ORIGINAL ARTICLE

Long-term outcomes of transcatheter self-expanding aortic valve implantations in inoperable and high surgical–risk patients with severe aortic stenosis: a single-center single-valve registry

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KEY WORDS
aortic stenosis, self-expanding valve, transcatheter aortic valve implantation

ABSTRACT

BACKGROUND Transcatheter aortic valve implantation (TAVI) is being increasingly used in patients with longer life expectancy. Data on long-term outcomes are still limited.

AIMS The aim of the study was to assess the clinical outcomes of patients treated with TAVI and identify baseline and procedure-related factors influencing long-term survival.

METHODS Symptomatic patients with critical aortic stenosis who were inoperable or had high surgical risk were qualified for TAVI. Between August 2012 and December 2017, 248 consecutive patients treated with self-expanding Medtronic valve implantation at American Heart of Poland in Bielsko-Biała were prospectively enrolled. Patients were followed for 30 days after the procedure and subsequently annually. All events were classified according to the Valve Academic Research Consortium-2 (VARC-2) criteria and assessed. Survival was compared between the subgroups defined by the EuroSCORE II (European System for Cardiac Operative Risk Evaluation II) and with matched representatives from the general population.

RESULTS The median (interquartile range) follow-up was 3.4 (2.5–4.6) years, and the longest follow-up lasted 7.8 years. A total of 92 patients (37.1%) died during the follow-up. The Kaplan–Meier estimates for cumulative mortality at 1, 3, 5, and 7 years were: 11.3%, 26.8%, 42.1%, and 60.6%. Patients with EuroSCORE II greater than 6% experienced worse survival compared with those with EuroSCORE II 6% or less ($P = 0.008$). Patients with EuroSCORE II 6% or less had similar survival to the general population. Male sex, baseline eGFR of less than 50 ml/min/1.73 m^2, chronic obstructive pulmonary disease, moderate / severe paravalvular leak, absence of postdilatation, major vascular complication, and stroke at 30 days were independently associated with long-term mortality.

CONCLUSIONS TAVI with a self-expanding Medtronic valve implantation according to a consistent protocol was associated with favorable outcomes. Patients with lower EuroSCORE II scores had the same prognosis as the actuarial survival of the general population.

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WHAT'S NEW?

Transcatheter aortic valve implantation (TAVI) is a leading therapeutic option for elderly patients with symptomatic aortic stenosis. Data on long term outcomes, especially with regards to the Polish population, are still limited. Here we aimed to assess clinical outcomes of patients who underwent TAVI, focusing on identifying baseline and procedure related factors influencing long term survival. In the cohort of high risk and inoperable Polish octogenarians, we observed a 39.4% cumulative 7-year survival. Furthermore, patients with lower EuroSCORE II (European System for Cardiac Operative Risk Evaluation II) (≤6%) had the same prognosis compared with the actuarial survival of matched representatives from the general population. Interestingly, postdilatation appeared as a new important factor positively influencing survival, although further investigation is warranted.

INTRODUCTION Since its introduction in 2002 into clinical practice, transcatheter aortic valve implantation (TAVI) has become a leading therapeutic option for patients with aortic stenosis (AS). It has evolved as the treatment of choice for elderly patients with symptomatic severe AS who are considered extreme- or high-surgical-risk candidates.[1] Based on randomized trials showing noninferiority compared with surgical aortic valve replacement (SAVR) in intermediate-risk patients, TAVI is now increasingly used in younger and lower-risk patients.[2,3] However, as TAVI is used in patients with longer life expectancy, long-term data on the durability of TAVI prostheses are of increasing importance and are still limited. While contemporary TAVI is associated with low periprocedural morbidity and mortality, some patients, due to other factors (comorbidities, demographics, anatomy, technical issues), might not fully benefit from the procedure and have an unfavorable late outcome.

Herein, we present our own single-center experience with the TAVI program, using a single self-expanding system according to a standardized protocol. Our prospective observational study aims to assess clinical outcomes of patients who underwent TAVI, focusing on the identification of baseline and procedure-related risk factors influencing long-term survival.

