0.007
Direct aortic, n (%)	24 (4.7)	18 (13.8)	6 (3.7)	0 (0)	<0.001
Procedure					
Predilatation, n (%)	351 (69.4)	122 (93.8)	102 (62.2)	127 (59.9)	<0.001
Postdilatation, n (%)	165 (32.6)	27 (20.8)	62 (37.8)	76 (35.8)	0.003
Procedure time[b], min (IQR)	150 (100–200)	208 (163–240)	165 (140–190)	100 (80–150)	<0.001
Contrast, ml	204.9 (72.1)	214.6 (67.3)	208.5 (72.4)	193 (74.3)	0.03
Radiation dose, mGy (IQR)	1212 (789–1980)	1160 (800–1855)	1254 (803–2066)	1224 (719–1965)	0.63
Anesthesia					
General anesthesia, n (%)	301 (59.5)	124 (95.4)	120 (73.2)	57 (26.9)	<0.001
Conscious sedation, n (%)	205 (40.5)	6 (4.6)	44 (26.8)	155 (73.1)	<0.001
Access closure					
Percutaneous, n (%)	380 (75.1)	81 (62.3)	119 (72.6)	180 (84.9)	<0.001
Surgical, n (%)	126 (24.9)	49 (37.7)	45 (27.4)	32 (15.1)	<0.001

[a]Other valves used were Engager, Allegra, JenaValve, and Accurate Neo.

[b]Time measured from patients arrival at the cath lab or hybrid room until leaving, includes anesthetic preparations

(Figure 1). There were between-group differences in terms of post-procedural and 1-year AVA with lowest values recorded for G1 (post-procedural AVA: G1 1.70 [1.5–1.8] cm^2 vs G2 1.86 [1.7–2.0] cm^2 vs G3 1.90 [1.7–2.1] cm^2; *P* <0.001; 1-year AVA: G1 1.66 [1.5–1.8] cm^2 vs G2 1.80 [1.7–1.9] cm^2 vs G3 1.80 [1.6–2.0] cm^2, *P* = 0.002). Sustained reduction in mean transvalvular gradients with no significant differences between groups was observed (Figure 1).

Functional status

Almost two-thirds of patients referred to TAVI were severely symptomatic (NYHA class III and IV) (Figure 2). In 67.6% of cases performing TAVI helped to completely relieve the signs of heart failure (NYHA I) or leave only minor symptoms (NYHA II 24.1%). This positive effect was maintained in survivors at 1-year observation (NYHA I in 72.4% and NYHA II in 21.3% of cases).

Clinical outcomes and 1-year mortality

Postprocedural outcomes improved significantly over time in terms of reducing major or life-threatening bleeding (G1 26.9%, G2 12.8%, G3 9.4%; *P* <0.001), major vascular complications (G1 15.4%, G2 8.5%, G3 5.7%; *P* = 0.02), and moderate to severe paravalvular leakage (G1 16.2%, G2 11%, G3 7.5%; *P* = 0.046) (Table 3). Moreover, patients in G3 had the shortest length of hospital stay. On the other

hand, stroke rate and need for permanent pacemaker implantation did not decrease with time (Table 3).

During the 12-month follow-up after TAVI, mortality from all causes was significantly lower in G3 (9.1%) as compared with G1 (20%; *P* = 0.004) and G2 (17.7%; *P* = 0.02) (Figure 3). In the Cox proportional-hazards model, chronic kidney disease stage >3 and post-TAVI stroke were independently correlated with 1-year mortality. Femoral access had the potential of improving 1-year survival as compared with non-transfemoral delivery routes (Table 4).
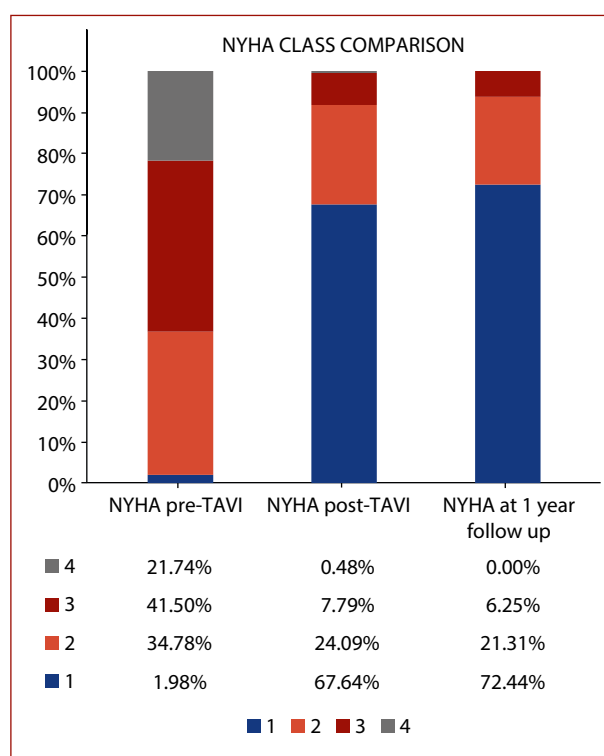
DISCUSSION

