ORIGINAL ARTICLE

# Comparison of transcatheter aortic valve implantation outcomes in patients younger than 85 years and those aged 85 years or older: a single-center study

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**KEY WORDS**

age, aortic stenosis, transcatheter aortic valve implantation, cardiovascular mortality, transcatheter valve replacement

**ABSTRACT**

**INTRODUCTION** The number of elderly patients requiring treatment of aortic stenosis is expected to grow steadily due to increasing lifespan. Transcatheter aortic valve implantation (TAVI) is an alternative treatment for patients with aortic stenosis considered nonoptimal candidates for surgical valve replacement.

**OBJECTIVES** We aimed to assess age-related differences in 30-day and 1-year cardiovascular mortality, Valve Academic Research Consortium-2 (VARC-2)–defined complications in patients undergoing TAVI, by comparing outcomes in patients younger than 85 years and those aged 85 years or older.

**PATIENTS AND METHODS** The study group included patients who underwent TAVI at the Institute of Cardiology, Warsaw from January 2009 to July 2019. Clinical, procedural, and follow-up data were retrospectively collected and compared in 2 groups defined according to age: group 1, younger than 85 years (417) and group 2, aged 85 or older (200).

**RESULTS** The surgical risk profile assessed by the EuroSCORE II was significantly higher in the group of older patients (median [interquartile range], 6.5% [3.5%–17.3%] vs 7.2% [3.4%–18.1%]; $P = 0.002$); 30-day and 1-year cardiovascular mortality was 4.3% in group 1 as compared with 5% in group 2 ($P = 0.69$) and 10.8% in group 1 as compared with 9.4% in group 2 ($P = 0.51$), respectively. The rate of VARC-2-defined complications was similar in both groups, with the exception of major vascular complications (3.12% vs 8.5%; $P = 0.004$) and major bleeding (10.8% vs 18.5%; $P = 0.008$), which were more prevalent in older patients.

**CONCLUSIONS** Cardiovascular mortality at 1 month and 1 year following TAVI is similar in patients aged 85 years or older and in those younger than 85 years.

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**INTRODUCTION** The prevalence of aortic valve stenosis (AS), the most common acquired valvular heart disease, increases with age. As life expectancy is increasing, the number of patients requiring treatment for AS is expected to grow steadily.[1,2] Advanced age is a known risk factor in surgical aortic valve replacement (SAVR). Introduction of transcatheter aortic valve implantation (TAVI) provided an effective and less-invasive alternative for patients who are considered moderate to high risk or are not suitable candidates for surgery.[3,4] Advantages of TAVI over SAVR, including shorter hospital stay and faster recovery, are particularly relevant in elderly patients.[5] Previous studies have shown that advanced age itself is not a predictor of inferior safety or efficacy of TAVI, demonstrating similar rates of complications and mortality in younger and older patients.[5-7]

**WHAT'S NEW?**

Transcatheter aortic valve replacement (TAVI) is a well-established alternative for treatment of patients who are not suitable for surgical aortic valve replacement. Patients older than 85 years represent a substantial fraction of those undergoing TAVI. We present the largest Polish single-center study comparing short and mid-term results of TAVI in patients younger than 85 years as compared with those aged 85 years or older.

The aim of this study was to assess age-related differences in outcomes among patients undergoing TAVI at our center younger than 85 years and those aged 85 years or older.

**PATIENTS AND METHODS** The study group included all patients who underwent TAVI at the Institute of Cardiology in Warsaw from January 2009 to July 2019. Patients with severe symptomatic AS were referred for a valve replacement procedure. Decision on choosing TAVI over SAVR was made by the institutional Heart Team.

All patients evaluated for TAVI underwent standard screening with transthoracic echocardiography and multislice computed tomography for the assessment of the aortic valve, aortic annulus, aorta, as well as the potential access site: subclavian, iliac, or femoral. In selected patients, transesophageal echocardiography was also performed.