METHODS **Study population** Patients with the initial AS diagnosis based on echocardiography (aortic valve area <1 cm^2 or indexed valve area <0.6 cm^2/m^2, mean gradient >40 mm Hg or maximum jet velocity >4 m/s or velocity ratio <0.25)[1] were referred to our center from the network of nearby cardiology departments. The final eligibility for TAVI was established based on the consensus of the local Heart Team including a cardiologist, cardiac surgeon, and anesthesiologist. Symptomatic patients with critical AS and inoperable / high surgical risk or in whom SAVR was contraindicated were qualified for TAVI. Patients who presented with acute or decompensated heart failure, multiorgan failure, reduced left ventricular ejection fraction of less than 50% due to AS and had long waiting time (>3 months) on a waiting list for TAVI underwent balloon aortic valvuloplasty (BAV) as a bridging procedure. Our strategy was based on data suggesting that BAV improves the short-term functional status and survival.[4] Exclusion criteria were: severe concomitant diseases with life expectancy of less than 6 months (eg, neoplastic diseases), aortic annulus size beyond recommended range (diameter >29 mm, perimeter >91 mm for Corevalve; diameter >30 mm, perimeter >94 mm for EvolutR), and lack of informed consent of the patient for the procedure. Previous implanted biological prosthesis (SAVR) and bicuspid aortic valve were not an exclusion. Of the total 253 patients with AS undergoing TAVI between August 2012 and December 2017 at American Heart of Poland in Bielsko-Biała, 248 consecutive patients treated with a self-expanding revalving system (Medtronic Inc., Minneapolis, Minnesota, United States) were prospectively enrolled. We excluded 5 patients treated in the initial period of the program using other systems (2 patients with Boston Scientific Lotus, 2 with Medtronic Engager, 1 with Edwards Sapien).

Clinical follow-up Each patient signed informed consent for prospective data collection and analysis. Due to the design of the study, ethics committee approval was not required. Follow-up data were collected from outpatient clinic patient visits, through telephone calls with the patient / family or the referring physician, and from external medical reports. Patients were followed for 30 days after the procedure and subsequently annually. The final mortality record was created with the registry of citizens of the Polish National Health Fund (*Narodowy Fundusz Zdrowia*, NFZ) using unique patient identifiers. The survival status for the whole study cohort was verified in June 2020. We were unable to reach contact with 5 patients, and their status was categorized as dead. The date of death was stated as the date of the last follow-up. All analyzed events were classified according to the Valve Academic Research Consortium-2 (VARC-2) criteria.[5]

Transcatheter aortic valve implantation Before TAVI, all patients underwent selective coronary angiography and multislice computer tomography (MSCT) assessment of the heart, aorta, and peripheral vasculature. In the case of significant concomitant coronary artery disease requiring revascularization, percutaneous intervention was performed before TAVI during a separate session. Prosthesis sizing and access route were at the operator's discretion based

on the MSCT and echocardiographic findings. All patients received acetylsalicylic acid (75 mg daily, lifelong) and clopidogrel (75 mg daily for 3–6 months, unless other conditions for prolonged anticoagulation or dual antiplatelet therapy occurred). During the intervention, unfractionated heparin was administered to achieve an activated clotting time of 250 to 300 seconds for the duration of the procedure. The TAVI procedures were carried out in a hybrid room by the Heart Team. General anesthesia, transesophageal echocardiography (TEE), and femoral access through surgical cut-down were preferred. In most cases, direct valve implantation was done. Only in the presence of massive calcifications, extreme tight stenosis, or difficulties in passing through the native aortic valve predilatation with an undersized balloon was considered. Minimum 5 minutes after prosthesis deployment, valve performance was determined using TEE, aortography, and direct hemodynamic assessment. Balloon postdilatation was performed at the discretion of the operators. Residual transvalvular gradients (mean >20 mm Hg), moderate / severe perivalvular regurgitation, or incomplete valve expansion (asymmetric stent with over 2:1 stent diameter ratio in 2 opposite views by TEE or aortography) qualified patient to postdilatation. Balloon diameter was chosen individually based on MSCT annulus measurements and severity / distribution of calcifications. After the procedure, the femoral artery puncture site was surgically closed, and control angiography was done to exclude acute vascular complications. Patients were transferred to the postoperative area for 12 to 24 hours.

