

Early and Mid-Term Mortality After Transcatheter Aortic Valve Implantation: Five-Year Experience from the KOSUTAVI Study

ABSTRACT

Background: Although transcatheter aortic valve implantation (TAVI) outcomes are well-documented, predictors of mortality beyond conventional surgical risk scores and valve-related factors in real-world, high-risk cohorts require further elucidation. This study aimed to identify the key determinants of 30-day and 1-year mortality following TAVI, with a focus on both patient-specific and procedure-specific complications.

Methods: The KOSUTAVI study is a single-center, retrospective cohort analysis of 859 consecutive high-risk individuals with severe aortic stenosis undergoing TAVI between 2020 and 2025. Primary endpoints were 30-day and 1-year all-cause mortality. Multivariate Cox regression and Kaplan–Meier analyses were used to identify independent risk factors.

Results: Mean age was 78.7 ± 6.5 years, and mean Society of Thoracic Surgeons score was 7.4 ± 2.2 . The 30-day and 1-year mortality rates were 6.5% (n = 56) and 12.4% (n = 107), respectively. The 5-year all-cause mortality rate was 26.3%. In multiple Cox's analysis, chronic renal failure (hazard ratio [HR] = 7.75, $P = .008$, 95% CI = 1.29–16.54), presentation with cardiogenic shock (HR = 5.83, $P = .028$, 95% CI = 1.19–15.41), major vascular injury (HR = 22.7, $P = .019$, 95% CI = 1.89–45.91), and cardiac tamponade (HR = 17.9, $P = .012$, 95% CI = 8.13–52.62) were independently associated with 30-day mortality. While these factors were all significant in univariate analysis for 1-year mortality, they did not retain independence in the multiple model. Valve type, access route, and sex were not associated with increased mortality.

Conclusion: In a high-risk TAVI population, early mortality is predominantly driven by pre-existing renal dysfunction and acute procedural complications (shock, vascular injury, and tamponade), rather than valve-specific factors. These findings underscore the critical importance of optimizing renal function before the procedure and implementing advanced vascular protection strategies to improve early survival after TAVI.

Keywords: Aortic stenosis, mortality, renal failure, risk factors, transcatheter aortic valve implantation, vascular complications

INTRODUCTION

Aortic stenosis (AS) is a prevalent and life-threatening valvular heart disease. The development of transcatheter aortic valve implantation (TAVI) has revolutionized its treatment, providing a minimally invasive alternative to surgical aortic valve replacement (SAVR) for individuals across the entire risk spectrum.^{1,2}

Despite its established efficacy and expanding indications, a significant proportion of high-risk patients continue to experience early mortality after TAVI. Although risk prediction models such as the STS-PROM (Society of Thoracic Surgeons Predicted Risk of Mortality) and EuroSCORE are valuable tools, they primarily incorporate preoperative patient variables and often fail to fully capture the profound impact of periprocedural complications on short-term survival.^{3,4} Notably, the interplay between baseline frailty markers (e.g., advanced renal dysfunction) and acute procedural complications (e.g., vascular injury and cardiac tamponade) as drivers of early mortality is not fully characterized in contemporary real-world registries from experienced centers.



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Therefore, the present KOSUTAVI study aimed to analyze a contemporary 5-year experience from a high-volume center to (1) determine the precise rates of 30-day and 1-year mortality in an exclusively high-risk TAVI cohort, and (2) identify the independent patient- and procedure-specific predictors of early mortality, with a focus on factors extending beyond traditional surgical risk metrics.

METHODS

Study Design and Population

This was a single-center, retrospective cohort study analyzing all consecutive patients who underwent TAVI for severe AS at the authors' hospital between January 1, 2020, and January 1, 2025. All patients had a minimum follow-up duration of 1 year, during which they were closely monitored. The study received ethical approval from the relevant Institutional Committee on Research Ethics. Because of the retrospective nature of the study and the use of anonymized data, the requirement for informed consent was waived by the Ethics Committee.

Inclusion criteria included patients aged >65 years with severe AS (defined below) who were classified as high-risk for SAVR due to the presence of comorbidities (chronic renal failure and advanced lung disease), advanced age, or prior cardiac surgery (except mechanical aortic valve replacement).

Exclusion criteria included age <65 years, concomitant severe mitral/tricuspid/pulmonary valve disease, presence of a mechanical aortic valve, life expectancy of less than 1 year due to non-cardiac conditions (e.g., active malignancy), incomplete follow-up data, non-severe AS diagnoses, duplicate records, and missing essential clinical variables.

Definitions and Clinical Assessment

Severe AS was defined according to current guidelines.² High-gradient normal-flow AS (HGNFAS) required an EF $\geq 50\%$, mean gradient ≥ 40 mm Hg, $V_{\max} \geq 4.0$ m/s, and AVA ≤ 1 cm². Low-flow, low-gradient AS (LFLGAS) with reduced

LVEF was defined as EF $<50\%$, mean gradient <40 mm Hg, AVA ≤ 1 cm², and stroke volume index ≤ 35 mL/m²; dobutamine stress echocardiography was used for further stratification.⁵

All patients underwent multi-slice cardiac computed tomography for annular sizing, access planning, and calcium scoring. An Agatston score >2000 AU in men and >1200 AU in women was considered indicative of severe AS.^{6,7} The diagnosis of chronic kidney disease was defined by a glomerular filtration rate (GFR) of <60 mL/min/1.73 m². Carotid artery disease was categorized as stenosis $>50\%$.