TAVI procedures were performed using Edwards Sapien, Sapien XT, or Sapien 3 (Edwards Lifesciences, Irvine, California, United States); CoreValve, EvolutR, EvolutR Pro, or Engager (Medtronic, Minneapolis, Minnesota, United States); and Lotus or Acurate (Boston Scientific, Marlborough, Massachusetts, United States) prostheses. The femoral artery was the preferred route of vascular access. Subclavian, transapical, or direct aortic access routes were considered second choice. Immediately after the procedure, its effectiveness was assessed on echocardiography. Additional transthoracic echocardiography was performed on the day of discharge and during follow-up visits at day 30, 180, and 360, then annually.

Procedural details and all clinical baseline and follow-up data were prospectively collected in local database and, since January 2013, also within the PolTAVI National Registry. We were able to obtain complete follow-up data regarding mortality at 1 month and 1 year. Long-term follow-up was available for 488 of 502 patients (97.2%) at 2 years and for 255 of 273 patients (93.4%) at 5 years of follow-up. We have obtained mortality data from the National Registry of Population (*Narodowy Spis Powszechny*). The primary endpoint was all-cause mortality at 1 month and 1 year. Secondary endpoints were procedural complications defined according to the Valve Academic Research Consortium-2 (VARC-2) Document and a composite endpoint of VARC-2-defined life-threatening or major bleeding, periprocedural myocardial infarction (MI), periprocedural stroke, new pacemaker prior to discharge or in-hospital death (definitions are presented in Supplementary material, *Table S1*).

**Statistical analysis** We assessed the normality of distribution of variables using the Shapiro–Wilk test. Continuous variables were displayed as medians and interquartile ranges (IQRs) and categorical variables as percentage frequencies. Clinical and echocardiographic data were compared using the Mann–Whitney test (ordinal and continuous variables) and the $\chi^2$ test (categorical variables). Survival differences between group 1 and group 2 were assessed using the cumulative Kaplan–Meier curves and the significance of survival differences was estimated using the log-rank test. The Cox regression analysis was used to determine the predictive value of clinical and procedural data, as well as the incidence of VARC-2-defined endpoints concerning the cumulative in-hospital mortality and mortality at 30 days and 1 year. A $P$ value of less than 0.05 was considered significant in all calculations. Statistical analysis was performed using the SPSS analysis software system (version 26, IBM corp., Armonk, New York, United States).

**Ethics** This study was approved by the institutional review board. Patient written informed consent was not required in this retrospective study.

**RESULTS** The study cohort included 617 consecutive patients who underwent TAVI at the Institute of Cardiology in Warsaw, Poland, between January 2009 and July 2019. Patients were divided into 2 age groups with a cutoff value of 85 years: group 1, younger than 85 years (n = 417), and group 2, aged 85 or older (n = 200). Mean (SD) age was 76.8 (7.9) for group 1 and 87.4 (2.1) for group 2. Age structure of patients in quartiles divided according to the procedure date is presented in Supplementary material (*Figure S1*). Baseline group characteristics and comparison are presented in TABLE 1. The surgical risk profile assessed by the EuroSCORE II was higher in the older group of patients (median [IQR], 6.5% [3.5%–17.3%] vs 7.2% [3.4%–18.1%]; $P = 0.002$). There were no statistically significant differences in the prevalence of atrial fibrillation, chronic obstructive pulmonary disease, diabetes mellitus, or previous cerebrovascular disease.

Periprocedural and postprocedural patient characteristics and outcomes are summarized in TABLE 2. Transfemoral approach was used in 79.9% (n = 493) of all cases. While the rates of VARC-2 defined bleeding and vascular complications were similar in both groups, major vascular complications (3.1% vs 8.5%; $P = 0.04$) and major bleeding (10.8% vs 18.5%; $P = 0.008$) were more prevalent in older patients. There was no statistically significant difference between the 2 groups in terms of other VARC-2-defined endpoints.