Statistical analysis Normality of data distribution was tested using the Shapiro–Wilk test. Data were presented as median (interquartile range [IQR]) when normality assumptions were not met. For the categorical variables, absolute and relative frequencies were reported. The Kaplan-Meier analysis with 95% CIs was used to estimate cumulative long-term survival. The log-rank test was used for survival comparisons between groups. Survival was also compared with matched reference individuals from the general population by utilizing life tables obtained from government sources (Central Statistical Office, Główny Urząd Statystyczny).[6] The average life expectancy from life tables adjusted to age, sex, and year was assigned to every patient from our cohort. A survival curve was plotted based on the median of the average life expectancy.

Patients were stratified into 2 categories in terms of perioperative risk assessed by the EuroSCORE II (European System for Cardiac Operative Risk Evaluation II) (above and below 6%). To determine the factors influencing all-cause mortality, univariable and multivariable analyses with the Cox regression model have been performed. Parameters in univariable analysis with a P value of less than 0.1 have been tested in multivariable analysis with the backward method. The variables taken into consideration were: male sex, baseline eGFR of less than 50 ml/min/1.73 m^2, chronic obstructive pulmonary disease, moderate / severe paravalvular leak, postdilatation, major vascular complication, and stroke at 30 days. All statistical analyses were performed using the MedCalc software, version 18.5 (MedCalc, Ostend, Belgium).

RESULTS A total of 248 patients have been treated with self-expanded Medtronic valve implantation in our TAVI center from August 2012 to December 2017. Baseline characteristics and procedural data are presented in TABLES 1 and 2. All patients had severe symptomatic AS and were inoperable or had high risk for traditional surgery (SAVR). Women consitutted 60% of patients and the median (IQR) age was 81 (76–84) years. The majority of patients presented with a New York Heart Association class III/IV (65.7%), almost half of the patients had a history of coronary artery disease (43.1%), diabetes mellitus (37.9%), and chronic kidney disease (42.7%). Most of the patients (98.8%) were treated via transfemoral route and surgical cut-down, under general anesthesia with TEE guidance. Clinical follow-up was available for all patients except 5, with a median (IQR) observation period of 3.4 (2.5–4.6) years and the longest follow-up of 7.8 years.

Early outcomes In the study cohort, we observed a 3.2% all-cause mortality, 2.4% all-stroke, and 0.8% myocardial infarction rates at 30 days. Major vascular complications occurred in 4.8%, and life-threatening or disabling bleeding in 3.6% of patients. Because of atrioventricular conduction disturbances, a new permanent pacemaker was implanted in 16 cases (7.2%). In every fourth patient (27%) after the procedure, acute kidney injury was diagnosed, most in stage 1. The median (IQR) hospital stay was 5 (4–6) days, including 3 (2–3) days in the postoperative room. Early clinical outcomes are presented in TABLE 3.

Long-term outcomes The median (IQR) follow-up was 3.4 (2.5–4.6) years. From the whole study cohort, 92 patients (37.1%) died during almost 8 years of observation and 76% of deaths were classified as cardiovascular. The median calculated survival was 5.8 years (95% CI, 5.1–6.6). The Kaplan–Meier estimates for cumulative all-cause mortality at 1, 3, 5, and 7 years were: 11.3%, 26.8%, 42.1%, and 60.6% (FIGURE 1). Patients with EuroSCORE II greater than 6% experienced worse survival compared with those with EuroSCORE II 6% or less (P = 0.008).

TABLE 1 Baseline characteristics

Variable	Result
Age, y	81 (76–84)
Female sex	148 (59.7)
Body mass index, kg/m^2	27.8 (25.4–31.2)
Logistic EuroSCORE, %	15.1 (9.7–23.8)
EuroSCORE II, %	6.9 (3.9–10.9)
NYHA class III or IV	163 (65.7)
CCS class III or IV	66 (26.6)
Clinical history	
Arterial hypertension	227 (91.5)
Diabetes mellitus	94 (37.9)
Atrial fibrillation	95 (38.3)
Coronary artery disease	107 (43.1)
Previous myocardial infarction	49 (19.7)
Previous PCI	70 (28.2)
Valve-in-valve	10 (4)
Previous cardiac surgery	56 (22.6)
Bridge balloon aortic valvuloplasty	108 (43.5)
Permanent pacemaker	25 (10.1)
eGFR <50 ml/min/1.73 m^2	106 (42.7)
Left ventricular ejection fraction <50%	128 (51.6)
Left ventricular ejection fraction <35%	25 (10.1)
Chronic obstructive pulmonary disease	40 (16.1)
Peripheral artery disease	86 (34.7)
Pulmonary hypertension	49 (19.8)
Echocardiographic findings	
Aortic valve area, cm^2	0.7 (0.6–0.8)
Mean aortic valve gradient, mm Hg	48 (39–55)
Left ventricular ejection fraction, %	50 (45–55)
Moderate or severe mitral regurgitation	89 (35.9)
Bicuspid anatomy	34 (13.7)

Data are presented as number (percentage) or median (interquartile range).