This analysis demonstrates that TAVI has been constantly evolving over the last decade. Starting with baseline characteristics, it is apparent that the approval of lower-risk groups in the guidelines has been subsequently implemented in real-life settings and reflected by lower values of logistic Euroscore. However, this change was not derived from decreasing patients' age, which throughout the whole study was almost constant and close to 80 years on average, but rather from the smaller burden of concomitant diseases (e.g. fewer history of coronary artery bypass grafting, myocardial infarction, stroke, chronic kidney disease (CKD) and better baseline left ventricle function). This observation is in line with the results of randomized trials and registries, which compared TAVI and SAVR in populations with in-

Table 3. Clinical outcomes

	All	Group 1 (2010–2013)	Group 2 (2014–2016)	Group 3 (2017–2019)	*P*-value
	n = 506	n = 130	n = 164	n = 212	
Hospital stay, days median (IQR)	10 (4–18)	15 (7–24)	11 (7–17)	7 (4–14)	<0.001
Moderate or severe PVL, n (%)	55 (10.9)	21 (16.2%)	18 (11%)	16 (7.5%)	0.046
Major or life-threatening bleeding, n (%)	76 (15)	35 (26.9%)	21 (12.8%)	20 (9.4%)	<0.001
Major vascular complications, n (%)	46 (9.1)	20 (15.4%)	14 (8.5%)	12 (5.7%)	0.02
Stroke[a], n (%)	17 (3.4)	5 (3.8%)	4 (2.4%)	8 (3.8%)	0.40
TIA[a], n (%)	8 (1.6)	2 (1.5%)	4 (2.4%)	2 (0.9%)	0.37
Permanent pacemaker, n (%)	84 (16.6)	22 (16.9%)	24 (14.6%)	38 (17.9%)	0.63
30-day all-cause mortality, n (%)	34 (6.7)	10 (7.7%)	15 (9.1%)	9 (4.2%)	0.28

[a]All cerebroembolic accidents occurred during the index hospitalization.

Abbreviations: IQR, interquartile range; PVL, paravalvular leak; TIA, transient ischemic attack. All definitions according to VARC-2 criteria

Figure 2. Functional status before and after TAVI.

Abbreviations: CI, confidence interval; HR, hazard ratio; NYHA, New York Heart Association

Table 4. Cox proportional hazard analysis for 1-year all-cause mortality analysis

	P-value	HR	95% CI	
			Low	Upper
CKD stage >3	0.007	2.205	1.236	3.935
Femoral access	0.02	0.515	0.3	0.885
Post-TAVI stroke	0.02	2.709	1.167	6.291

Abbreviations: CI, confidence interval; CKD, chronic kidney disease; HR, hazard ratio

mediate and recent experience (part of G2 and G3) were most probably behind the gradual reduction of clinically relevant post-procedural complications: e.g. major and life-threatening bleeding, major vascular complications and paravalvular regurgitation — all of which negatively impact survival after TAVI [16–21]. Also, growing experience with newer devices was the probable reason for the shortening of procedural time and lesser amounts of the contrast used. Despite best efforts some complications did not improve with time — the need for permanent pacemaker implantation remained quite substantial and close to 20% — although this can be perceived as a normal rate with self-expanding prostheses (at least before new "cusp overlap" implantation techniques were introduced, which is after the analyzed periods), which accounted for 100% of bioprostheses in G3.