**TABLE 1** Baseline characteristics of the study patients

| Variable | Age <85 years (n = 417) | Age ≥85 years (n = 200) | *P* value |
|---|---|---|---|
| Age, y, mean (SD; range) | 76.8 (7.9; 31–84) | 87.4 (2.1; 85–93) | – |
| BMI, kg/m$^2$, median (IQR) | 27.2 (24.3–31.1) | 25.4 (23–28.3) | <0.001 |
| BSA, m$^2$, median (IQR) | 1.8 (1.7–1.9) | 1.7 (1.7–1.9) | <0.001 |
| Male sex, n (%) | 166 (39.7) | 84 (42) | 0.59 |
| Diabetes mellitus, n (%) | 167 (40.1) | 64 (32) | 0.053 |
| COPD, n (%) | 79 (18.9) | 28 (14) | 0.13 |
| Previous cerebrovascular disease, n (%) | 55 (13.2) | 23 (11.5) | 0.55 |
| AF, n (%) | 137 (32.9) | 74 (37) | 0.31 |
| Previous valvular surgery, n (%) | 26 (6.2) | 6 (3) | 0.09 |
| Permanent pacemaker, n (%) | 56 (13.4) | 35 (17.5) | 0.18 |
| LVEF, %, median (IQR) | 60 (50–65) | 60 (50–65) | 0.92 |
| AVA, cm$^2$, median (IQR) | 0.7 (0.5–0.8) | 0.6 (0.5–0.7) | 0.028 |
| Maximum AVG, mm Hg, median (IQR) | 85 (71–102) | 88 (69–106) | 0.63 |
| Mean AVG, mm Hg, median (IQR) | 50 (40–61) | 48 (39–65) | 0.91 |
| EuroSCORE II, %, median (IQR) | 6.5 (3.5–17.3) | 7.2 (3.4–18.1) | 0.002 |
| GFR, ml/min, median (IQR) | 72 (55.5–90) | 50.1 (38.5–60.9) | <0.001 |
| Hemoglobin, g/dl, median (IQR) | 12.2 (11.2–14.1) | 12 (10.9–13.1) | 0.01 |
| Platelet count, ×10$^3$/µl, median (IQR) | 176.8 (142.8–220) | 164.5 (130–213.3) | 0.046 |

Abbreviations: AF, atrial fibrillation; AVA, aortic valve area; AVG, aortic valve gradient; BMI, body mass index; BSA, body surface area; COPD, chronic obstructive pulmonary disease; GFR, glomerular filtration rate; IQR, interquartile range; LVEF, left ventricular ejection fraction

The results of the univariable Cox regression are presented in TABLES 3 and 4. No in-hospital or 30-day mortality increase was observed in group aged 85 or older. Age was not related to increased risk of in-hospital, 30-day, and 1-year mortality in the univariable Cox regression modelling.

Within the entire cohort, the cumulative mortality rates were 4.1% before discharge, 4.7% at 30 days, and 14.4% at 1 year. The Kaplan–Meier analysis showed no significant differences in all-cause in-hospital mortality (3.8% vs 4.5%; *P* = 0.69), mortality at 30 days (4.3% vs 5.5%; *P* = 0.51) and within the first year (12.8% vs 17.9%; *P* = 0.06). Thirty-day mortality related to cardiovascular causes (defined according to VARC-2) was 4.3% (n = 18) in group 1 and 5% (n = 10) in group 2 (*P* = 0.69). One-year cardiovascular mortality was 11.4% (n = 44) in group 1 and 13.2% (n = 25) in group 2 (*P* = 0.51) (FIGURES 1-4). The 2-year mortality rate was 21.7% (n = 154) with no significant difference between the groups (19.8% vs 25.9%; *P* = 0.13). Cumulative mortality at 5 years did not differ between the groups either and equaled to 45.1% in younger patients versus 49.3% in the older group (*P* = 0.43).

**DISCUSSION** We present the largest Polish single center study comparing short and midterm results of TAVI in patients younger than 85 years as compared with those aged 85 years or older.