Abbreviations: CCS, Canadian Cardiovascular Society; eGFR, estimated glomerular filtration rate; NYHA, New York Heart Association; PCI, percutaneous coronary intervention

Patients with EuroSCORE II 6% or less had similar survival when compared with the general population (FIGURE 2). The rate of stroke was 4.8%, and the rate of new pacemaker implantation was 9.7% in long-term follow-up, including 30 days post-TAVI. Valve thrombosis was diagnosed in 2 patients (0.8%). Both patients received vitamin K antagonists with complete resolution and good clinical outcome. The impact of baseline characteristics and periprocedural factors on the Kaplan–Meier survival was shown in Supplementary material, *Figures S1–S7*.

The predictors of long-term survival assessed by univariable and multivariable analyses are shown in TABLE 4. In the multivariable Cox analysis, the independent predictors of cumulative late mortality were male sex, baseline eGFR of less than 50 ml/min/1.73 m^2, chronic obstructive pulmonary disease, moderate / severe paravalvular leak, absence of postdilatation, major vascular complication, and stroke at 30 days.

DISCUSSION

We presented a single-center experience of TAVI implantation in inoperable / high-risk patients with severe AS, utilizing a self-expandable Medtronic system. The key findings from our study are as follows: 1) the 7-year cumulative estimated survival rate was 39.4%, 2) patients with EuroSCORE II 6% or less had equal survival rate when compared with the actuarial survival of representatives of the general population, 3) male sex, baseline eGFR of less than 50 ml/min/1.73 m^2, chronic obstructive pulmonary disease, moderate / severe paravalvular leak, absence of postdilatation, major vascular complication, and stroke at 30 days were the independent predictors of cumulative late mortality.

In our cohort, the cumulative, estimated all-cause mortality rates were 11.3%, 26.8%, 42.1%, and 60.6% at 1, 3, 5, and 7 years. At the median follow-up of 3.4 years, the observed mortality was 37.1%. Advanced age (81 years) and inoperable / high-risk profile of the treated population (Logistic EuroSCORE, 15.1%; EuroSCORE II, 6.9%) explain the observed long-term mortality rates. These observations coincide with the results of previously published studies. In the randomized PARTNER 1 (Placement of Aortic Transcatheter Valves) trial, patients after TAVI in the inoperable arm had 5-year mortality rate of 71.8%, and in the high-risk arm, 67.8%.[7,8] Low mortality in our cohort (42.1%) may be explained by a lower preoperative risk in our patients compared with those enrolled in the PARTNER trials (Logistic EuroSCORE, 15.1% vs 29.3%, respectively). Additionally, in the PARTNER study, patients were treated with the balloon-expandable Sapien valve, while our cohort was treated entirely using a self-expanding Medtronic revalving system. Gleason et al[9] report 55.3% 5-year mortality in the randomized CoreValve US trial in high-risk patients treated with a self-expanding valve. The study enrolled patients comparable with our cohort in terms of Logistic EuroSCORE (17.6% vs 15.1%) and at a slightly more advanced age (83.2 vs 81 years). In the randomized CHOICE (Comparison of Transcatheter Heart Valves in High Risk Patients With Severe Aortic Stenosis: Medtronic CoreValve vs Edwards SAPIEN XT) study, which compared 2 types of valves, a 5-year mortality rate of 53.4% in

TABLE 2 Procedural data

Variable		Result, n (%)
Device success		238 (96)
Valve implanted	CoreValve	93 (37.5)
	Evolut R	147 (59.3)
	Evolut Pro	8 (3.2)
Postprocedure paravalvular leak	None / trace	197 (79.4)
	Mild	39 (15.7)
	Moderate	8 (3.2)
	Severe	2 (0.8)
General anesthesia		245 (98.8)
Transfemoral access		245 (98.8)
Direct aortic access		3 (1.2)
Transesophageal echocardiography		245 (98.8)
Balloon predilatation		63 (25.4)
Balloon postdilatation		41 (16.5)
Second valve implanted		11 (4.4)