Procedural Details and Endpoints

Procedures were performed via transfemoral access (98.4%) under local or general anesthesia by experienced operators. Valve selection (self-expanding or balloon-expandable) was at the operator's discretion. The primary endpoint was all-cause mortality at 30 days. Secondary endpoints included all-cause mortality at 1 year and 5 years, cardiovascular mortality, and periprocedural complications (vascular injury, major bleeding, stroke, acute kidney injury, cardiac tamponade, and need for permanent pacemaker). The adjudication of all adverse events was conducted by an independent clinical events committee, which was blinded to procedural details.

Statistical Analysis

Continuous variables are expressed as mean $\pm$ SD or as median (interquartile range). These were compared using Student's *t*-test or the Mann–Whitney *U*-test. Categorical variables are expressed as numbers (percentages) and were compared using Fisher's exact test or Pearson's chi-square. Time-to-event outcomes were evaluated using Kaplan–Meier survival analysis and compared using the log-rank test. Thirty-day mortality, cumulative 1-year mortality, and landmark mortality between day 31 and 1 year were analyzed separately. The identification of predictors of mortality was achieved through a combination of univariate and multiple Cox proportional hazards regression analyses.

Univariate Cox proportional hazards regression models were used to identify predictors of mortality. Multiple Cox's regression models were subsequently constructed using clinically relevant covariates selected *a priori* (including age, sex, Society of Thoracic Surgeons [STS] score, chronic kidney disease, left ventricular ejection fraction, emergency presentation, cardiogenic shock, valve type, major vascular injury, and cardiac tamponade), together with variables showing a significance level of $P < .10$ in univariable analyses, in accordance with current recommendations for regression modeling.

The proportional hazards assumption was evaluated using Schoenfeld residuals. Variables with $>10\%$ missing data were excluded from multivariable analyses or were handled using multiple imputation where appropriate. Remaining missing values were analyzed using complete-case analysis, with sensitivity analyses confirming the robustness of the findings.

All statistical analyses were performed using R statistical software (version 4.5.0; R Foundation for Statistical Computing,

HIGHLIGHTS

- In a high-risk, real-world transcatheter aortic valve implantation (TAVI) cohort ($n=859$), 30-day and 1-year all-cause cumulative mortality rates were 6.5% and 12.4%, respectively.
- Chronic renal failure, presentation with cardiogenic shock, major vascular injury, and cardiac tamponade emerged as independent predictors of 30-day mortality.
- Valve type (self-expanding vs. balloon-expandable), access route, and sex showed no association with increased mortality risk.
- Early mortality was driven by patient frailty (renal dysfunction) and acute procedural complications, rather than by valve-specific factors.
- The findings of this study emphasize pre-procedural renal optimization and advanced vascular protection as critical to improving early survival after TAVI.

Vienna, Austria) through the RStudio integrated development environment (Posit Software, PBC, Boston, MA, USA), together with IBM Statistical Package for the Social Sciences Statistics version 20.0 (IBM Corp., Armonk, NY, USA). A 2-sided *P*-value <.05 was considered statistically significant.

RESULTS

Baseline and Procedural Characteristics

Of an initial 908 patients, 859 with severe AS formed the final study cohort (Figure 1). The mean age was 78.7 ± 6.5 years, 45.1% of patients were female, and the mean STS score was 7.4 ± 2.2, confirming a high-risk population (Table 1). The prevalence of comorbidities was high: hypertension (89.1%), coronary artery disease (60.4%), diabetes (42.9%), and chronic renal failure (28.9%). Most patients had HGNFAS (80.4%). The mean aortic valve calcium score was 3318 AU, and the mean implanted valve size was 27.1 ± 3.1 mm. Self-expandable valves were used in 84.6% of cases (Tables 1-5). Valve platform, brand-specific size, and 30-day mortality are detailed in Table 5.

Mortality Outcomes

The overall 30-day, 1-year, and 5-year all-cause mortality rates were 6.5% (n=56), 12.4% (n=107), and 26.3% (n=226),

respectively (Table 1). Among elective cases, the 30-day mortality rate was 3.5% (n=20). Cardiovascular deaths constituted 78.6% of in-hospital 30-day mortality (Table 1). Kaplan–Meier analysis revealed that cardiovascular mortality predominated within the first 30 days post-TAVI (Figure 2 A). Cardiogenic shock, chronic kidney disease (GFR <60 mL/min/1.73 m²), major vascular injury, and cardiac tamponade were each significantly associated with mortality after TAVI (Figure 2 B); a landmark analysis of mortality between day 31 and 1 year is shown in Figure 2 C.

Cardiovascular causes accounted for 44/56 (78.6%) of deaths within 30 days, 15/51 (29.4%) of deaths between day 31 and 1 year, and 21/119 (17.6%) of deaths beyond 1 year. Acute renal failure, hemorrhages, sepsis, and pneumonia were among the leading causes of non-cardiac death (Table 2).

Procedural Complications

The most prevalent major complications were the need for blood transfusion (13.1%), vascular injury (6.6%), iliac/femoral stenting (5.1%), and cerebrovascular events (3.4%). Tamponade occurred in 2.7% of patients and was associated with a 30-day mortality rate of 52.2% (12/23). The permanent pacemaker implantation rate was 12.8% (Table 1). Vascular