Although advanced age is considered an important surgical risk factor and is included in all surgical risk calculators used also to assess the procedural risk of TAVI, the main finding of our retrospective analysis is that there are no significant differences in TAVI outcomes between patients younger than 85 and aged 85 or older. This confirms previous findings suggesting that transcatheter treatment is a reasonable choice in selected older patients with AS.[5-7]

We did not observe significant differences between the groups in terms of factors that are usually related to a higher risk of TAVI complications, such as previous cerebrovascular disease, chronic obstructive pulmonary disease, or low left ventricular ejection fraction. Differences in the general characteristics of the subgroups included higher body mass index and body surface area index, higher hemoglobin and platelet count and better renal function in the younger group of patients. The surgical risk as assessed by the EuroSCORE II was significantly higher in the older, which may also result from including age itself in the calculator.

Our results, which are in favor of elderly patients, correspond with data published by Havakuk et al[7] who also compared outcomes in patients aged 85 or younger as compared with those older than 85 years and found no statistical differences in terms of 30-day mortality. However, 480-day mortality in their study was significantly higher in the older group. In the FRANCE-2 (French Aortic National CoreValve and Edwards-2) registry assessing 346 nonagenarian patients, Yamamoto et al[8] demonstrated a 30-day mortality of 11.2% in patients older than 90 years, with no significant difference compared with patients aged 80 to 84 or 85 to 89 years, which is similar to our mid-term results.

Further data to support the choice of transcatheter method in elderly patients may be derived from the PARTNER 1 (Placement of Aortic Transcatheter Valves) trial. It was not designed solely to assess age impact on TAVI, but it enrolled patients with the mean age of 93 in the TAVI arm. In the group of transfemoral TAVI access, 30-day mortality was 4% and the 3-year mortality was 48%, in the group of transapical access, it was 12% and 54%, respectively and, considering clinical characteristic of these patients, all of which were at high surgical risk, may be considered a more than acceptable outcome.[3]

Results of the above-mentioned trials strengthened the position of TAVI as a reasonable treatment option for elderly patients with severe AS.

Another important study is the American registry of 24 025 patients published by Arsalan et al,[9] presenting TAVI outcomes at 30 days and 1 year of patients aged 90 years or older old versus those younger. As opposed to our results and the results of previously mentioned studies, short- and mid-term survival rates were significantly lower in