TABLE 3 Early outcomes

Variable		Result
Minor vascular complication		7 (2.8)
Major vascular complication		12 (4.8)
Minor bleeding		12 (4.8)
Major bleeding		10 (4)
Life-threatening or disabling bleeding		9 (3.6)
Valve reintervention		3 (1.2)
Urgent sternotomy		9 (3.6)
Peripheral angioplasty/surgery		9 (3.6)
Acute kidney injury	Stage 1	56 (22.6)
	Stage 2	10 (4)
	Stage 3	1 (0.4)
Blood transfusion		50 (20.2)
In-hospital all-cause mortality		8 (3.2)
30-days all-cause mortality		8 (3.2)
In-hospital stroke		4 (1.6)
30-days stroke		6 (2.4)
In-hospital myocardial infarction		2 (0.8)
30-days myocardial infarction		2 (0.8)
New permanent pacemaker (30-days)		16 (7.2)
Days in ICU		3 (2–3)
Days in hospital		5 (4–6)

Data are presented as number (percentage) or median (interquartile range).

Abbreviations: ICU, intensive care unit

the balloon-expandable and 47.6% in the self-expanding valve group were observed, with no statistically significant differences. Both groups were comparable to each other and our group of patients in terms of age (81.9 vs 79.6 vs 81 years, respectively) and surgical perioperative risk (Logistic EuroSCORE, 21.5% vs 22.1% vs 15.1%, respectively).[10]

While the above data on 5-year outcomes of TAVI in high-risk population comes from randomized trials, data on survival beyond 5-years are derived only from registries and observational researches. Deutsch et al[11] report that 7 years after CoreValve implantation, 23.2% of high-risk patients were still alive. The findings of the high-volume Italian center, representing a contemporary real-world population, show 28% 7-year survival.[12] Long-term follow-up up to 8.9 years after TAVI and favorable 35% survival after 7 years was documented by Holy et al.[13] In our cohort, we found a cumulative 7-year survival rate of 39.4%, which is comparable with the previous study.

Reduced survival in patients after TAVI when compared with the general population matched for age was reported by other authors.[14] Given the patient high-risk profile and comorbidities, the finding that our cohort survival was significantly worse than for the whole population was anticipated (FIGURE 1). Expectedly, patients at higher perioperative risk (EuroSCORE II >6%) experienced significantly worse survival comparing with those at lower risk (EuroSCORE II ≤6%; $P = 0.008$). Interestingly, the group of post-TAVI patients with EuroSCORE II 6% or less had similar survival when compared with the actuarial survival of a matched representative population (FIGURE 2). These data suggest that in octogenarians with a potentially fatal disease, such as AS, TAVI is a safe and effective method of treatment, which equalizes the patient's life prognosis to a contemporary general population.

We diagnosed valve thrombosis in 2 patients in our cohort (0.8%) during follow-up. The observed incidence is low and comparable (1.1%) with recently published data from a multicenter Polish registry of valve thrombosis (ZAK-POL TAVI).[15]

Based on the multivariable Cox analysis, we identified several baseline and procedure-related factors as being independently associated with long-term mortality after TAVI (TABLE 4). Most of them are well known and have been previously described.[16-20] Interestingly, we found that balloon postdilatation was an independent predictor of long-term survival (HR, 0.35; 95% CI, 0.16–0.75; $P = 0.008$). To the best of our knowledge, this observation has not been reported so far. Two publications suggest an opposite correlation between postdilatation and long-term mortality. Hahn et al[21] showed in a subanalysis of the PARTNER 1 trial a pronounced