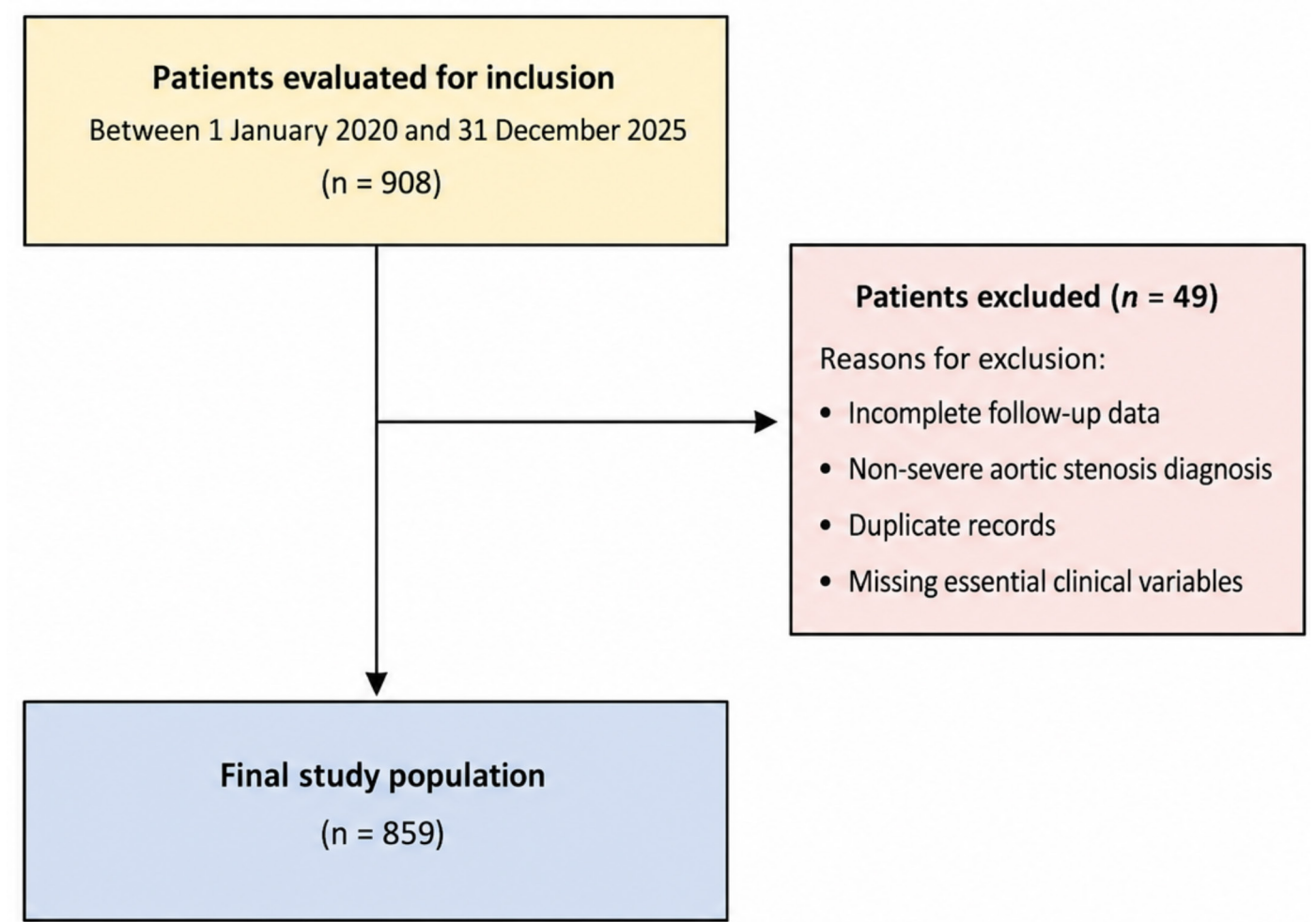


Figure 1. Flowchart showing patients included and excluded from the study.

Table 1. Baseline, Procedural Characteristics, and In-Hospital Outcomes Stratified by 30-Day Survival Status

Variables	30-Day Survivors (n = 803)	30-Day Non-Survivors (n = 56)	P
Demographics			
Age, years	78.6 ± 6.5	81.1 ± 7.2	.007
Female, sex	368 (45.8%)	19 (33.9%)	.085
STS score	7.4 ± 2.0	8.0 ± 2.1	.116
Functional status (NYHA)			
NYHA class II	624 (77.7%)	29 (51.8%)	<.001
NYHA class III	170 (21.2%)	21 (37.5%)	<.001
NYHA class IV	8 (1.0%)	6 (10.7%)	<.001
Comorbidities			
Hypertension	718 (89.4%)	46 (82.1%)	.27
Diabetes mellitus	343 (42.7%)	21 (37.5%)	.553
Smoking	103 (12.8%)	10 (17.9%)	.365
Hyperlipidemia	227 (28.3%)	7 (12.5%)	.011
Coronary artery disease	478 (59.5%)	34 (60.7%)	.934
Prior PCI	254 (31.6%)	15 (26.8%)	.56
Prior CABG	143 (17.8%)	10 (17.9%)	1
Chronic kidney disease [†]	218 (27.1%)	28 (50.0%)	<.001
Dialysis-dependent	13 (1.6%)	3 (5.4%)	.133
Prior stroke	82 (10.2%)	7 (12.5%)	.738
Carotid artery disease [‡]	54 (6.7%)	10 (17.9%)	.005
Pulmonary arterial hypertension	52 (6.5%)	8 (14.3%)	.044
COPD	152 (18.9%)	8 (14.3%)	.509
Cancer	75 (9.3%)	2 (3.6%)	.228
Prior valve surgery	39 (4.9%)	2 (3.6%)	.942
Prior permanent pacemaker	29 (3.6%)	2 (3.6%)	1
Pre-procedural clinical status			
Elective cases	739 (92.0%)	20 (35.7%)	.001
Emergency cases (Cardiogenic shock, pulmonary oedema)	64 (7.9%)	36 (64.3%)	.001
AS type: HGNFAS [§]	640 (79.7%)	43 (76.8%)	.072
AS type: LFLGAS [§]	163 (20.3%)	13 (23.2%)	.072
Pre-procedural laboratory data			
Creatinine, mg/dL	1.28 ± 0.64	1.69 ± 1.50	.204
GFR, mL/min/1.73 m ²	63.4 ± 20.1	48.2 ± 20.4	.01
Albumin, g/dL	3.78 ± 0.44	3.54 ± 0.59	.227
Hemoglobin, g/dL	11.6 ± 1.9	10.9 ± 1.7	.156
BNP, pg/mL	570 (253-1056)	2536 (1684-2612)	.052
C-reactive protein, mg/L	11.0 ± 18.0	30.8 ± 30.8	.049
WBC, ×10 ³ /μL	7.2 ± 2.5	8.0 ± 3.1	.287
Platelets, ×10 ³ /μL	229 ± 73	224 ± 97	.456
Aortic valve calcium score, AU	2952 (2021-4206)	2636 (1846-4036)	.638
Pre-procedural echocardiography			
Left ventricular EF, %	56.9 ± 11.8	55.3 ± 13.7	.482
Mean aortic gradient, mm Hg	45.8 ± 12.8	39.9 ± 15.9	.094
Aortic valve area, cm ²	0.71 ± 0.18	0.76 ± 0.11	.706
Systolic PA pressure, mm Hg	43.3 ± 14.4	47.7 ± 17.9	.478
Procedural details			
Transfemoral access	790 (98.4%)	52 (92.9%)	.763
Balloon-expandable valve	126 (15.7%)	7 (12.5%)	.533