**TABLE 2** Procedural characteristics and outcome of the study patients

| Variable | | Age <85 years (n = 417) | Age ≥85 years (n = 200) | *P* value |
|---|---|---|---|---|
| General anesthesia | | 238 (57.1) | 103 (51.5) | 0.19 |
| Transfemoral TAVI | | 332 (79.6) | 161 (80.5) | 0.79 |
| Predilatation | | 226 (54) | 117 (58.5) | 0.46 |
| Contrast volume, ml | | 200 (150–200) | 180 (130–200) | 0.21 |
| Radiation dose, mGY | | 1080.5 (611.8–1769.5) | 930 (549.3–1638.5) | 0.1 |
| LVEF prior to discharge, % | | 60 (50–65) | 60 (50–65) | 0.98 |
| Maximum AVG, mm Hg | | 17 (12–24) | 16.3 (12–22) | 0.63 |
| Mean AVG, mm Hg | | 7 (0–11) | 7 (3.6–12) | 0.89 |
| Minimum GFR, ml/min | | 90 (50.8–90) | 65.5 (47.5–90) | <0.001 |
| Minimum hemoglobin, g/dl | | 10 (8–11.3) | 10 (9.2–10.9) | 0.051 |
| Minimum platelet count, $\times 10^3/\mu l$ | | 107.4 (81–137.3) | 97 (73.2–132.5) | 0.09 |
| Need for RBC transfusion | | 111 (26.6) | 61 (30.5) | 0.31 |
| Total units of RBC transfused, n | | 0 (0–1) | 0 (0–1) | 0.35 |
| Length of hospitalization, d | | 10 (7–15) | 11 (7–15) | 0.89 |
| Coronary artery occlusion | | 3 (0.7) | 2 (1) | 0.72 |
| Annulus rupture | | 4 (0.9) | 0 | 0.17 |
| Need for pacemaker implantation | | 65 (15.6) | 27 (13.5) | 0.49 |
| VARC-2 endpoints | Minor vascular complications | 40 (9.6) | 20 (10) | 0.87 |
| | Major vascular complications | 13 (3.1) | 17 (8.5) | 0.004 |
| | Minor bleeding | 63 (15.1) | 26 (13) | 0.48 |
| | Major bleeding | 45 (10.8) | 37 (18.5) | 0.008 |
| | Life-threatening bleeding | 19 (4.6) | 8 (4) | 0.75 |
| | Periprocedural myocardial infarction | 3 (0.7) | 2 (1) | 0.71 |
| | Periprocedural stroke | 5 (1.2) | 6 (3) | 0.11 |
| | Composite endpoint[a] | 181 (43.4) | 87 (43.5) | 0.98 |
| All-cause mortality | In-hospital | 16 (3.8) | 9 (4.5) | 0.69 |
| | 30-day | 18 (4.3) | 11 (5.5) | 0.51 |
| | 1-year (n = 596) | 52 (12.8) | 34 (17.9) | 0.06 |
| | 2-year (n = 488) | 66 (19.8) | 40 (25.9) | 0.13 |
| | 5-year (n = 255) | 82 (45.1) | 36 (49.3) | 0.42 |
| Cardiovascular mortality | 30-day | 18 (4.3) | 10 (5) | 0.69 |
| | 1-year (n = 596) | 46 (11.4) | 25 (13.2) | 0.51 |

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

a Composite endpoint: composite of VARC-2 defined life-threatening or major bleeding, periprocedural myocardial infarction, periprocedural stroke, new pacemaker prior to discharge or/and in-hospital death

Abbreviations: RBC, red blood cells; TAVI, transcatheter aortic valve replacement; VARC-2, Valve Academic Research Consortium-2, others, see TABLE 1

**TABLE 3** Univariable Cox regression analysis for the association between cumulative in-hospital mortality and age

| Variable | Hazard ratio | 95% CI | *P* value |
|---|---|---|---|
| Age, y | 0.943 | 0.863–1.031 | 0.20 |
| Aged ≥85 years | 0.512 | 0.080–3.284 | 0.48 |

**TABLE 4** Univariable Cox regression analysis for the association between cumulative 1-year mortality and age

| Variable | Hazard ratio | 95% CI | *P* value |
|---|---|---|---|
| Age | 1.017 | 0.968–1.069 | 0.50 |
| Aged ≥85 years | 0.768 | 0.377–1.568 | 0.47 |

the group of older patients with 30-day mortality of 5.9% as compared with 8.8% ($P$ <0.001) and 1-year mortality of 22% as compared with 24.8% ($P$ <0.001). However, there were no significant differences between the groups in terms of rates of stroke, aortic valve reintervention, or myocardial infarction at 30 days or 1 year.

The largest analysis to date is the report of outcomes of TAVI in 71 095 patients aged 90 years or older published by Deharo et al[10] which, similarly to the American registry, showed significantly higher all-cause and cardiovascular mortality in nonagenarians as compared with patients younger than 90, with a higher rate of rehospitalization

FIGURE 1 Kaplan–Meier survival curve showing time-to-event outcomes for 30-day cumulative survival