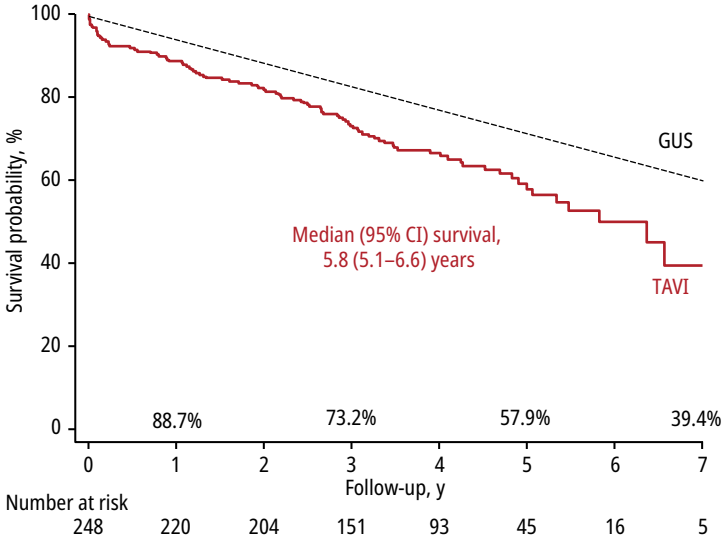

FIGURE 1 Long-term survival of patients after transcatheter aortic valve implantation (TAVI) and the expected survival curve of representatives from the general population matched for age, sex, and year (based on life tables obtained from the Polish Central Statistical Office [GUS]).

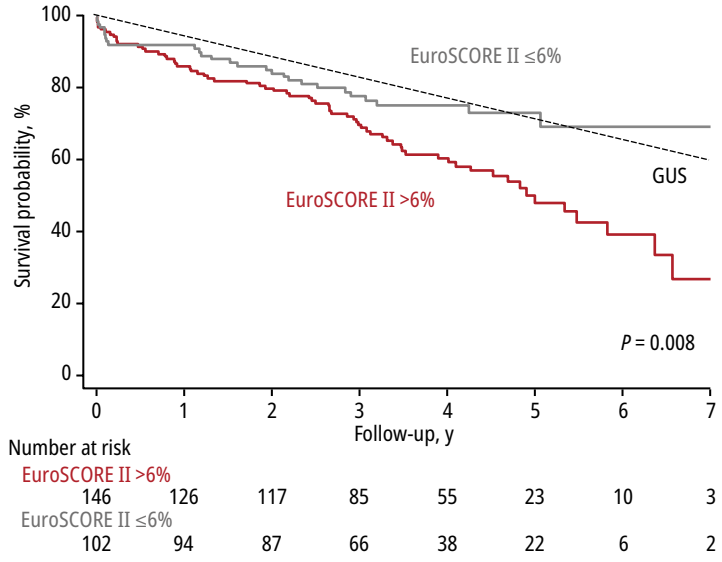

FIGURE 2 Long-term survival of patients after transcatheter aortic valve implantation stratified according to EuroSCORE II ≤6% and EuroSCORE II >6% and the expected survival curve of representatives from the general population matched for age, sex, and year (based on life tables obtained from the Polish Central Statistical Office [GUS]).

trend toward increased 1-year mortality with postdilatation (HR, 1.30; 95% CI, 0.99–1.70; $P = 0.054$).[21] In the study assessing the incidence and clinical impact of balloon postdilatation after CoreValve prosthesis implantation, Barbanti et al[22] reported that the need for postdilatation was associated with higher all-cause mortality (HR, 1.43; 95% CI, 1.03–1.98; $P = 0.04$). In both trials, after adjustment for other factors, multivariable analyses revealed no association between postdilatation and death. A systematic review and meta-analysis of 6 studies comparing 889 patients who had balloon postdilatation with 4118 patients without postdilatation, showed no differences in 1-year mortality rates (HR, 0.98; 95% CI, 0.61–1.56; $P = 0.92$).[23] Balloon postdilatation following self-expanding valve implantation is a widely adopted strategy to optimize hemodynamic results, associated with a 75% reduction in the frequency of moderate / severe paravalvular leak.[24] According to our standardized protocol, we used postdilatation to optimize valve expansion in 41 patients (16.5%). One of the possible explanations for superior long-term survival in patients with postdilatation may be obtaining a larger aortic orifice. Secondly, there are reports that even mild paravalvular leak may be associated with increased long-term mortality.[23] Identification and quantification of the post-TAVI leaks are challenging, imprecise, and frequently subjective. Also, the effect of periprocedural underestimation of paravalvular leak severity in some patients cannot be ruled out. Further more extensive studies focused on this issue are needed, especially as it has an impact on patient prognosis and is modifiable during the procedure.