(Continued)

Table 1. Baseline, Procedural Characteristics, and In-Hospital Outcomes Stratified by 30-Day Survival Status (Continued)

Variables	30-Day Survivors (n = 803)	30-Day Non-Survivors (n = 56)	P
Self-expanding valve	687 (85.5%)	39 (69.6%)	.183
Implanted valve size, mm	27.1 ± 3.2	26.7 ± 2.7	.734
Post-TAVI permanent pacemaker	105 (13.1%)	4 (7.1%)	.278
Post-procedural echocardiography			
Left ventricular EF, %	57.2 ± 11.4	59.0 ± 10.4	.718
Mean residual gradient, mm Hg	9.5 ± 4.1	6.0 ± 1.7	.073
Systolic PA pressure, mm Hg	41.0 ± 11.5	42.5 ± 10.6	.733
In-hospital complications and clinical events			
Major vascular injury	41 (5.1%)	16 (28.6%)	<.001
Iliac/femoral stent placed	30 (3.7%)	14 (25.0%)	<.001
Retroperitoneal hemorrhage	15 (1.9%)	11 (19.6%)	<.001
Pseudoaneurysm	34 (4.2%)	0 (0.0%)	.224
Cardiac tamponade	11 (1.4%)	12 (21.4%)	<.001
Annular rupture	0 (0.0%)	4 (7.1%)	<.001
Referral to emergency surgery	13 (1.6%)	15 (26.8%)	<.001
Cardiac arrest during procedure	3 (0.4%)	25 (44.6%)	<.001
Blood transfusion	89 (11.1%)	24 (42.9%)	<.001
Emergency dialysis	13 (1.6%)	9 (16.1%)	<.001
Myocardial infarction	0 (0.0%)	3 (5.4%)	<.001
Intracranial event	3 (0.4%)	1 (1.8%)	.627
Post-TAVI stroke	24 (3.0%)	5 (8.9%)	.046
Valve malposition/dislocation	8 (1.0%)	1 (1.8%)	1
Valve-in-valve implantation	20 (2.5%)	1 (1.8%)	1
IABP required	1 (0.1%)	2 (3.6%)	.002
ECMO required	0 (0.0%)	1 (1.8%)	.078
Valvular endocarditis	5 (0.6%)	0 (0.0%)	1
In-hospital outcomes			
ICU stay, days	1.8 ± 3.1	5.2 ± 5.5	<.001
Total hospital stay, days	12.1 ± 7.3	10.1 ± 7.0	.008
Follow-up duration, days	707 ± 428	5 ± 6	<.001

Reported as median (interquartile range); P-value by Mann–Whitney U-test.

AS, aortic stenosis; AU, Agatston units; BNP, B-type natriuretic peptide; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; ECMO, extracorporeal membrane oxygenation; EF, ejection fraction; GFR, glomerular filtration rate; HGNFAS, high-gradient normal-flow aortic stenosis; IABP, intra-aortic balloon pump; LFLGAS, low-flow low-gradient aortic stenosis; NYHA, New York Heart Association; PA, pulmonary artery; PCI, percutaneous coronary intervention; STS, Society of Thoracic Surgeons; WBC, white blood cell count.

[†]Defined as GFR < 60 mL/min/1.73 m².

[‡]Defined as stenosis > 50% on carotid duplex ultrasonography.

[§]HGNFAS: High-gradient normal-flow AS (EF ≥ 50%, mean gradient ≥ 40 mm Hg); LFLGAS: Low-flow, low-gradient AS (EF < 50%, mean gradient < 40 mm Hg, stroke volume index ≤ 35 mL/m²).

Table 2. Causes of Death Within 30 Days, 31 Days-1 Year, and Beyond 1 Year After TAVI

Cause of Death	30-Day (n = 56) (%)	31 Days-1 Year (n = 51) (%)	Beyond 1 Year (n = 119) (%)
Cardiovascular	44 (78.6)	15 (29.4)	21 (17.6)
Cerebrovascular (stroke)	4 (7.1)	8 (15.7)	Not specified
Pneumonia	5 (8.9)	4 (7.8)	Not specified
Sepsis	3 (5.4)	3 (5.9)	Not specified
Other/not recorded	0 (0.0)	21 (41.2)	Not specified

TAVI, transcatheter aortic valve implantation.

complication subtypes overlapped substantially, as detailed in Table 3.