It can be hypothesized that decreasing surgical risk (especially observed in recent experience period G3) combined with multifactorial improvements in periprocedural care and prosthesis implantation are the reasons behind better 1-year survival exceeding 90% in G3. Importantly, 2 independent risk factors for 1-year mortality were found, i.e. baseline CKD stage >3 and post-procedural stroke. As the first baseline factor is non-modifiable or only partly modifiable, the latter at least theoretically could be prevented or minimized. The rate of stroke was comparable with those described elsewhere, but considering its negative impact on quality of life and mortality, preventive measures, namely brain protection devices, although still not recommended, should be strongly considered in the future for selected individuals [22, 23].
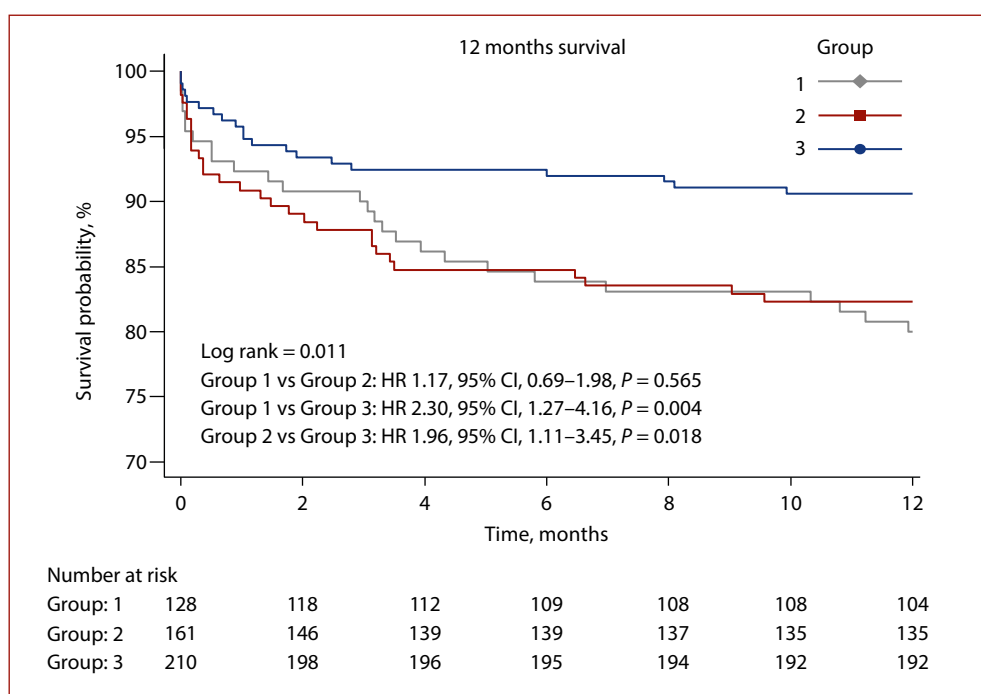
termediate surgical risk [13, 14]. Also of note, in the early experience period, significantly higher mean transvalvular pressure gradients prior to the procedure were noted – possibly due to earlier referral and/or broader inclusion of low-flow, low-gradient AS at 2017–2019 period [15].

Throughout the years, broadening of indications for TAVI was accompanied by some relevant modifications in the periprocedural technique — reflected mostly by wide utilization of transfemoral access (over 90%) and conscious sedation (almost 75%) in our recent experience period. Significant improvements in delivery systems (size reduction and flexibility) and bioprosthesis design (repositionability and sealing cuffs) available from a part of inter-

Figure 3. Kaplan-Meier curve with time-to-event analysis for 12-month survival in groups

In our dataset, we observed a clear survival improvement in short-term observation accompanied by stable echocardiographic parameters up to 1 year. The aim of future studies and registries should also focus on the assessment of long-term bioprosthetic performance [24, 25].

Limitations

First, the obvious disadvantage of the current study is its retrospective nature, which is always burdened with its inherent limitations. Second, the larger cohort of TAVI recipients would allow for a more comprehensive analysis on a year-by-year basis and could point at more independent predictors of mortality. However, the present dataset is one of the largest in Poland to date. Finally, since the intermediate experience period, only self-expanding bioprostheses were available with their unique advantages and limitations.

CONCLUSIONS

Transcatheter aortic valve implantation has grown from an innovative intervention reserved only for highest-risk or inoperable patients with severe AS into an almost default procedure in elderly patients irrespective of baseline risk. Interestingly, the age of TAVI recipients remained unchanged over the last decade and did not add to the overall risk reduction. Decreasing surgical risk coupled with improvements in delivery systems, bioprosthesis design, implantation technique, and periprocedural care resulted in fewer complications and better 1-year survival in the 2017–2019 period.

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