Limitations The current study is a single-center nonrandomized study, and the findings may not apply to other centers with possibly different organizational structures and patient demographics. The results are self-reported with no independent data validation. Due to incompleteness, late echocardiographic data were not analyzed and they could be valuable in the context of prosthesis durability.

Conclusions Based on our single-center experience, TAVI with a self-expanding Medtronic valve according to a standardized protocol allows for achieving favorable early and late outcomes in a high-risk and inoperable elderly population. At a median follow-up of 3.4 years, the observed survival was 62.9%, while at longest, 7-year follow-up after the procedure, the cumulative survival rate was 39.4%. Patients with a lower EuroSCORE II (≤6%) had the same prognosis compared with the actuarial survival of the representative population. Baseline and procedure-related factors were identified as being independently associated with long-term mortality. Postdilatation was a new factor positively influencing survival, and thus requires further investigations.

SUPPLEMENTARY MATERIAL

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

ARTICLE INFORMATION

CONFLICT OF INTEREST None declared.

TABLE 4 Predictors of all-cause mortality in long-term follow-up after transcatheter aortic valve implantation

Covariate	Univariable analysis (Cox)		Multivariable analysis (Cox)	
	HR (95% CI)	*P* value	HR (95% CI)	*P* value
Male sex	1.5 (0.99–2.25)	0.05	1.59 (1.02–2.47)	0.04
Coronary artery disease	1.09 (0.71–1.66)	0.7	–	–
Diabetes mellitus	1.21 (0.80–1.83)	0.35	–	–
Atrial fibrillation	1.33 (0.88–2)	0.18	–	–
Arterial hypertension	0.57 (0.3–1.08)	0.09	–	–
eGFR <50 ml/min/1.73 m^2	2.01 (1.33–3.03)	<0.001	2.10 (1.36–3.24)	<0.001
COPD	2.07 (1.28–3.34)	0.003	1.92 (1.16–3.2)	0.01
Peripheral artery disease	1.23 (0.81–1.87)	0.32	–	–
Previous PCI	0.73 (0.45–1.19)	0.22	–	–
Pulmonary hypertension	1.4 (0.88–2.25)	0.15	–	–
Previous myocardial infarction	1.09 (0.66–1.78)	0.74	–	–
Previous cardiac surgery	1.12 (0.7–1.79)	0.64	–	–
Valve-in-valve	0.7 (0.22–2.22)	0.55	–	–
NYHA class IV	0.95 (0.23–3.84)	0.94	–	–
EuroSCORE II ≤6%	0.55 (0.35–0.85)	0.009	–	–
LVEF <35%	0.62 (0.34–1.14)	0.12	–	–
Severe mitral regurgitation pre-TAVI	1.80 (0.97–3.28)	0.06	–	–
III/IV aortic regurgitation pre-TAVI	1.15 (0.73–1.83)	0.55	–	–
Paravalvular leak ≥2	2.9 (1.35–6.28)	0.007	3.9 (1.68–9.04)	0.001
Bridge balloon aortic valvuloplasty	1.07 (0.71–1.62)	0.73	–	–
Balloon predilatation	1.05 (0.66–1.65)	0.84	–	–
Balloon postdilatation	0.45 (0.22–0.93)	0.03	0.35 (0.16–0.75)	0.008
Bicuspid aortic valve	1.35 (0.82–2.24)	0.24	–	–
Minor vascular complication	1.05 (0.33–3.31)	0.93	–	–
Major vascular complication	2.82 (1.42–5.61)	0.003	3.80 (1.84–7.86)	< 0.001
Minor bleeding	1.38 (0.56–3.41)	0.48	–	–
Major bleeding	0.72 (0.23–2.27)	0.58	–	–
Life-threatening or disabling bleeding	2.1 (0.92–4.79)	0.08	–	–
Stroke at 30-days	2.67 (0.97–7.36)	0.06	3.32 (1.16–9.49)	0.02
New pacemaker at 30-days	0.74 (0.3–1.82)	0.51	–	–
Acute kidney injury	0.72 (0.44–1.18)	0.2	–	–
Blood transfusion	1.27 (0.79–2.05)	0.32	–	–

Abbreviations: COPD, chronic obstructive pulmonary disease; HR, hazard ratio; LVEF, left ventricular ejection fraction; TAVI, transcatheter aortic valve implantation; others, see TABLE 1

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