Predictors of 30-Day Mortality

Patients who expired within 30 days presented more frequently with advanced symptomatic status (NYHA III/IV, cardiogenic shock) and had significantly higher rates of chronic renal failure and carotid disease, as well as lower albumin and hemoglobin levels and higher creatinine ($P < .05$ for all) (Table 1). Hypertension, diabetes mellitus, smoking, hyperlipidemia, cerebrovascular accident, chronic obstructive pulmonary disease, cancer, coronary artery disease, and dialysis dependence were each significantly associated with 30-day mortality (Figure 3).

Table 3. Frequency and Overlap of Vascular Complications Following TAVI

Vascular Category	Total, n (%)	Overlap with Major Rupture
Major vascular injury (iliac/femoral rupture)	57 (6.6)	—
Iliac/femoral stent placed	44 (5.1)	44 also had rupture
Retroperitoneal hemorrhage	26 (3.0)	26 also had rupture
Pseudoaneurysm (femoral)	34 (4.0)	0 overlap with rupture
Any vascular complication (unduplicated)	97 (11.3)	—

TAVI, transcatheter aortic valve implantation.

Table 4. Multiple Cox Proportional Hazards Regression Analysis for 30-Day All-Cause Mortality

Variables	HR (corrected)	95% CI	P
Chronic kidney disease (GFR <60)	7.75	1.29-16.54	.008
Cardiogenic shock	5.83	1.19-15.41	.028
Major vascular injury	22.7	1.89-45.91	.019
Cardiac tamponade	17.9	8.13-52.62	.012

GFR, glomerular filtration rate; HR, hazard ratio. The bolded *P*-values in table indicate that these variables are statistically significant independent risk factors for 30-day all-cause mortality.

Multiple Cox regression analyses identified 4 independent predictors of 30-day all-cause mortality (Table 4):

- Chronic renal failure (HR=7.75, *P*=.008, 95% CI=1.29-16.54).
- Presentation with cardiogenic shock (HR=5.83, *P*=.028, 95% CI=1.19-15.41).
- Major vascular injury (HR=22.7, *P*=.019, 95% CI=1.89-45.91).
- Cardiac tamponade (HR=17.9, *P*=.012, 95% CI=8.13-52.62).

For cumulative 1-year mortality, the same factors were significant in univariate analysis; however, none retained statistical significance in the multiple model (Table 5). The adjusted Cox model illustrated 30-day all-cause mortality (Figure 4).

The distribution of follow-up duration differed significantly according to 30-day mortality status. Patients who died

Table 5. Distribution of Transcatheter Heart Valve Systems, Brand, Company, Valve Size, and 30-Day Mortality

Valve System	n = 859 (%)	Mean Size (mm)	30-Day Mortality (%)
Balloon-expandable (total)	133 (15.4)	25.8 ± 2.9	5.3
Myval (Meril)	117 (13.6)	25.6 ± 2.8	5.1
Edwards SAPIEN (Edwards Lifesciences LLC)	16 (1.86)	26.7 ± 3.7	4.5
Self-expanding (total)	726 (84.5)	27.7 ± 2.5	4.6
Evolut R/Pro (Medtronic)	523 (60.8)	28.0 ± 2.4	4.2
Portico (Abbott)	97 (11.2)	27.8 ± 2.6	4.5
ACURATE Neo (Boston Scientific)	67 (7.8)	26.6 ± 1.8	4.8
Navitor (Abbott)	26 (3.0)	27.6 ± 2.1	4.9
Allegra (NVT)	13 (1.5)	27.0 ± 1.4	6.1

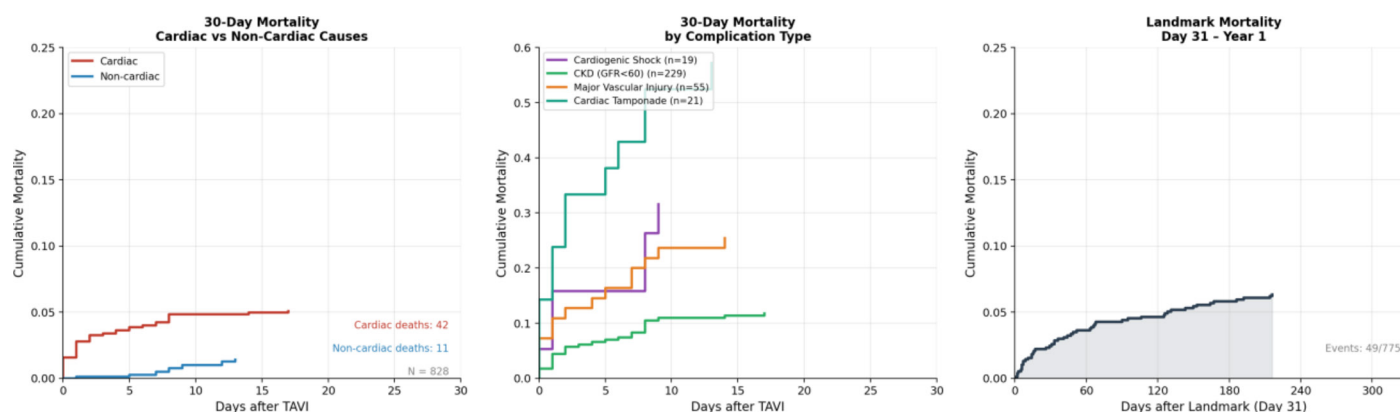


Figure 2. Kaplan-Meier curves of 30-day cumulative mortality stratified by (A) cause of death (cardiac vs. non-cardiac) and (B) complication subgroups (cardiogenic shock, chronic kidney disease [GFR <60 mL/min/1.73 m²], major vascular injury, and cardiac tamponade) undergoing TAVI. (C) Landmark analysis of mortality occurring between day 31 and year 1 among patients surviving the first 30 days (n = 775; 49 events).