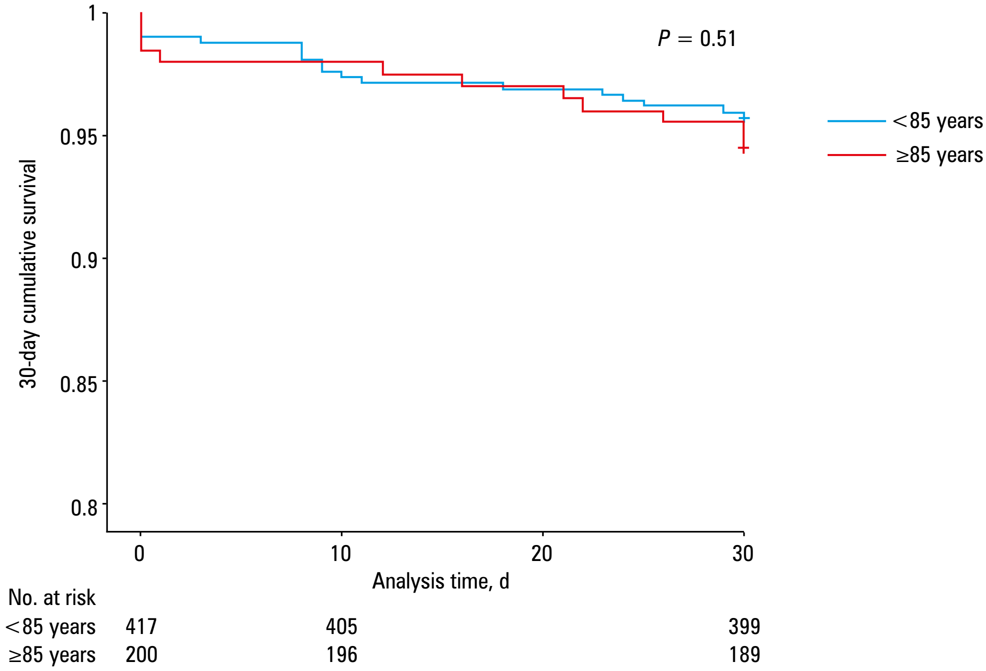
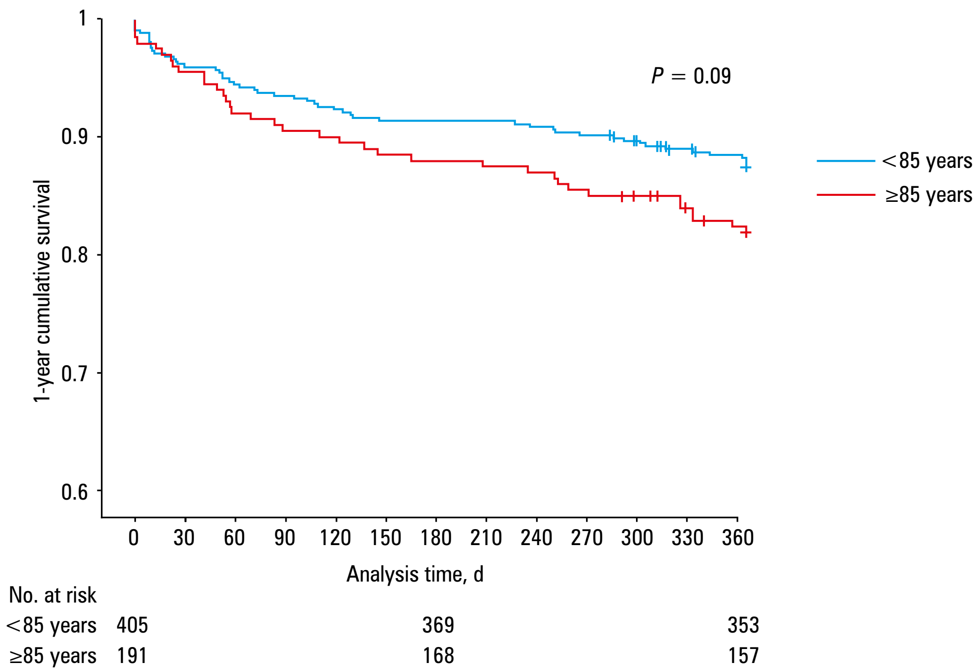



FIGURE 2 Kaplan–Meier survival curve showing time-to-event outcomes for 1-year cumulative survival




due to heart failure (HF) and higher incidence of combined endpoint of stroke, rehospitalization for HF, and cardiovascular death. As this study also compared outcomes of nonagenarians treated with TAVI and those receiving medical treatment only, showing lower incidence of rehospitalization and cardiovascular death, the authors concluded that age alone should not be a discriminatory factor for valve replacement procedure.