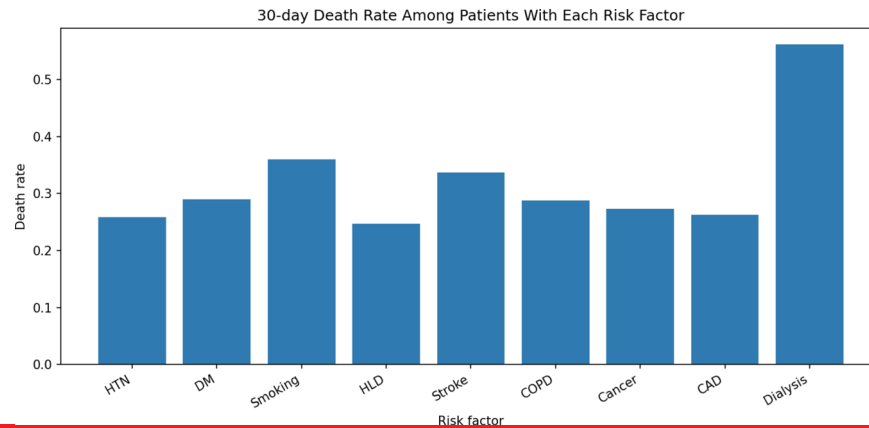


Figure 3. Thirty-day mortality rate according to baseline clinical risk factors.

within 30 days demonstrated a markedly shorter follow-up time, whereas survivors showed a broader and more right-skewed distribution with longer follow-up durations, as illustrated by the separation of kernel density estimates between the 2 groups (Figure 5).

Kaplan–Meier curves of 30-day mortality stratified by complication subgroup—cardiogenic shock, chronic kidney disease (GFR <60 mL/min/1.73 m²), major vascular injury, and cardiac tamponade—in 859 patients undergoing TAVI are shown in Figure 6.

Self-expanding valves were associated with a numerically lower crude 30-day mortality rate than balloon-expandable valves (4.6% vs. 5.3%). Mortality was broadly consistent across the major valve platforms (4.1%-5.1%), with the exception of the Allegra valve (6.1%, n = 13), a finding that should be interpreted cautiously given the small subgroup size. These platform-level data did not translate into an independent

association between valve type and mortality in the multivariable model (Table 5).

DISCUSSION

The predominant finding of the present KOSUTAVI study is that in a contemporary, real-world cohort of high-risk patients undergoing TAVI, early (30-day) mortality is independently predicted not by valve type or access route, but by the confluence of a key baseline comorbidity—chronic renal failure—and several acute, catastrophic procedural complications: cardiogenic shock, major vascular injury, and cardiac tamponade.

The authors observed 30-day mortality rate of 6.5% aligns with reports from other real-world registries of high-risk patients, such as the UK TAVI registry (7.1%) and large single-centre series (8%-8.2%).⁸⁻¹¹ This consistency confirms that despite advances in technology and experience, a core group of high-risk patients remains vulnerable in the immediate

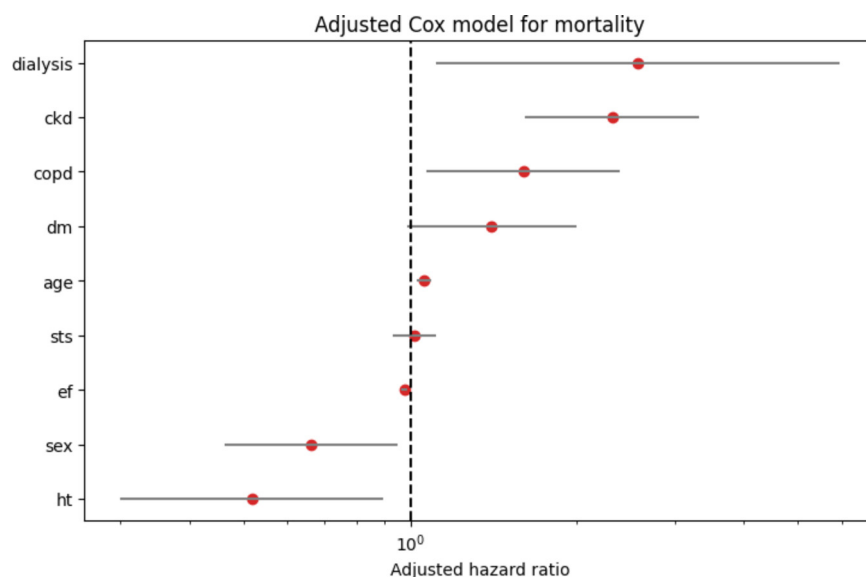


Figure 4. Forest plot of the adjusted multivariable Cox proportional hazards model for 30-day all-cause mortality. HT, hypertension; Sex, male sex; EF, left ventricular ejection fraction (%); STS, STS predicted risk of mortality score; Age, age (years); DM, diabetes mellitus; COPD, chronic obstructive pulmonary disease; CKD, chronic kidney disease (eGFR <60 mL/min/1.73 m²); Dialysis, dialysis dependence.

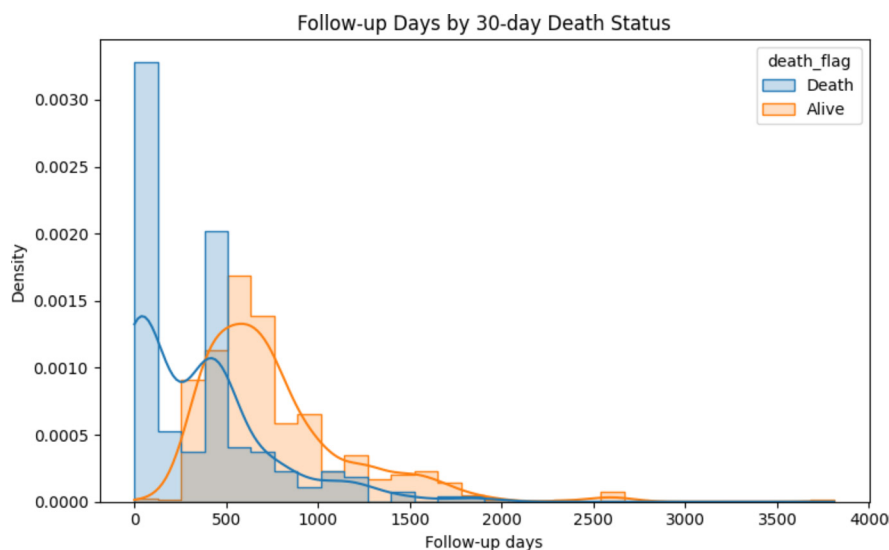


Figure 5. Histogram with kernel density estimates showing the distribution of follow-up duration according to 30-day mortality status. Blue represents patients who died within 30 days after TAVI, and orange represents those alive beyond 30 days. The observed separation reflects the shorter follow-up among patients experiencing early mortality. TAVI, transcatheter aortic valve implantation.

post-procedural period. Notably, the authors' 1-year mortality rate of 12.4% appears favorable, potentially reflecting effective post-discharge management in survivors of the initial high-risk phase.

The potent association between chronic renal failure and early mortality is a recurrent theme in TAVI outcomes research.⁹⁻¹⁵ This study reinforces its paramount importance. Renal dysfunction is a marker of systemic endothelial disease, frailty, and diminished physiological reserve, rendering patients less tolerant of procedural hypotension, contrast load, and bleeding.¹⁵⁻¹⁹ It should not be viewed merely as a comorbidity but as a critical indicator of overall vulnerability that mandates aggressive pre-procedural optimization, including hydration protocols and possibly hemodynamic monitoring to avoid contrast-induced and hypoperfusion-mediated renal injury.

The independent predictive power of cardiogenic shock at presentation underscores a critical patient selection and procedural timing issue.^{14,16-19} These patients represent the highest-acuity subset, in whom TAVI is often a salvage therapy. This study's data suggest that despite successful valve implantation, the burden of pre-existing myocardial injury and multi-organ hypoperfusion often leads to a fatal outcome. This finding challenges the practice of emergent TAVI in unstable patients and highlights the need for more effective mechanical circulatory support strategies as a bridge to stabilization and subsequent TAVI.

Tamponade is a rare complication of TAVI, with incidence rates ranging from 0.2% to 4.3%. In this study, consistent with the existing literature, tamponade was detected in 23 patients (2.7%) during TAVI, of whom 12 (52.2%) died within the first 30 days.²⁰⁻²² A total of 17 patients with tamponade were referred for surgical intervention. The remaining patients underwent pericardiocentesis.

Major vascular complications are a direct reflection of procedural technique and patient anatomy. Their strong link to early mortality is unsurprising but crucial to recognize. This study's vascular complication rate (6.6%) is consistent with modern registries using smaller sheath systems.¹³⁻¹⁹ These findings shift the focus from whether a complication occurs to how it is prevented and managed.^{14-19,22} They provide compelling evidence for the routine use of pre-procedural CT angiography for meticulous access planning, the preferential use of the smallest possible delivery systems, and the immediate availability of surgical or percutaneous rescue capabilities within the hybrid operating room.

Interestingly, and contrary to some previous studies,¹²⁻²⁴ the authors found no independent relationship between mortality rate and valve type, access route (almost entirely transfemoral), or left ventricular ejection fraction. This finding suggests that, in the hands of experienced operators using contemporary devices, the "valve-related" outcome is optimized.

Stroke represents one of the most serious complications associated with TAVI, with potentially devastating consequences. The incidence of stroke is approximately 2%-4% within 30 days.^{16-19,25} Factors identified as increasing the risk of stroke include the following: embolization of calcified deposits during valve implantation; inadequate anticoagulation during the procedure; and new-onset or pre-existing atrial fibrillation.²⁵ In the course of this study, the rate of cerebrovascular accident (ischemic and hemorrhagic) was 8.9%.

A recognized limitation of the present study is that although multidetector computed tomography (MDCT) is routinely performed for annular sizing, vascular access planning, and aortic valve calcium assessment, detailed CT-derived anatomical variables were not systematically incorporated into the analysis. Consequently, the contribution of anatomical