Our findings are in line with the 1-year survival reported in the FRANCE-2 registry, which showed no difference in age-stratified groups. We observed a relatively low 30-day (18 [4.3%] vs 9 [4.6%]; $P = 0.83$) and 1-year (52 [12.7%] vs 32 [16.7%]; $P = 0.19$) all-cause mortality rate which might reflect careful selection of TAVI candidates at our institution. As mentioned in the discussion of the FRANCE-2 registry and, probably, also in relevance to our study, the lack of statistical significance of 1-year mortality rates could possibly result from a limited number of older patients included in the analyses.[8]

According to surgical risk calculators and data from randomized trials, age itself increases the surgical risk and the risk of periprocedural complications.[11,12] As highlighted in the early experiences with TAVI and confirmed in the randomized control trials, vascular complications and access-site bleeding are the most common procedural complications which impact procedure outcomes. Their rate increases with the age of patients.[13,14] Our study, in accordance with most reports, showed significant difference between the groups in terms of the rate of major vascular complications (3.1%

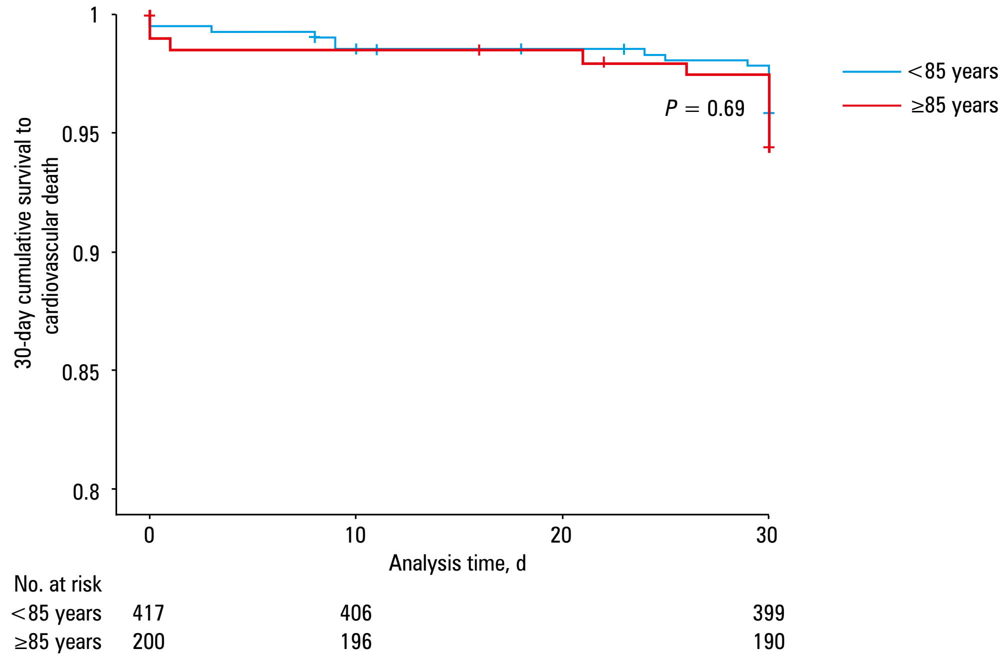



**FIGURE 3** Kaplan–Meier survival curve showing time-to-event outcomes for 30-day cumulative survival to cardiovascular death

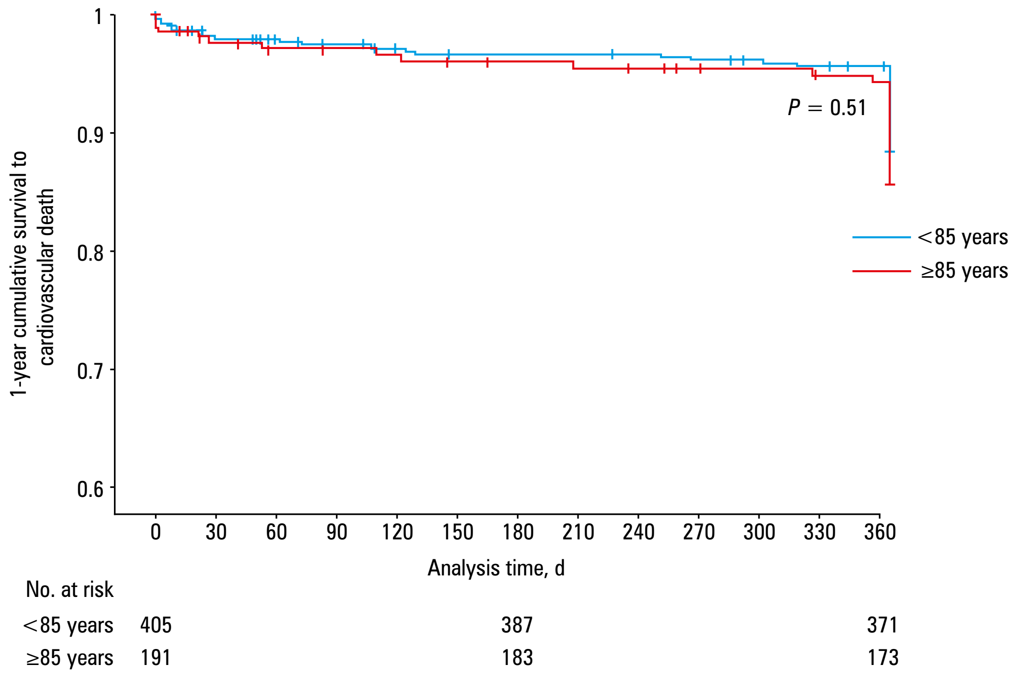



**FIGURE 4** Kaplan–Meier survival curve showing time-to-event curves for 1-year cumulative survival to cardiovascular death

vs 8.5%; $P = 0.04$) and major bleeding complications (10.8% vs 18.5%, $P = 0.008$). Major vascular complications were identified as an independent risk factor for death at 1 month ($P < 0.001$) and at 1 year ($P = 0.001$) for the entire cohort and may be considered an important factor worsening prognosis for the procedure outcome.

Since the time TAVI became a treatment of choice for high-risk patients with AS,[15] a number of studies have been conducted to assess the efficacy and safety of this procedure in the subpopulation of elderly patients.[5-9] Randomized controlled trials confirmed the noninferiority and, subsequently, superiority of the transcatheter procedure over SAVR in high, intermediate and, recently, low-risk patients with AS.[3,4,16] Elderly patients may particularly benefit from lower invasiveness of this method. The results of our analysis support this and provide additional data strengthening the position that with proper assessment, TAVI is a safe and effective procedure regardless of advanced age.

Taking into consideration the limited life expectancy, TAVI in advanced-age patients may still remain arguable, nevertheless in view of the available data and our results, the concern that older patients may have worse procedural and periprocedural outcomes seems unjustified.

**Study limitations** Our analysis, similarly, to most existing reports, is limited to single-center experience with relatively small cohorts of patients and, therefore, provides limited decision-making information. It would benefit the analysis if additional data regarding rehospitalizations and frailty were obtained, and if we prospectively collected information on the quality of life to assess the subjective impact of the procedure.

## SUPPLEMENTARY MATERIAL

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

## ARTICLE INFORMATION

**CONTRIBUTION STATEMENT** MD and AP conducted the study and were responsible for analysis and interpretation of data. All authors contributed to the study concept design and supervision as well as to manuscript drafting and revision, and approved of the final version of the manuscript.

**CONFLICT OF INTEREST** None declared.



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