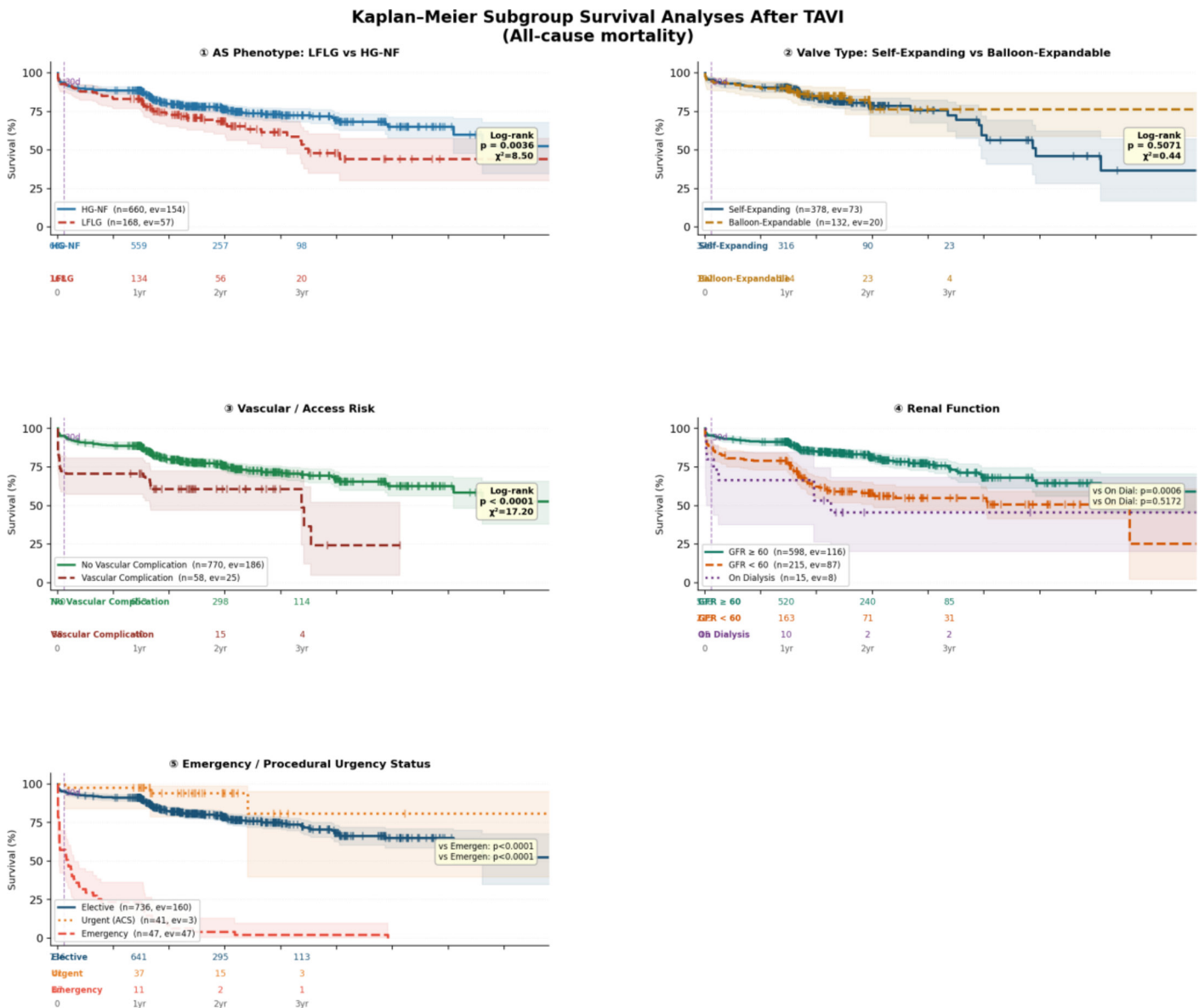


Figure 6. Kaplan–Meier curves of 30-day mortality stratified by complication subgroup—cardiogenic shock, chronic kidney disease (GFR < 60 mL/min/1.73 m²), major vascular injury, and cardiac tamponade—in 859 patients undergoing TAVI. GFR, glomerular filtration rate; TAVI, transcatheter aortic valve implantation.

characteristics to the development of vascular complications and cardiac tamponade may have been underestimated. To better define the anatomical risk profile associated with these complications, future prospective registry-based studies incorporating standardized MDCT acquisition and reporting protocols are warranted. Such an approach would enable more comprehensive risk stratification and provide a stronger evidence base to further elucidate the anatomical determinants of procedural complications following TAVI.

This is the single-center study with the largest patient population in the authors' country, as based on the literature review conducted so far.

Study Limitations

This study has several limitations. The retrospective, single-center design may limit generalizability. The inclusion of

only high-risk patients and the mix of elective and emergency cases reflects a specific real-world scenario but prevents comparison with lower-risk groups. As this study was conducted before the application of VARC-3 (Valve Academic Research Consortium 3) assessment criteria, outcome definitions are based on variables recorded by clinicians, rather than on independent clinical events committee assessment. Moreover, because of the retrospective nature of the study and the variability in archived CT reporting across the study period, detailed measurements such as annular area, annular perimeter, left ventricular outflow tract calcification burden, coronary height, sinus of Valsalva dimensions, and iliofemoral vessel characteristics were not consistently available for all patients. Information on causes of death beyond the first year was incomplete, as a proportion of deaths occurred outside the hospital setting

without systematic cause-of-death adjudication, which may have limited the accuracy of long-term cause-specific mortality analyses. Variability in experience levels among operators, while reflecting real-world practice, may also be a confounding factor.

CONCLUSION

In conclusion, the KOSUTAVI study delivers a clear and timely message: the most significant factors threatening early survival for high-risk patients undergoing TAVI are impaired renal function, vascular damage, pericardial injury, and admission with cardiogenic shock. To improve early outcomes, the clinical paradigm must evolve beyond perfecting the valve placement procedure to implement integrated care pathways that prioritize pre-TAVI renal optimization, enhanced vascular access planning and protection, and robust protocols for the prevention and immediate management of hemodynamic collapse and tamponade. Future research should target interventions in these specific, high-impact areas.

Ethics Committee Approval: This study was approved by the Ethics Committee of University of Health Science Kartal Koşuyolu High Specialization Research Hospital (Approval No: 2025/02/1011, Date: 18.02.2025).

Informed Consent: Not applicable (retrospective study using anonymized database records; informed consent was waived by the Ethics Committee).

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